How Much is Enough ... Selecting the add for Multifocal IOLs.

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Medical Director, Associated Eye Care
DISCLOSURE

• Alcon
• ClarVista
• Bausch and Lomb
• Ivantis
• i-Veena
• Kala
• Lifecore
• Mati
• Ocular Therapeutics
• Omeros
• PowerVision
• PRN
• RPS
• Shire
• TearLab
• TearScience
• VisionCare
• WaveTec
Why So Many MF Powers?

• Performance differences with different add powers
  – e.g. ReSTOR 2.5/3.0; Tecnis MF 4.0/3.25/2.75
  – Bifocal vs. Trifocal designs

• Meet demand of patients with various near and/or intermediate task needs

• Differences in design than may influence visual disturbances such as glare and haloes

• No single style MF IOL can fill in all the gaps throughout the entire range of vision
TECNIS® MULTIFOCAL FAMILY OF 1-PIECE IOLs

Technical specifications

<table>
<thead>
<tr>
<th>OPTIC CHARACTERISTICS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Powers:</strong></td>
<td>+5.0 D to 34.0 D in 0.5 D increments</td>
</tr>
<tr>
<td><strong>Diameter:</strong></td>
<td>6.0 mm</td>
</tr>
<tr>
<td><strong>Shape:</strong></td>
<td>Biconvex, anterior aspheric surface, posterior diffractive surface</td>
</tr>
<tr>
<td><strong>Add Power (IOL Plane):</strong></td>
<td>+2.75 D (ZKB00)  +3.25 D (ZLB00) +4.0 D (ZMB00)</td>
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<tr>
<td><strong>Add Power (Spec Plane):</strong></td>
<td>+2.01 D (ZKB00)  +2.37 D (ZLB00) +3.0 D (ZMB00)</td>
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<tr>
<td><strong>Material:</strong></td>
<td>UV-blocking hydrophobic acrylic</td>
</tr>
<tr>
<td><strong>Refractive Index:</strong></td>
<td>1.47</td>
</tr>
<tr>
<td><strong>Chromatic Aberration (Abbe Number):</strong></td>
<td>55</td>
</tr>
<tr>
<td><strong>Spherical Aberration:</strong></td>
<td>-0.27</td>
</tr>
<tr>
<td><strong>Edge Design:</strong></td>
<td>ProTEC frosted, continuous 360° posterior square edge</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BIOMETRY†</th>
<th>CONTACT ULTRASOUND</th>
<th>OPTICAL</th>
</tr>
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<tbody>
<tr>
<td><strong>A-Constant:</strong></td>
<td>118.8†</td>
<td>119.3††</td>
</tr>
<tr>
<td><strong>Theoretical AC Depth:</strong></td>
<td>5.40 mm</td>
<td>5.72 mm</td>
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<tr>
<td><strong>Surgeon Factor:</strong></td>
<td>1.68 mm</td>
<td>1.96 mm</td>
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<table>
<thead>
<tr>
<th>HAPTIC CHARACTERISTICS</th>
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<tr>
<td><strong>Overall Length:</strong></td>
<td>13.0 mm</td>
</tr>
<tr>
<td><strong>Style:</strong></td>
<td>C</td>
</tr>
<tr>
<td><strong>Material:</strong></td>
<td>UV-blocking hydrophobic acrylic</td>
</tr>
<tr>
<td><strong>Design:</strong></td>
<td>Haptics offset from optic</td>
</tr>
</tbody>
</table>

The TECNIS® Multifocal Family of Lenses provide vision (20/25 or better) throughout the full range of vision: distance, intermediate and near.¹

BINOCULAR DEFOCUS CURVE AT 6 MONTHS³⁻²

Distances (cm) in the graph are approximate. ZM900 (+4.0 D) data are historical from a separate clinical study using the same test methodology.

1. TECNIS® Multifocal 1-Piece IOL DFU. Abbott Medical Optics Inc., Santa Ana, Calif.
2. TECNIS® Multifocal 1-Piece Low Add DFU. Abbott Medical Optics Inc., Santa Ana, Calif.
Spectacle independence in any lighting condition

All TECNIS® Multifocal IOLs provide significantly increased overall spectacle independence.¹,²

¹ TECNIS® Multifocal 1-Piece IOL DFU. Abbott Medical Optics Inc., Santa Ana, Calif.
More than 90% of TECNIS® Multifocal +2.75 D patients report no difficulty with night vision.

