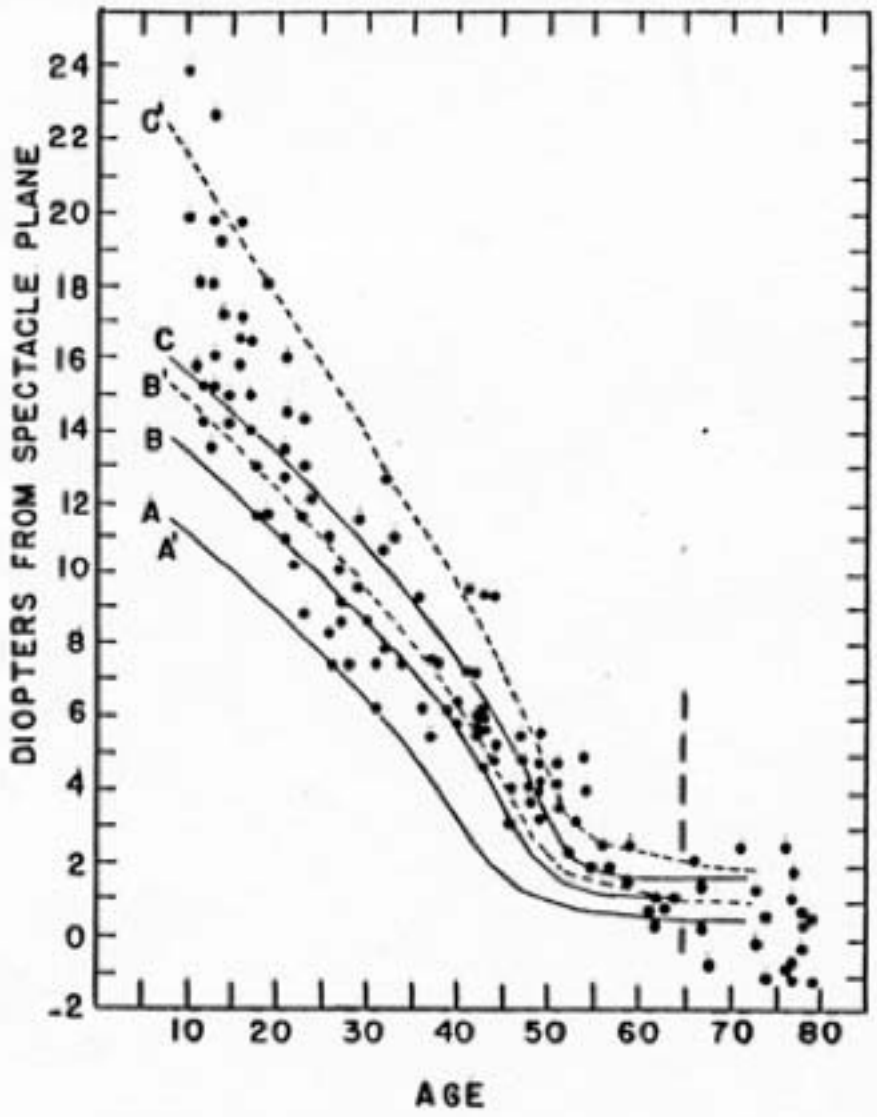
Surgical Options for the Treatment of Presbyopia

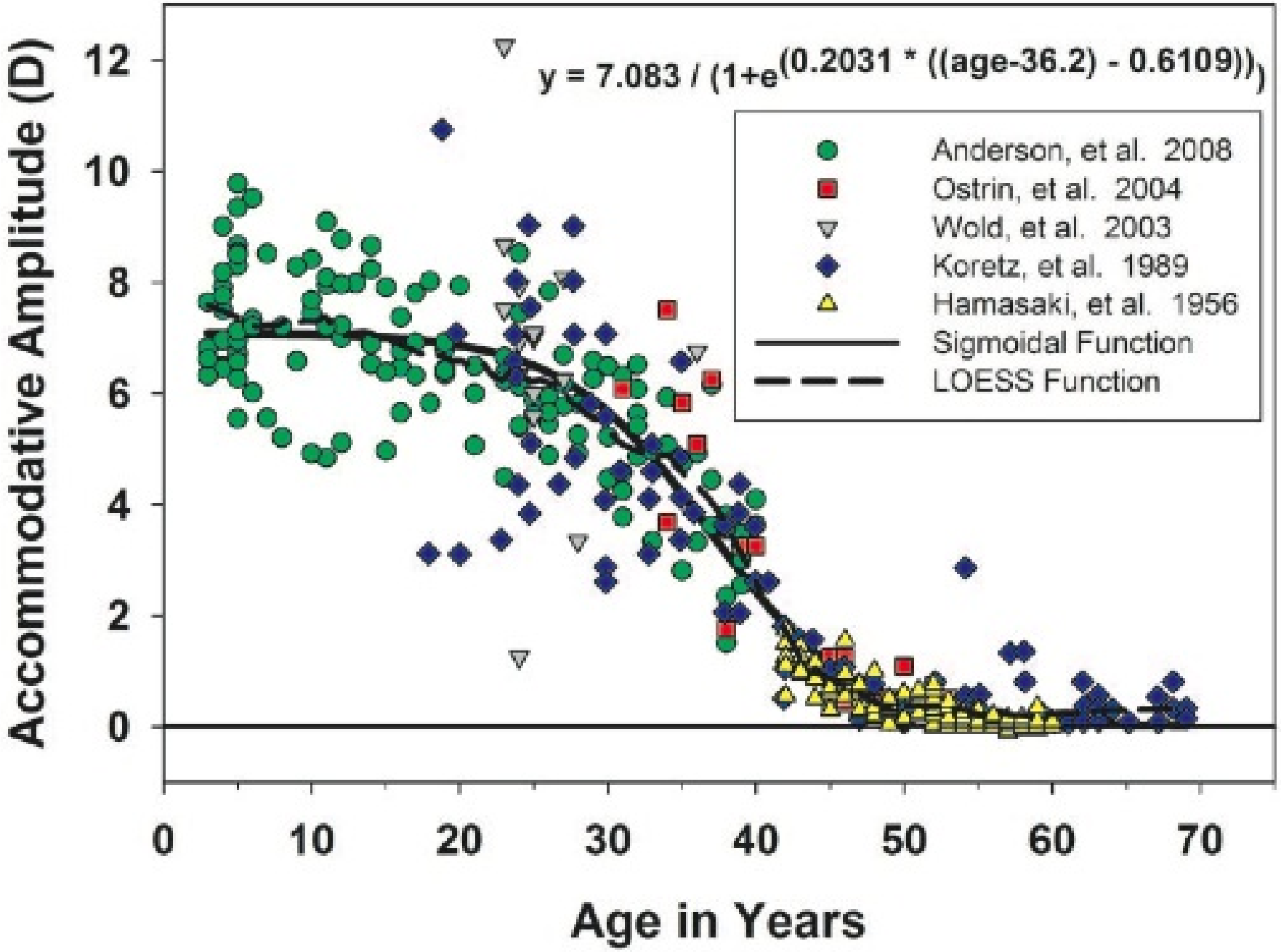
Lance J. Kugler, MD
Wang Vision Institute
Nashville, TN



Age	*Donders*	*Duane*
10 yrs.....	19.70 D.	13.50 D.
15.....	16.00	12.50
20.....	12.70	11.50
25.....	10.40	10.50
30.....	8.20	8.90
35.....	6.30	7.30
40.....	5.00	5.90
45.....	3.80	3.70
50.....	2.60	2.00
55.....	1.80	1.30
60.....	1.00	1.00

Table 1—Comparison of normal Amplitudes of Accommodation for Donders (1864) and Duane (1912). From Hirsch, 1960.

