

# European Clinical Experience with Phakic Angle-Supported IOL: Four-Year Postop

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Financial Disclosure: Consultant, Alcon Laboratories, Inc.  
Alcon Laboratories, Inc. sponsored the study and provided statistical and presentation support.

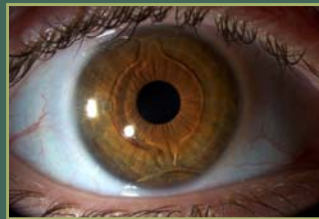
## Purpose

- To evaluate safety and effectiveness outcomes of the phase 3 European clinical investigation of the angle-supported AcrySof Phakic Lens

## Test Article

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- AcrySof Cachet Phakic Lens
  - Angle-supported
  - Foldable, single-piece design
  - Implanted via Monarch II IOL Delivery System
  - 6.0 mm optic
  - Overall lengths:
    - 12.5 mm
    - 13.0 mm
    - 13.5 mm
    - 14.0 mm



## Methods

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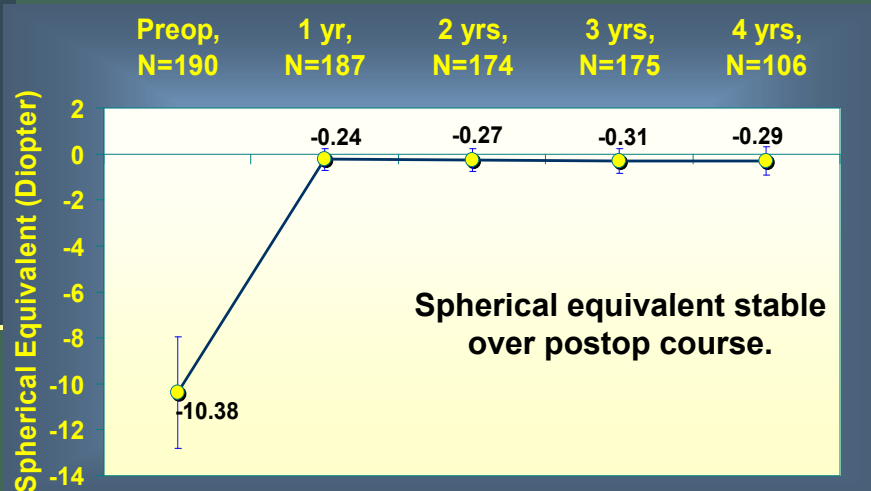
- Prospective, multicenter, European clinical trial
- 190 subjects with unilateral implantation
- Average preop spherical equivalent of  $-10.38 \pm 2.43$  diopter (D)
- >18 years of age
- Stable moderate to high myopia
- Good general and ocular health

# Methods

## ■ Parameters Evaluated

- **Spherical Equivalent**
  - 100% ETDRS chart @ 4 m
- **Visual Acuity**
  - Uncorrected (UCVA) and Best-Corrected VA (BCVA)
  - 100% ETDRS chart @ 4 m
- **Ocular Signs**
  - Aqueous cells by slitlamp
  - Aqueous flare by slitlamp
  - Corneal edema (central & peripheral)
- **Endothelial cell density (ECD)**
  - Konan Non-Con Robo Specular Microscope
  - Center method
  - 6 month baseline

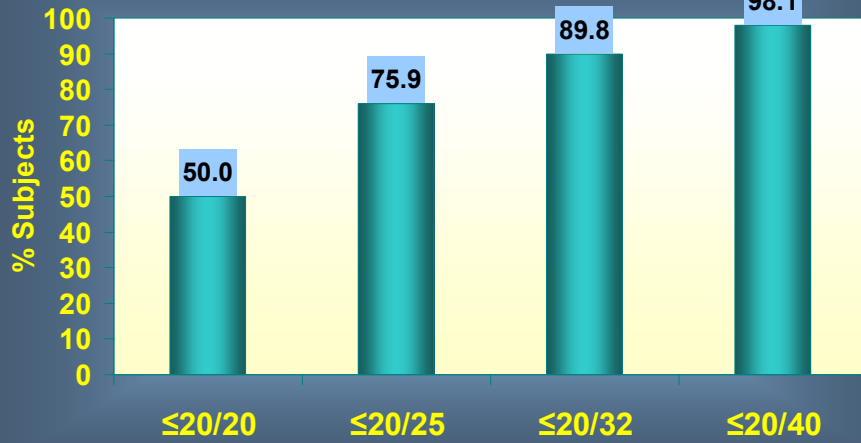
# Change in Spherical Equivalent Preop through 4 years



