

Scleral Spacing Procedure (SSP) for the treatment of presbyopia

Lance J. Kugler, MD
Patti Fries, OD

LaserVision Omaha
University of Nebraska Medical Center
Omaha, NE

Presbyopia Correction

Static Correction

- **Cornea Related**
 - Monovision
 - Multifocality
 - KAMRA Implant
- **Lens Related**
 - Monovision
 - Multifocal lens implant
 - ReStor, ReZoom, Tecnis MF

Dynamic Correction

- **Lens Related**
 - Accommodative lens implant
 - Crystalens, etc.
- **Sclera Related**
 - Improve the accommodative ability of the crystalline lens
 - Scleral Spacing Procedure (SSP)

Presbyopes

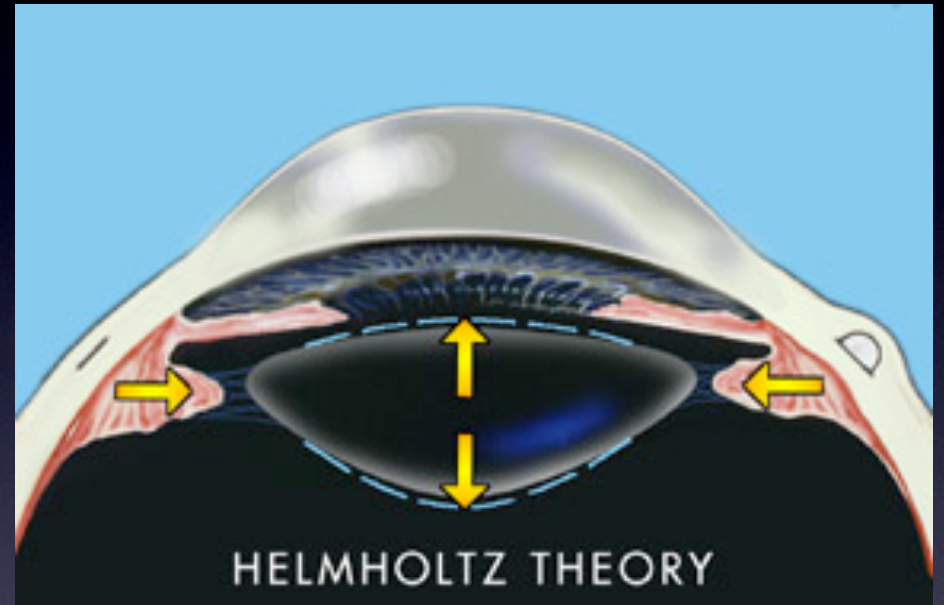
- 100 million presbyopes in the US
- 42 million plano - presbyopes in the US

Plano presbyopes

- The most difficult patient group to satisfy
- Uncompromising to any changes in distance vision
- Surgical emmetropes (post LASIK) have additional complicating factors of IOL power calculation error for RLE

Etiology?

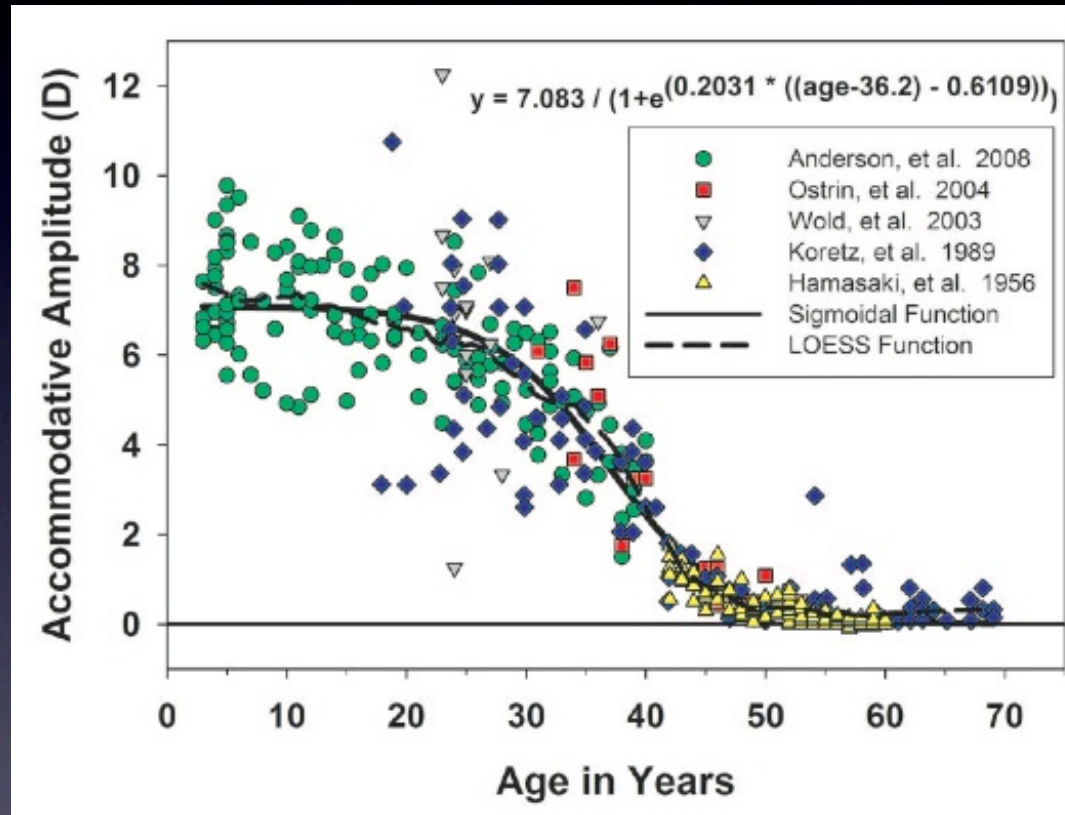
- Hemholtz
 - “...if the pull of the zonule is relaxed in accommodation for near vision, the equatorial diameter of the lens will diminish, and the lens will get thicker in the middle, both surfaces becoming more curved”



Fundamental problem with Hemholtz Theory

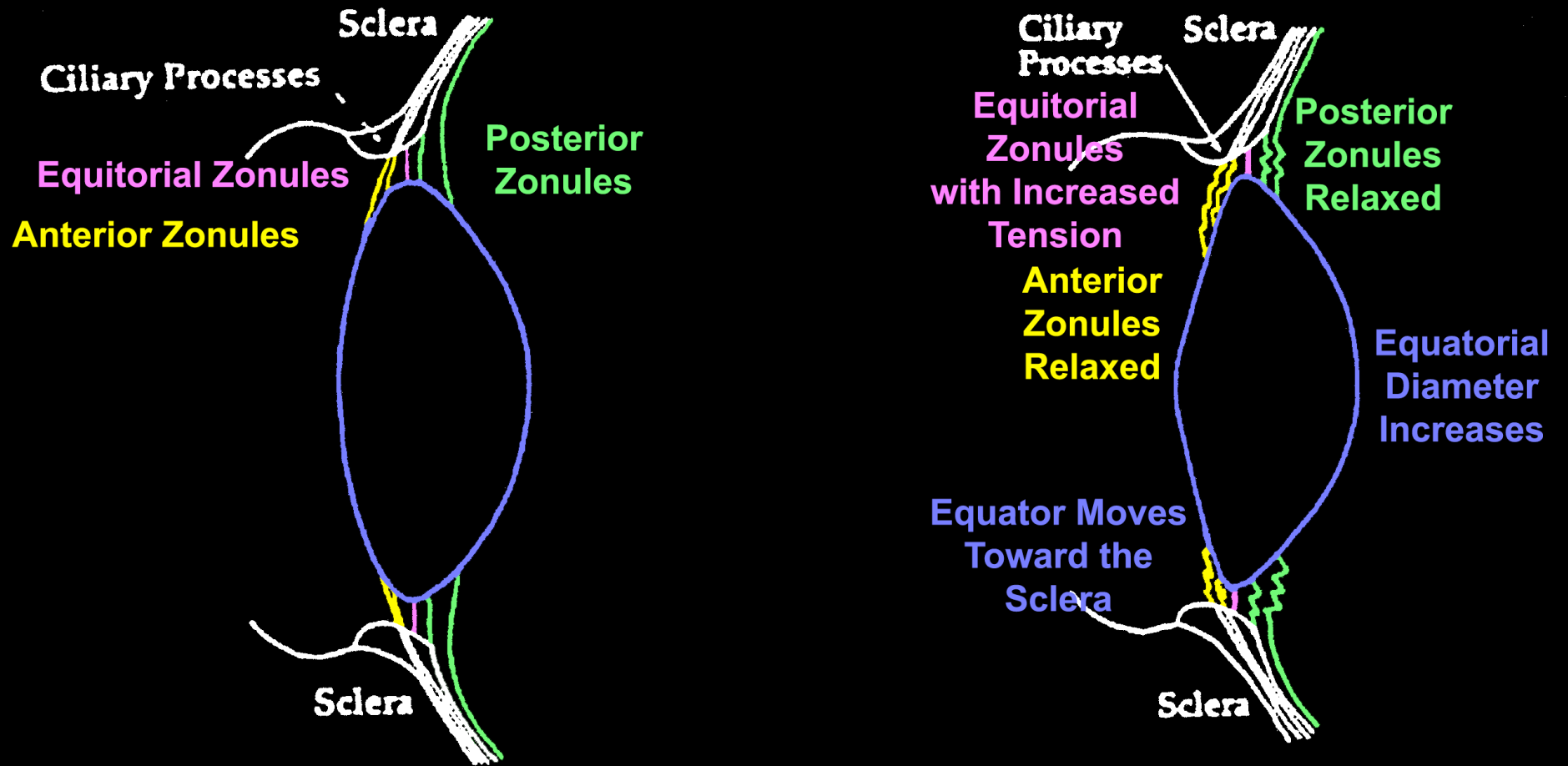
- Cataract surgeons know density of the crystalline lens varies significantly between patients of the same age
- Yet accommodative amplitude is remarkably predictable

