Quality of Vision With Multifocal Progressive Diffractive Lens: Two-Year Follow-up

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Dr Piovella has the following Financial interest or relationships to disclose as consultant:
- Abbott Medical Optics
- Aaren Scientific
- BVI Beaver Visitec International
- Carl Zeiss Meditec
- Ocular Therapeutix
- Tearsceince

Dr Mocellin has not financial interest or relationships to disclose

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Quality of Vision
Effect of Contrast Reduction

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All multifocal IOLs provide adequate performance for Far and Near distances at nominal 3 mm pupil and differences can be shown towards the limits of the pupil range: 2 mm and 5 mm.

Sources: IOL data are from the FDA submission for the optic profile.

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Diffractive MIOL : ReSTOR™ (Alcon)

Diffraction Efficiency : % Light Distribution and Light Loss

Light Loss" graph is absolute light energy; Far and Near graphs are relative values.

Advantages
- Distance Dominant
- Diffractive Optics allow for Far and Near vision
- Apodized diffractive design to reduce halos

Disadvantages
- May not have sufficient Near at large pupils
- No provision for intermediate focus
- Substantial percent of light is outside range of vision for small to medium pupils

% LIGHT DISTRIBUTION

<table>
<thead>
<tr>
<th></th>
<th>Near</th>
<th>Intermediate</th>
<th>Far</th>
<th>Outside Range of Vision</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mm pupil</td>
<td>40%</td>
<td>0%</td>
<td>40%</td>
<td>20%</td>
</tr>
<tr>
<td>5 mm pupil</td>
<td>10%</td>
<td>0%</td>
<td>84%</td>
<td>6%</td>
</tr>
</tbody>
</table>
Diffractive MIOL - TECNIS® (AMO - Abbott)

Diffraction Efficiency: % Light Distribution and Light Loss

**Advantages**
- Diffractive Optics allow for Distance and Near vision for full range of pupils

**Disadvantages**
- No provision for intermediate vision
- Substantial percent of light is outside range of vision

<table>
<thead>
<tr>
<th>% LIGHT DISTRIBUTION</th>
<th>LIGHT “LOSS”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Near</td>
<td>Intermediate</td>
</tr>
<tr>
<td>------</td>
<td>--------------</td>
</tr>
<tr>
<td>2 mm pupil</td>
<td>40%</td>
</tr>
<tr>
<td>5 mm pupil</td>
<td>40%</td>
</tr>
</tbody>
</table>
**Monofocal Technology**

Visual Acuity Sensitivity to Residual Refractive Error as Function of Pupil Size *(Patent of Jack Holladay)*

Visual Acuity (20/24) with 0.50 D Defocus and 5mm Pupil Size

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### Pupil size

<table>
<thead>
<tr>
<th>Pupil Size</th>
<th>2.0</th>
<th>3.0</th>
<th>4.0</th>
<th>5.0</th>
<th>6.0</th>
<th>7.0</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TDL</strong></td>
<td>20/09</td>
<td>20/06</td>
<td>20/04</td>
<td>20/04</td>
<td>20/03</td>
<td>20/03</td>
</tr>
<tr>
<td><strong>0.0</strong></td>
<td>20/10</td>
<td>20/09</td>
<td>20/10</td>
<td>20/10</td>
<td>20/11</td>
<td>20/11</td>
</tr>
<tr>
<td><strong>0.50</strong></td>
<td>20/12</td>
<td>20/15</td>
<td>20/19</td>
<td>20/24</td>
<td>20/28</td>
<td>20/30</td>
</tr>
<tr>
<td><strong>1.00</strong></td>
<td>20/19</td>
<td>20/24</td>
<td>20/33</td>
<td>20/44</td>
<td>20/52</td>
<td>20/56</td>
</tr>
<tr>
<td><strong>2.00</strong></td>
<td>20/36</td>
<td>20/49</td>
<td>20/68</td>
<td>20/95</td>
<td>20/121</td>
<td>20/130</td>
</tr>
</tbody>
</table>

TDL indicates Theoretical Diffraction Limits

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• Toric vs. spherical it is **two times difference**: the effect of 1 D cylinder error on VA is about 0.5 D spherical refractive error.