TECNIS® Multifocal IOLs have a full diffractive posterior surface making the optic pupil-independent, which is especially important for low-light conditions.

History of apodized diffractive IOLs—ReSTOR®

2000  
3-piece diffractive-refractive apodized Add. 4.0

2004  
single-piece diffractive-refractive apodized Add. 4.0

2005  
single-piece diffractive-refractive apodized Add. 4.0 blue filtering

2007  
single-piece diffractive-refractive apodized Add. 4.0 aspheric blue filtering

2009  
single-piece diffractive-refractive apodized Add. 3.0 aspheric blue filtering

2010  
single-piece diffractive-refractive apodized Add. 3.0 aspheric blue filtering Toric (EU)

2015  
single-piece diffractive-refractive apodized Add. 2.5 aspheric blue filtering
Physical Comparison

- Both +4.0 D and +3.0 D have 3.6 mm Apodized Diffractive region
- +4.0 D central zone diameter = 0.74 mm
- +3.0 D central zone diameter = 0.86 mm
Binocular Defocus Curve

Source: AcrySof® IQ ReSTOR® IOL Package Insert
Study Design

• Prospective

• Randomized

• Subject masked

• 6 month duration with FDA submission at 3 months

• 300 subjects bilaterally implanted with either
  – AcrySof® IQ ReSTOR® IOL +3.0 D Model SN6AD1
  – AcrySof® IQ ReSTOR® IOL +4.0 D Model SN6AD3

• Approximately 20 subjects at each site
Uncorrected Binocular Photopic Distance VAs
All Implanted, 3 month postoperative, Cumulative

Source: AcrySof® IQ ReSTOR® IOL Package Insert
Uncorrected Intermediate Photopic VAs
All Implanted, 3 month postoperative, 50 cm

Provides a one line or more improvement in binocular intermediate VA.

Source: AcrySof® IQ ReSTOR® IOL Package Insert
Uncorrected Binocular Photopic Near VAs
All Implanted, 3 month postoperative, Cumulative, Standard Distance

Standard distance: 33 cm for Model SN6AD3 and 40 cm for Model SN6AD1

Source: AcrySof® IQ ReSTOR® IOL Package Insert
Overall Frequency of Spectacle Wear
(Bilateral comparison)

How often do you wear eyeglasses?

Never
Sometimes
Always

IQ ReSTOR® IOL +3.0 D [N=138]
IQ ReSTOR® IOL +4.0 D [N=131]

Source: AcrySof® IQ ReSTOR® IOL Package Insert
Visual Disturbances
Visual Disturbances Mean Impact Ratings
3 months postop (following second eye implant)

<table>
<thead>
<tr>
<th>Disturbance</th>
<th>None/Mild</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
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<tbody>
<tr>
<td>Problems with Night Vision</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Problems with Color Perception</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Halos</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Glare/Flare</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Double Vision</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Distorted Near Vision</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Distorted Far Vision</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Blurred Near Vision</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Blurred Far Vision</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

None/Mild = 0 to 2
Moderate = 3 to 5
Severe = 6 to 7

Source: AcrySof® IQ ReSTOR® IOL Package Insert
Over 95% of ReSTOR® IOL +3.0 D Patients Would Have the Same Implant Again

Would you have the same implant again?