## Uncorrected Visual Acuity 4 years postop

Mean logMAR UCVA:  $0.06 \pm 0.16$

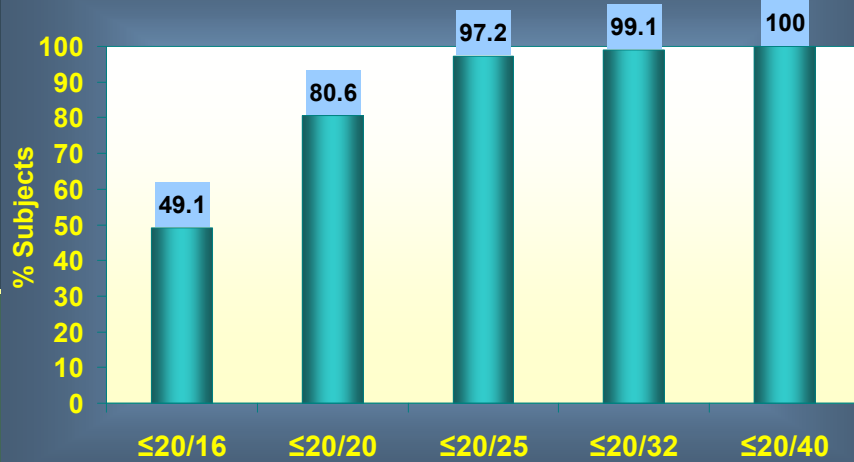
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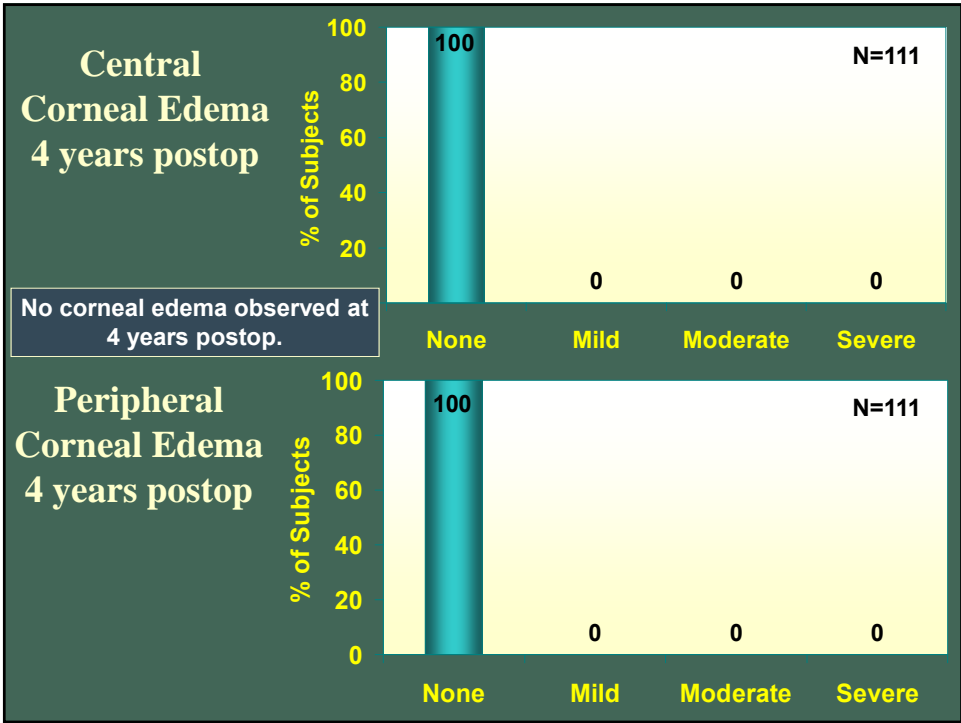
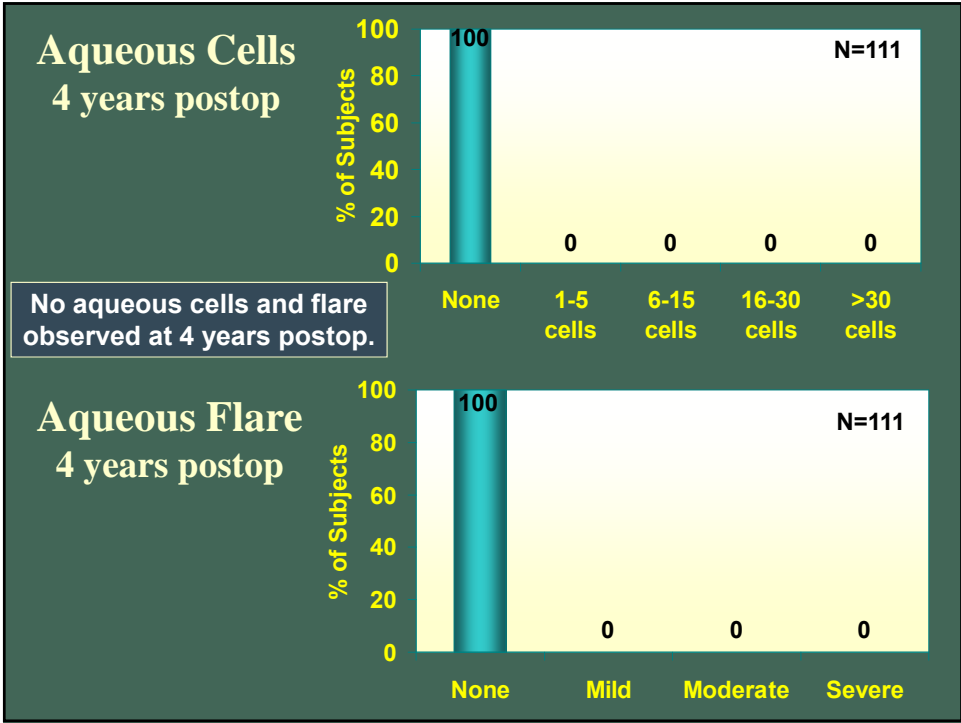