• In Multifocal lenses, VA sensitivity to refractive error depends on a multifocal design.

• Refractive Multifocal Technology was close to monofocal for the width of the Distance Peak in Defocus Curve measurements.

• **Diffractive Multifocal Technology** width of the Distance Peak was about half the monofocal width.

• The effect of **refractive error** was about **twice more sensitive** to than in case of a monofocal optic

• In case of OptiVis, the lens was designed with increased width of Distance Peak as compared with conventional bifocal diffractive multifocal
• Posterior multifocal surface consists of 3 zones:

• Zone 1 of Progressive Refractive powers for Far and Intermediate within central 1.5 mm diameter

• Apodized Diffractive Zone 2 for Far with 2.5 D Effective Add for Near within 1.5 to 3.8 mm diameter

• Peripheral Refractive Zone 3 is shaped for bi-sign aspherization
Central Progressive power zone

- Zone 1 Power profile starts with Intermediate power at the center of the lens

- Power profile shape is to extend focus range from Far to intermediate distances

- Negative surface slop of Zone 1 and part of Base Surface of the Diffractive Zone 2 is to expand Depth of Focus at Far to intermediate

- A Refraction zone has advantage of utilizing 100% of light for retinal image thus reducing the overall light loss as compare with any other diffraction optic

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Initial Diffractive groove is to direct light to Near focus

Zone 2 groove heights reduce towards periphery in order to direct more light to Far

Light Loss is smaller with more unequal Far to Near light split

OptiVis apodization allocates the smallest surface area for equal Far to Near light split where light loss is the largest
Other Aspherics are designed to compensate for a selected level of Corneal spherical aberration. This leads to a significant reduction of image contrast at large pupils with Cornea of different Asphericity and Lens decentration or tilt.

- **Bi-sign asphericity** is that at \( \approx 3 \text{ mm} \) diameter it has Eye aberration similar to with spherical IOL but the opposite sign. As the pupil increases, the aberration of opposite sign to the central lens area kicks in to balance out a total Eye aberrations at large pupil.

- **Bi-sign asphericity balances out aberration at large pupil** within the lens itself for any corneal asphericity thus reducing a reliance on specific corneal shape. The resulted improvement in image contrast at large pupils is maintained for different corneal Asphericities and even with Lens decentration or tilt.

 Balanced Aberrations at Large Pupil
Advantages:

1. Intermediate focus in addition to Far and Near foci
2. Improved Apodization to minimize light “loss”
3. Reduction in both, light “loss” and fraction of light to Near focus at large pupil – this is to reduce nighttime dysphotopsia

<table>
<thead>
<tr>
<th>% LIGHT DISTRIBUTION</th>
<th>LIGHT “LOSS”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Near</td>
</tr>
<tr>
<td>2 mm pupil</td>
<td>34%</td>
</tr>
<tr>
<td>3 mm pupil</td>
<td>47%</td>
</tr>
<tr>
<td>4 mm pupil</td>
<td>31%</td>
</tr>
<tr>
<td>5 mm pupil</td>
<td>20%</td>
</tr>
</tbody>
</table>

4. Bi-sign Aspherization to improve retinal image contrast at large pupil for different corneal asphericities and even lens decentration and tilt
Second Generation Multifocal Diffractive IOL
What is the Difference?

