

The AcrySof Cachet Phakic IOL Results of the European Multicenter Study

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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

Phakic IOLs – Personal Experience

- Nuvita IOL
- Vivarte / GBR IOL
- Verisyse IOL
- Veriflex IOL
- AcrySof Cachet Phakic IOL

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[®]

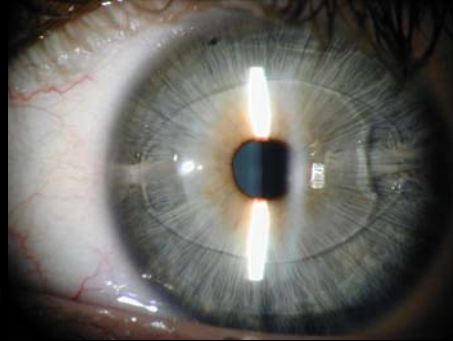
- HEMA 26%
- Large vault, close to endothelium
- Progressive endothelial cell loss



Unacceptable results

Artisan / Verisyse IOL

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



Artiflex / Veriflex

- Advantages
 - Small incision
 - No suture
- Disadvantages:
 - Difficult surgery
 - Iridectomy required
 - Uveitis frequent

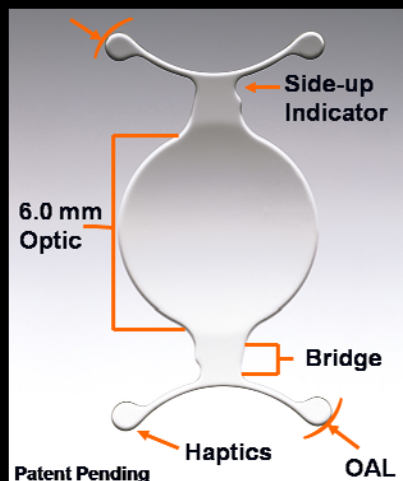


Acrysof Cachet Phakic IOL

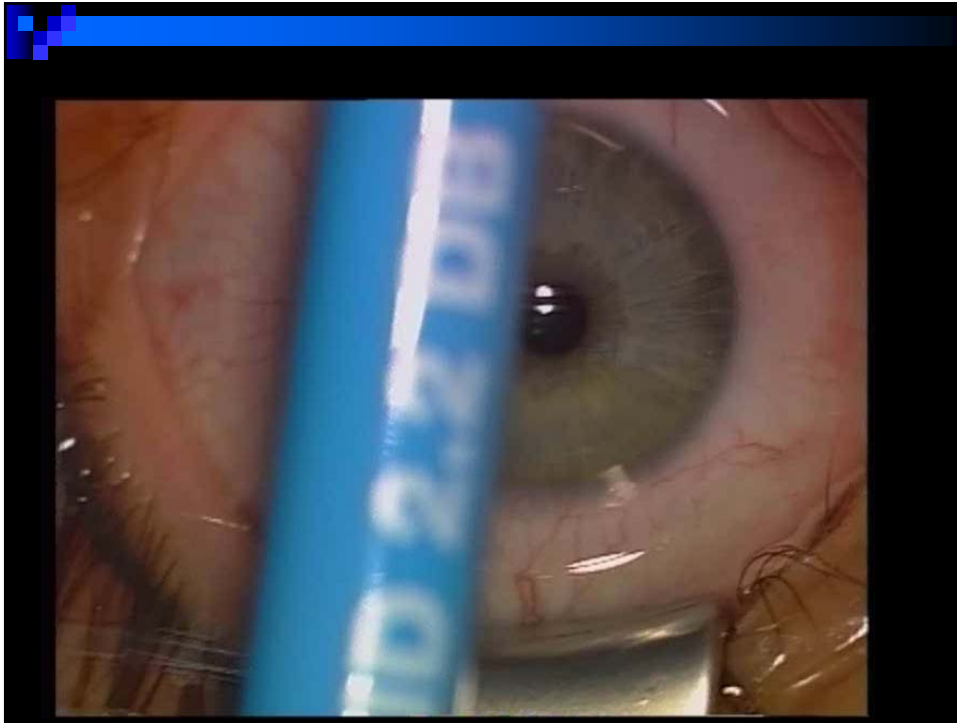
- CE marked since 2008
- Single piece, AcrySof® material, angle supported
- Foldable insertion



