

Two-Year Results of Scleral Implants for Presbyopia Treatment

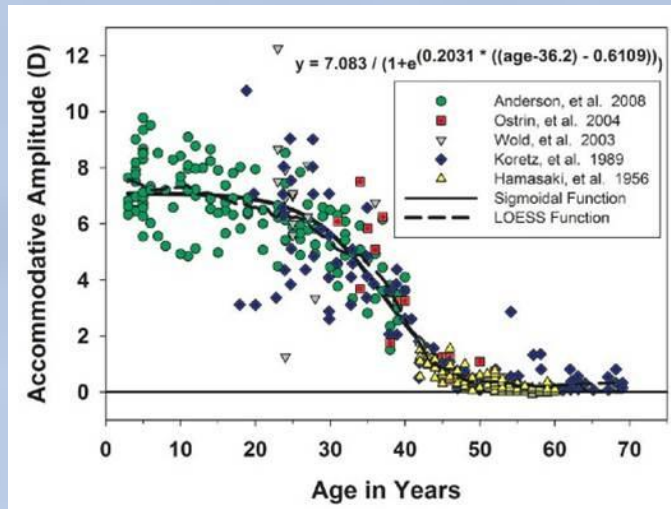
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Financial Interest Disclosure:
Principal Investigator, US FDA Clinical Trial
Refocus Group provides research funding and travel expenses

Background – Presbyopia

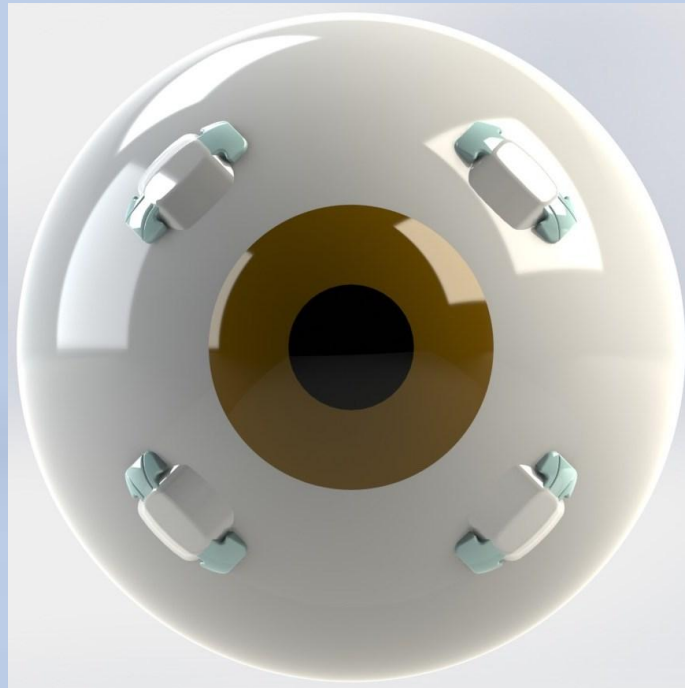
- Age-related loss of accommodative amplitude
- Begins between age 40-50
- Represents over 90 million people in the US ¹
- Accommodative amplitude decreases sigmoidally with increasing age ²



