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Course IC 13

“Phakic IOL Implantation: How to Improve Patient Safety, Satisfaction, and Complication Management”

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Saturday, Sept 17, 2011
2.30 PM – 4.30 PM
Index

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

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

Achieving Success Safely with Phakic IOLs
David R Hardten MD

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

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

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

ADDRESSES

Pag. 3
Pag. 6
Pag. 8
Pag. 11
Pag. 16
Pag. 19
Pag. 29
“Posterior Chamber Phakic Refractive Lens (Prl) 12
Years Surgical Technique Evolution”
Dimitrii Dementiev MD

Introduction
The last years more and more refractive surgeons are looking to use not only the corneal refractive procedures (RK, KM, LASIK, PRK, LASEK) for myopia and hyperopia correction, but also the phakic implants. It was just approved that the quality of vision after the refractive implants is much better that after corneal procedures, especially in high refractive error eyes. The evidence of reversibility, stability (no regression was noticed) and high predictability of the final refractive effect of the implants make this kind of surgery to become more popular among the refractive surgeons all over the globe. During this course it will be described my personal experience with Phakic Refractive Lens (PRL IOL TECH/Carl Zeiss) implantation and will be shown the evolution of PRL implantation surgical technique and instruments I use for this procedure. The follow-up and complications will be discussed.

PRL characteristics
Manufactured from high refractive index (RI) silicone the third-generation PRL does not come in contact with the anterior capsule of the crystalline lens because of hydrophobicity of the material and specificity of its curvature duplicating that of the crystalline lens. The edges of the PRL haptics are located on the zonular fibers and the implant "floats" in the posterior chamber, maintaining distance from the anterior capsule. This floating allows the aqueous to pass under the PRL, keeping the lens metabolism unchanged. No synechiae between the PRL and the crystalline lens or between the PRL and the iris have been seen in long-term follow-up. Such possible complications, such as cataract formation and pigmentary glaucoma, have not been noticed in 8-year follow-up.
There are 3 models of PRL available:
1. Model 101 for myopia correction
2. Model 100 for myopia correction (for small w-w eyes)
3. Model 200 for hyperopia correction
The width of the implant is 6 mm. PRL myopic models come in 10.8-mm and 11.3-mm lengths and the optic diameter ranges from 4.5 mm to 5.0 mm. The power of the myopic model ranges from -3 D to -20 D. The hyperopic model has a length of 10.6 mm and the optic diameter is 4.5 mm. The power of the hyperopic model ranges from 3 D to 15 D. The power of the myopic and hyperopic implants increases in 0.5 D increments.
Patient selection
Criteria for PRL implantation include myopia from -3 D to -30 D and hyperopia from 3 D to 15 D. Because the anterior chamber of patients with hyperopia is usually shallow, it is safer to limit the hyperopic correction for PRL implantation to a maximum of 11 D unless there is a deep anterior chamber. In cases with astigmatism greater than 1 D, additional astigmatic keratotomy or laser in situ keratomileusis (LASIK) surgery is recommended to correct the astigmatism. PRL implantations can be performed for keratoconus correction with a high myopic component and for overcorrection of a previous refractive procedure such as radial keratotomy, photorefractive keratectomy, or LASIK. Exclusion criteria is: clouded or non-transparent cornea, cataracts, lens subluxation, glaucoma or ocular hypertension, a shallow anterior chamber (less than 2.5 mm), vitreoretinal problems that preclude good vision or require posterior segment intervention, previous ocular surgery, such as vitreoretinal surgery or glaucoma filtration. Additionally, patients younger than 55 years of age are best suited for PRL implantation.

Surgical steps and techniques
For PRL implantation, I recommend the Dementiev trapezoid PRL diamond blade (Rumex International, Miami, U.S.A.) for clear corneal incisions between 3.0 mm and 3.5 mm and the Dementiev diamond paracentesis 1-mm blade (Rumex International) for paracentesis. The Dementiev PRL titanium loading block (Duckworth & Kent, Hertfordshire, England) and the titanium Dementiev forceps for PRL implantation (Duckworth & Kent) or stainless steel forceps can be used for loading and insertion. Other instruments are available for other surgical steps, such as the Dementiev PRL titanium double-ended haptic spatula (Duckworth & Kent) for manipulation or the Dementiev PRL titanium diamond dust-covered manipulator (Rumex International).