Percent of Subjects

- IQ ReSTOR® IOL +3.0 D [N=138]
- IQ ReSTOR® IOL +4.0 D [N=131]

Source: AcrySof® IQ ReSTOR® IOL Package Insert
AcrySof® IQ ReSTOR® +2.5D IOL
# AcrySof® IQ ReSTOR® IOL

<table>
<thead>
<tr>
<th>Parameter</th>
<th>+2.5 D</th>
<th>+3.0 D</th>
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</thead>
<tbody>
<tr>
<td>Model number</td>
<td>SV25T0</td>
<td>SN6AD1</td>
</tr>
<tr>
<td>ADD power @ IOL plane</td>
<td>+2.5 D</td>
<td>+3.0 D</td>
</tr>
<tr>
<td>ADD power @ Spectacle Plane</td>
<td>+2.0 D</td>
<td>+2.5 D</td>
</tr>
<tr>
<td>Central ring diameter</td>
<td>0.94 mm</td>
<td>0.86 mm</td>
</tr>
<tr>
<td># steps</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Apodized Diffractive Area</td>
<td>8.4 mm²</td>
<td>10.2 mm²</td>
</tr>
<tr>
<td>Energy distribution (3 mm IOL plane)</td>
<td>Dist: 69% Near: 18.0%</td>
<td>Dist: 59% Near: 25.5%</td>
</tr>
<tr>
<td>Asphericity</td>
<td>-0.2µm</td>
<td>-0.1µm</td>
</tr>
</tbody>
</table>

1. Alcon data on file
Light Distribution  ReSTOR 2.5 vs. ReSTOR 3.0

AcrySof IQ ReSTOR +2.5 DFU;
AcrySof IQ ReSTOR +3.0 DFU.
Mean Defocus Curves by Lens Model

ReSTOR +2.5 versus IQ (SN60WF)
Patients implanted with AcrySof® IQ ReSTOR® +2.5 D IOLs experienced 3.3% severe glare.

Patients implanted with AcrySof® IQ Monofocal IOLs experienced 3.8% severe glare.
Blended vision is simulated with ReSTOR +3.0 in one eye and ReSTOR +2.5 in the other eye

- Blended vision is a strategy that corrects two eyes with different optics
  - OS: Design A + OD: Design B

- Different IOLs provide different sets of visual benefits. Many experienced cataract surgeons use blended vision strategy and choose the best combination of lens implants to match their patients’ individual needs.
  - Example: OS: ReSTOR +3.0D OD: ReSTOR+2.5D

  To provide extended range of vision from intermediate to near

- The simulated binocular images were derived from monocular ReSTOR+3D/+2.5D images, with a method suggested by a psychophysical study (Rabin 1995)*.

The simulated images show ReSTOR +3.0 and ReSTOR +2.5 have different best nears.

Binocular ReSTOR +3.0

Best Near at 2.25D

Binocular ReSTOR +2.5

Best Near at 1.88D
Blending approach results with similar distance vision and improved near vision compared to binocular ReSTOR +2.5

**Binocular ReSTOR +2.5**

**Binocular ReSTOR +3.0 / ReSTOR +2.5**
ReSTOR 2.5D and 3.0D

- Clinical outcomes of:
  - bilateral ReSTOR +2.5 D implantation
  - vs. implantation of ReSTOR +2.5 D in the dominant eye and ReSTOR +3.0 D in the fellow eye
Study Design and Methods

- **Binocular defocus testing**
  - Defocus from −5.0 D to +2.0 D in 0.5 D increments
  - Binocular LogMAR acuity was recorded at each increment using ETDRS charts.

- **Reading Performance**
  - Reading acuity and speed were measured using the Radner reading test with distance correction.

- **Contrast Sensitivity**
  - Contrast sensitivity was measured using the Vector Vision CSV-1000 chart.

*ETDRS=Early Treatment of Diabetic Retinopathy Study; logMAR=logarithm of the minimum angle of resolution*
Results

- **BINOCULAR DEFOCUS CURVE WITH DISTANCE CORRECTION**
  - Good range of vision (visual acuity ≥20/40) was observed with
    - Bilateral ReSTOR +2.5 D: 0 D to −2.5 D
    - Contralateral ReSTOR +2.5 D/+3.0 D: 0 D to −3.5 D
  - Near visual acuity at 40 cm was better with contralateral ReSTOR +2.5 D/+3.0 D.
Results

- **Radner Reading Performance**: 3 months post surgery, distance corrected
  - Reading speed was similar between bilateral ReSTOR +2.5 D and contralateral ReSTOR +2.5 D/+3.0 D.
  - Reading acuity was better in the contralateral ReSTOR +2.5D/+3.0 D group by 1 line compared with bilateral ReSTOR +2.5 D.