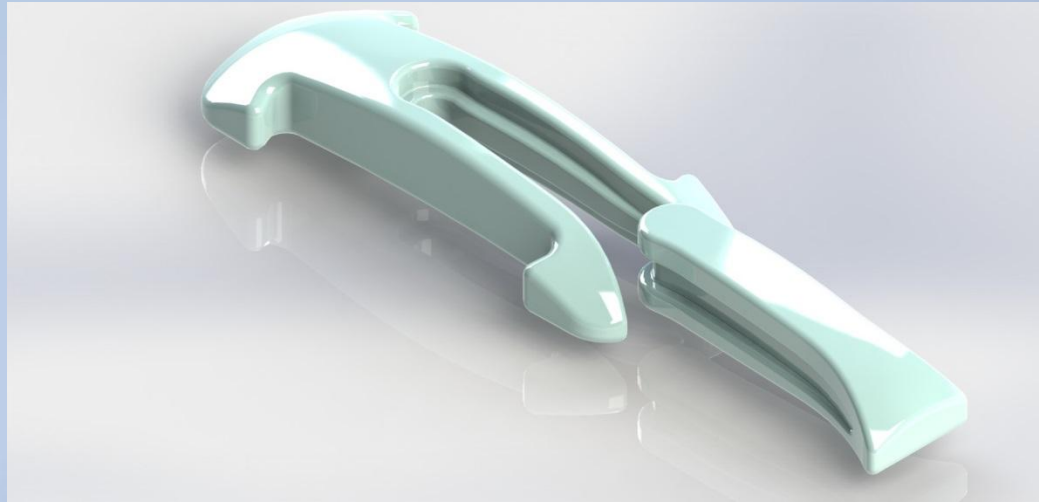
- Static options for the surgical correction of presbyopia:
 - Cornea-related
 - Monovision (excimer laser)
 - Multifocality (excimer laser)
 - Lens-related
 - Monofocal IOL (monovision)
 - Multifocal IOL (ReSTOR, ReZoom)
- Dynamic options for the surgical correction of presbyopia:
 - Lens-related
 - Accommodative IOL (Crystalens)
 - Sclera-related
 - **The Refocus Procedure**

The Refocus Procedure

- Four small plastic segments (Refocus Scleral Implants) are implanted circumferentially in the four oblique quadrants of the sclera

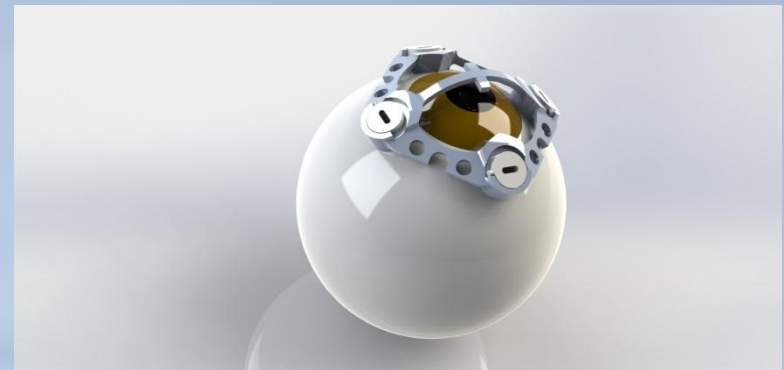
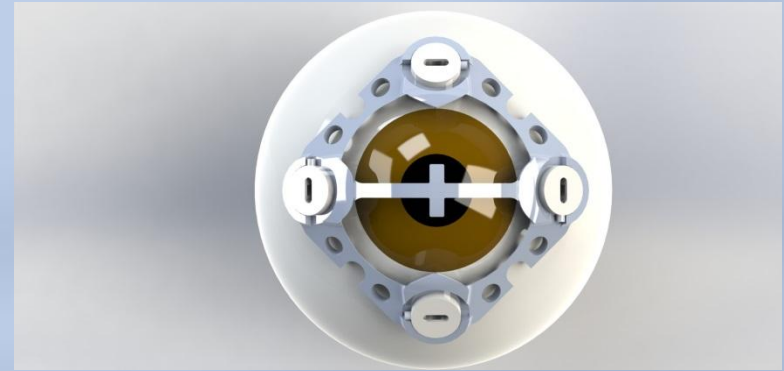
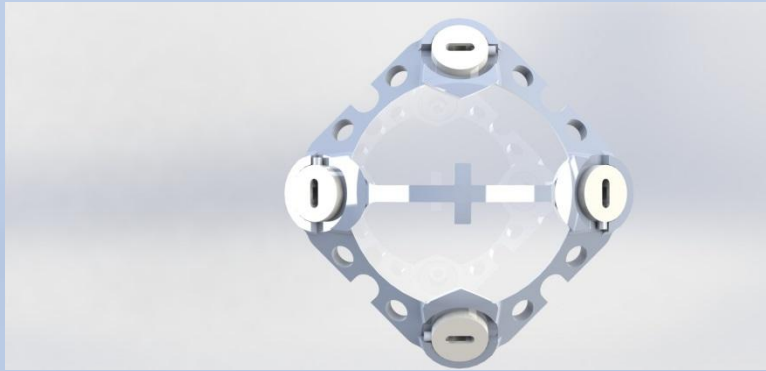