Accommodation



Anderson et. al. Minus-Lens–Stimulated Accommodative Amplitude Decreases Sigmoidally with Age: A Study of Objectively Measured Accommodative Amplitudes from Age 3. IOVS. 2008(49):2919-26

Schachar (2001)



Zonule structure and function remain poorly understood



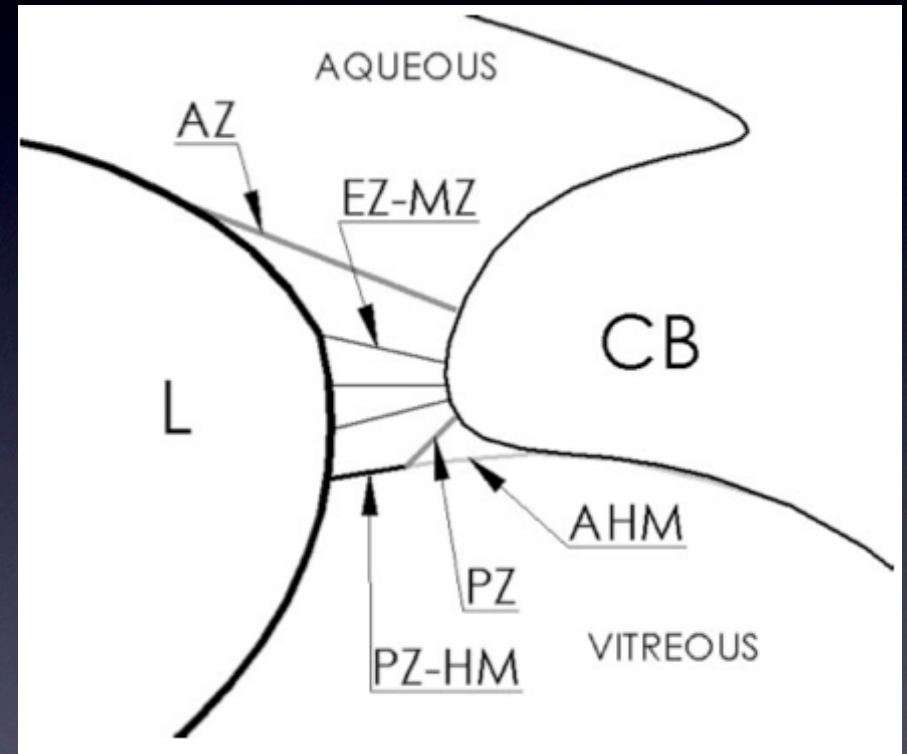
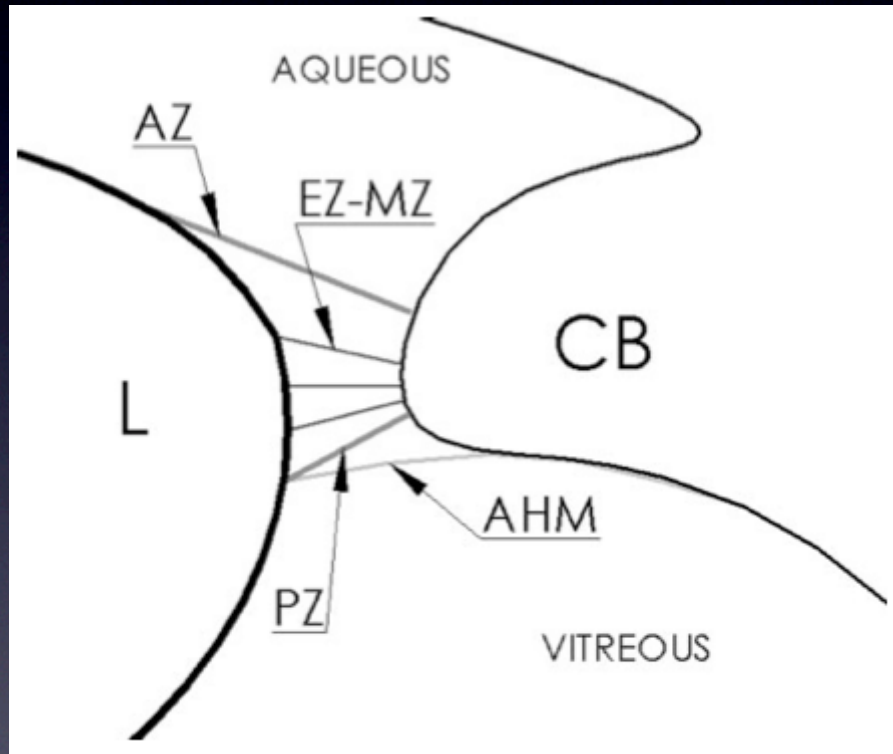
Bernal et. al. Evidence for Posterior Zonular Fiber Attachment on the Anterior Hyaloid Membrane. IOVS 2006(47):4708-13

Zonule structure and function remain poorly understood



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Decreased Zonular Tension With Age