FIGURE 1. Loss of accommodation over time. Comparison of amplitude trend according to Donders (dots) and Duane (curves). Vertex = 14 mm. A, B, and C = Duane's minimum, mean, and maximum monocular values. A', B', and C' = Duane's binocular values. From Hirsh, 1960


y = 7.083 / (1+e^(0.2031 * ((age-36.2) - 0.6109)))
Anderson, et al. 2008
Ostrin, et al. 2004
Wold, et al. 2003
Koretz, et al. 1989
Hamasaki, et al. 1956
Sigmoidal Function
LOESS Function
Accommodative Amplitude (D)
0
2
4
6
8
10
12
0
10
20
30
40
50
60
70
Age in Years

Presbyopia in the Emmetrope – the most difficult group to satisfy

- Patients with good uncorrected distance vision are uncompromising to any changes in distance vision
- Post-LASIK emmetropes have added difficulty with refractive lens exchange due to IOL power determination

Surgical Correction of Presbyopia

STATIC CORRECTION

- Cornea Related:
  - Monovision
  - Multifocality
  - Pinhole Implant (Karma implant)
- Lens Related:
  - Exchange the lens
  - Multifocal lens implant

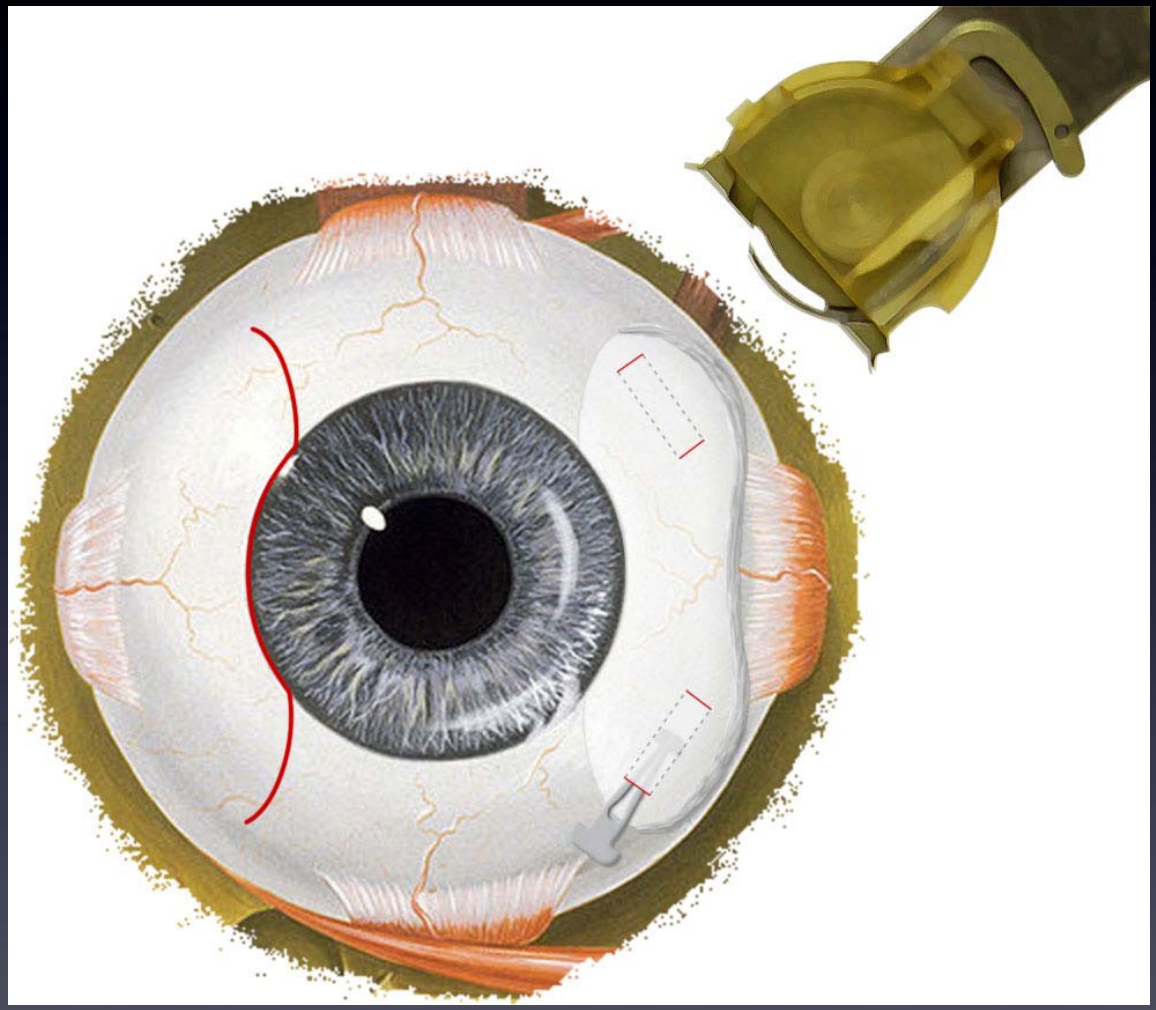
DYNAMIC CORRECTION

- Lens Related:
- Exchange the lens
- Accommodating lens - Crystalens
- Scleral Related:
- Improve the natural lens' focusing power
- Scleral Spacing Procedure ("SSP")

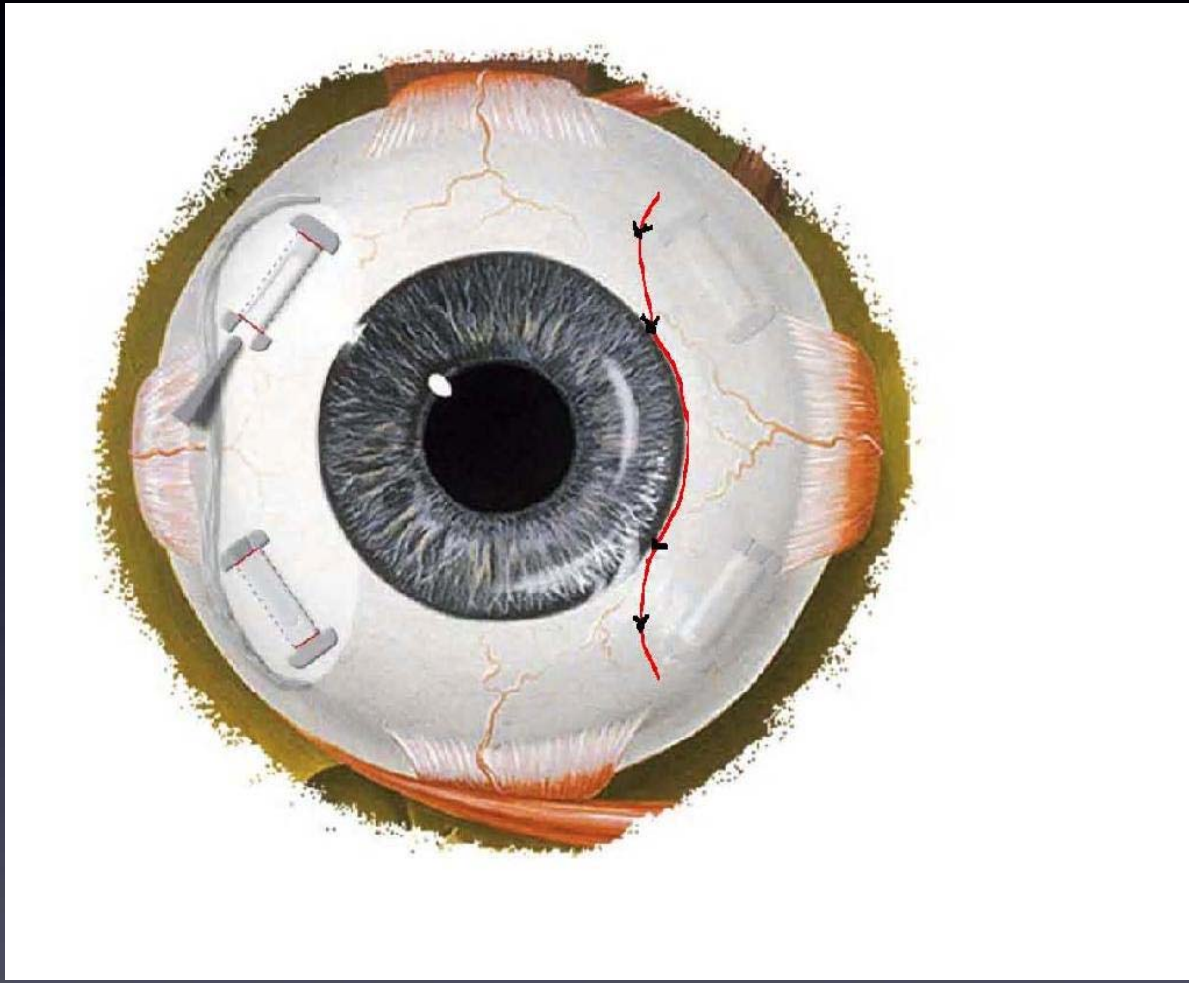
SSP for Presbyopia in the Emmetrope

- SSP alters the configuration of the sclera around the lens equator in four oblique quadrants.
- SSP does not involve surgery on the visual axis.
- SSP is designed to correct presbyopia with a ciliary muscle / zonule / natural lens approach.
- The PSI (implants) are removable, thus SSP is reversible.