The Refocus Scleral Implant



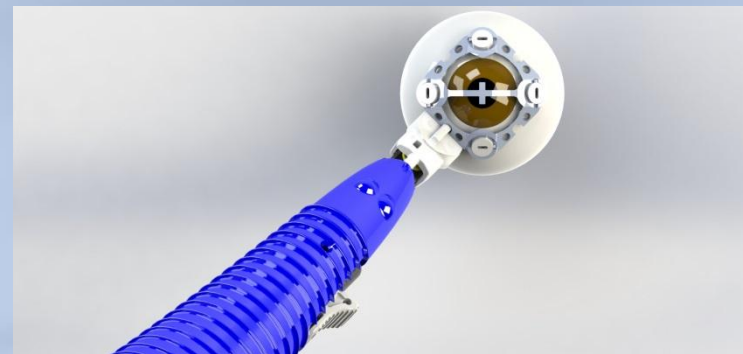
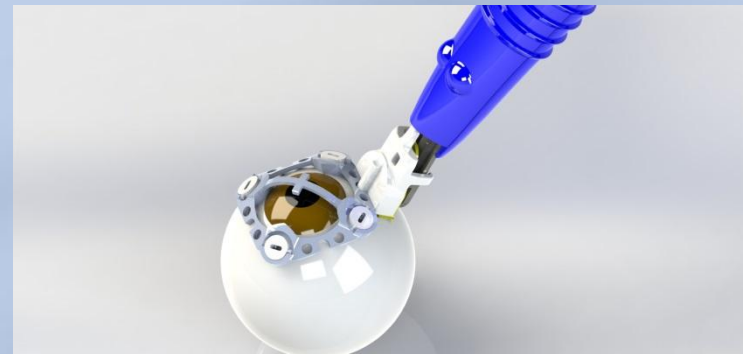
Oculock Device

- Oculock locks with 4-point fixation
- Scleratome docks into position
- No marking required



Disposable Sclerotome

- Easy to use
 - Lightweight/ergonomic
- Docks with Oculock
- Facilitates uniform tunnel creation
 - Position = 4mm from limbus
 - Length = 4mm
 - Depth = 400 μ