<table>
<thead>
<tr>
<th></th>
<th>Bilateral ReSTOR +2.5 D</th>
<th>Contralateral ReSTOR +2.5 D/+3.0 D</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>46</td>
<td>43</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>73.2±30.0</td>
<td>76.8±27.3</td>
</tr>
<tr>
<td>Reading speed, wpm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading acuity, logRAD</td>
<td>0.30±0.18</td>
<td>0.19±0.13</td>
</tr>
</tbody>
</table>

logRAD=Reading Acuity Determination; wpm=words per minute
Results

- **Binocular Contrast Sensitivity:** At 3 months postimplantation, contrast sensitivity was similar with bilateral ReSTOR +2.5 D and contralateral ReSTOR +2.5 D/+3.0 D with and without glare under mesopic and photopic conditions.

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**Mean Mesopic Contrast Sensitivity**

**Mean Photopic Contrast Sensitivity**

Cpd = cycles per degree
Figure 2. Change in mean distance-corrected visual acuity from far to near by diopters of added astigmatism in the +3.00 D multifocal IOL group.

Anterior Apodized Diffractive Aspheric Surface

Same design as current AcrySof IQ ReStor +3.0D

- 9 apodized diffractive steps for +3.0D add power
- Negative 0.1 micron spherical aberration factor corrects for the positive spherical aberration of the cornea

Posterior Toric Lens Surface

Same design as current AcrySof Toric IOL

- Posterior toric axis marks
- Posterior toric surface
- Allows the lens to correct pre-existing corneal astigmatism
Trifocal IOLs
FineVision / Toric

- **Add:** 3.5 D / 1.75 D
  - Optic: Aspheric trifocal diffractive
  - Material: 25% hydrophilic acrylic
  - Filtration: UV and blue light blocker
  - Optic body diameter: 6.15mm
  - Overall diameter: 10.75mm
  - Angulation: 5°
  - from +10D to +35D (0.5D steps)
  - Toric from +6D to +35D (0.5D steps)

Quellen: Herstellerangaben
AT LISA TRI / Toric

- Add: 3.33 D / 1.66 D

  - Optic: Aspheric trifocal/ bifocal diffractive
  - Material: 25% hydrophilic acrylic with hydrophobic surface
  - Filtration: UV blocker
  - Optic body diameter: 6 mm
  - Overall diameter: 11 mm
  - Angulation: -
  - from +0D to +32D (0.5D steps)
  - Toric from -10D to +24D (0.5D steps)

Quellen: Herstellerangaben
Binocular uncorrected visual acuity

- Uncorrected distance visual acuity (UDVA):
  - $-0.1 \pm 0.1$ logMAR
- Uncorrected intermediate visual acuity (UIVA):
  - $0.0 \pm 0.1$ logMAR
- Uncorrected near visual acuity (UNVA):
  - $0.0 \pm 0.1$ logMAR
Monocular Defocus curve

Defocus curve

Visual acuity [logMAR]

Defocus [D]
Visual Disturbances

Optical phenomenon

- Glare: 28.0%
- Double Vision: 12.0%
- Starburst: 8.0%
- Halo: 60.0%
- No: 12.0%

Contrast sensitivity

- Photopic: 1.8
- Mesopic: 1.58
- Mesopic+Glare: 0.96
- CS [logCS]

Patients [%]

- Glare
- Double Vision
- Starburst
- Halo
- No

Summary (Trifocal)

• Good visual acuity at far, intermediate and near distance (0.1 logMAR or better)

• High patient satisfaction despite optical phenomenon
  ▪ 23 of 25 patients would choose same IOL again
  ▪ IOL independency
    ▪ 100% complete spectacle independence at far and intermediate distance
    ▪ 12% occasional near correction use
Conclusion

• The use of MF IOLs remains a tradeoff between decreased spectacle independence and visual disturbances.
• New options give patients a choice in near and intermediate vision with less compromise in visual disturbances.
• New options will give the surgeon the ability to correct corneal astigmatism:
  ▪ MF Toric IOLs
• Surgeons now have options of blended vision with different add powers to meet the individual patient needs.