SSP Surgical Technique



SSP Surgical Technique

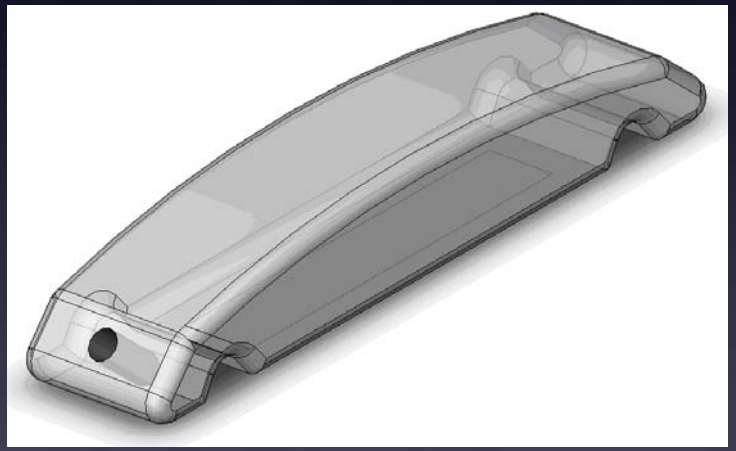


SSP FDA Study timeline

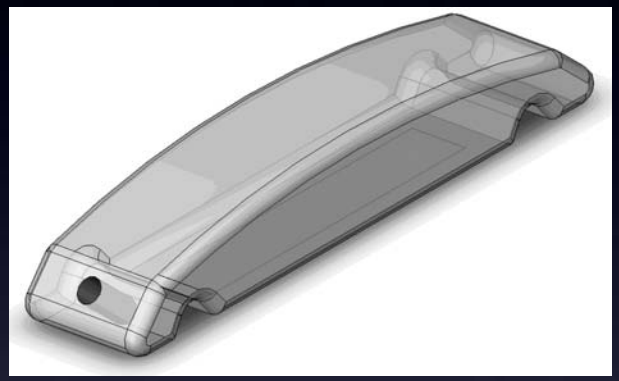
- Phase I March 2000 – 29 eyes monocular surgery
- Phase II Feb 2004 – 61 eyes (monocular) 32 control pts
- Phase III Aug 2005- 123 eyes, 79 patients
  (binocular at separate time OK)
- FDA enrollment deferred – summer 2006.
- Redesigned scleral implant approved – June 2009

Original PresVIEW® Scleral Implant (PSI) used in early FDA Study

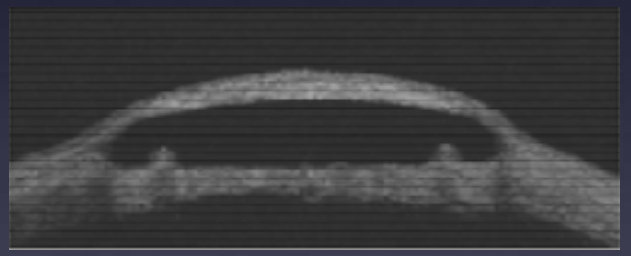
- Grooves at ends of implant were designed to attach to scleral incision and reduce lateral slippage, **BUT...**



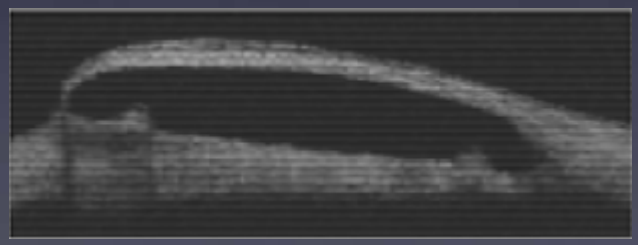
Original PresVIEW® Scleral Implant (PSI) in early FDA Study



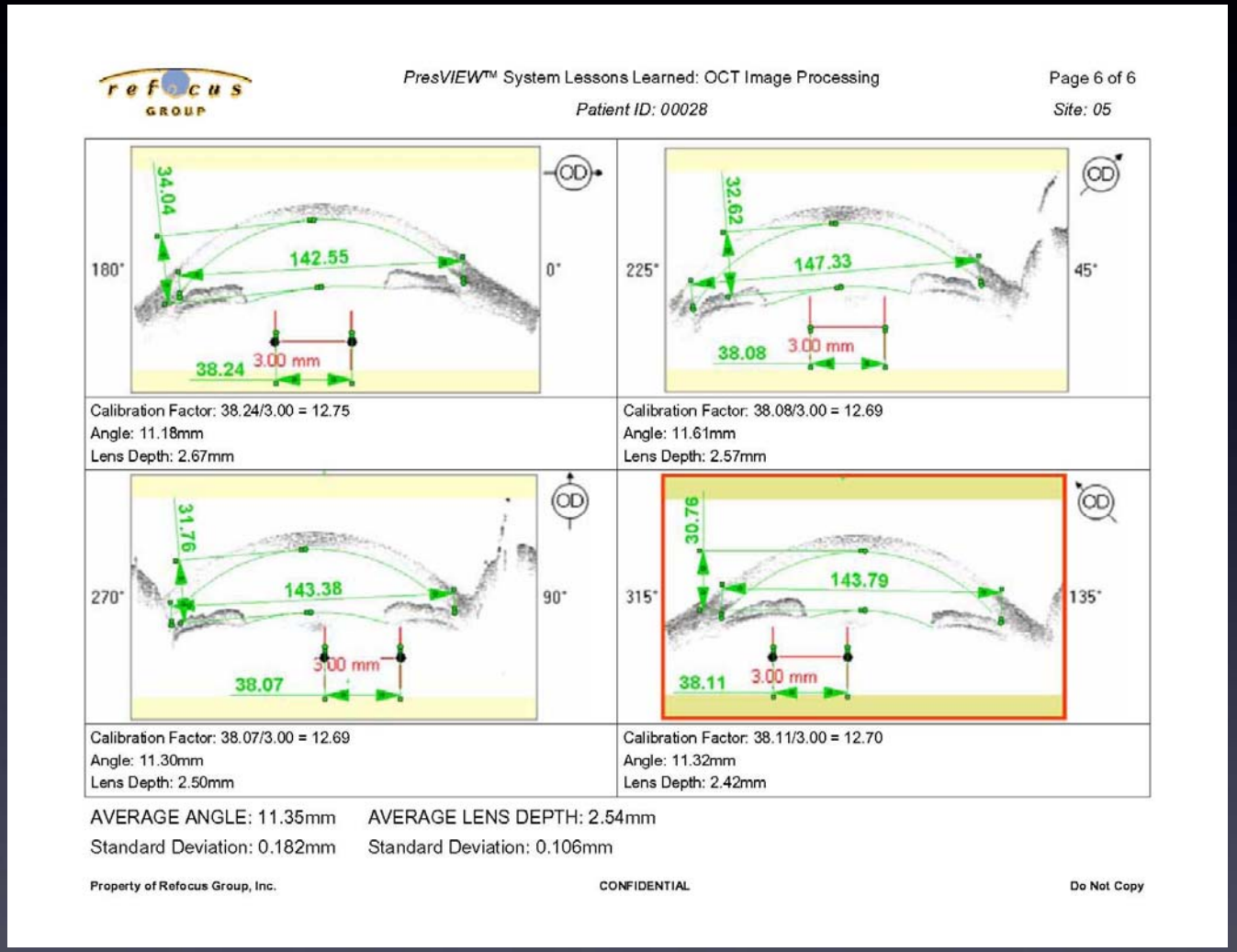
- Visante OCT image analysis identified the displacement issue.



- 77% of patients had at least one displacement.



