**Light Adjustable Lens (LAL)**

- Incorrect lens power: one of the most common reasons for explanting IOLs

**Incorrect Lens Power**

- IOL explant/exchange
- Piggyback pseudophakic IOL
- Piggyback phakic IOL
- Corneal refractive procedures: LASIK, corneal incisions, corneal thermal keratoplasty, intrastromal corneal ring segments…
- For refractive lens exchange: “Bioptics” procedure

**Light Adjustable Lens (LAL)**

- Calhoun Vision: three-piece silicone lens with photosensitive silicone subunits that move within the lens under a low intensity near-UV light
- Non-invasive postoperative adjustment of the lens power
- 6.0 mm optic; 13.0 mm diameter
- Optic refractive index: 1.43
- Square optic edges (PCO prevention)
- Modified C, PMMA haptics
- Optic-haptic angulation of 10°
**Light Adjustable Lens (LAL)**

### LAL Material Formulation

- Silicone matrix polymer
- Macromer
- Photoinitiator
- Ultraviolet light absorber

**Adding Power to the LAL**

- Increased power
- "lock-in"

**Subtracting Power from the LAL**

- Iris light
- Decreased power

**Light Adjustable Lens (LAL): Laboratory Results**

- Interference fringes before and after treatment (-1.5 D of myopic correction)
- Resolution efficiency before and after treatment: not compromised

**LAL: Mechanism for dioptric change (hyperopic)**

- Treatment (2-4 weeks after implantation)
- - Myopic treatment: irradiation of the lens edges
- - Astigmatic treatment: band-shaped pattern
- - Higher order aberrations: new digital delivery system (Carl Zeiss Meditec)
- - Use of sunglasses with UV absorbers in outside activities before treatment and "lock-in"
**Light Adjustable Lens (LAL)**

- Light application (365 nm) device: similar to slit lamp coupled with computer
- Irradiation system: mercury arc lamp
- Pupil dilation, topical anesthesia, 0.835X contact lens with hydroxypropylmethylcellulose
- Reticule target (6.0 mm diameter) aligned with the edge of the optic (focus at the optic-haptic junctions)
- Enter base power and correction needed
- -2.0 D for a +20.0 D LAL: 10 mw/cm² for 120 seconds
- “Lock-in”: higher intensity

**Digital Light Delivery System**

*Designed and Manufactured By Carl Zeiss Meditec AG*

- Modified slit-lamp device
- Digital chip with 1.3 million microscopic mirrors
- Worldwide installation and service by Zeiss
- System and software sold by Calhoun

**Light Adjustable Lens (LAL): Animal Studies**

- *In vivo*, rabbit studies:
  - Histopathological studies: biocompatibility
  - Optical bench testing: reproducibility
- *In vitro* studies: no cytotoxicity after Nd:YAG laser
### LAL digital light delivery device: Tetrafoil pattern

### LAL digital light delivery device: Astigmatic pattern

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- 12 cats (similarity with the human cornea)
- "Lock-in" treatment: near UV (365 nm), 250 mW/cm², central 6.0 mm of right cornea, 120 seconds
- Sacrifice (3 cats) 1 day, 1 week, 1 and 3 months

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- Vital staining of cornea: Trypan blue/Alizarin red

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### Light Adjustable Lens (LAL)

- Initial clinical application: pseudophakic lens for cataract surgery
- Technology can be applied to accommodating, phakic lenses…
- Use in conjunction with wavefront sensing: full customization
- Initial clinical trials: 2004
- Availability: 2006 in Europe (?)
- Availability: 2008 in the US (?)

---

<table>
<thead>
<tr>
<th>Sacrifice</th>
<th>Cell Damage (OS)</th>
<th>Cell Damage (OD)</th>
<th>P Value</th>
</tr>
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<tbody>
<tr>
<td>Day 1</td>
<td>0.223 +/- 0.079</td>
<td>0.224 +/- 0.183</td>
<td>0.403 (NS)</td>
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<tr>
<td>Day 7</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Day 30</td>
<td>0.042 +/- 0.072</td>
<td>0.074 +/- 0.065</td>
<td>0.381 (NS)</td>
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<tr>
<td>Day 60</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Day 90</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Day 180</td>
<td>0.064 +/- 0.101</td>
<td>0.074 +/- 0.193</td>
<td>0.601 (NS)</td>
</tr>
</tbody>
</table>
Initial Clinical Results - 13 Patients with Spherical Correction - All within 0.25 D of intended outcome (Dr. Chayet, Mexico)