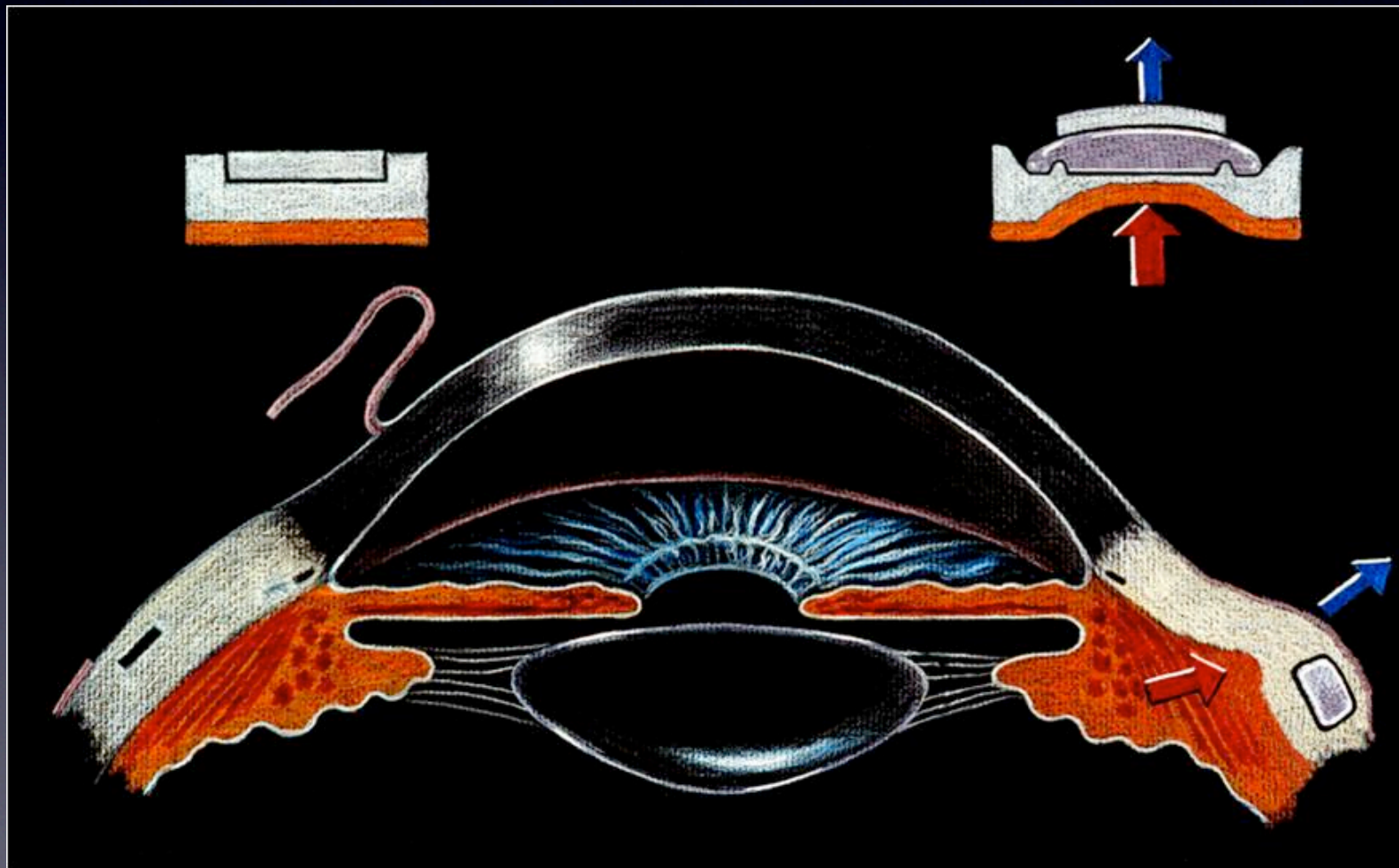
49 y/o

26 y/o

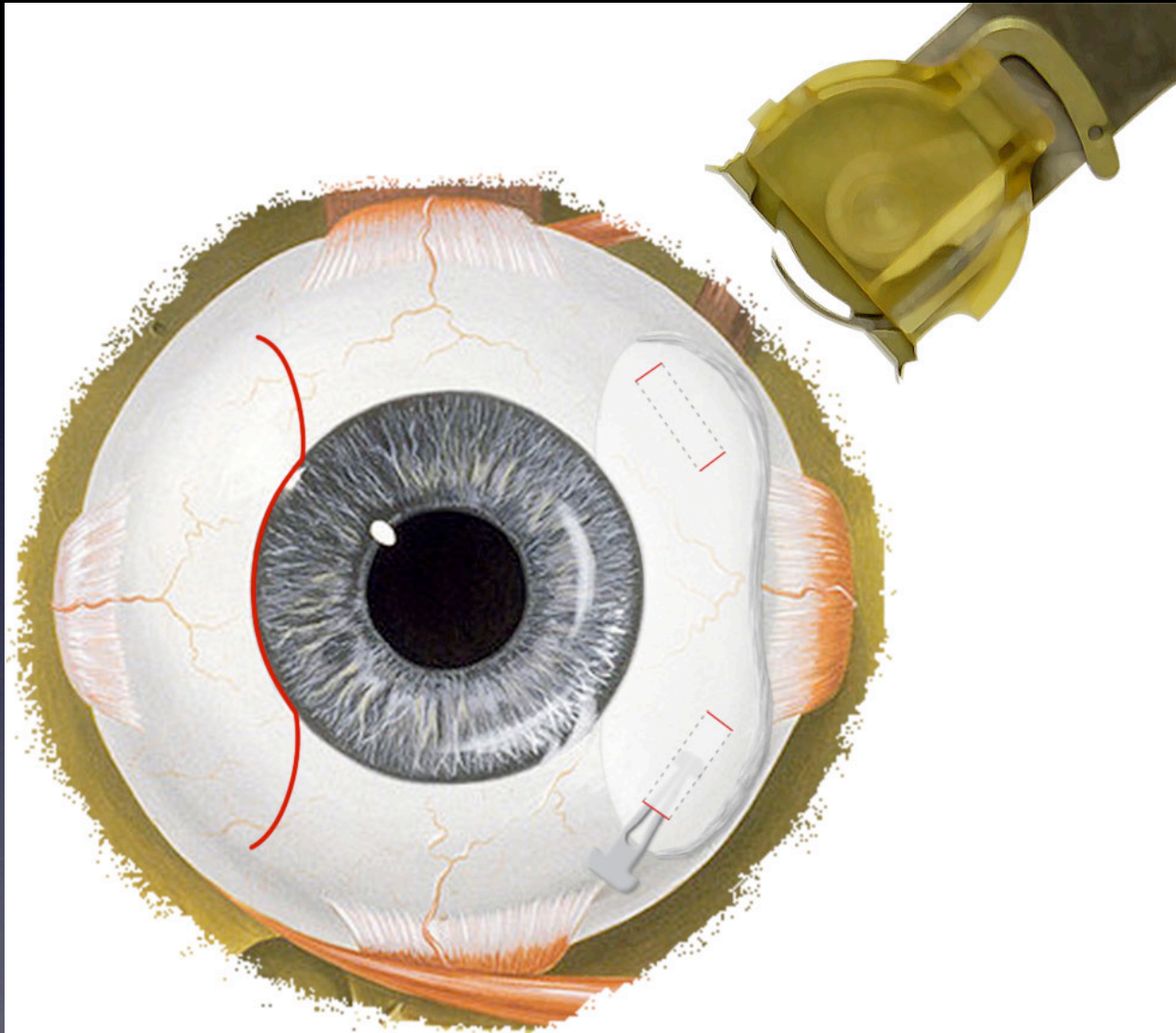


Strenk et. al. Magnetic resonance imaging of the anteroposterior position and thickness of the aging, accommodating, phakic, and pseudophakic ciliary muscle. J Cataract Refract Surg 2010; 36:235–241