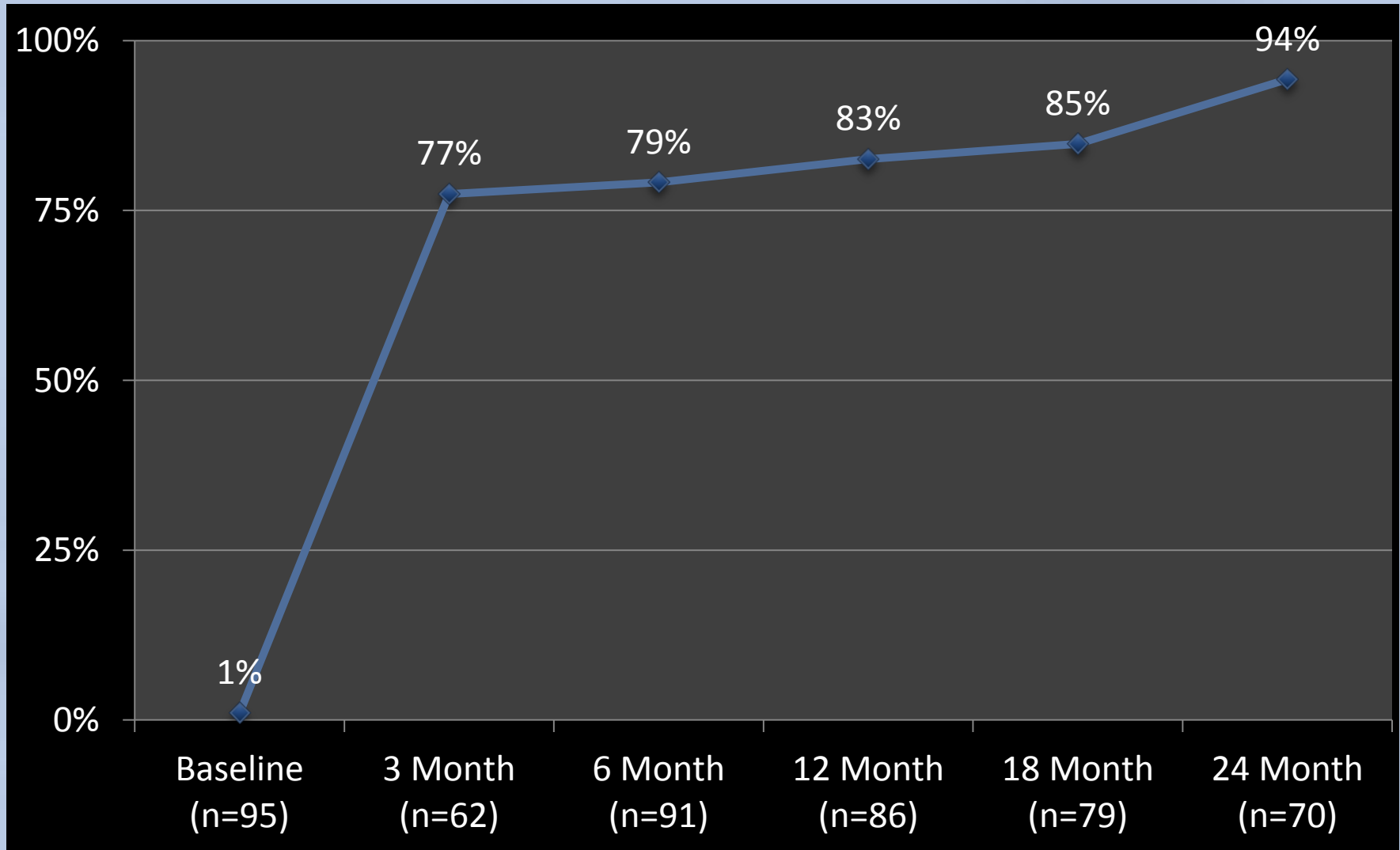


Refocus Study (Nashville)

- 48 subjects (95 eyes) with presbyopia and a manifest refraction spherical equivalent (MRSE) between +0.75D and -0.50D received the Refocus Procedure as part of a multi-center clinical trial
- Pre-operative measurements included corrected and uncorrected distance and near visual acuity, manifest refraction, and cycloplegic refraction
- Patients were then evaluated at 1 day, 1 week, 1, 3, 6, 12, 18 and 24 months after the procedure; measurements were repeated at each visit and compared as a function of pre-operative parameters