OCT Imaging – Study of Implant Positioning



refocus GROUP

PresVIEW™ System Lessons Learned: OCT Image Processing

Page 6 of 6

Patient ID: 00028

Site: 05

Calibration Factor: 38.24/3.00 = 12.75
Angle: 11.18mm
Lens Depth: 2.67mm

Calibration Factor: 38.08/3.00 = 12.69
Angle: 11.61mm
Lens Depth: 2.57mm

Calibration Factor: 38.07/3.00 = 12.69
Angle: 11.30mm
Lens Depth: 2.50mm

Calibration Factor: 38.11/3.00 = 12.70
Angle: 11.32mm
Lens Depth: 2.42mm

AVERAGE ANGLE: 11.35mm
Standard Deviation: 0.182mm

AVERAGE LENS DEPTH: 2.54mm
Standard Deviation: 0.106mm

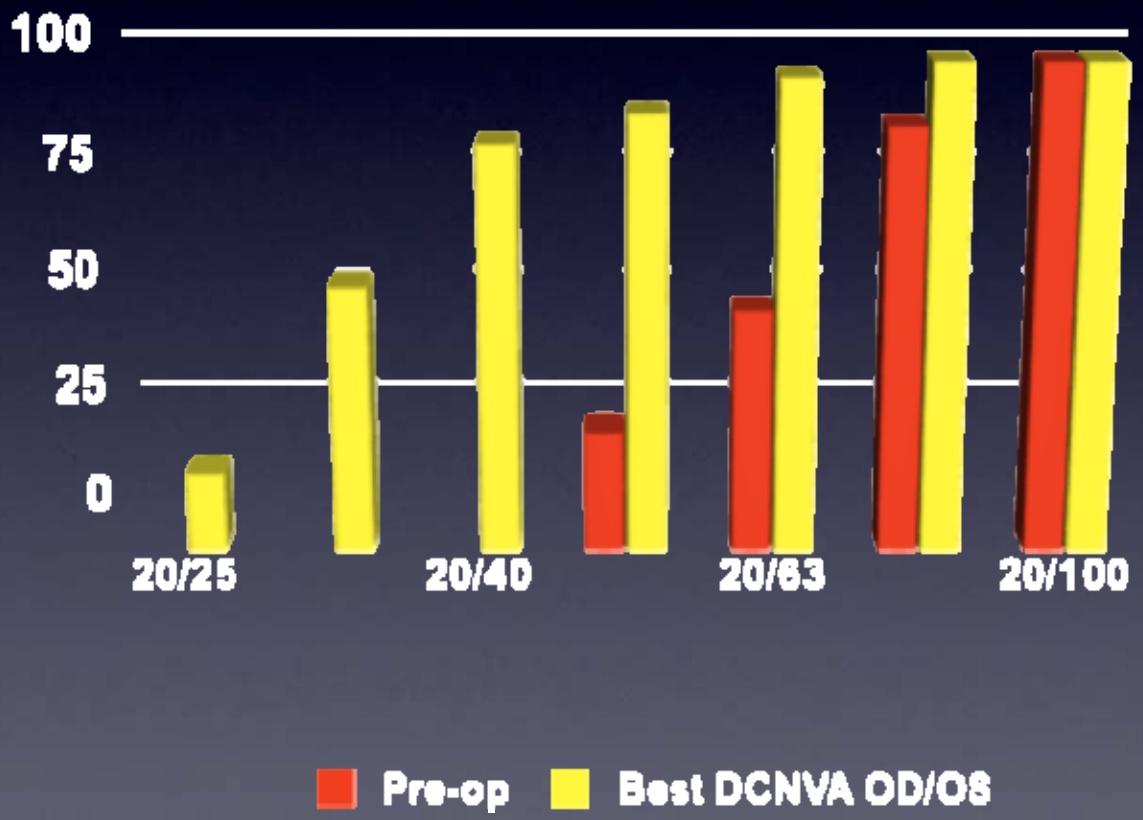
SSP Surgical Technique and Design Issues

- Implant displacement.
- Location of implants relative to limbus varied widely.
- Depth of surgical incisions varied widely.

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

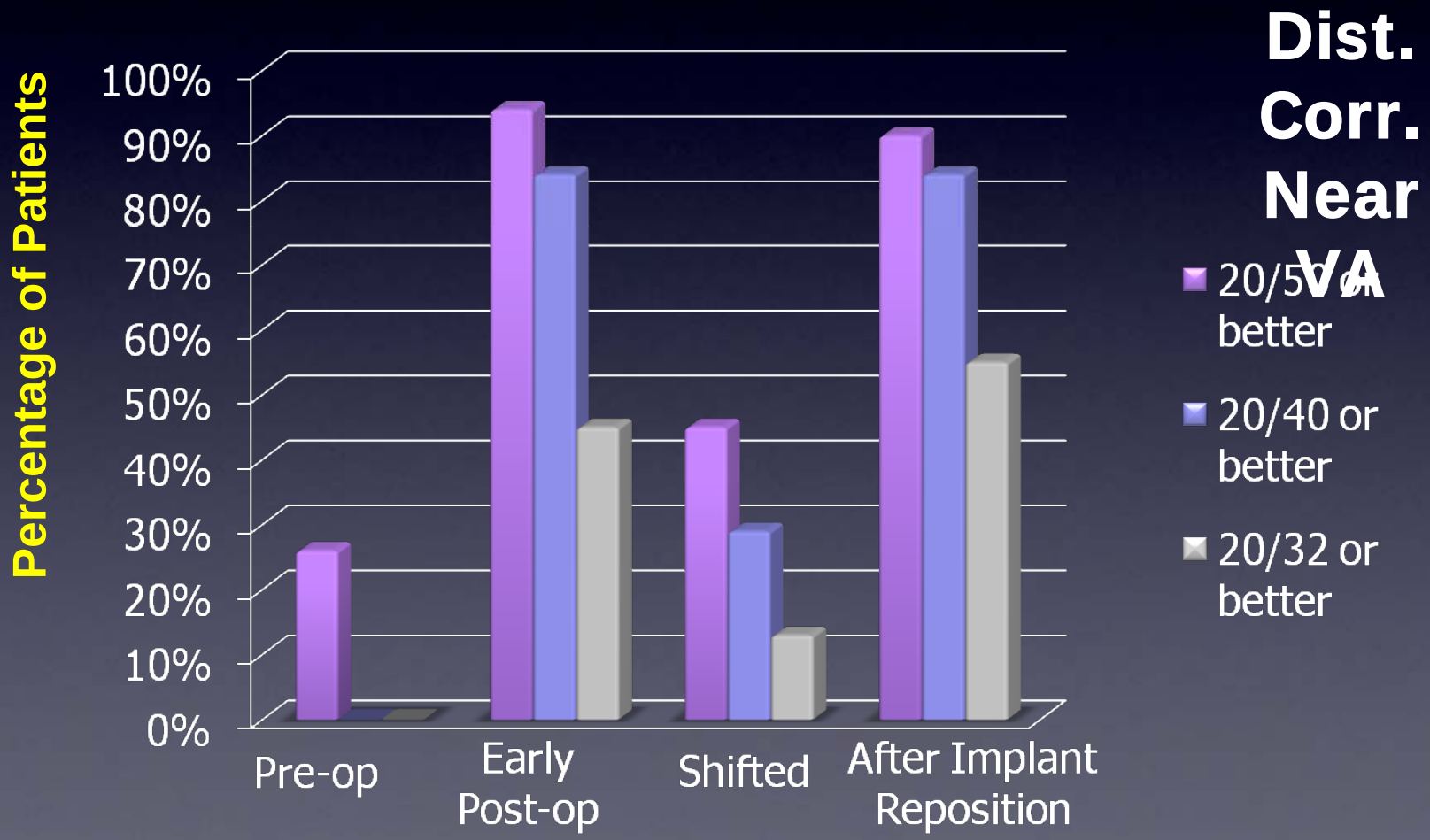
- Patients with Stable Implants Only (n=22)

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



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

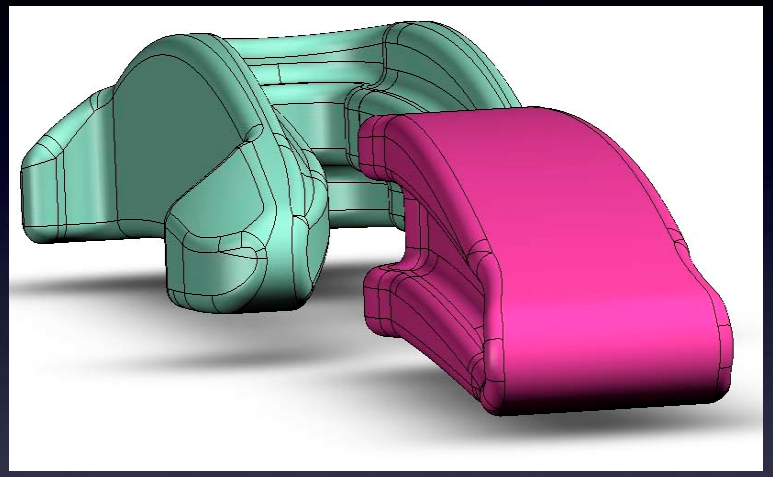
After implants are repositioned,
over 80% of these Patient's eyes also improve to 20/40 !!



