

LONG-TERM RESULTS WITH PHAKIC IOLS

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Financial Interests

- Consultant to AMO Inc.
- Consultant to Alcon Inc.
- Consultant to Technolas GmbH
- Consultant to LenSx Inc.

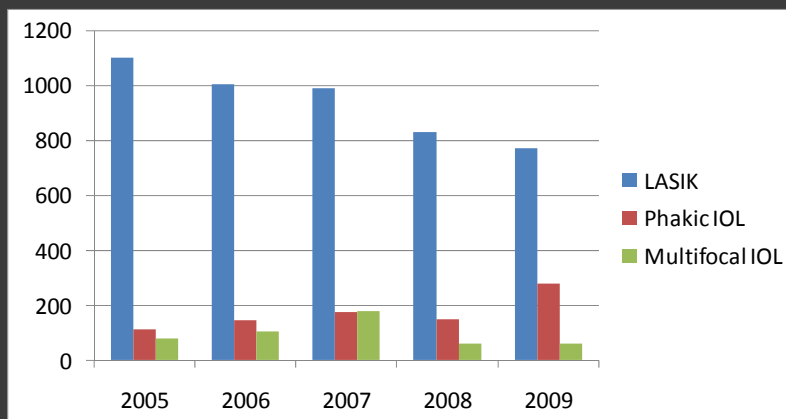
- Clinical investigator for AcuFocus Inc.

Do We Need Phakic IOLs ?

YES !

- The range of LASIK is limited
- LASIK in high myopia causes halos etc.
- No expensive lasers required
- Phakic IOLs are reversible

Refractive Procedures, FreeVis LASIK Centre, Mannheim



Phakic IOLs – Personal Experience

- ◉ Nuvita IOL
- ◉ Vivarte / GBR IOL

- ◉ Verisyse IOL
- ◉ Veriflex IOL

- ◉ AcrySof Cachet Phakic IOL

POSTERIOR CHAMBER

Posterior Chamber: ICL

- FDA approved
- No personal experience



- Sanders DR, Doney K, POCO M, ICL in treatment of myopia study group
US FDA clinical trial of the ICL for moderate to high myopia: three-year follow up
Ophthalmology 2004; 111:1683-1692
- 526 eyes
cumulative endothelial cell loss 8.4%-9.7% at three years (3.2% per year) (*not stated if it included surgical loss !*)
2.7% anterior subcapsular opacities; 0.6% nuclear sclerosis; 0.6% cataract extraction and ICL explantation

- Sanders DR

Anterior subcapsular opacities and cataracts 5 years after surgery in the Visian Implantable Collamer Lens FDA trial

J Refract Surg 2008; 24:566-570

- 526 eyes, 311 at 5 years
anterior subcapsular opacities in 6%
- 1-2% cataracts, mainly high myopes and older patients

**HOW MUCH ENDOTHELIAL
CELL LOSS IS ACCEPTABLE ?**

ISO 11979-10:2006

- Ophthalmic implants – intraocular lenses
Part 10: phakic intraocular lenses
 - Assumes annual loss of 2%, which means less than 2% per year should be acceptable

Summary ICL

- FDA approved
- Long-term safety established

- Easy to implant
- 2 iridectomies required
- Cataract a potential problem ?

ANTERIOR CHAMBER HISTORICAL DESIGNS

Nuvita IOL

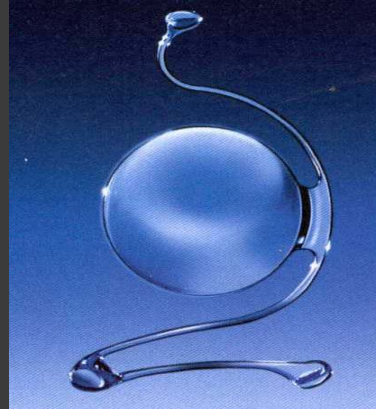
- ◉ Sizing very difficult
 - Pupil ovalization in 50 %
 - IOL exchanged in many cases



Unacceptable results

Vivarte / GBR

- Sizing very difficult
 - Decentration frequent
 - Pupil ovalization occurs frequently
 - Significant endothelial cell loss



Unacceptable results

ICARE

- HEMA 26%
- Large vault, close to endothelium
- Progressive endothelial cell loss

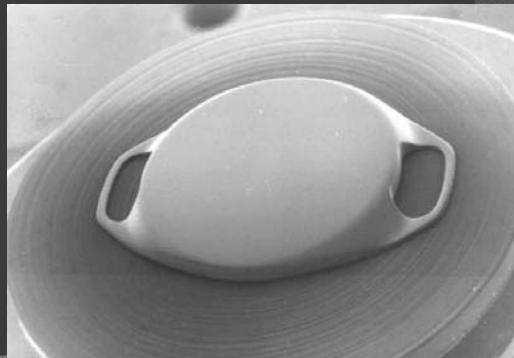


Unacceptable results

ANTERIOR CHAMBER CURRENT DESIGNS

Verisyse IOL

- ◉ FDA approved for myopia
- ◉ Outside US
 - Hyperopia
 - Toric design
- ◉ Surgery
 - Large incision, causing astigmatism
 - Iridectomy
 - Difficult

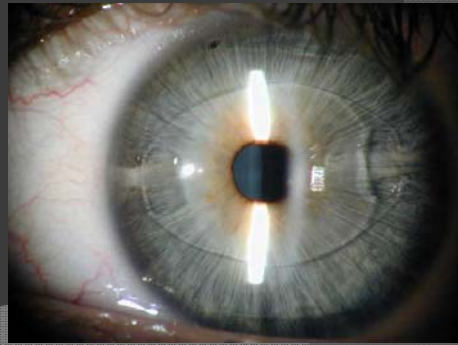


- Saxena R, Boekhoorn SS, Mulder PG, Noordzij BG, van Rij G, Luyten GP
Long-term follow up of endothelial cell change after Artisan phakic intraocular lens implantation.
Ophthalmology 2008; 115:608-613
- 82 eyes at 1 year, 13 eyes at 7 years
Endothelial cell loss 8.3% at 5 years (1.7% per year)