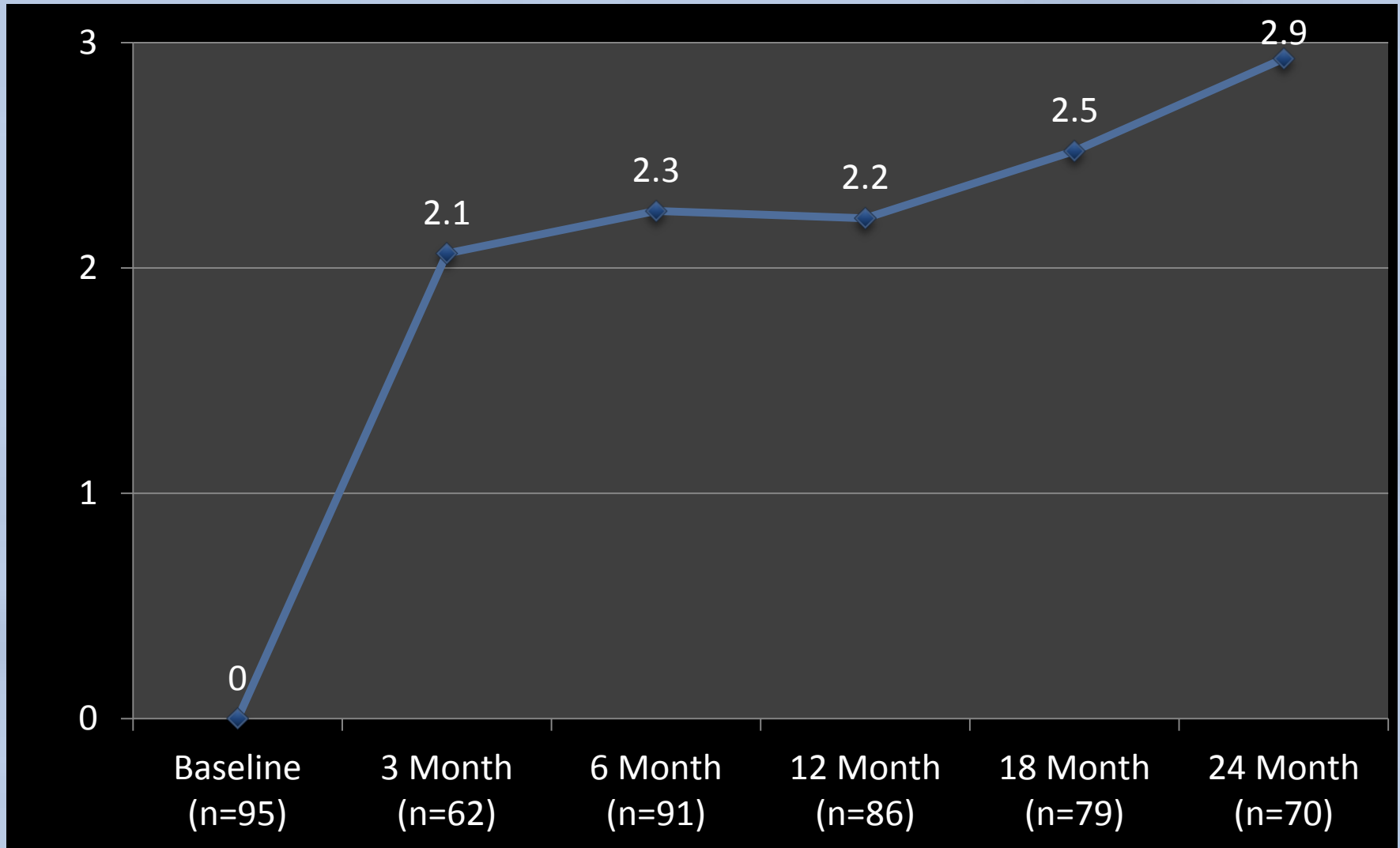
Post-Operative 20/40 or Better – All Eyes