Second Generation Implant and Improved Surgical Instrumentation

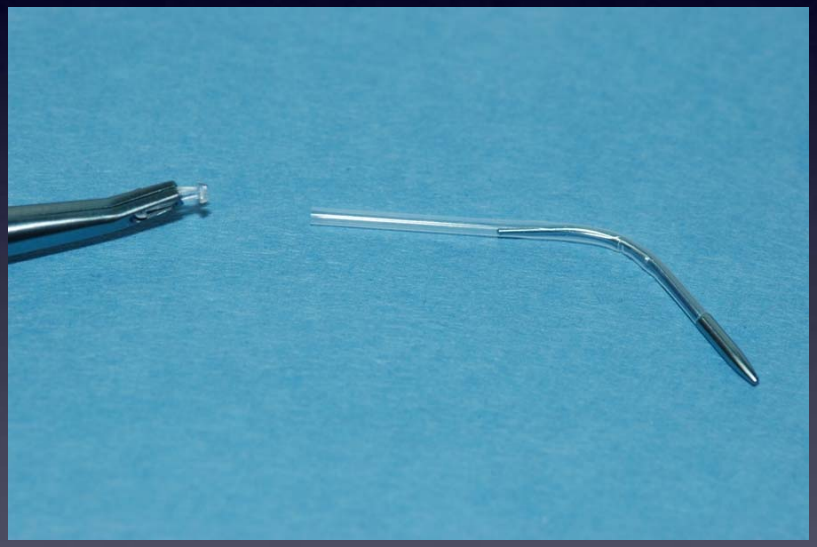
- Third party research engineering firm enlisted
  - second quarter 2006.
- New stable implant design identified, manufactured, validation testing - early 2007.
- Initial test surgeries - summer 2007.
- Extensive clinical testing – 2007 & 2008.
- Better surgical instrumentation

PresView Scleral Implant (“PSI”) 2008 – Two Part Locking Design

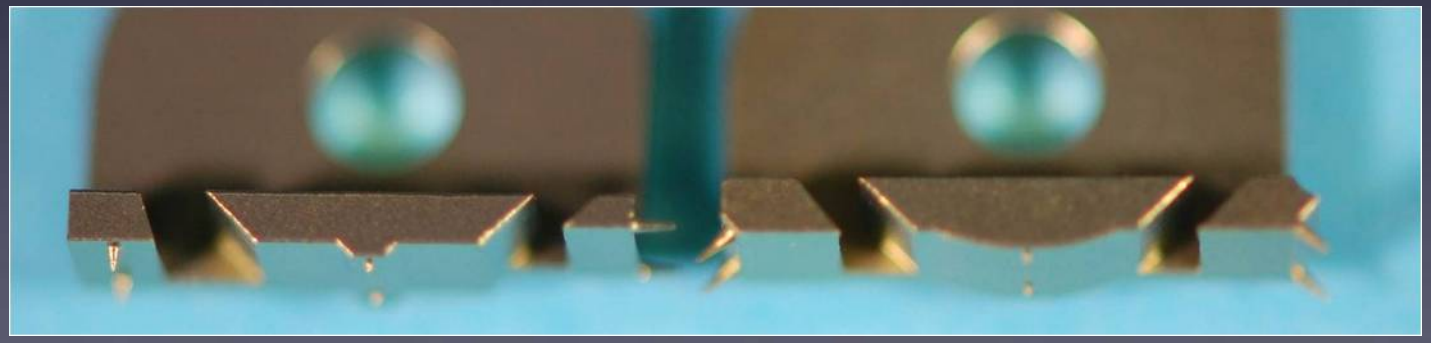


PresView Scleral Implant Delivery System

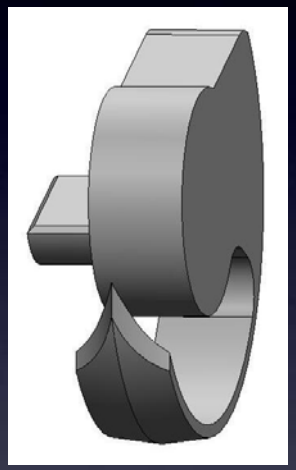
Implant insertion - tubing with suture technique

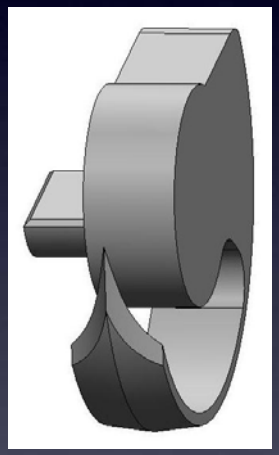


PresView Scleral Implant (“PSI”)
2007 - 2008 – Multiple Footplates Tested

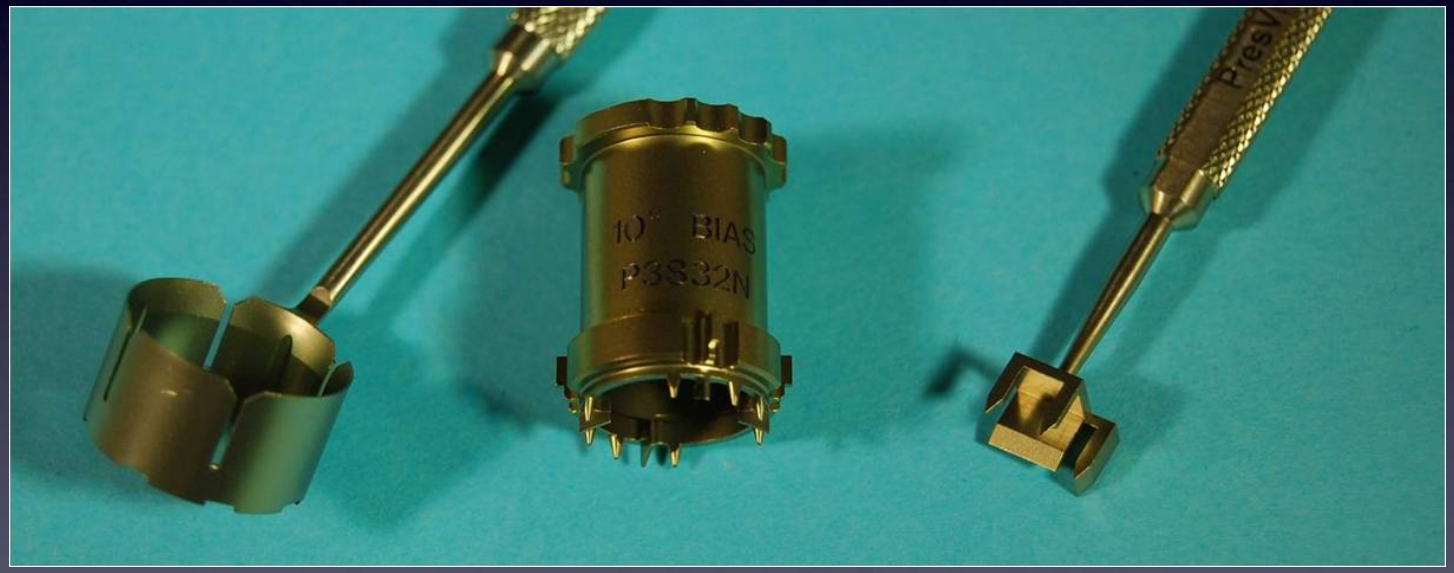


PresView Scleral Implant (“PSI”)
2007 - 2008 – Sharper Blade Tested





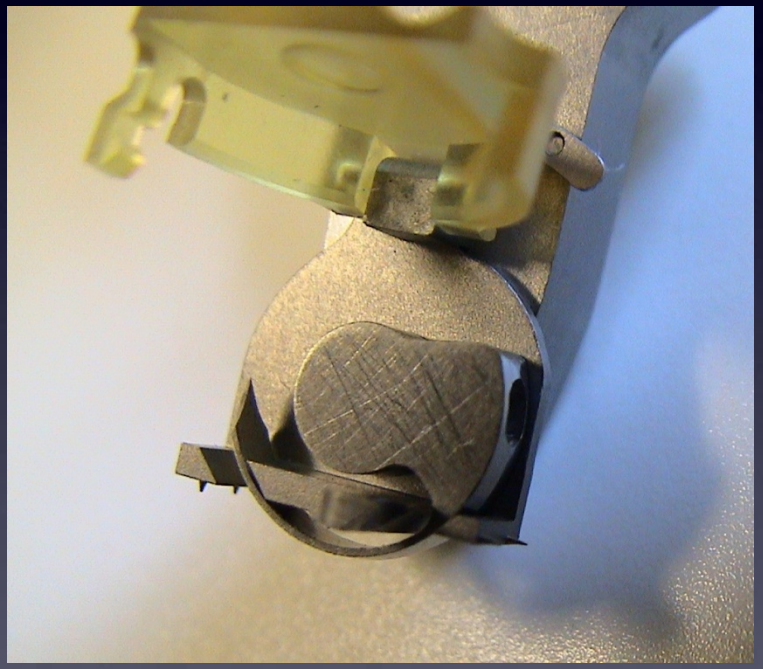
PresView Scleral Implant (“PSI”)
2007 - 2008 – Marking Enhancements