Acrysof Cachet Phakic IOL



Optic	6.0 mm
Overall Length	12.5 to 14.0 mm
Diopter Range	-6.0 to -16.5 D

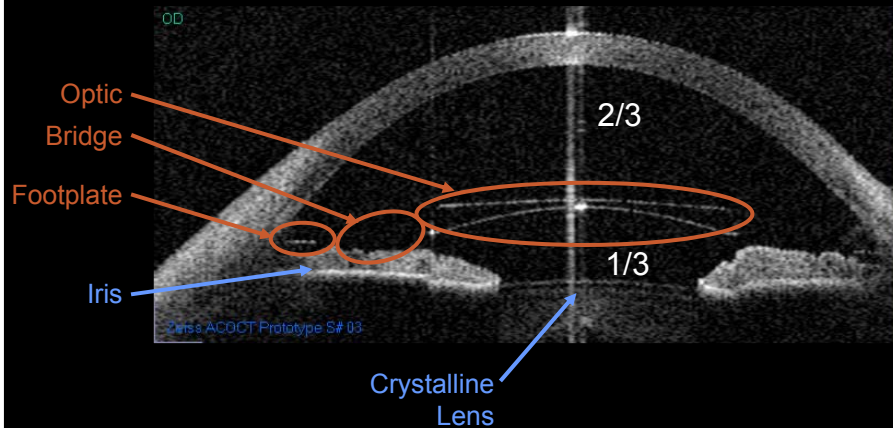


1st Implant 6. Dec. 1999, Mannheim



Cachet IOL Position *in vivo* (no iridectomy/iridotomy required)

Anterior Chamber OCT



*ZEISS is a registered trademarks of Carl Zeiss AG.

Study Details

- Phase 3 European Clinical Trial
- Non-randomized, open label, single arm
- Unilateral implantation of 190 subjects with the AcrySof® Caché™ Phakic Lens
- 5 year follow-up
- Results reported for 48 subjects @ 4 years
- Safety & Effectiveness Endpoints
 - Uncorrected VA, Best Corrected VA, Spherical Equivalent, Predictability of Refraction, Endothelial Cell Density(ECD), Postop Inflammation, Serious Adverse Events

Study Criteria

■ Main Inclusion Criteria

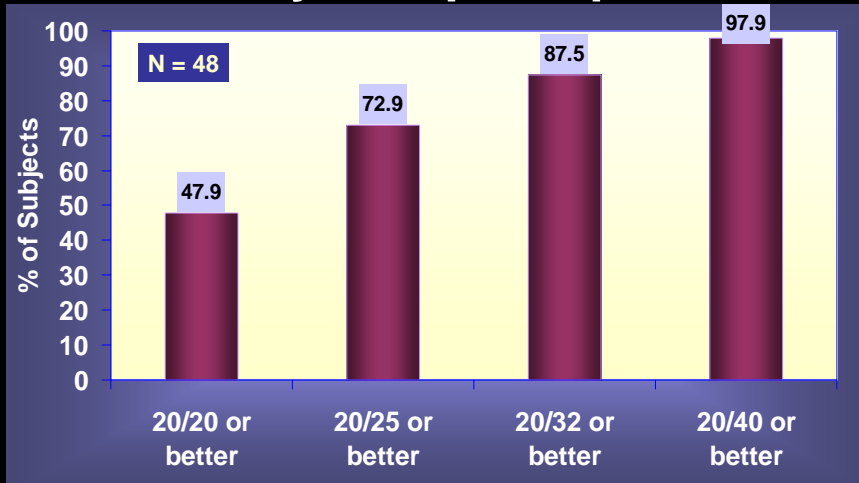
- Adults ≥ 18 years of age
- Stable, high myopia
- Good general and ocular health
- Able to comprehend & sign informed consent