-2.50  -2.00  -1.50  -1.00  -0.50  0.00  0.50  1.00  1.50  2.00  2.50

Power Change

Targeted  Actual

<table>
<thead>
<tr>
<th>Patient</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
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<tbody>
<tr>
<td>Targeted</td>
<td>-2.5</td>
<td>-2.0</td>
<td>-1.5</td>
<td>-1.0</td>
<td>-0.5</td>
<td>0.0</td>
<td>0.5</td>
<td>1.0</td>
<td>1.5</td>
<td>2.0</td>
<td>2.5</td>
<td>3.0</td>
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<tr>
<td>Actual</td>
<td>-2.5</td>
<td>-2.0</td>
<td>-1.5</td>
<td>-1.0</td>
<td>-0.5</td>
<td>0.0</td>
<td>0.5</td>
<td>1.0</td>
<td>1.5</td>
<td>2.0</td>
<td>2.5</td>
<td>3.0</td>
</tr>
</tbody>
</table>

Initial Clinical Results - Astigmatic Correction (Dr. Chayet, Mexico)

<table>
<thead>
<tr>
<th></th>
<th>Pre-Adjust</th>
<th>2 Month Post-Adjust</th>
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<tbody>
<tr>
<td>UCVA</td>
<td>20/30-</td>
<td>20/20-</td>
</tr>
<tr>
<td>BCVA</td>
<td>20/20</td>
<td>20/20</td>
</tr>
<tr>
<td>MR</td>
<td>0.0-0.125 X</td>
<td>0.0-0.50 X</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

Light Adjustable Lens (LAL): Astigmatism Correction

Corneal Map

Wavefront

Yellow Intraocular Lenses

- The natural human crystalline lens yellows with age
- Progressive increase in absorbance within the blue range of the visible spectrum
- Blue-light was shown to have significant retinal phototoxicity
- Blue-light absorbing (yellow) IOLs: Reduction of the risk for macular degeneration (indirect evidence)

SmartYellow™ Lens

- Proprietary hydrophobic acrylic material (Photochromic Matrix), Medennium Inc.
- Three-piece lens, blue-colored PVDF haptics*
- UV-near blue absorption curve similar to the AcrySof® Natural lens when exposed to UV light
- Standard UV absorbing IOL in an indoor environment

**SmartYellow™ Lens: In vitro study**

Before exposition to UV light

During exposition to UV light

**SmartYellow™ Lens: In vivo study**

Rabbit eyes (6-month study)

**SmartYellow™ Lens: After rabbit sacrifice and IOL explantation**

Before exposition to UV light

During exposition to UV light

**Photochromic changes:**
- Reversible
- Reproducible
- Stable over time
- Biocompatible in rabbits

*This innovative concept of a photochromic IOL deserves further investigation, including evaluation of the lens when exposed to natural sunlight and to white light sources...*

**Clinical Study**

- Dr. Guillermo Avalos, Mexico
- SmartYellow™ Lens = Photochromic Matrix Acrylic Aurium®
- 10 subjects; 10 eyes implanted with Aurium® and 10 eyes implanted with Matrix Acrylic
- Examination at 1, 3, 14, and 30 days postoperatively
- BCVA at 30 days outdoors and indoors

**Clinical Study**

- Aurium® provides blue light protection outdoors and equal or better visual acuity under UV light
- Aurium® performs similarly to regular Matrix indoors
- Subjective evaluation indicates that subjects prefer the Aurium®
BCVA Outdoors vs. Illumination Condition
* Full Sun (3), Shade (2), Sun Glasses (1)

<table>
<thead>
<tr>
<th>BCVA Log MAR</th>
<th>0.058</th>
<th>0.078</th>
<th>0.088</th>
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<tbody>
<tr>
<td>Relative Light Intensity</td>
<td>3.5</td>
<td>3</td>
<td>2.5</td>
</tr>
</tbody>
</table>

Matrix Acrylic Vs. Aurium BCVA Indoors

- Light adjustable materials
- Photochromic materials
- Potential to cause an impact on IOL manufacture

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