Scleral Spacing Procedure (SSP) for the treatment of presbyopia

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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

Schachar (2001)

Diagram showing the relationship between ciliary processes, zonules, and sclera. The diagram illustrates the movement of the equator toward the sclera with increased tension in the equatorial zonules, resulting in a decreased equatorial diameter.
Zonule structure and function remain poorly understood

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Decreased Zonular Tension With Age

49 y/o  26 y/o

Scleral Spacing Procedure
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!!

Percentage of Patients

- Pre-op
- Early Post-op
- Shifted
- After Implant Reposition

Legend:
- 20/50 or better
- 20/40 or better
- 20/32 or better
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

- 20/25
- 20/32
- 20/40
- 20/50
- 20/62
- 20/80
- 20/100

Pre-op (106)
3M (102)
6M (76)
9M (34)
Average DCNVA Monocular

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<th>Time</th>
<th>Data</th>
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<tr>
<td>3 month</td>
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<td>6 month</td>
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<td>9 month</td>
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30
Average Lines of Improved DCNVA Monocular

3 months n=102
6 months n=76
9 months n=

Y-axis: 0, 1.00, 2.00, 3.00, 4.00
X-axis: 3 months, 6 months, 9 months
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