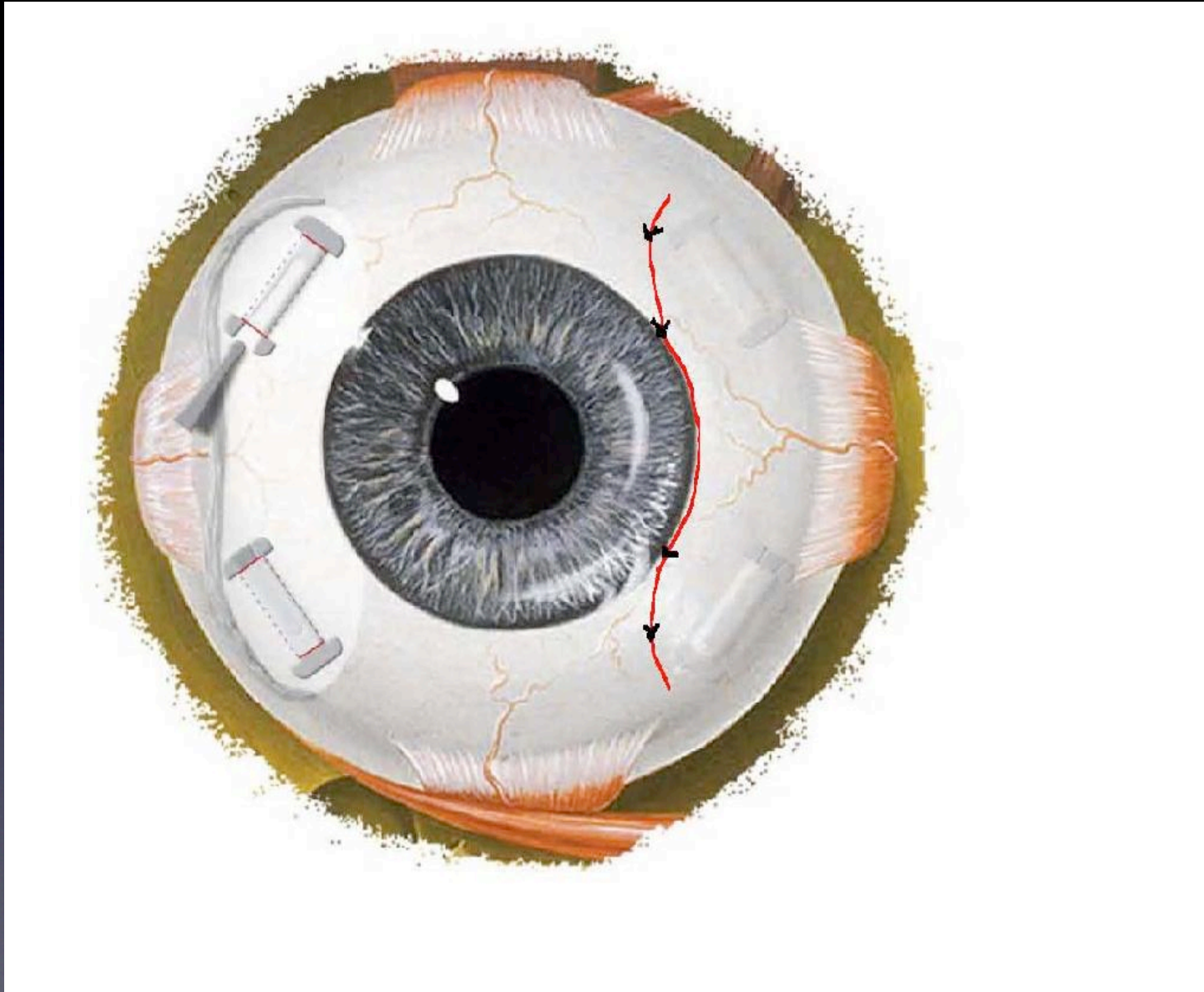
Scleral Spacing Procedure



Surgical Technique



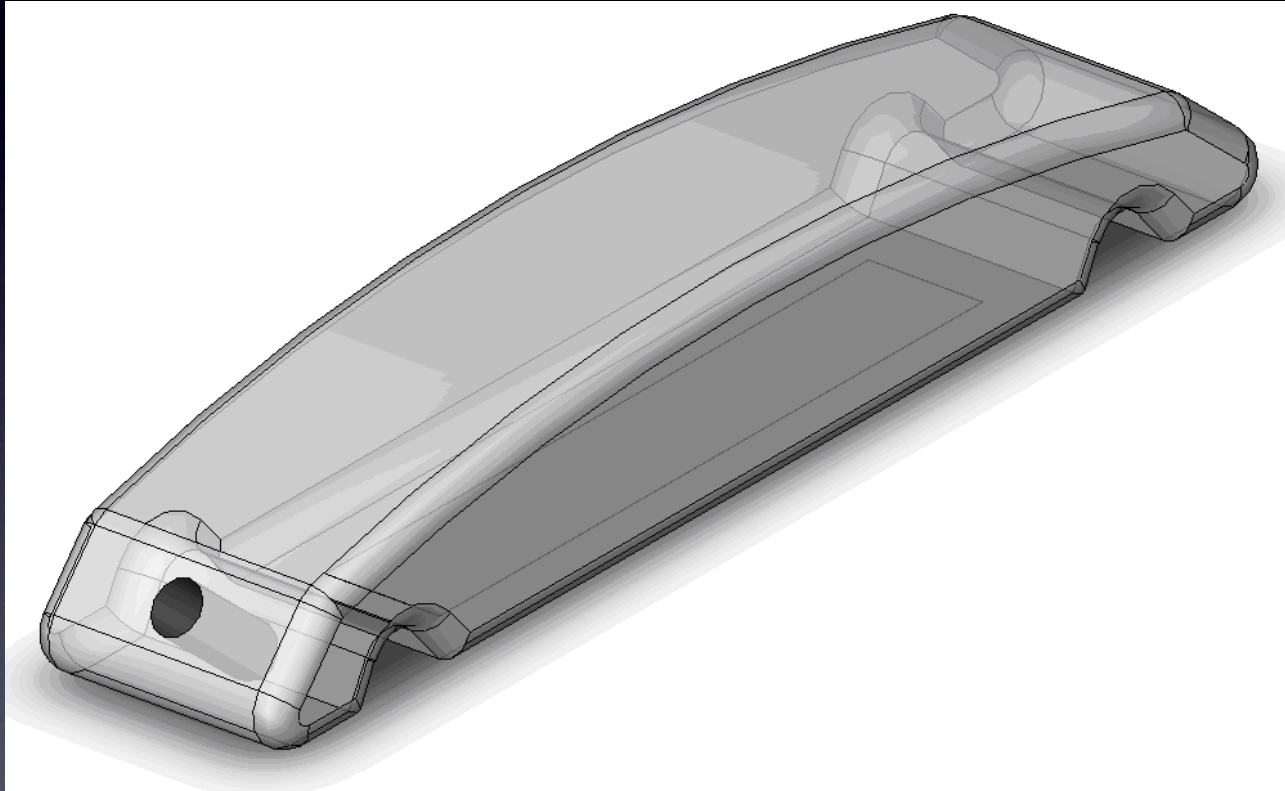
Surgical Technique



FDA Timeline

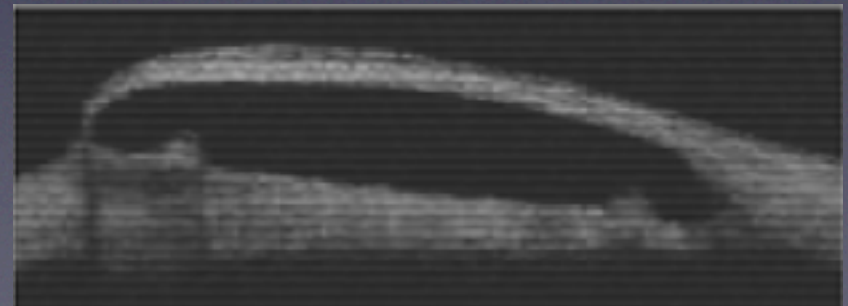
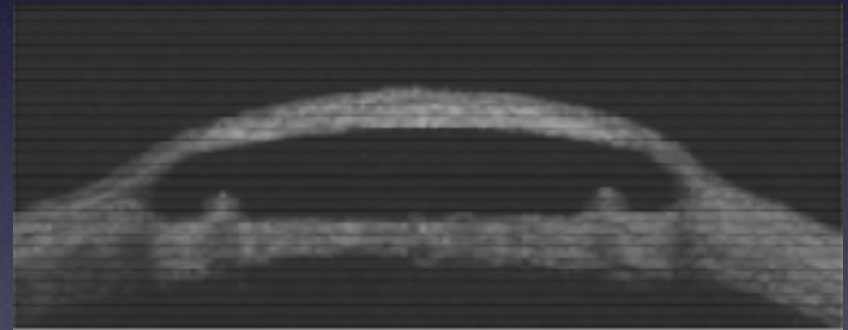
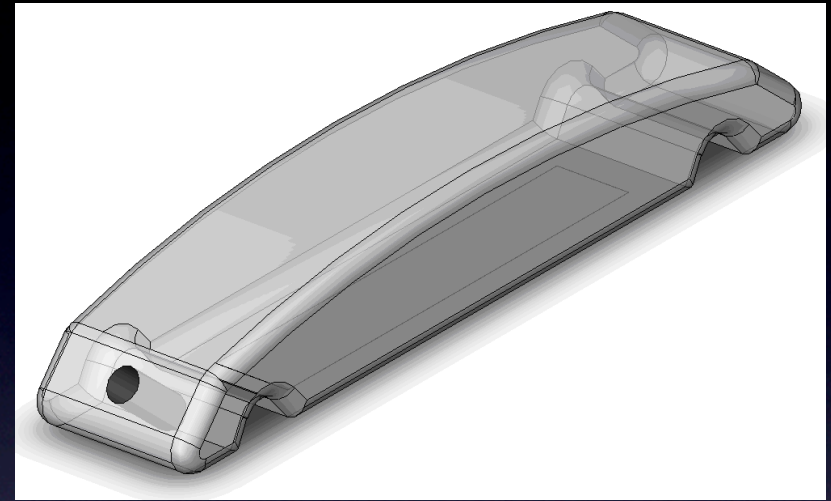
- Phase I March 2000 – 29 eyes monocular surgery
- Phase II Feb 2004 – 61 eyes (monocular) 32 control pts
- Phase III Aug 2005- 123 eyes, 79 patients
- FDA enrollment deferred – summer 2006.
- Redesigned scleral implant approved – June 2009
- Three sites enrolled, late 2009 - early 2010