Distance Corrected Near Visual Acuity (DCNVA) @ 40cm – Sloan EDTRS Chart



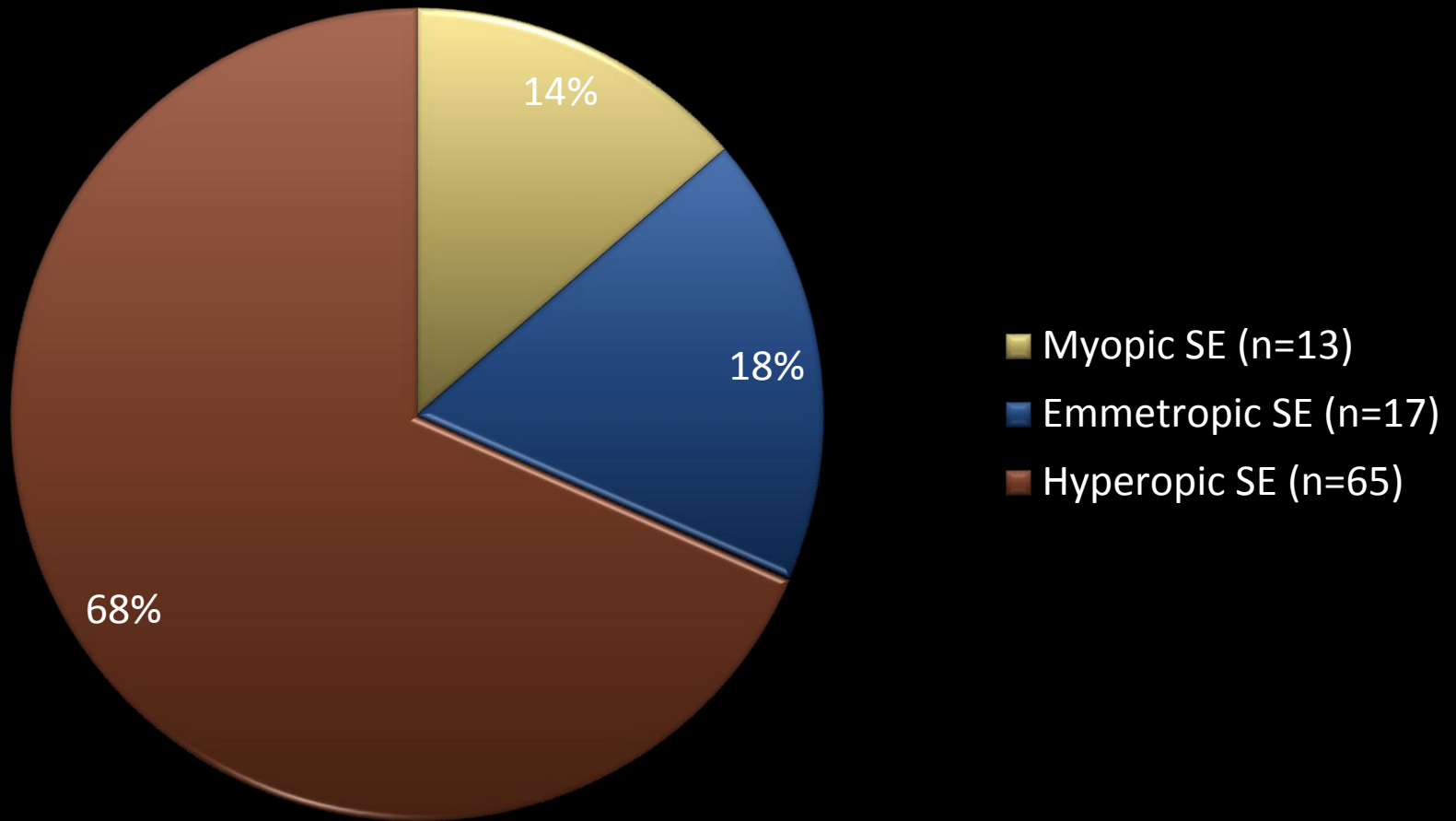
Lines of Improvement from Baseline – All Eyes

