Surgical Options for the Treatment of Presbyopia

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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.
Accommodative Amplitude (D)

Age in Years

\[ y = \frac{7.083}{1+e^{0.2031 \times ((\text{age}-36.2) - 0.6109)}} \]

- Ostrin, et al. 2004
- Wold, et al. 2003
- Hamasaki, et al. 1956

Sigmoidal Function
LOESS Function
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

Calibration Factor: 38.24/3.00 = 12.75
Angle: 11.15mm
Lens Depth: 2.87mm

Calibration Factor: 38.08/3.00 = 12.69
Angle: 11.81mm
Lens Depth: 2.87mm

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: 2.49mm

AVERAGE ANGLE: 11.35mm  AVERAGE LENS DEPTH: 2.54mm
Standard Deviation: 0.182mm  Standard Deviation: 0.106mm

Property of Refocus Group, Inc.
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.


- 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

preop n=85  6 months n=85
Central American Clinical Data
-% Cumulative Sloan Monocular Distance Corrected Near Visual Acuity
Two-Part Implant Design

![Graph showing visual acuity data for different distances and time points. The graph indicates improvement in visual acuity from preoperative to 12-month follow-up for 20/25, 20/40, 20/63, and 20/100 distances. The data shows a significant improvement in visual acuity over time.]
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 instrumentation
  - 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