Current SSP Incision System
(to be replaced with new system in 2010)

PresView Incision System

Circular blade forms partial thickness scleral tunnel



Central American Clinical Site Redesigned Implant, System and Approach

- Larger, Longer Two-Part Implant

  More Surface Area At Ends – Greater Vaulting

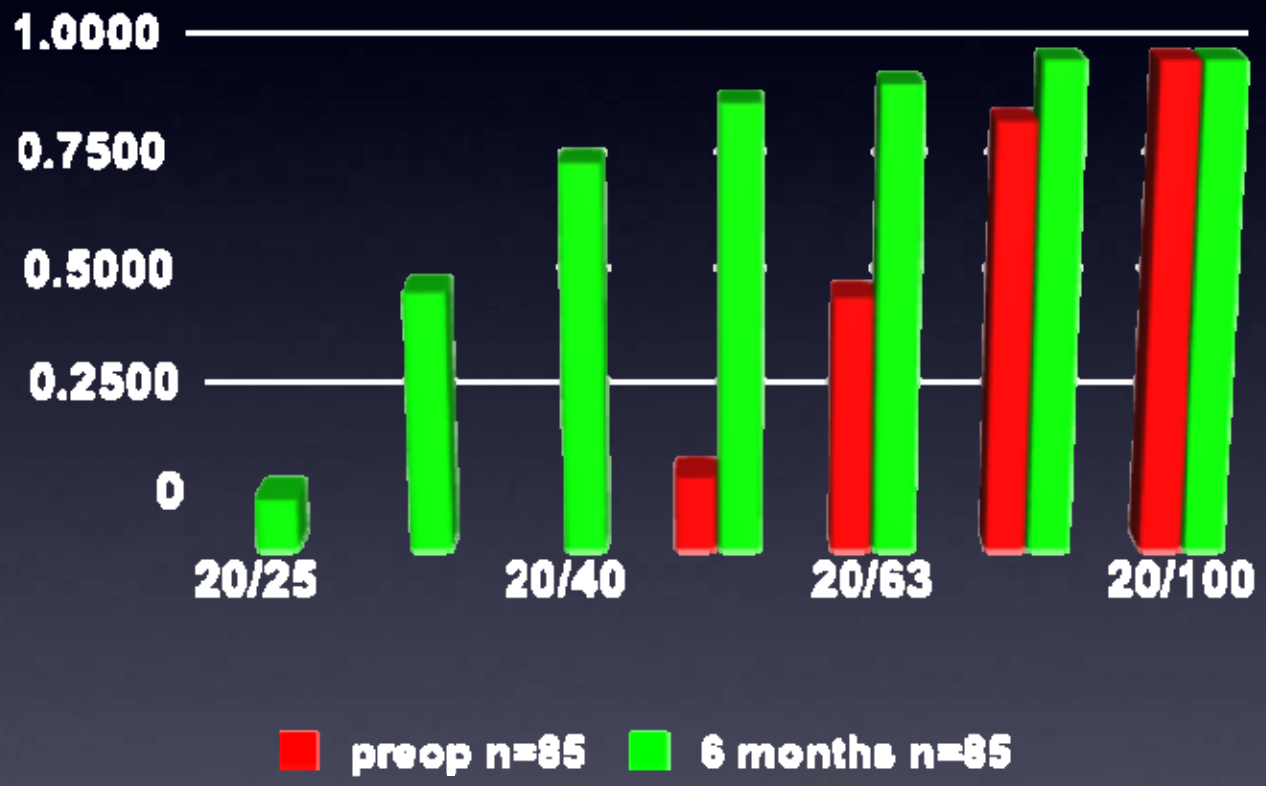
- Applied Tear Film Therapy

- Applied Vision Exercise

Central American Clinical Data

% Cumulative Sloan Monocular Distance Corrected Near Visual Acuity

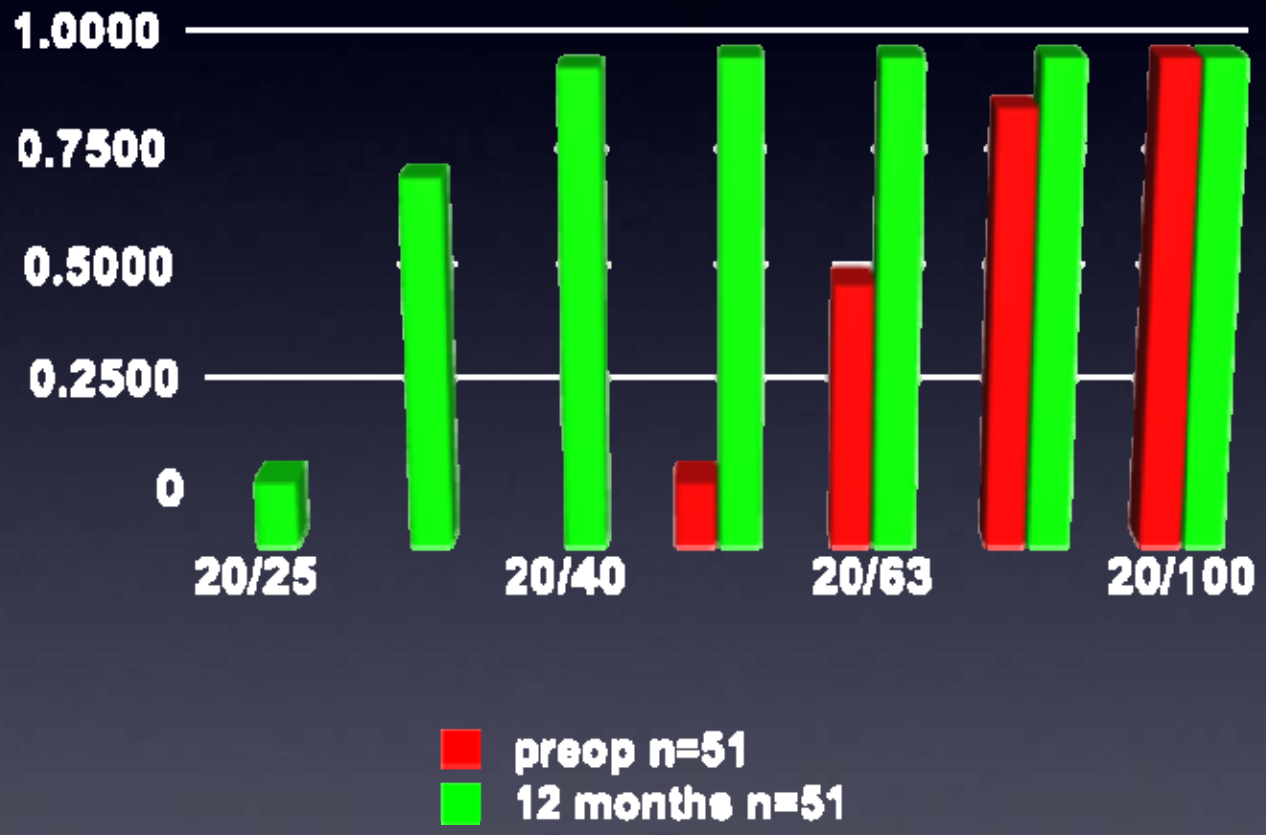
Two-Part Implant Design



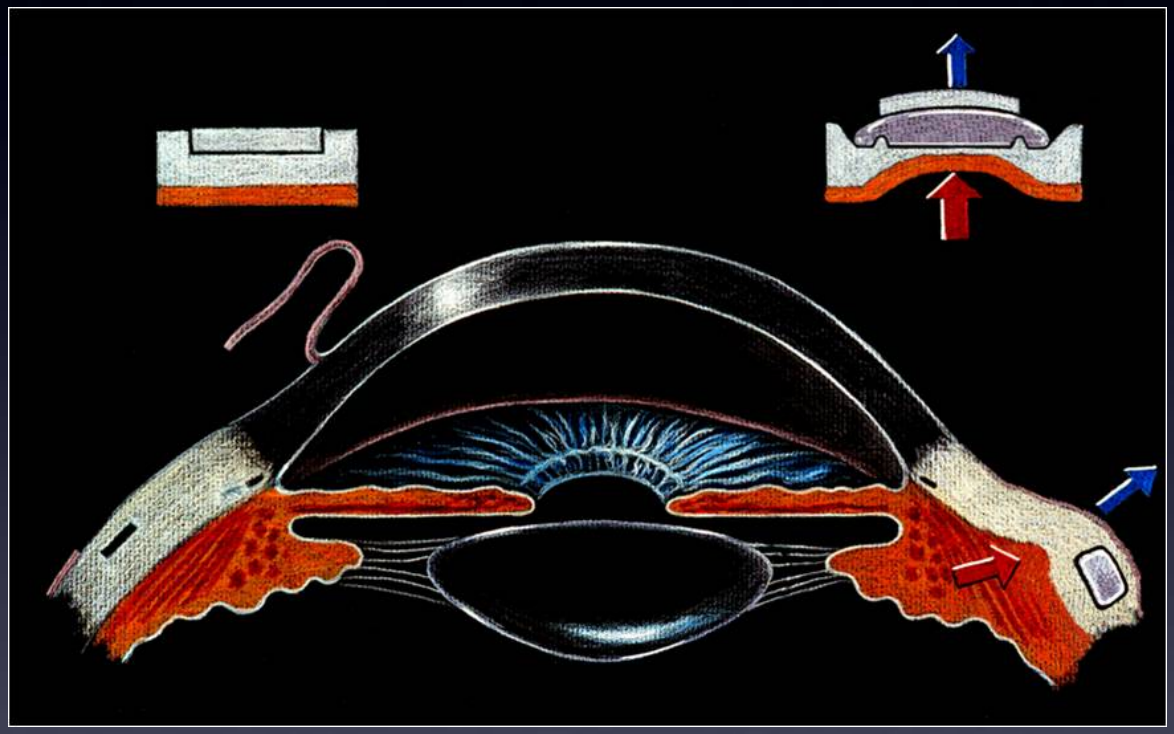
Central American Clinical Data

-% Cumulative Sloan Monocular Distance Corrected Near Visual Acuity

Two-Part Implant Design



Scleral Spacing Procedure – Mechanism of Action



SSP – Mechanism of Action
Triad of Accommodation

- Both eyes converge.