The PRL is supplied in a plastic sterile container. After the container is opened, the implant must be removed from the packaging using PRL Dementiev forceps, with the anterior surface of the lens facing up and the posterior surface facing down. The implant must not come in contact with the skin, conjunctiva, lids, lashes, or corneal epithelium because microelements can be attracted to and become deposited on the lens surface. The PRL is then placed on the PRL loading block and grasped by the forceps lengthwise. The edge of the implant must correspond to the end of the forceps. The PRL is self-folding during its insertion in the anterior chamber through the incision. After the implant has been grasped in the correct manner and orientated in the forceps, it is irrigated using balanced salt solution from a syringe. It is important to carefully inspect the implant and, with fine forceps, gently remove any foreign matter or fibers that may have attached to its surface. Once the lens has been determined to be free of foreign particles, the surgeon can prepare the PRL for insertion. The surgical steps for implanting the PRL can be seen in Figures 1 and 2. After the PRL unfolds under the iris, the viscoelastic is removed either by the aspiration mode on the phacoemulsification machine, washing out, or manual irrigation and aspiration.

Figure 1. (From left to right) 3-mm clear corneal incision; viscoelastic insertion; paracentesis at 12 o’clock.

FIGURES 1 AND 2 COURTESY OF DIMITRII DEMENTIEV, MD.

Figure 2. (From left to right) PRL insertion (self folded); PRL opening in the anterior chamber; under-iris placement of the IOL.
Intraoperative complications

PRL-induced damage to the posterior pigment surface of the iris caused by improper implantation can be avoided by injecting viscoelastic under the iris. Care must be taken when a manual iridectomy is performed to ensure that the iris is not pulled strenuously through the paracentesis, which can cause iris damage and bleeding. The iridectomy must be completely open (including the pigmentary surface of the iris) to prevent postoperative pupillary block.

The most significant risks of improper PRL implantation are damage to the crystalline lens and cataract formation due to sudden blade insertion, eyeball movement, or insufficient viscoelastic in the anterior chamber. A surgeon must always be prepared to convert the surgery (in case of lens damage) to phacoemulsification with IOL implantation. Other causes of lens damage include contact between the forceps and the anterior capsule of the lens, pushing the implant on the lens, inadvertent movement of irrigation or aspiration needle, and forceful balanced salt solution irrigation.

Contact between the forceps and the endothelium must be avoided. The PRL is soft, but it is made of silicone and studies have shown that silicone can damage endothelial cells in the case of contact with the implant. However, my experience has shown that even if the edge of the lens touches the endothelium, damage does not occur. This may be due to the high endothelial cell density in patients younger than 55 years of age.

To avoid damage to the zonular fibers, the PRL must be released under the iris using no extra force.

Postoperative complications

If the patient experiences postoperative pain, complains of vision loss, or has a headache in the temple area, the patient may be checked at the slit lamp to determine intraocular pressure (IOP). High IOP may be present if the anterior chamber is shallow, the pupil does not react to light or is sluggish, residual viscoelastic is noted in the anterior or posterior chambers, or the gap between the PRL and the anterior capsule is too large.

The patency of the iridectomy (visual and red reflex) must be evaluated. The iridectomy may be increased by YAG laser if it is small. For high IOP resulting from residual viscoelastic in the chamber, prescribing Diamox (acetazolamide, Wyeth Laboratories) up to 250 mg a day and keeping the pupil dilated will help reabsorb the viscoelastic. Beta-blockers may also be used until the IOP is normalized.