■ Main Exclusion Criteria

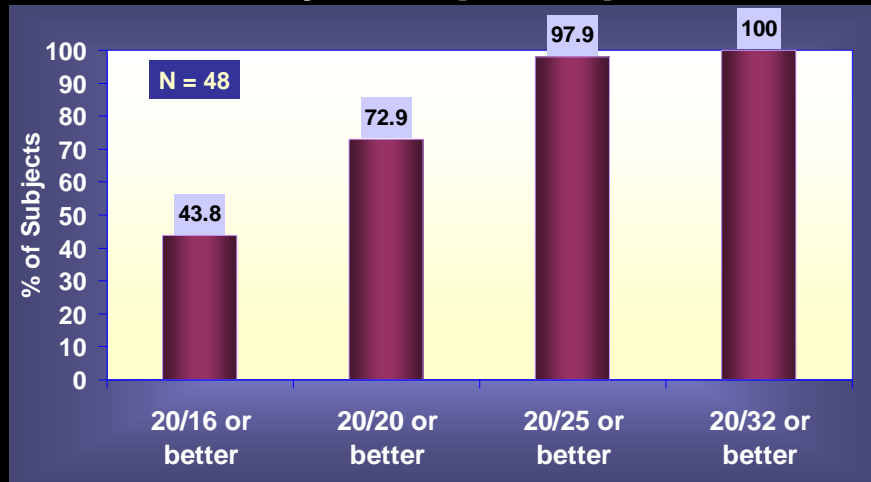
- Anterior chamber depth < 3.2 mm
- Non-qualifying ECD per age criteria
- Previous corneal surgery
- Mesopic pupil diameter > 7.0 mm
- Astigmatism > 2.0 D



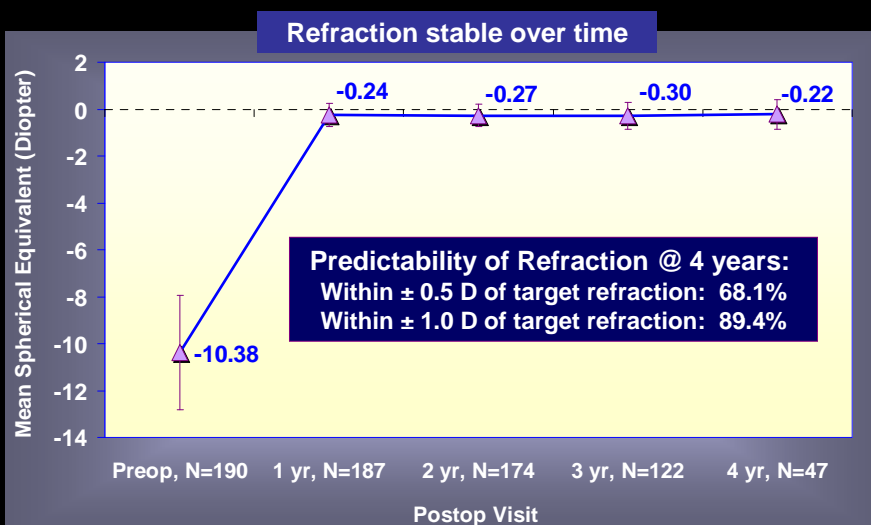
Uncorrected Visual Acuity 4 years postop



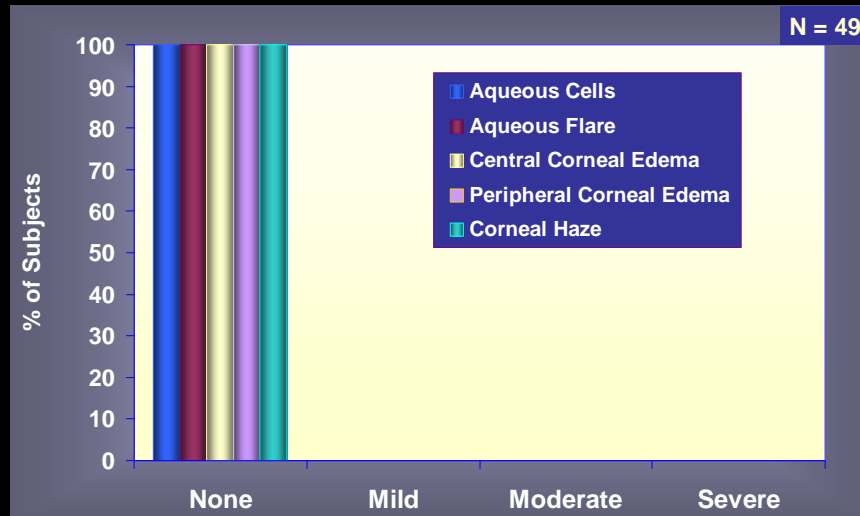
Best Corrected Visual Acuity 4 years postop