- Pupils experience miosis (constriction).
- Ciliary muscles contract

SSP – Patient Selection
Key to Success

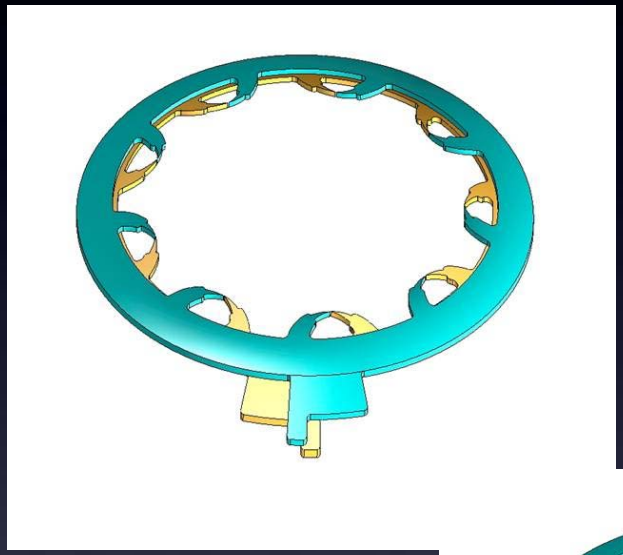
- Patient understanding and cooperation.
- Muscle rehabilitation required.
- Commitment to near vision activities.
- Use of reading glasses prevents rehabilitation.

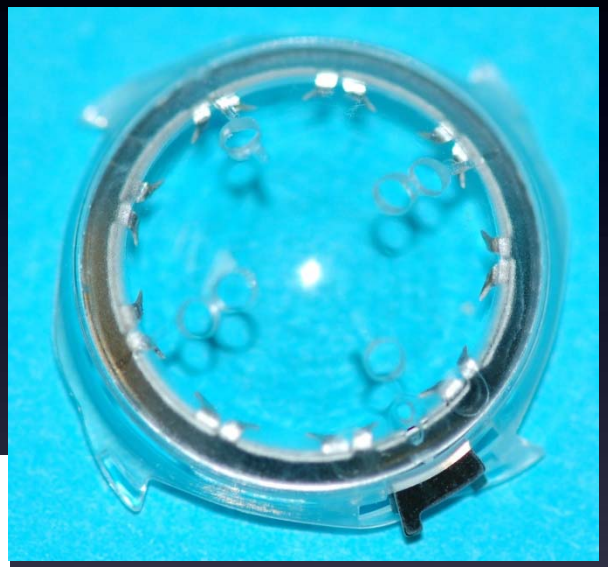
Scleral Spacing Procedure – Additional Development Activities

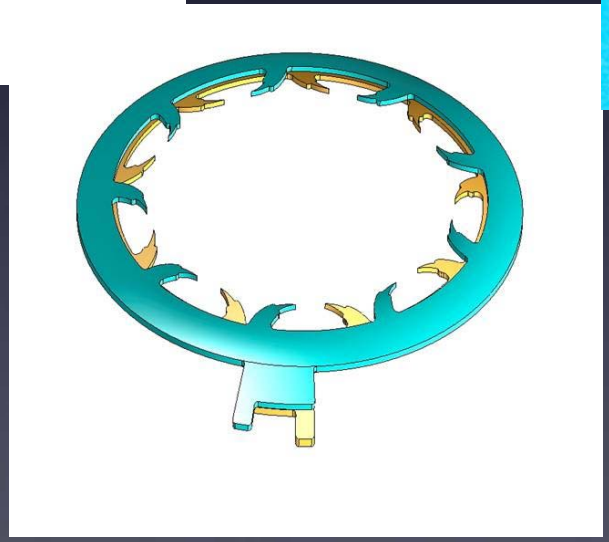
- Lightweight spring powered incision device.
- Improved device for fixation of the eye.
- Ultimately - docking of the incision device to the fixation device.
- Objective – shorter, more repeatable surgery.

New SSP Incision System – late 2010

New Ocu-Lock Fixation Device – Concept Prototypes







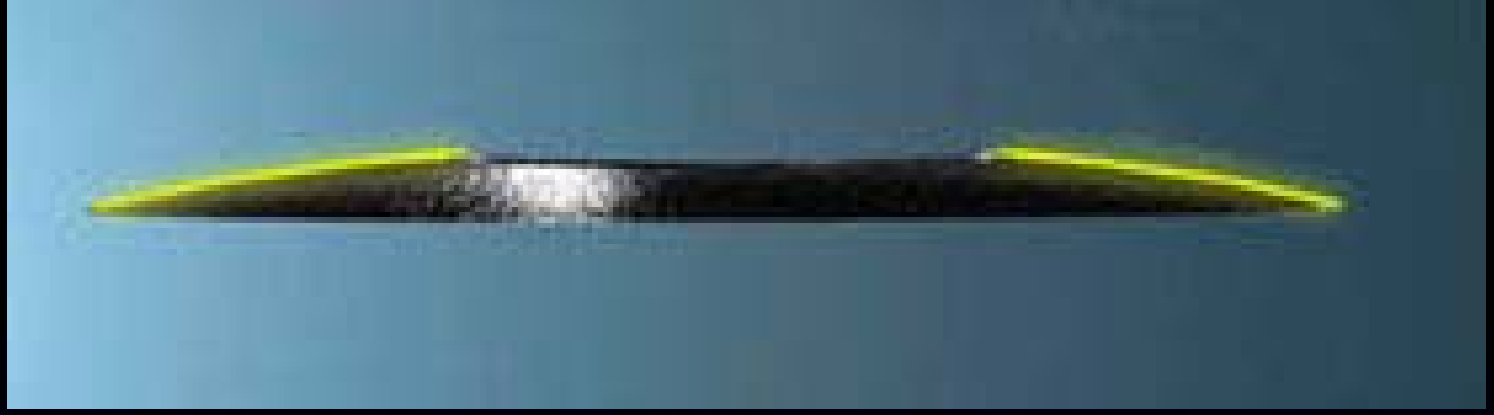
SSP for Presbyopia in the Emmetrope - Conclusions