## Best Corrected Visual Acuity 4 years postop

Mean logMAR BCVA:  $-0.05 \pm 0.11$

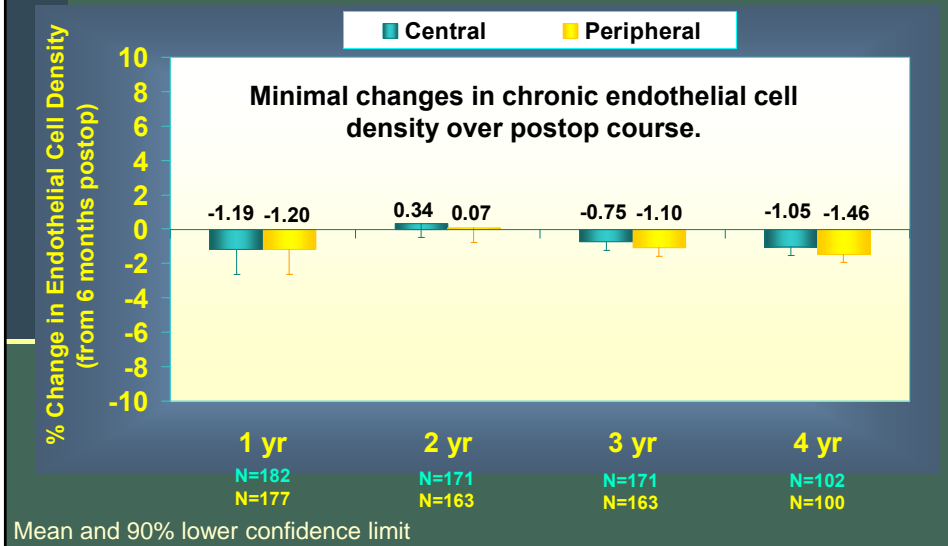
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## Endothelial Cell Density

Mean Annualized % Change from 6 months postop



## Conclusions

- At 4 years postoperative, European clinical results of the AcrySof Cachet Lens revealed:
  - Refraction stable
  - Good visual acuity
  - No observations of aqueous cells, flare, or corneal edema
  - Minimal annualized chronic ECD changes
  - Study is ongoing through 5 years