Original PresView Implant Design



Original PresView Implant Design

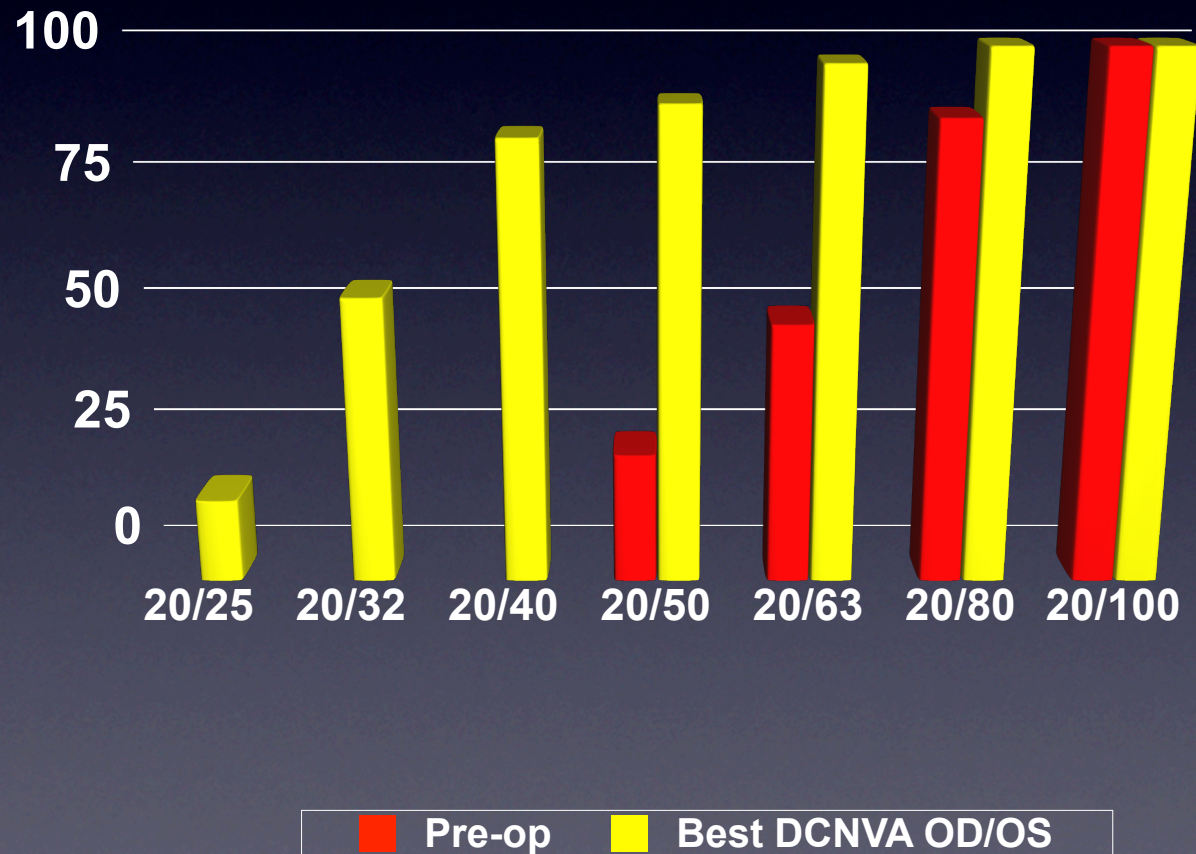
- some patients were losing effect over time
- Etiology initially not clear
- OCT Imaging showed segment slippage
- 1 segment: 50% effect
- 2 segments: 100% effect



Early FDA Study -% Cumulative Sloan Monocular Distance Corrected Near Visual Acuity

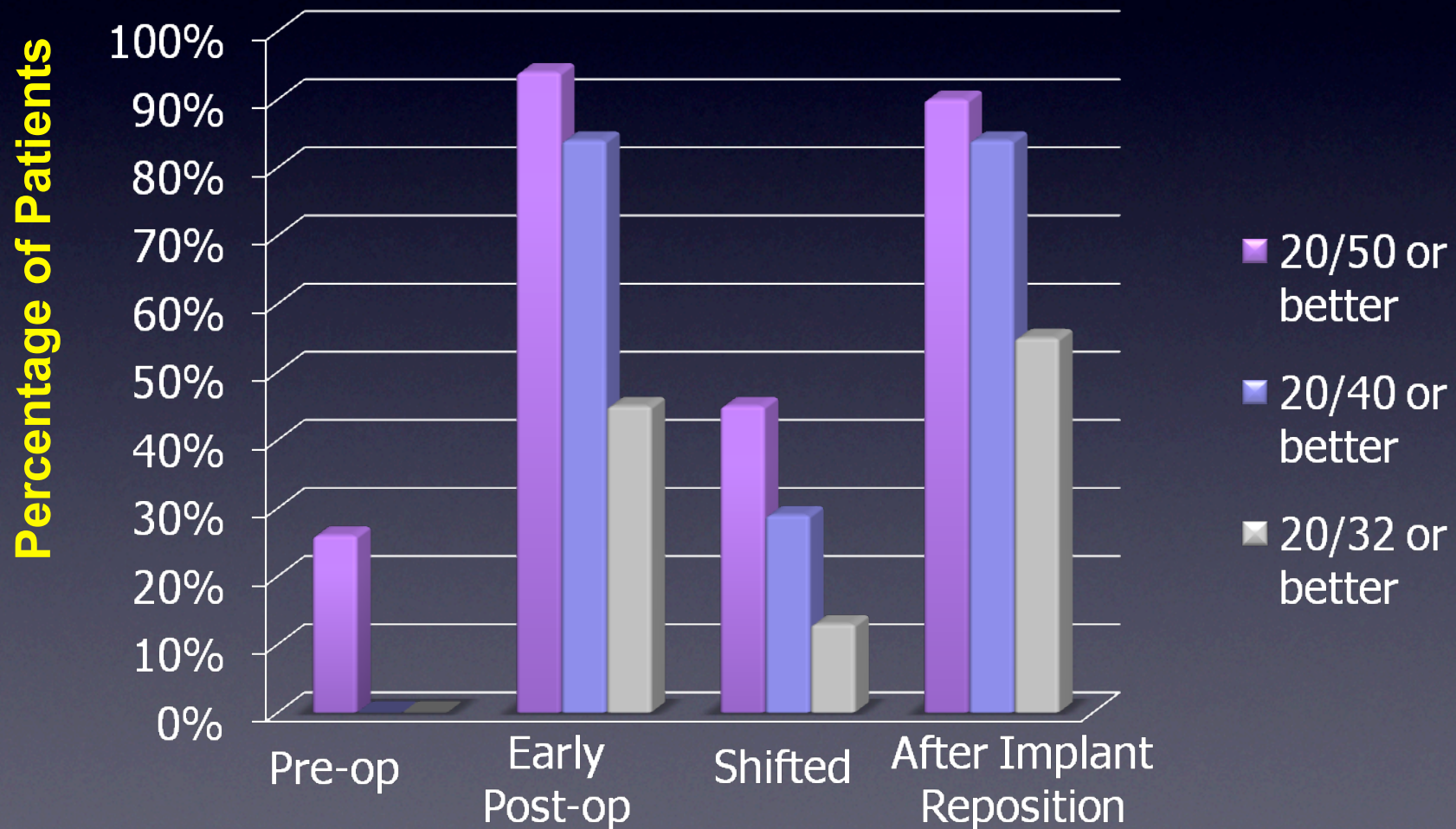
- Patients with Stable Implants Only (n=22)

About 83% of patients improve to 20/40 , 52% improve to 20/32 !!

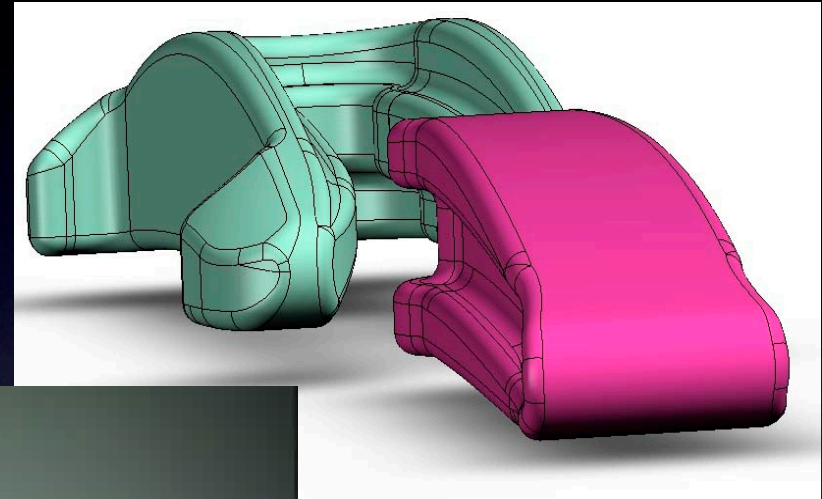


Surgical Repositioning and Suturing of Shifted Implants (n=30)

After implants are repositioned,
over 80% of these Patient's eyes also improve to 20/40 !!