In some cases, increased IOP was observed at the 1-week postoperative visit. The increased IOP ranged from 21 mm Hg to 27 mm Hg. All of these cases were treated typically with Timoptol (timolol maleate, Merck & Co.) and oral Diamox. At 2 weeks postoperatively, IOP was normal (17 mm Hg or less). Thus far, we have only had two cases of a subcapsular opacity approximately 13 months postoperatively. One patient had been implanted with a second-generation PRL. The patient lost one line of best-corrected visual acuity (BCVA) and had poor contrast sensitivity. In the future, phacoemulsification with an IOL may be necessary.

Iridocyclitis is rare in the early postoperative period, but was detected in some hyperopic eyes implanted with second-generation PRLs. If a patient complains that vision is decreasing, but there is no pain, iridocyclitis cannot be ruled out. When examining this patient at the slit lamp, there may be flare and cell in the anterior chamber, some synechia between the PRL and the pupil, or the pupil may be small and difficult to dilate. To treat iridocyclitis, I recommend using a combination subconjunctival injection (steroids, atropine, and adrenaline), systemic steroids, and maximum mydriasis.

Results

The preoperative spherical equivalent refractive error of the patients we have implanted was 16% from 5 D to 7 D, 37% from 7 D to 10 D, and 47% greater than 10 D. For patients with preoperative astigmatism, astigmatic keratotomy was performed approximately 1 month after the PRL procedure. In 66.1% of the cases, emmetropia was achieved. In 26.8%, a residual undercorrection (myopia) of no greater than -1 D occurred and 7.1% of the eyes needed additional spectacle correction of more than -1.0 D and less then -2.5 D (in all 6 eyes, the goal was to leave some residual myopia and all were presbyopic). In 46.6% of the eyes, there was no loss of any lines of BCVA. In 54%, an increase in lines of vision BCVA was noted. In 3.3%, one line of BCVA was lost. Postoperative best-uncorrected visual acuity (UCVA) was superior to preoperative BCVA in 55.1% (66/122 eyes) of the eyes. No eyes had UCVA worse than 20/200 at the last postoperative visit. PRL implantation is safe, predictable, reversible, and inexpensive. The PRL is able to achieve an immediate and stable refractive effect and increase UCVA and BCVA. PRL implantation is relatively safe and easy to perform for any skilled cataract surgeon. The complications have been minor and treatable. The two main issues that require follow-up are subcapsular opacity and pigment dispersion that may lead to glaucoma and although no cases have been seen with the third-generation PRL, monitoring continues. Our study shows that there is not pigment dispersion in negative-powered silicon PRLs but some slow dispersion in the positive-powered PRLs. The ultrasound biomicroscopy study demonstrated that the PRL does not touch the anterior capsule, but more information is needed about contact between the PRL and the capsule and iris.

With promising results and modern surgical and diagnostic equipment, PRL implantation is becoming one of the most exciting areas of refractive surgery.
Conclusions

Posterior Chamber Refractive Implants is good alternative in refractive surgery, especially in correction of high refractive error. Clinical results showed it predictability, stability of the refraction in long term post-op. reversibility and possibility to correct extremely high myopia till –30.00D. It was approved that the quality of vision after phakic implants is much better then after corneal refractive procedure.
To avoid the possible mistakes complications it is strongly recommended to make a right patient selection and to follow customized surgical technique that was shown at this course.

“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 50mµ. 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.

Fig 2 : AC Diameter with the AC OCT

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. 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.
“Achieving Success Safely with Phakic IOLs”
David R Hardten MD

Initial Step: Commit to their Usefulness

Why Phakic IOLs?
• They play a real role in the management of higher refractive errors
• Technique is learnable by intraocular surgeons
• Verisyse and ICL Visian 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
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

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

Optimizing Efficiency
Special Orders Don’t Upset Us
• 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 staff training – careful MR & CR & IOL calculations
  Counselor training – normal postop course similar to cataract surgery, with about 1-4 weeks between eyes.
  Prepare in advance consent forms, postop instructions, follow-up visits, etc.
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 preop work: PI’s and Block for Verisyse
Extra postop 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