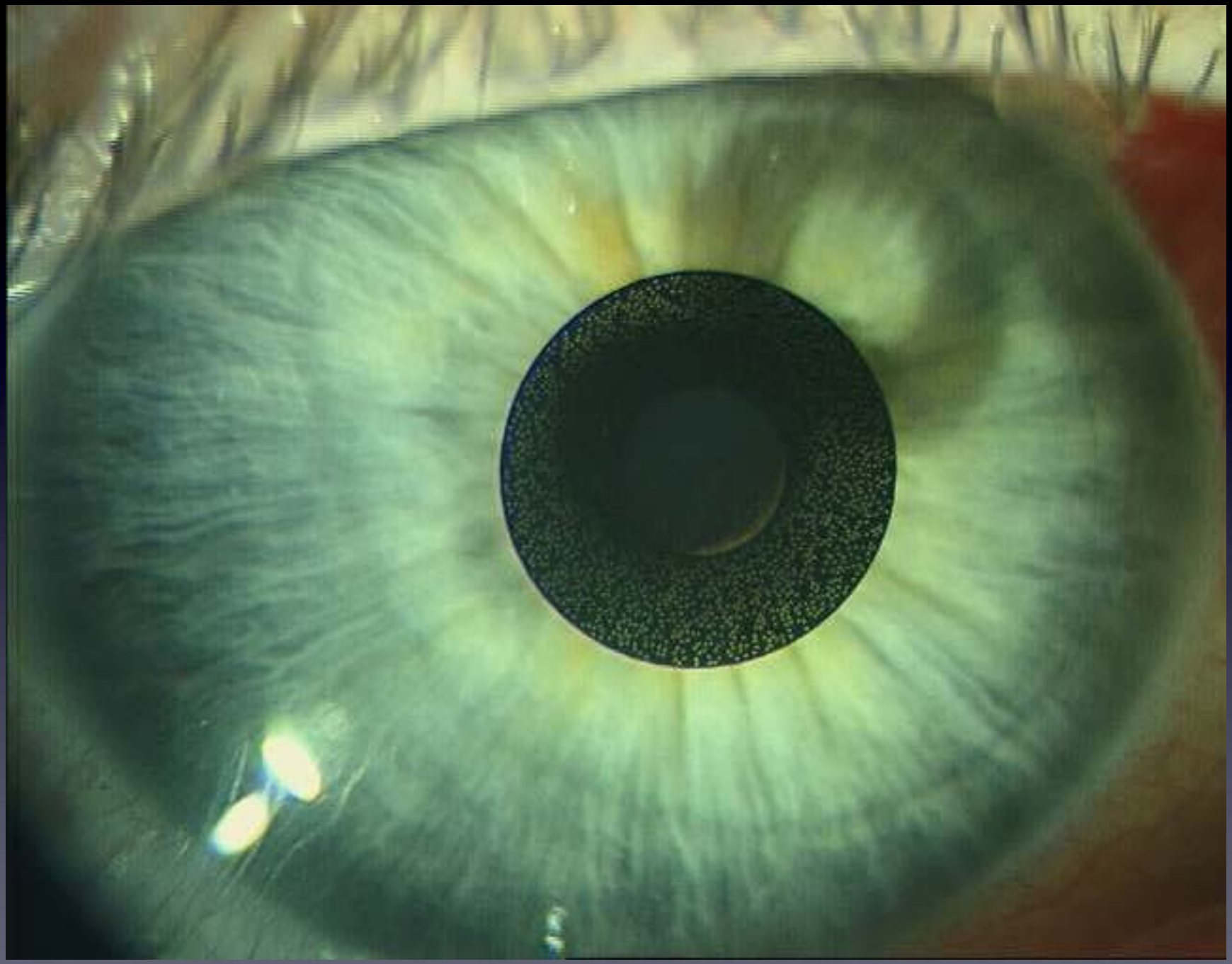
- NO change in:
  - Visual Axis or Cornea
  - Manifest Rx
  - Contrast Sensitivity
  - Axial length
  - Topography
- The PSI is removable, SSP is reversible.
- Only Presbyopia option not impacting visual axis.

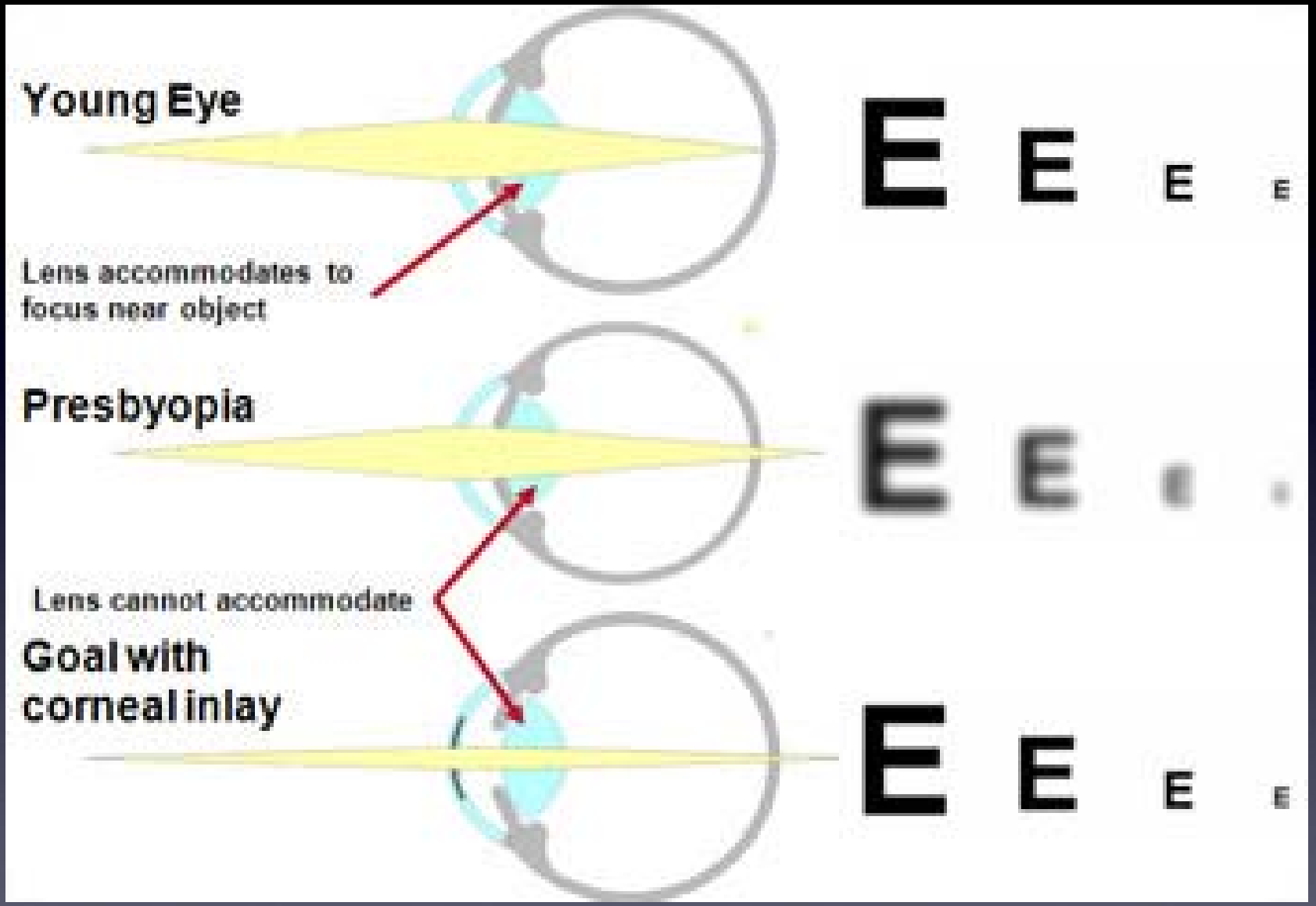
Refocus – Sponsor of SSP
Current Activities & Plans

- Site enrollment
  - USA: FDA study – presbyopia.
  - Canada: glaucoma studies
  - EU: Marketing clinical trials – presbyopia & glaucoma.
- Scientific project research
  - Mode of action
- Improved instumentation
  - Disposable Scleratome / Ocu-lock.
- Commercialization in the EU – 2011

Karma Acufocus Inlay






Young Eye
Lens accommodates to focus near object
Presbyopia
Lens cannot accommodate
Goal with corneal inlay