- OptiVis Central Area is 2.1 sq. mm.
- ReStor and Acri.Lisa Central Area is 1.3 sq. mm.
- ReStor and Acri.Lisa Central Areas is the First Diffraction Groove that works together with the other diffraction grooves
- OptiVis Central Area acts as a stand alone refractive zone of Progressive power range which complements the lens diffraction grooves to provide Intermediate foci
- Other differences - optimized Apodization to reduce light outside the range of vision and improved Aspherization to minimize effect of lens tilt and decentration

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Materials and Methods

OptiVis™ implanted in 82 eyes of 41 patients (38 Bilateral implantation)
Mean age: 70.37 ± 6.25 years.
Follow-up: 2 year (18 eyes)
Follow-up: 764.65 ± 54.12 days

• Uncorrected VA (UCVA), Near (UCNVA) and Distance (DCNVA)
• Best corrected distance VA (BCDVA) Distance
• Intermediate VA, uncorrected (UNIVA) and distance corrected
• Near VA

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Manifest Refraction: Spherical Equivalent
82 Eyes

Outcome for targeted refraction

<table>
<thead>
<tr>
<th>Time</th>
<th>DIOPTERS</th>
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<tbody>
<tr>
<td>Preop</td>
<td>0.07</td>
</tr>
<tr>
<td>1 Week PO</td>
<td>-0.12</td>
</tr>
<tr>
<td>1 Month PO</td>
<td>-0.26</td>
</tr>
<tr>
<td>3 Months PO</td>
<td>-0.1</td>
</tr>
<tr>
<td>6 Months PO</td>
<td>-0.1</td>
</tr>
<tr>
<td>1 Year PO</td>
<td>-0.26</td>
</tr>
<tr>
<td>2 Year PO</td>
<td>-0.07</td>
</tr>
</tbody>
</table>
Monocular Far Visual Acuity:
82 Eyes

Far Vision Outcome

**UCVA**

<table>
<thead>
<tr>
<th>Time</th>
<th>Preop</th>
<th>1 Week PO</th>
<th>1 Month PO</th>
<th>3 Months PO</th>
<th>6 Months PO</th>
<th>1 Year PO</th>
<th>2 Years PO</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>0.23</td>
<td>0.71</td>
<td>0.91</td>
<td>0.94</td>
<td>0.8</td>
<td>0.91</td>
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</table>

**BCVA**

<table>
<thead>
<tr>
<th>Time</th>
<th>Preop</th>
<th>1 Week PO</th>
<th>1 Month PO</th>
<th>3 Months PO</th>
<th>6 Months PO</th>
<th>1 Year PO</th>
<th>2 Years PO</th>
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<tbody>
<tr>
<td></td>
<td>0.42</td>
<td>0.76</td>
<td>0.99</td>
<td>1</td>
<td>0.99</td>
<td>0.96</td>
<td>0.95</td>
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</table>
### Two years Binocular Near* Vision Visual Acuity
**41 Patients – 82 Eyes**

<table>
<thead>
<tr>
<th></th>
<th>MEAN ETDRS 20/#</th>
<th>MEAN JAEGER</th>
<th>BEST VISION MEAN DISTANCE</th>
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<tbody>
<tr>
<td>UCNVA PHOTOPIC</td>
<td>34.13</td>
<td>3</td>
<td>40.16 cm</td>
</tr>
<tr>
<td>DCNVA PHOTOPIC</td>
<td>33.88</td>
<td>3</td>
<td>39.79 cm</td>
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### Two years Binocular Intermediate* Vision at 70 cm
**41 Patients – 82 Eyes**

<table>
<thead>
<tr>
<th></th>
<th>MEAN ETDRS 20/#</th>
<th>MEAN JAEGER</th>
<th>DISTANCE</th>
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<tbody>
<tr>
<td>UNCORRECTED INTERMEDIATE VISION</td>
<td>39.22</td>
<td>4</td>
<td>70 cm</td>
</tr>
<tr>
<td>DISTANCE CORRECTED INTERMEDIATE VISION</td>
<td>39.22</td>
<td>4</td>
<td>70 cm</td>
</tr>
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* Used same ETDRS Logarithmic Visual Acuity Chart “2”

