Presview Scleral Implants for Presbyopia

The Role of the Sclera in Restoring Accommodation

San Francisco Feb, 2008

Barrie Soloway, MD FACS
Director, Vision Correction
New York Eye and Ear Infirmary
Financial Interest Statement

• Refocus Group
  • Medical Director
    • Paid consultant fees
    • Travel fees
  • FDA Investigator
    • Research equipment
    • Research stipends
• All devices CE marked EU, FDA IDE USA
Surgical Correction of Presbyopia

STATIC CORRECTION

- Cornea Related:
  - Monovision
  - Multifocality

- Lens Related:
  - Exchange the lens
  - Multifocal lens implant
  - Array / ReZoom
  - ReSTOR

DYNAMIC CORRECTION

- Lens Related:
  - Exchange the lens
  - Accommodating lens implant
    - Crystalens

- Sclera Related:
  - Improve the lens’ focusing power
  - Scleral Spacing w/ implants or laser
Presbyopia in the Emmetrope

• The most difficult group to satisfy
  • Patients with good DVSC may be uncompromising to any changes in distance vision
  • Surgical emmetropes (eg. Post-LASIK) have added difficulty with RLE due to IOL power determination
SSP for Presbyopia in the Emmetrope

- Refocus ScleralSpacing Procedure (SSP) uses 4 PresVIEW stability enhanced scleral implants (PSIse)
  - Alter the configuration of the sclera around the lens equator in four oblique quadrants
  - No surgery on the visual axis
  - Designed to correct presbyopia with a ciliary muscle/zonule/natural lens approach
Cumulative Sloan VA in FDA IDE mean lines improved 2.4
Cumulative MN read VA in FDA IDE mean lines improved 2.6
Original PresVIEW® System

- Complicated and error-prone measuring for placement combined with:
  - Free placement of footplate
  - Wide variation (>\(+1.00\) mm) in distance from the limbus and lack of tangentiality
  - Continued variation of patient outcomes
  - Mechanism of action ??
  - Led to “Lessons Learned” project
Lessons Learned Project

- Evaluation of post-op excellent and mediocre results to determine causes of the variability of results
- UBM evaluation stymied by PMMA material and smooth surfaces causing echoing and shadowing
- Formally commenced Feb 2006 with first USA available Visante (Zeiss) IR OCT units at three sites
Lessons learned: DEPTH

**SUMMARY:**
OCT post operative assessment and analysis on May 23rd, 2006
Surgery completed on February 15th, 2006
Eye: Right (OD)   Sex: F
Age: 52
Landolt C Chart Sloan @ 40CM MN Read @ 40CM
Baseline DCNVA: 20/80 20/50 20/40
1-Month DCNVA: 20/50 20/32 20/25
3-Month DCNVA: 20/80 (+0 lines) 20/40 (+1 line) 20/??

**DISCUSSION:**
Assessment of implant tangentially around the angle (ratio of distances, target value = 1.00), as well as assessment of position across the lamellar scleral tunnel, is provided below:

<table>
<thead>
<tr>
<th>ST (distance to angle)</th>
<th>SN (distance to angle)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CW: 4.27mm</td>
<td>CW: 4.17mm</td>
</tr>
<tr>
<td>CEN: 3.55mm</td>
<td>CEN: 3.25mm</td>
</tr>
<tr>
<td>CCW: 4.25mm</td>
<td>CCW: 3.27mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IT (distance to angle)</th>
<th>IN (distance to angle)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CW: 3.91mm</td>
<td>CW: 3.69mm</td>
</tr>
<tr>
<td>CEN: 3.46mm</td>
<td>CEN: 3.65mm</td>
</tr>
<tr>
<td>CCW: 4.30mm</td>
<td>CCW: 4.11mm</td>
</tr>
</tbody>
</table>

**ST:** 0.99 Stable
**IT:** 0.91 Stable

**OD:**
- Angle
  - ST: 3.59mm
  - SN: 3.25mm
- Limbus
- Pupil

**SN:** 0.78 Stable

**IN:** 0.90 Stable
Lessons learned: Tangent

IN (red = implant specs) (blue = OCT caliper measurements)

CCW
- Calibration Factor: 243.63/3.00 = 81.21
- Distance to Angle = 4.11mm, 4.42mm
- Tissue Above = 408 microns
- Tissue Below = 681 microns
- Implant Correlation:
  - Central Angular Error: 0.73° (excellent)
  - Base Width: 1.24mm (1.38mm)
  - Top Width: 1.28mm (1.38mm)
  - Thickness: 720 microns (490 microns)
  - Off Angular Error: 3.4% (excellent)