Last Follow-up Results
LVC after ph-IOL
• 22 eyes with at least 1 mo f/u (mean 5 mos)
• Mean SE last f/u = +0.12 + 0.31 D
• Mean Astig = 0.25 + 0.31 D
• UCVA 20/20 or better = 64%
• UCVA 20/25 or better = 82%
• UCVA 20/30 or better = 86%
• UCVA 20/40 or better = 95%
• In eyes with original BCVA 20/20
UCVA 20/20 or better = 76%
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
MR: -2.50 + 1.25 x 25
WR: -3.53 + 2.11 x 36
HOA: 0.89 μ
Coma: 0.41 μ
Trefoil: 0.79 μ
SA: 0.19 μ
Postop PRK – Custom
UCVA = 20/20

Case Selection Pearls
• 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
Rates low (<10%)
“Management Of Complications After Vivarte™ Phakic Anterior Chamber IOL Implantation”
Matteo Piovella MD Fabrizio I. Camesasca MD

Optical Coherence Tomography Basic Principles
256 Scans in 125 ms or 512 Scans in 250 ms transversal

VIVARTE™
ANTERIOR CHAMBER PHAKIC IOL
Optic diameter 5.5mm
Overall diameter 12.0,12.5,13.0mm
Reractive index 1.47
Diopter range -7.0 to -25.0 D

Before Phakic IOL Surgery it is mandatory to evaluate the AC shape
AC depth : endothelium safety
Internal Ø : to respect iris & pupil
Symmetry : to choose the right axis
CL rise & IOL vault : to respect the lens
### Personal Experience on Vivarte™ IOL

**34 Eyes (2001-2003)**

- IOL Power (mean ± SD): -15.00 ± 3.7 D
- IOL Power Range: -9.00 to -22.00 D
- IOL Size:
  - 120 n=3 9%
  - 125 n=27 79%
  - 130 n=4 12%
- White-to-white, IOL Master (mean ± SD): 12.3 ± 0.3 mm
- Surgical sizer (mean ± SD): 12.3 ± 0.3 mm
- Anterior Chamber Depth: 3.6 ± 0.2 mm

### Anterior Chamber Width 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 11.0 To 12.50 Mm
- W-T-W (Clear Cornea Add 0.5 Mm): 10.50 – 12.00 Mm

### Surgical Sizer Vs. Visante™

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<td>3 IOL due to too long haptics</td>
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<td>4 Lens due to AC diameter too big</td>
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<td>9 correct size IOLs:</td>
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**Vivarte™ IOL Removal**

**DRAMATIC EC Counts**

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When lens removal needs to be considered

ECC: ≤ 1500/mm²

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**Vivarte™ IOL Removal**

**TERRIFIC BSCVA!!!**

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<td>17</td>
<td>0.4</td>
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**Vivarte™ Needed bigger size IOL**

M.D. (B) Lupap Thapa 2007 (preop) 2007 Date of surgery: May 2007
Date of explantation: May 2007
Vivarte™ IOL
ECC Preop : LE n= 2304
Postop VA: LE 1.0 +1.50 +1.00 (60)
IOL Decentration
LE progressive ECC reduction (after 4 years n = 1098)

Explantation was performed at:

day 1447
IOL Removal – MD, 50 y.o., female

Vivarte™
Phakic Anterior Chamber IOL
B.S. (31y.o) cell 2481 (preop 2481)
Date of surgery Febr 2002

Normal round pupil and haptics correctly placed in the angle

Vivarte™
Phakic Anterior Chamber IOL
B.S. (31y.o) cell 2267 (preop 2141)
Date of surgery March 2002
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.

Refractive surgery patients require constant follow-up in time and proper technology (Visante™). 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 Visante™ 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 Low myopia</td>
<td>LASIK myopia/astigmatism</td>
</tr>
<tr>
<td>CK Low hyperopia</td>
<td>PRK low myopia</td>
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<tr>
<td>SES Presbyopia</td>
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<tr>
<th>Lens Based, Additive</th>
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<tr>
<td>Phakic IOLS myopia, hyperopia</td>
<td></td>
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<tr>
<td>Aphakic IOLS Crystalens, presbyopia</td>
<td></td>
</tr>
<tr>
<td>Keratophakia hyperopia, myopia ?</td>
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**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 grafiks 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.