Manifest Refraction



Postoperative Inflammation 4 years postop



Adverse Events

Cumulative through 4 years postop

Adverse Event Description	Rate (%) Out of 190 subjects
Corneal Haze	0.5% (n=1)
Retinal Detachment / Repair	0.5% (n=1)
BSCVA Loss > 0.2 logMAR	0.5% (n=1)
Raised IOP Requiring Treatment (@ ≥1 month postop)*	3.2% (n=6)
Cataract Formation [†]	4.7% (n=9)
Synechia	4.2% (n=8)
Hospitalization— Raised IOP on Operative day	4.2% (n=8)
Secondary Surgical Intervention	4.7% (n=9)

*Majority steroid responders

[†]Iatrogenic, age related, or concurrent condition (myopia)

Adverse Events, cont'd

No incidences of:

- Pupil Ovalization
- Cystoid Macular Edema
- Corneal Stromal Edema
- Hyphema
- Hypopyon / Endophthalmitis
- Lens Dislocation
- Pupillary Block
- IOL Repositioning

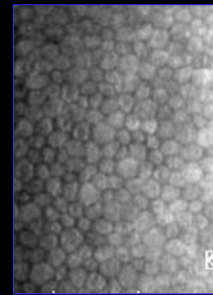
Out of 190
subjects

Corneal Endothelium Assessment

- Konan Noncon Robo specular microscope
 - 3 images each of the central and peripheral cornea
 - Image analyses at a central reading center
 - Endothelial cell density (ECD)
 - Percent hexagonality (% hex)
 - Coefficient of variation (CV)

Corneal Endothelium Assessment

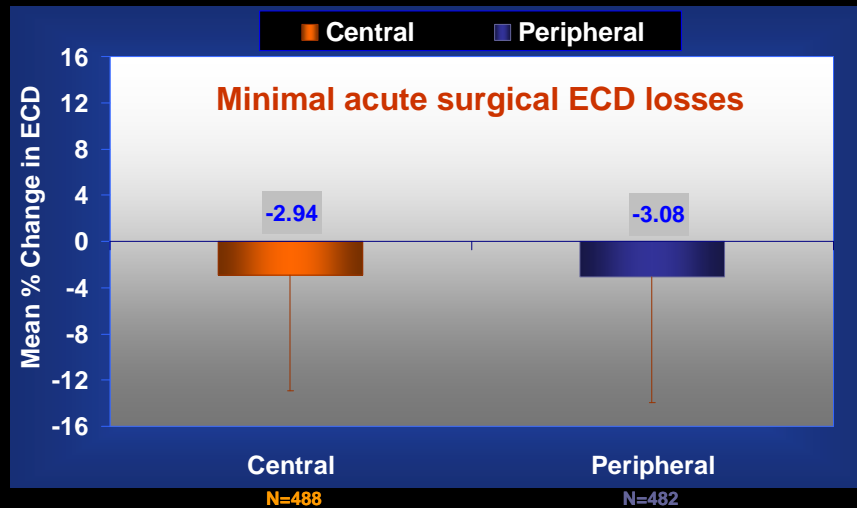
- Center method using Konan analysis software
- Center of cell dotted, plus center of adjacent cells
- Marked at least 100 contiguous cells for analysis of at least 50 cells



Corneal Endothelium Assessment

- Acute (surgical) losses calculated at 6 months from preop baseline
- Annualized chronic losses were calculated from 6 months postop baseline
- Percent hexagonality and coefficient of variation were calculated using a preop baseline