Distance Corrected Near Visual Acuity (DCNVA) @ 40cm – Sloan EDTRS Chart



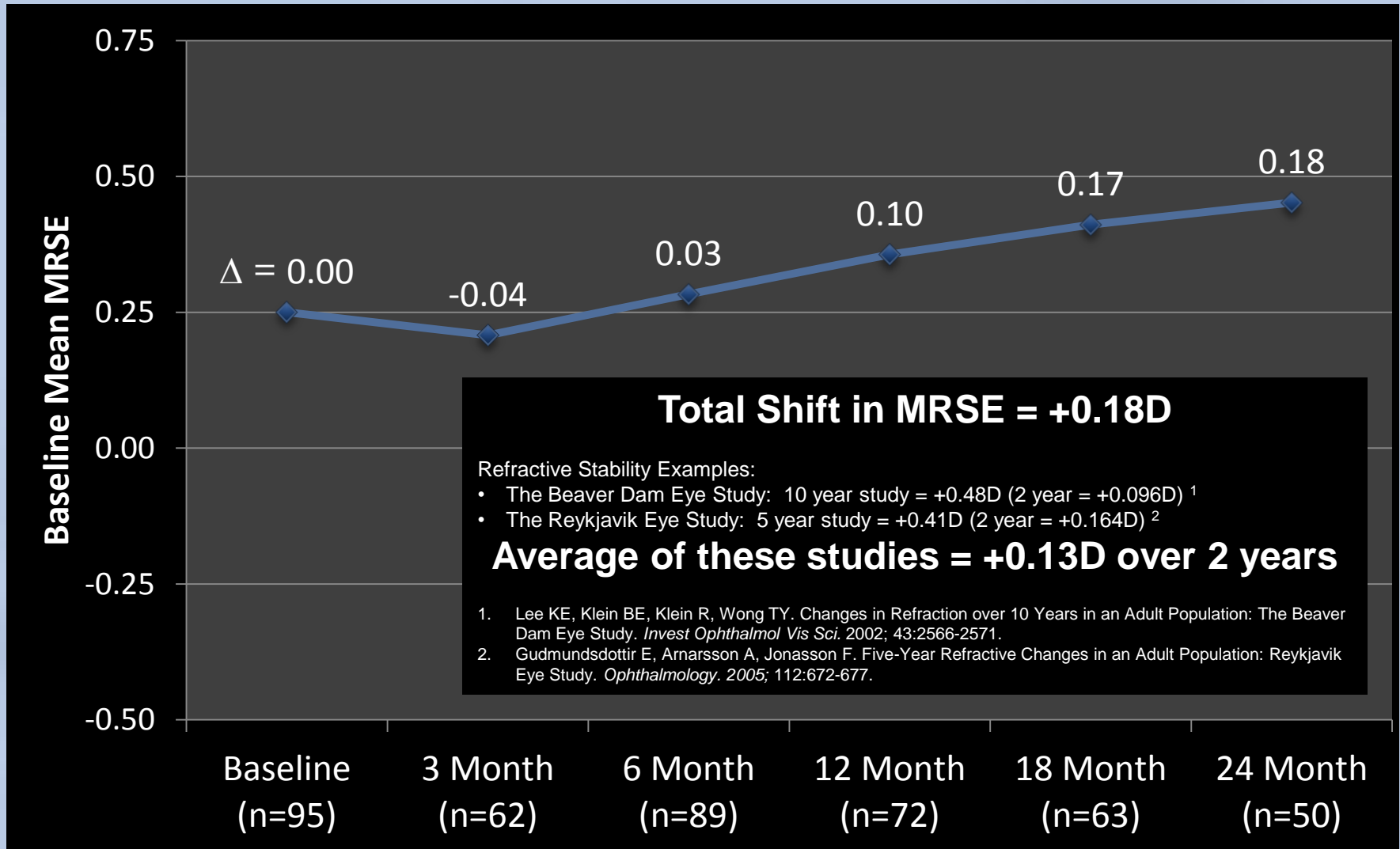
Refraction at Baseline

Distribution by Pre-op Manifest Refraction Spherical Equivalent (MRSE)



Refractive Stability Over Time

Change in Manifest Refraction Spherical Equivalent (MRSE)



Conclusions

- The Refocus Procedure shows promise as a potential surgical solution for age-related presbyopia in near emmetropic eyes
- Distance visual acuity is not affected
- Near vision improvement is maintained and improved throughout 2 year course of the study
- Appears to be a safe and effective procedure for presbyopic emmetropes