![Stability Grafik](image)

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.

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 trapezioidal shape, anterior entry
- Pulse the lens
- 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.
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.
Lens clarity was graded at all patient visits using the LOCS III Scale. This scale ranges from 0 to 5.9, and under this system, grade 1 was a trace opacity. Shown here is the photographic standard for a grade 1.

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 ever 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)

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<thead>
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<th>GENDER</th>
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<td>178</td>
<td>116</td>
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<td>6</td>
<td>23</td>
<td>16</td>
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<tr>
<td></td>
<td>84,7%</td>
<td>2,0%</td>
<td>7,8%</td>
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<td>22 to 45</td>
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<tr>
<th>PREOP. MRSE</th>
<th>Mean (SD)</th>
<th>Range</th>
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<tr>
<td>-10,1 (3.7)</td>
<td>-3,00 to -20,00 D</td>
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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
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)

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

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

Secondary ICL Surgeries

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
  * 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

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

Examples

- Pseudophakic bullous keratopathy
- Diabetes
- Contact lens wearers
**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
  

- 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

**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

**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.

**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.

**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.

**Risk of Complications in High Myopia**
- Retinal detachment (Ogawa and Tanaka, 1998)
  - Up to –3 D: 3.8%.
  - Up to –<D: 10.9%.
  - Above –D: 26.3%.
- Nuclear opacities (Younan et al., 2002)
  - Astigmatism: 1.7%.
  - Above –6 D: 3.8%.

**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
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<td><strong>GEORGES D BAIKOFF MD</strong>  &lt;br&gt; Clinique Monticelli  &lt;br&gt; 88 Rue du Commandant Rolland  &lt;br&gt; 13008 Marseille - France  &lt;br&gt; Ph. +33 4911-62228  &lt;br&gt; Fax +33 4911-62225  &lt;br&gt; e-mail: <a href="mailto:g.baik.opht@wanadoo.fr">g.baik.opht@wanadoo.fr</a></td>
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<td><strong>DAVID R HARDTEN MD</strong>  &lt;br&gt; Minnesota Eye Consultants  &lt;br&gt; Ste 100 710 E 24th St  &lt;br&gt; Minneapolis  &lt;br&gt; MN 55404-3840  &lt;br&gt; Ph: +1 612 813-3631  &lt;br&gt; Fax: +1 612 813-3658  &lt;br&gt; e-mail: <a href="mailto:drhardtten@mneye.com">drhardtten@mneye.com</a></td>
<td><strong>MICHAEL C KNORZ MD</strong>  &lt;br&gt; FreeVis LASIK Center,  &lt;br&gt; Klinikum Mannheim,  &lt;br&gt; Mannheim 68135  &lt;br&gt; Germany  &lt;br&gt; Ph.: 49-621-383-2242  &lt;br&gt; Fax: 49-621-383-1984  &lt;br&gt; e-mail: <a href="mailto:knorz@eyes.de">knorz@eyes.de</a></td>
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<tr>
<td><strong>MATTEO PIOVELLA MD</strong>  &lt;br&gt; Centro Microchirurgia Ambulatoriale  &lt;br&gt; Via Donizetti 24 20052 – Monza - Italy  &lt;br&gt; Ph.: +39 039389498  &lt;br&gt; Fax: +39 0392300964  &lt;br&gt; e-mail: <a href="mailto:piovella@piovella.com">piovella@piovella.com</a></td>
<td><strong>STEPHEN G SLADE MD FACS</strong>  &lt;br&gt; Ste 101 3900 Essex Lane  &lt;br&gt; Houston TX 77027-5111  &lt;br&gt; Ph: +1 713 626-5544  &lt;br&gt; Fax +1 713 626-7744  &lt;br&gt; e-mail: <a href="mailto:sgs@visiontexas.com">sgs@visiontexas.com</a></td>
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