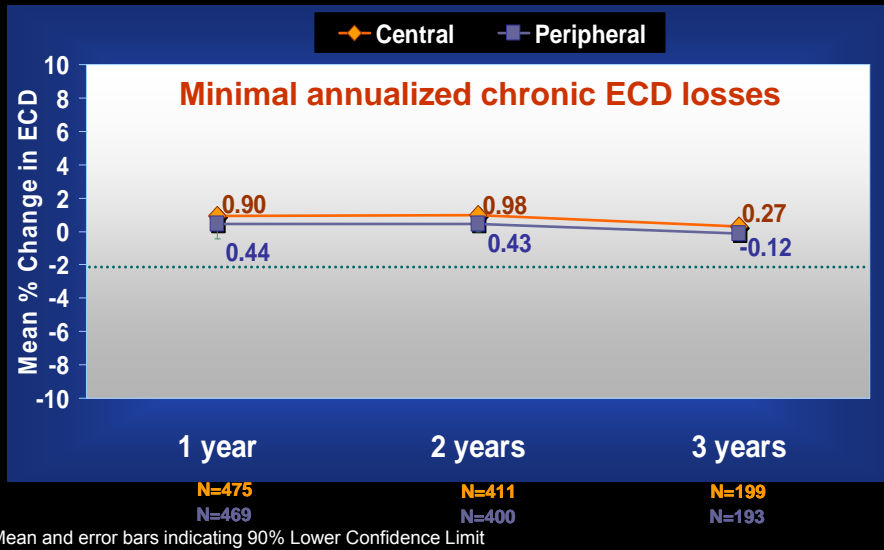
Acute Endothelial Cell Density 6 months from preop



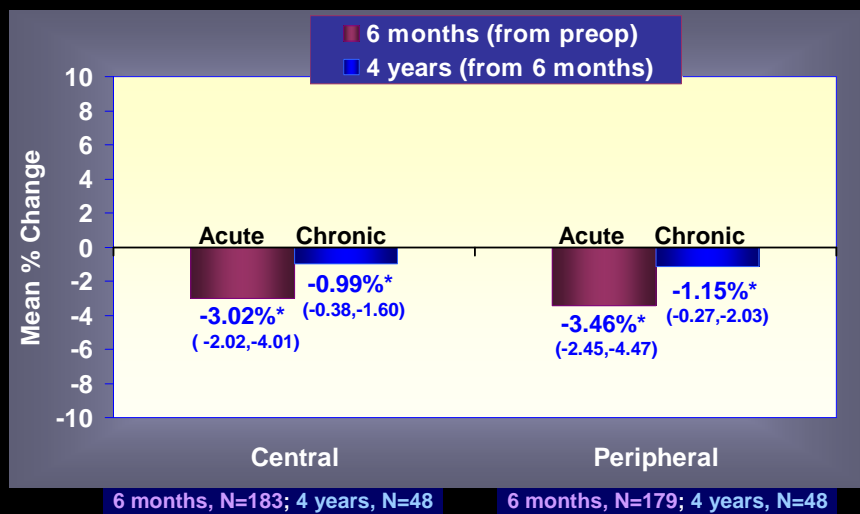
How Much Endothelial Cell Loss is Acceptable ?

- ISO 11979-10:2006
Ophthalmic implants – intraocular lenses
Part 10: phakic intraocular lenses
 - Assumes annual loss of 2%
 - This means less than 2% per year should be acceptable