CEN
- Calibration Factor: 242.72/3.00 = 80.91
- Distance to Angle = 3.85mm, 4.06mm
- Tissue Above = 406 microns
- Tissue Below = 719 microns
- Implant Correlation:
  - Central Angular Error: 2.37° (good)
  - Base Width: 1.29mm (1.38mm)
  - Top Width: 1.30mm (1.38mm)
  - Thickness: 858 microns (925 microns)
  - Off Angular Error: 1.7% (excellent)

CW
- Calibration Factor: 229.16/3.00 = 76.39
- Distance to Angle = 3.69mm, 4.12mm
- Tissue Above = 405 microns
- Tissue Below = 661 microns
- Implant Correlation:
  - Central Angular Error: 1.61° (good)
  - Base Width: 1.41mm (1.38mm)
  - Top Width: 1.23mm (1.38mm)
  - Thickness: 952 microns (450 microns)
  - Off Angular Error: 13.2% (poor)
Lessons learned: Position

PresVIEW™ System Lessons Learned: OCT Image Processing

Patient ID: 00028

Site: 05

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

Calibration Factor: 38.09/3.00 = 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
Lessons learned: Ciliary Body

Unaccommodated

Accommodated
Lessons Learned

- Grooves at ends of implant were designed to reduce lateral slippage BUT...

- Final infra-red OCT analysis showed 26% of implants were subluxated with a corresponding decrease in DCNVA

- Reposition and suturing this style PSI restored DCNVA
Sublux repair data at 1 mo $n=8$

NOTE: All sublux repair patients achieved 20/32 or better DCNVA at 1 month
Second Generation PSI (Intl – FDA) Stability Enhanced design development

- Complexity of suturing technique led to the quest for a more stable implant
- Our research engineering group development of more stable implant and ergonomic surgery began second quarter 2006
- New implant style identified, manufactured and validation testing early 2007
- Initial surgeries began summer 2007
PresView Stability Enhanced Scleral Implant PSIse
**International Data PSIse**

**USA FDA Clinical trials PSI**

<table>
<thead>
<tr>
<th></th>
<th>1 Month Post-op n=30</th>
<th>2 Months Post-op n=19</th>
<th>3 Months Post-op n=71 n=12</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/40 or better</td>
<td>87%</td>
<td>84%</td>
<td>49% 67%</td>
</tr>
<tr>
<td>20/32 or better</td>
<td>70%</td>
<td>68%</td>
<td>30% 67%</td>
</tr>
<tr>
<td>Mean lines improved</td>
<td>3.3</td>
<td>3.8</td>
<td>2.4 3.0</td>
</tr>
</tbody>
</table>
Tracey Wavefront Objective Accommodation Study

- Open field allows for measured eye to focus at varying distances
- Recent software changes (ver 3.1) by Tracey Technologies advocated to show objective accommodation
- 18 y/o emmetropes measured August 2007
- Post-op and Pre-op subject measurements began in late September 2007
- Study ongoing in USA, Latin America and EU
Accommodation in an 18 Y/O

Near Power Map
Dist Power Map

Near/Distance Difference Map: Downward shift Indicates accommodation, in this case ~3 Diopters
Control 1

YH OD Monocular

0.75 Diopters of Accommodation
Control 2

046 C-P OD Monocular

0.5 Diopters of Accommodation
BCNVA improved to 20/20 after SSP

3 Diopters of Accommodation
BCNVA improved to 20/20 after SSP
Correlating Accommodation and Improvement in Near Visual Acuity

Max Accom vs. Lines Improved for Oscar 4 Patients

\[ y = 0.379x + 0.842 \]

\[ R^2 = 0.838 \]
Conclusion

- Refocus Presview scleral implants safe and effective for presbyopic emmetropes
  - No change in distance parameters
  - Average 3 lines improvement in near acuity
- Subluxation of implant = loss of effect
  - New Stability Enhanced implant has 5x the subluxation resistance
  - No subluxation noted in surgeries performed since commencement in summer 2007
Current Activities

- Additional site enrollment and training
  - Latin America: R&D activities
  - EU: CRO controlled phase IV clinical trials
  - USA: FDA IDE phase III completion & PMA
- Importance of the PSIse position
  - OCT position analysis continues
  - Oculock and docking scleratome to ensure proper surgeon placement of PSIse
- Scientific project research
  - Posterior zonular theory of accommodation
  - Improvement of surgical technique
Oculock fixation
Disposable Scleratome
Thank You For Your Attention