Engineering Enhancements



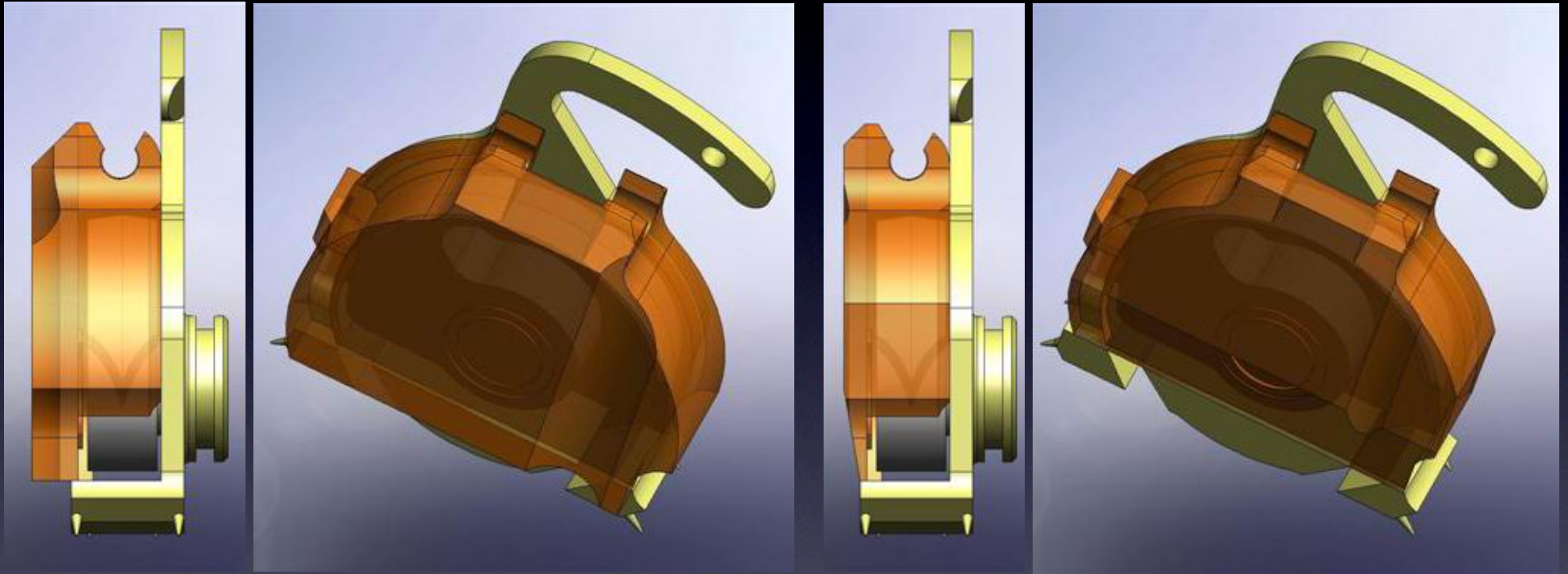
Two-piece interlocking implant

Engineering Enhancements



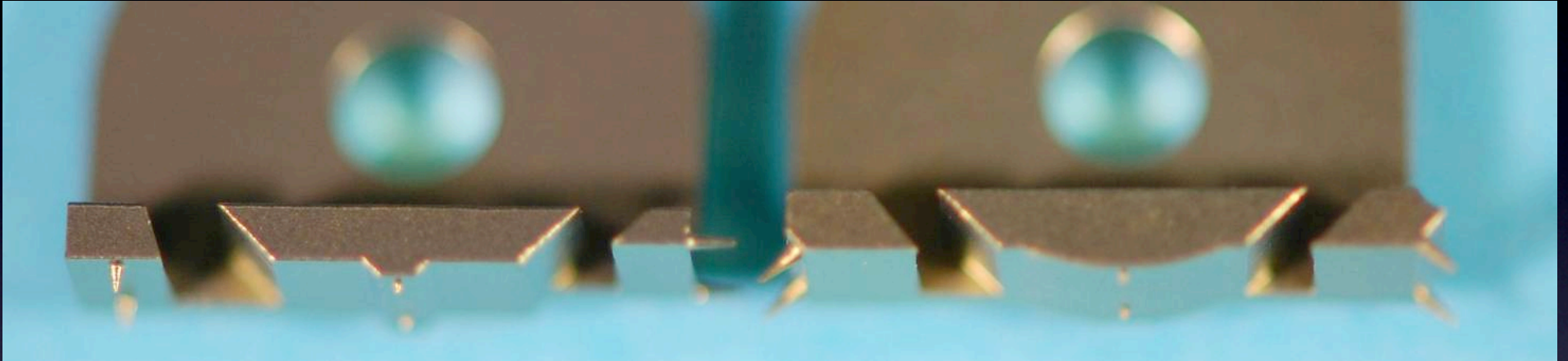
Improved marking system

Engineering Enhancements



Translucent blade cover

Engineering Enhancements



- Footplate design enhanced for improved:
 - Fixation
 - Depth
 - Length

Engineering Enhancements



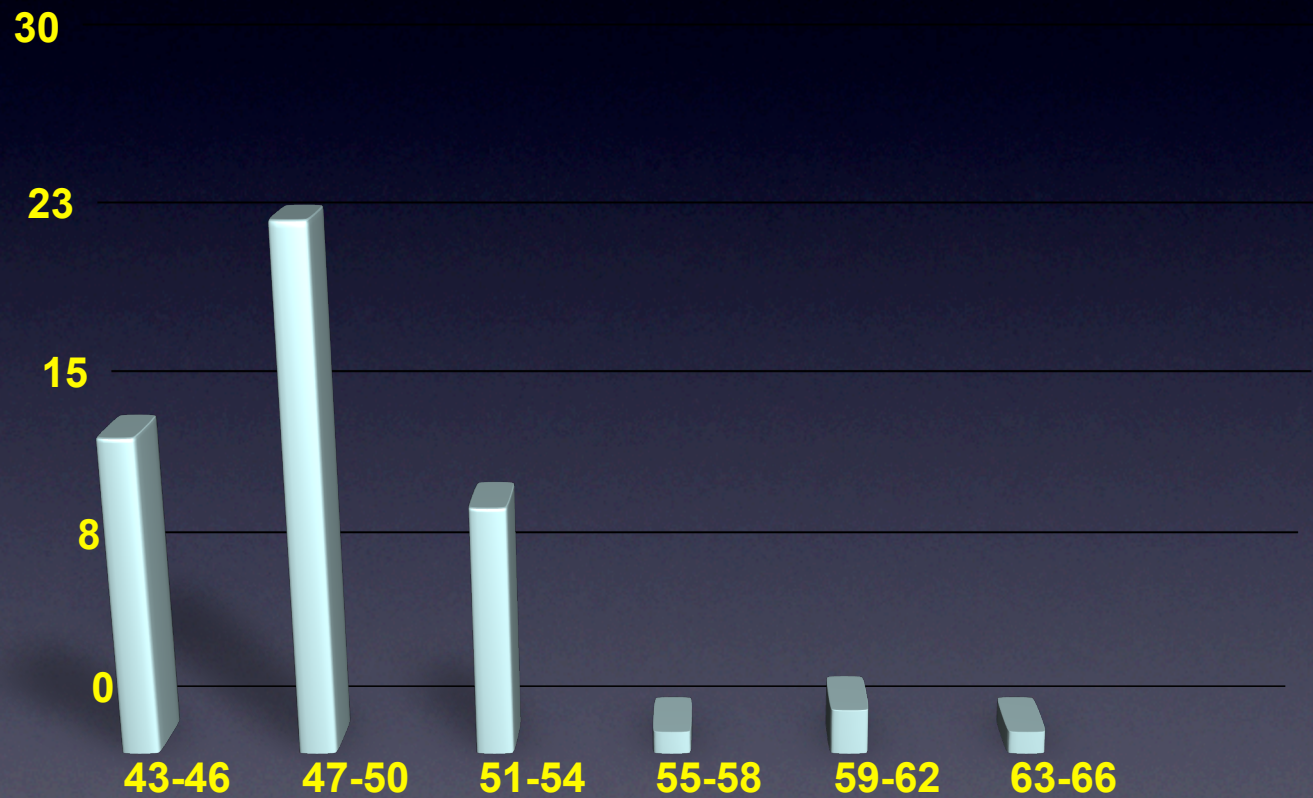
Blade redesigned for uniform depth and length

International Data

- Prospective trial
- 106 eyes (53 patients)
- All pre- and post-op exams
 - uniformly metered mesopic lighting
 - DCNV @ 40cm