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<table>
<thead>
<tr>
<th>Eye Axial Length</th>
<th>Formula</th>
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<tbody>
<tr>
<td>&lt;22.5</td>
<td>HOFFER Q</td>
</tr>
<tr>
<td>22.5-24.0</td>
<td>SRK-T/HAIGIS</td>
</tr>
<tr>
<td>24.0-26.0</td>
<td>HOLLADAY</td>
</tr>
<tr>
<td>&gt;26.0</td>
<td>SRK-T / HAIGIS / HOFFER Q</td>
</tr>
</tbody>
</table>

Biometry With IOL Master: Personal Experience

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### Biometry Using IOL Master

**Optivis Formula Related Constant**

<table>
<thead>
<tr>
<th>Nominal</th>
<th>Haigis</th>
<th>HofferQ</th>
<th>Holl.1</th>
<th>SRK/T</th>
<th>SRK II</th>
</tr>
</thead>
<tbody>
<tr>
<td>A=118.1</td>
<td>a0=0.77</td>
<td>pACD = 4.98</td>
<td>sf=1.20</td>
<td>A=118.0</td>
<td>A=118.1</td>
</tr>
<tr>
<td></td>
<td>a1=0.40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>a2=0.10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Getting Plano Post-operative Results

<table>
<thead>
<tr>
<th>REFRACTIVE TARGET</th>
<th>PLANO / +0.25</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>MULTIFOCAL IOLs</th>
<th>0.75 D</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORNEAL ASTIGMATISM TOLERANCE</td>
<td></td>
</tr>
</tbody>
</table>

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Control values for CS are derived from Hohberger paper

- 10-14 healthy phakic subjects for the following age groups <39; 40-49; 50-59; ≥60
- Functional Image Analyzer OPTEC 6500P
- Daytime (85 cd/m²), Nighttime (3 cd/m²) and Nighttime with Glare (3 cd/m²)
- Monocular testing
- Paper demonstrated strong age dependence of CS with age
Optivis contrast sensitivity
Daytime, Nighttime and Nighttime with glare

Diffractive Multifocal IOLs and Contrast Sensitivity

Acri.LISA
Acri.LISA Toric
Tecnis
Optivis

Contrast Sensitivity Testing (S) (Cone):
(functional image analysis testing)
Righteye Conditions (3 cm):
No glare

Contrast Sensitivity Testing (S) (Cone):
(functional image analysis testing)
Lefteye Conditions (3 cm):
No glare

Contrast Sensitivity Testing (S) (Cone):
(functional image analysis testing)
Righteye Conditions (3 cm):
With glare

Contrast Sensitivity Testing (S) (Cone):
(functional image analysis testing)
Lefteye Conditions (3 cm):
With glare

Microscopic Contrast Sensitivity Testing (Cone) (Cone):
(functional image analysis testing)
Righteye Conditions (3 cm):
No glare

Microscopic Contrast Sensitivity Testing (Cone) (Cone):
(functional image analysis testing)
Lefteye Conditions (3 cm):
No glare

Microscopic Contrast Sensitivity Testing (Cone) (Cone):
(functional image analysis testing)
Righteye Conditions (3 cm):
With glare

Microscopic Contrast Sensitivity Testing (Cone) (Cone):
(functional image analysis testing)
Lefteye Conditions (3 cm):
With glare

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82 Eyes with Optivis Multifocal implants:

Yag laser capsulotomy 29 eyes (36.25%)
Conclusions

• OptiVis multifocal design has a Provision for intermediate foci and clinically demonstrated excellent Intermediate vision in addition to Far and Near

• Contrast Sensitivity scores were comparable or exceeded the Average CS of Healthy eyes, age > 60 years, in Daytime condition and a small reduction at 12 and 18 c/deg at Nighttime condition for some patients

• Reference to optical/visual symptoms was prompted only by the Physician’s Questionnaire and no severe symptoms were reported
Thank you for your attention