- Tahzib NG, Nuijts RM, Wu WY, Budo CJ
Long-term study of Artisan phakic intraocular lens implantation for the correction of moderate to high myopia: ten-year follow up results
Ophthalmology 2007; 114:1133-1142
- 89 eyes
endothelial cell loss 8.9% at 10 years (0.9% per year)

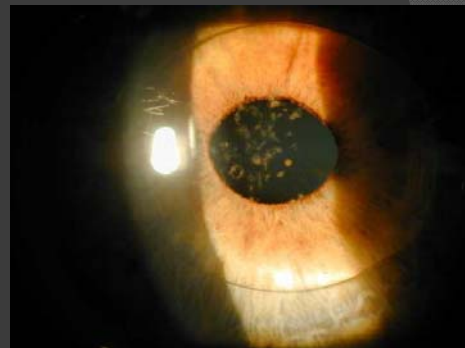
Summary Verisyse IOL

- Long-term safety established
- Difficult to implant
- Iridectomy required
- Large incision causes astigmatism
- Prolonged visual rehabilitation



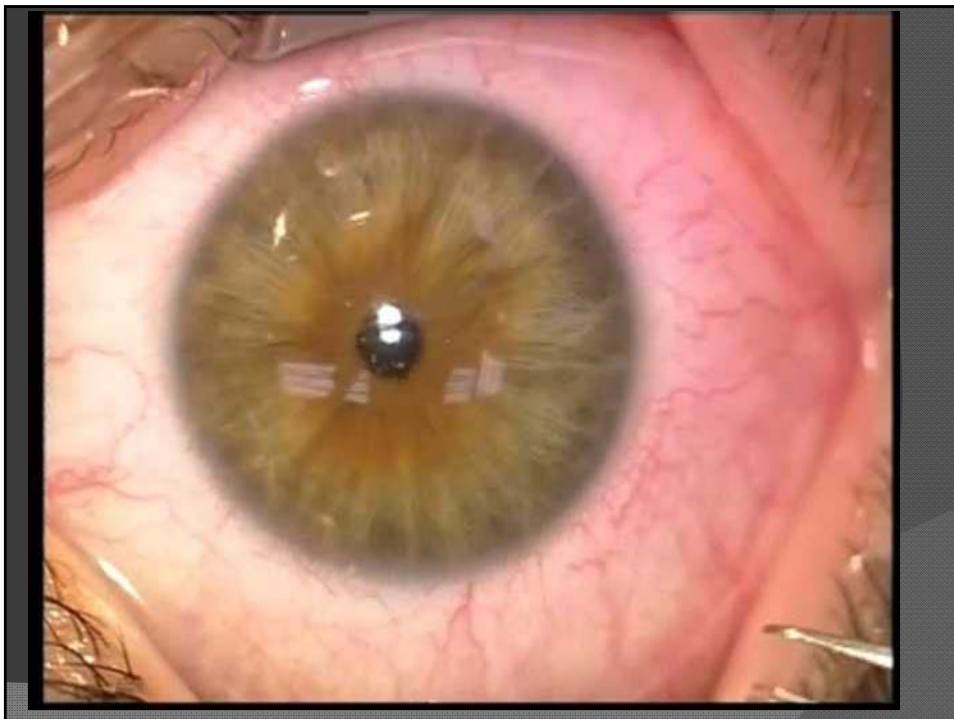
Summary Artiflex / Veriflex

- not FDA approved; no long-term data
- Advantages
 - Small incision
 - No suture
- Disadvantages:
 - Difficult surgery
 - Iridectomy required
 - Uveitis frequent



Acrysof Cachet Phakic IOL

- ⦿ not FDA approved (but CE marked)
- ⦿ Single piece, AcrySof material, angle supported
- ⦿ Foldable insertion



1st Implant 6. Dec. 1999, Mannheim



- Kohnen T, Knorz MC, Cochener B, Gerl RH, Arné JL, Colin J, Alió JL, Bellucci R, Marinho A

Acrysof angle-supported phakic intraocular lens for the correction of moderate-to-high myopia: one-year results of a multicenter European study. *Ophthalmology* 2009; 116:1314-1321

- 190 eyes, 161 at one year
endothelial cell loss from preop to one year 4.8%
(includes surgical loss !)

- Knorz MC, Lane SS, Holland S
Acrysof angle-supported phakic IOL for the correction of moderate to high myopia: Three-year interim results of an international multicenter study (*submitted for publication*)
- 360 eyes
Surgical ECC loss: (pre-op to 6 months) 3.31% centrally and 2.98% peripherally
Chronic ECC loss: (annualized from 6 months to 3 years) 0.4% centrally and 1.1% peripherally

Summary Acrysof Cachet IOL

- Not FDA approved
- Long-term safety established
- Easy to implant
- No iridectomy required
- Fast visual rehabilitation

Summary Phakic IOLs

- ⦿ Long-term proved phakic IOLs today
 - ICL (FDA approved)
 - Verisyse IOL (FDA approved)
 - Acrysof Cachet Phakic IOL (CE marked, investigational use only in US)
- ⦿ AcrySof Cachet Phakic IOL my favorite
 - Extremely easy to implant
 - No iridectomy required
 - No chronic ECC loss, no pupil ovalisation

THANK YOU !