International Data: Age distribution

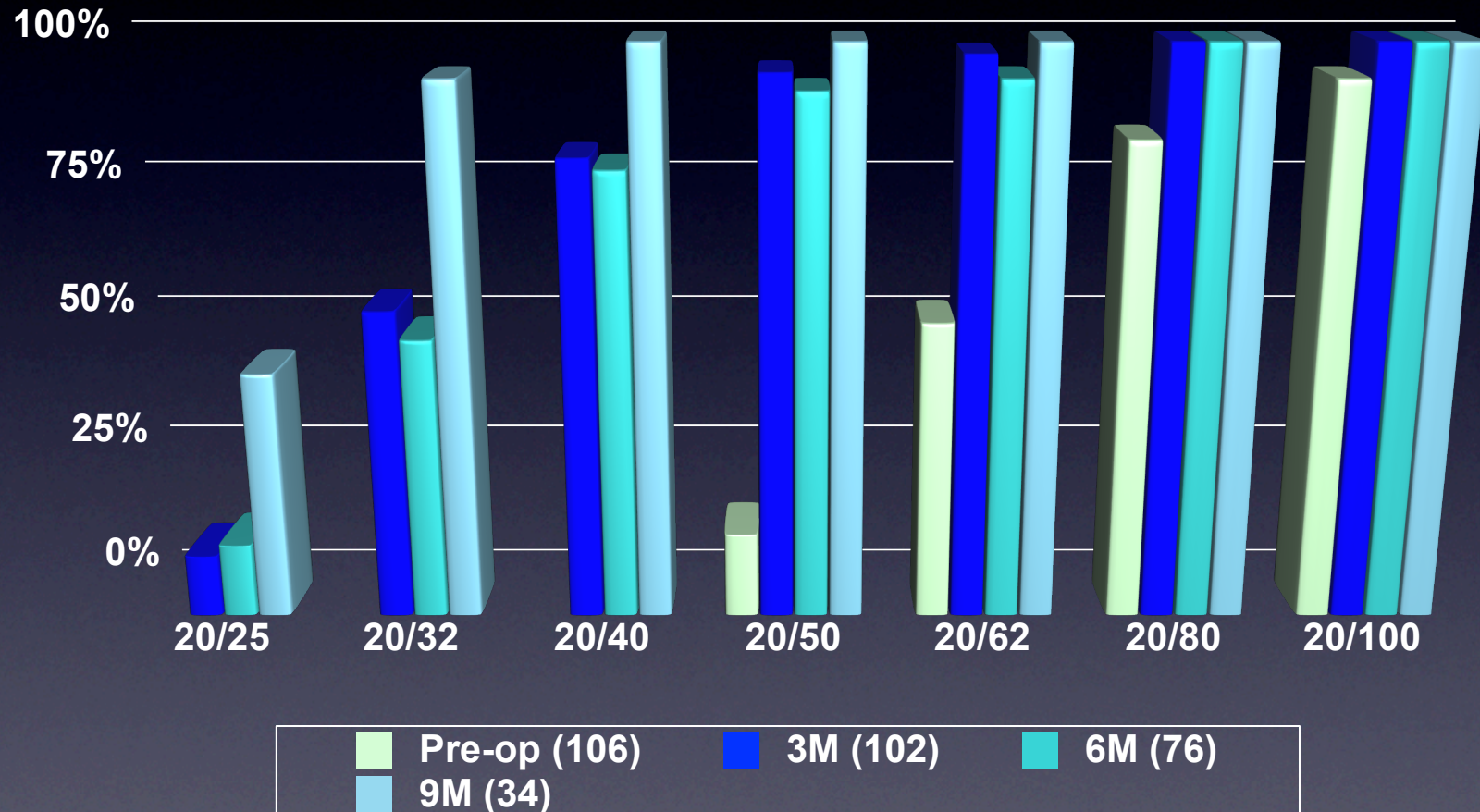
n=53, average age=49



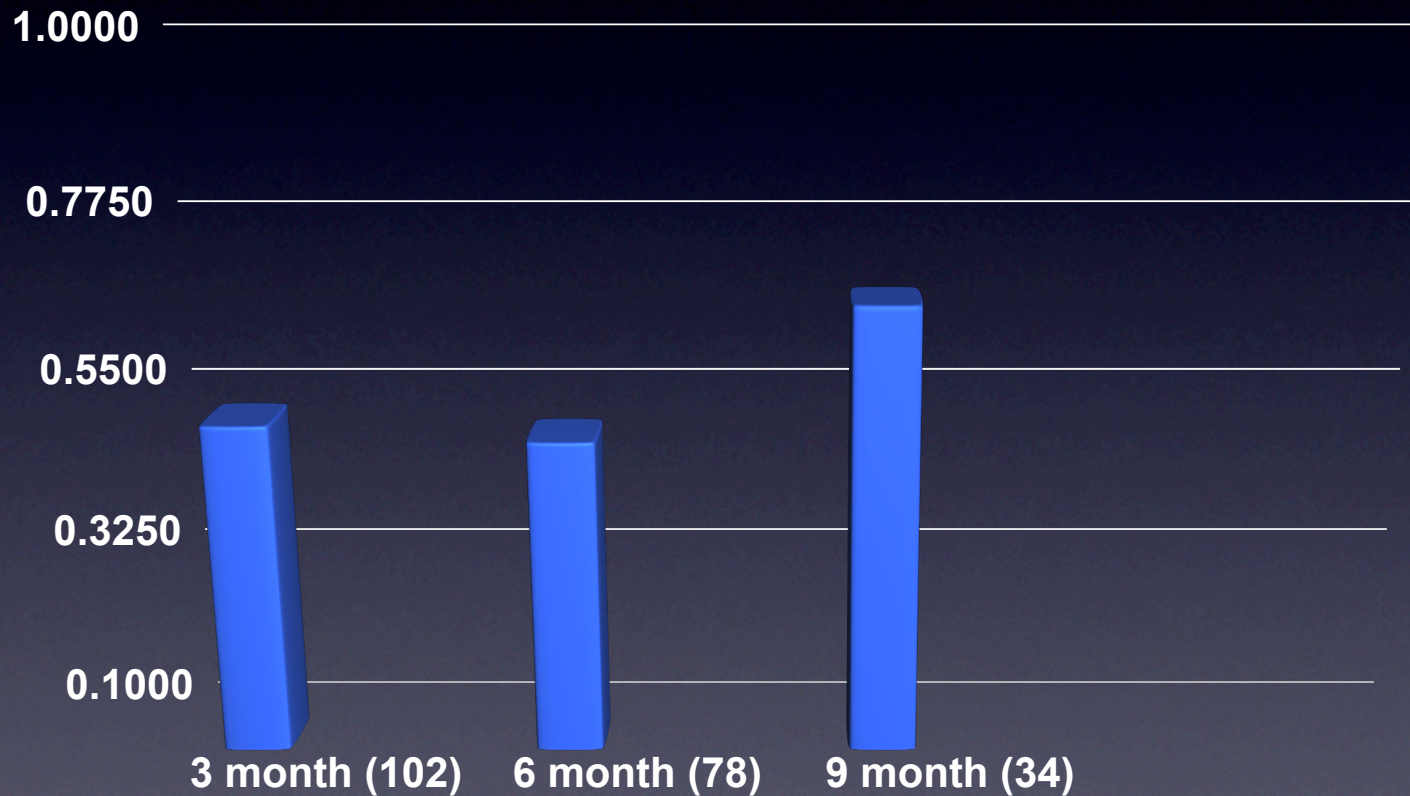
International Data: Distance Metrics

- No Surgery on the Visual Axis or Cornea
- No Changes in DCVA
- No Changes in Contrast Sensitivity
- No Changes in Topography
- No Changes in Axial Length