Chronic Endothelial Cell Density Annualized, from 6 months baseline

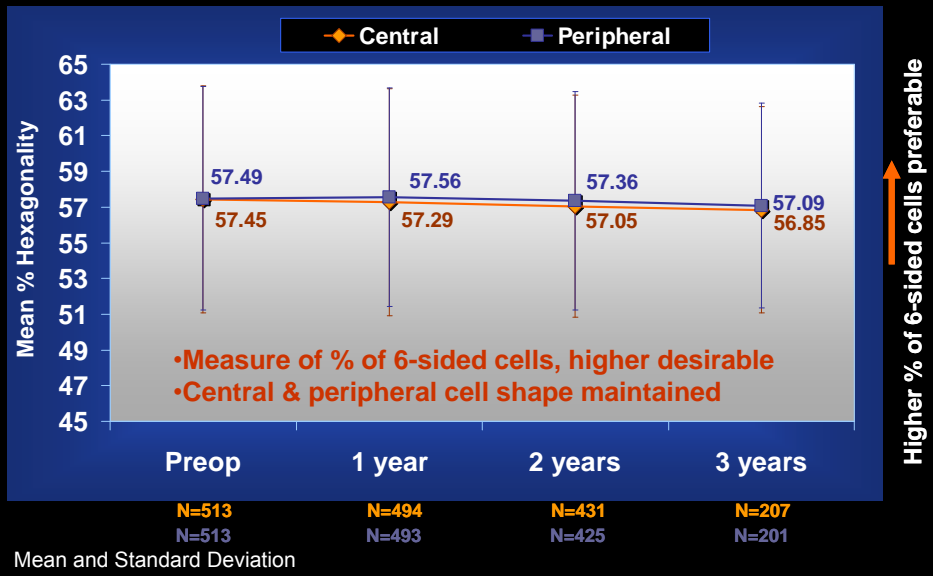


Endothelial Cell Density Mean % Change

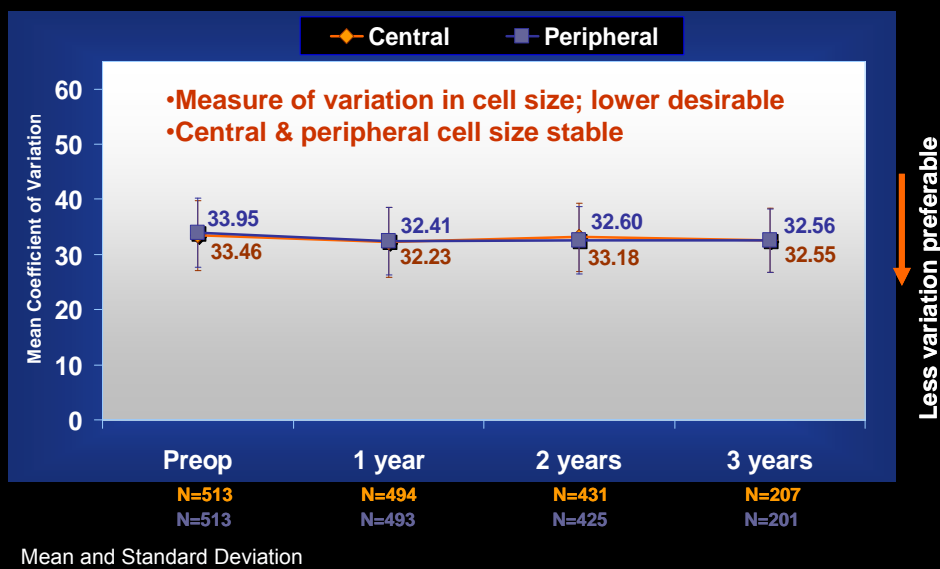


*Mean and 90% Upper & Lower Confidence Limits

Percent Hexagonality



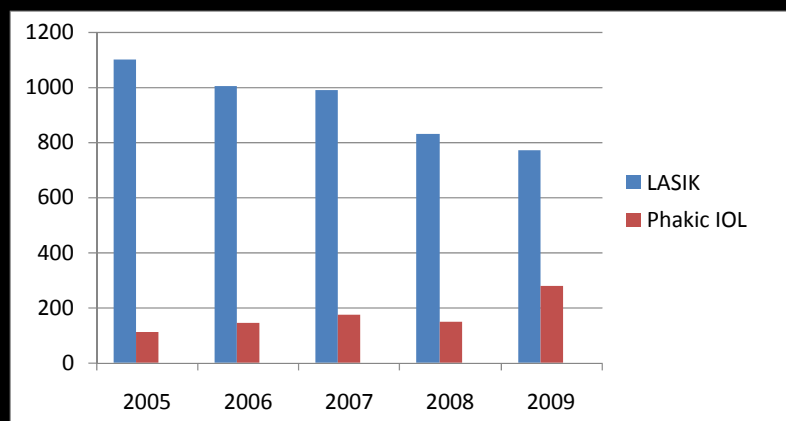
Coefficient of Variation



Summary Cachet IOL

- Excellent visual results
- Low incidence of adverse events
- No chronic ECC loss
- No pupil ovalization

Refractive Procedures, Mannheim



Personal Opinion

- AcrySof Cachet Phakic IOL my favorite
 - Topical anesthesia
 - Extremely easy to implant
 - No iridectomy required
 - Long-term safety established
 - Better visual acuity than LASIK !

Thank you