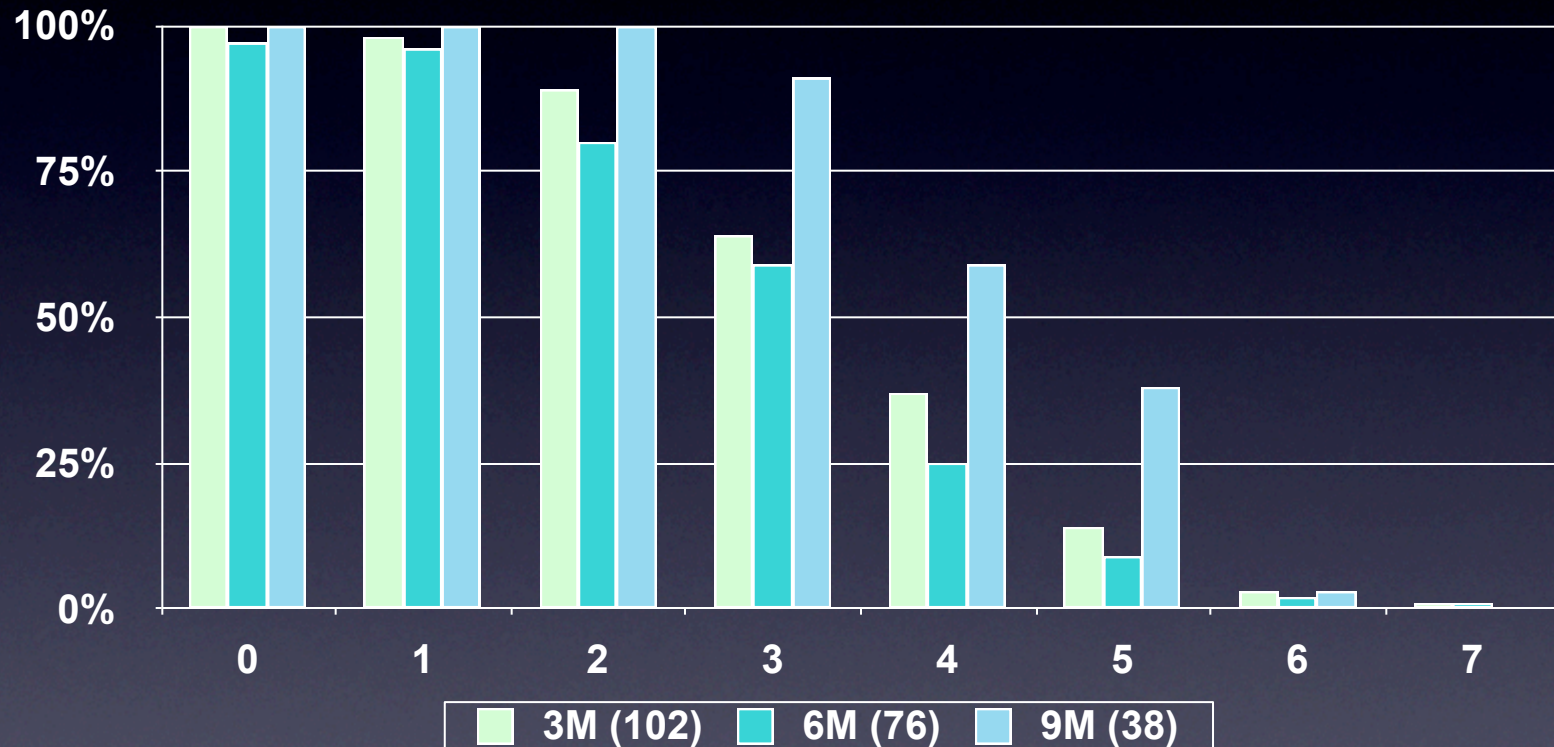
Cumulative Monocular Acuity Percent



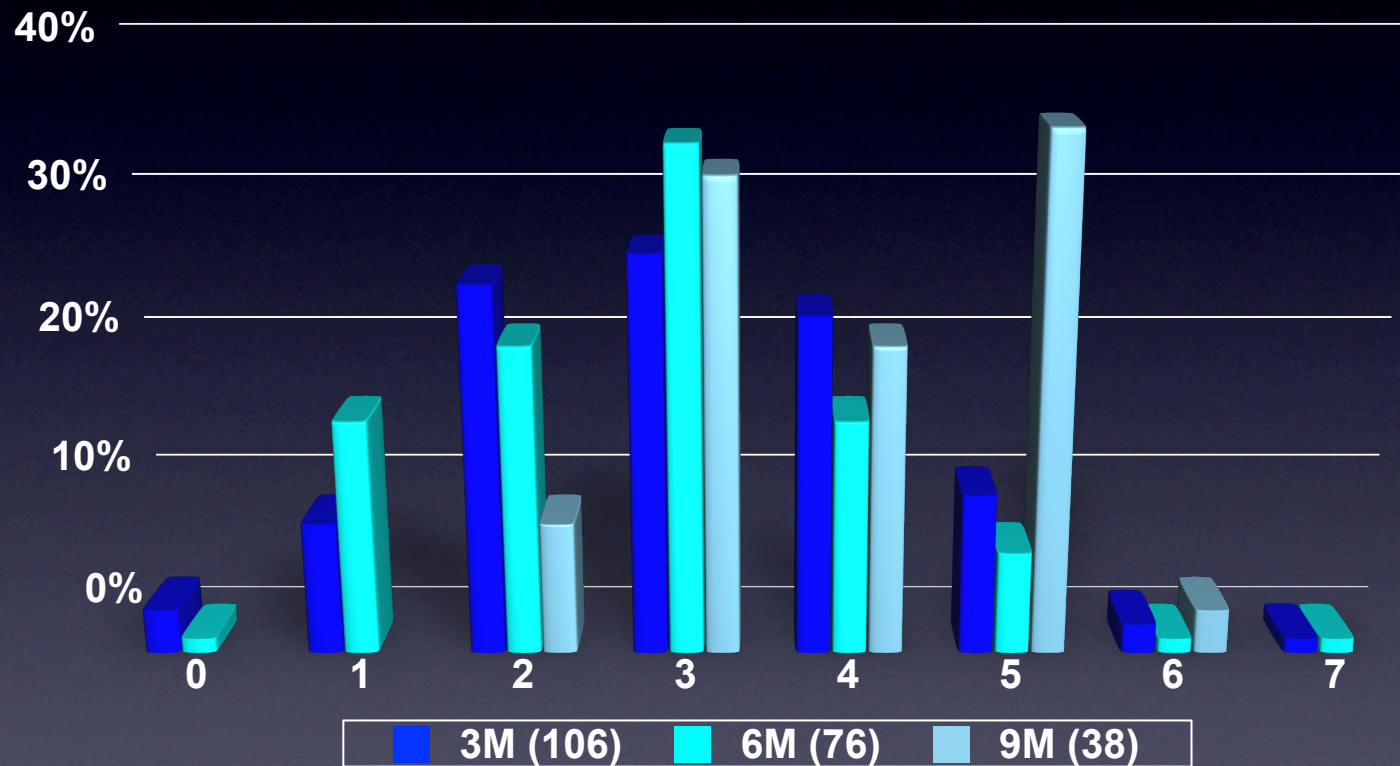
Average DCNVA Monocular



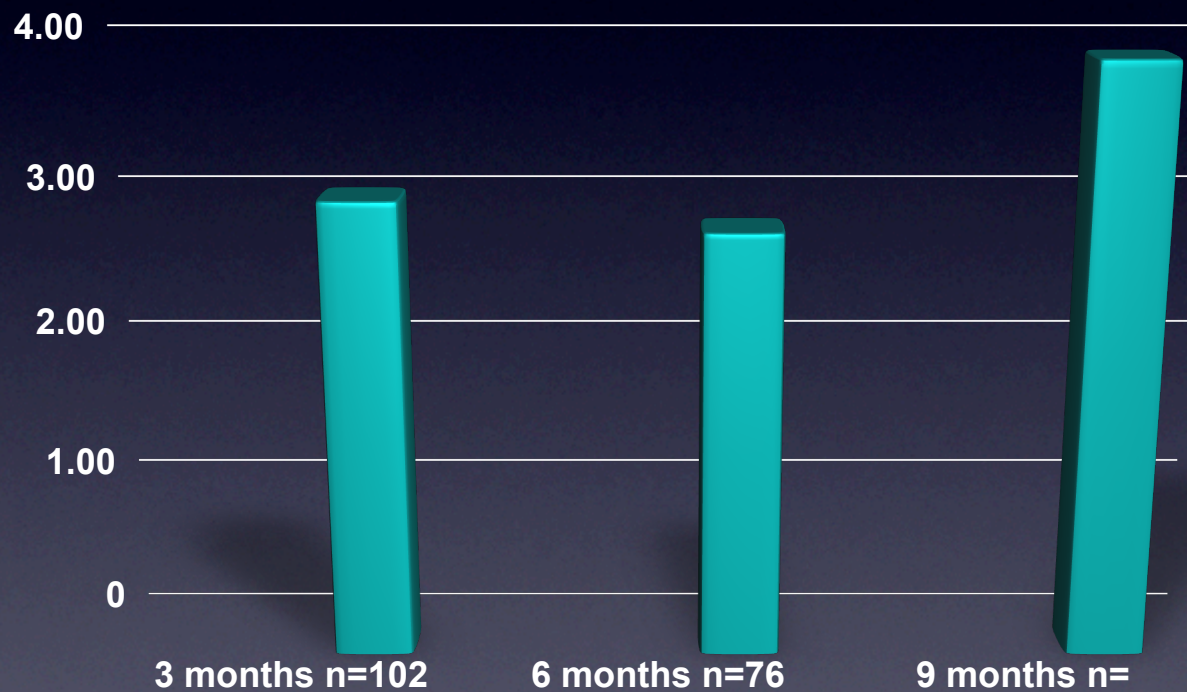
Cumulative Monocular Lines Percent



Monocular Lines Improvement Distribution Percent



Average Lines of Improved DCNVA Monocular



Conclusion

- Presbyopia is a complex mechanism, still poorly understood
- SSP with PresView scleral implants is a safe and effective procedure for presbyopic emmetropes
 - No change in distance parameters
 - Average 3.91 lines of near improvement
- The FDA trials currently in progress will provide additional long-term data on safety and effectiveness