Quality of Vision with a Wavefront Designed Intraocular Lens

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How should we measure the quality of vision?
Letter Recognition Tests...
...can’t tell the whole story
Quality of Vision

- The Contrast Sensitivity Function measures both optical and neural transfer of visual information.
Relationship between MTF and CSF

Modulation Transfer Function

Contrast Sensitivity Function
Wall Chart and View-In Testing
Contrast Sensitivity Testing

Peak Function

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Functional Vision

- The contrast sensitivity function predicts driving difficulty and crash involvement, falls and postural stability in the elderly, visual impairment in activities of daily living, and the performance of pilots in aircraft simulators.

Contrast Sensitivity Declines with Age

Contrast Sensitivity in 5 Age Groups

Contrast Sensitivity (Log units) vs. Spatial Frequencies
Why does the quality of vision decline with age?

…and what can we do about it?
Aberrations of Aging Eye and Cornea
Spherical Aberration

• Increases 0.15 % / year (p < 0.0001)
  
Lens Spherical Aberration: Negative to Positive


SA = AGE * 0.394 - 15.675

$r^2 = 0.634; p < 0.001$
• “An important compensatory role is played by the crystalline lens. Its presence serves to reduce spherical aberration.”

– El Hage, Berny. “Contribution of the crystalline lens to the spherical aberration of the eye.”

Young crystalline lens compensates for spherical aberration of cornea.
Aging crystalline lens increases spherical aberration of the eye.
Intraocular Lens = Spherical Lens

- IOLs have positive spherical aberration
- The contrast sensitivity of pseudophakic patients is no better than that of their age-matched counterparts without cataracts.
• An IOL designed to compensate for corneal aberrations will produce
  – lower total ocular aberrations
  – higher quality retinal images
  – improved visual performance
Design Procedure

- Number of Subjects = 71

Corneal elevation maps → Average corneal WA → Z9000 lens - modified prolate shape
Corneal Wavefront Aberration Coefficients

(average of 71 cataract patients preop)
TECNIS™ Foldable Lenses With Z-SHARP™ Optic Technology\textsuperscript{1,2}

- Next-generation silicone: polysiloxane
- Biconvex with modified prolate surface
  - Refractive index 1.46
  - 6.0 mm D
- Posterior and anterior sharp-edge design
- Polyvinylidene fluoride (PVDF) haptics
- Capsular C design

\textsuperscript{1}. Data on file. Pharmacia Corporation.
Optical Performance: Tecnis and Spherical IOL

MTF in model eye for 20D lenses

- Spherical lens
- Modified prolate lens

Frequency (c/mm)

MTF values decrease as frequency increases.
Surgical Tolerance

• Superior optical performance if...
  – Decentered less than 0.4 mm
  – Tilted less than 7 degrees
3mm pupil

5mm pupil

15 c/deg
DECENTRATION

15 c/deg, 3 mm and 5mm pupils
**Surgical Tolerance**

- Superior optical performance if...
  - Decentered less than 0.4 mm
  - Tilted less than 7 degrees

- Continuous curvilinear capsulorhexis and in-the-bag IOL placement
  - 0.15 mm, 1.13 degrees (Akkin, 1994)
  - 0.28 mm, 2.83 degrees (Muitlu, 1998)
  - 0.30 mm, 2.41 degrees (Hayashi, 1997)
Tecnis Clinical Data

- Ulrich Mester, MD
  Patrick Dillinger, MD
  Nicola Anterist, MD
- Roberto Bellucci, MD
  Lucio Buratto, MD
  Antonio Scialdone, MD
- Mark Packer, MD
  I. Howard Fine, MD
  Richard S. Hoffman, MD
- US FDA Monitored Multicenter Study (001)
Study Design - Mester, et al.¹

• Prospective, randomized, n = 45
• One eye received Tecnis lens
• Fellow eye received SI40 lens (AMO)
• 37 patients examined at all follow-up visits

Corneal and Total Aberrations, 4 mm pupil: Tecnis and SI40

Ocular Wavefront Aberration, 4 mm pupil

Wavefront Aberration of Z9000 and SI40 eyes

Wavefront Aberration (microns)

Zernike Coefficient
Spherical Aberration, 4 mm pupil
Z9000 vs. SI40 (n=30)

-0.04
-0.02
0
0.02
0.04
0.06
0.08
0.1
0.12

1 Month
3 Months

* * p<0.0001
Photopic Contrast Sensitivity

Contrast Sensitivity vs. Spatial Frequency (c/deg)

- **Tecnis**
- **SI40**

*P < 0.05

1Mester U et al. In press.
Mesopic Contrast Sensitivity

Contrast Sensitivity vs. Spatial Frequency (c/deg) for Tecnis and SI40 lenses. *P < 0.05

1Mester U et al. In press.
Comparison of Tecnis Performance With SI40 Performance¹

¹Mester U et al. In press.
Study Design - Bellucci, et al.

- 30 patients
- Senile cataract, no other eye pathology
- Scheduled for sequential bilateral surgery
- Randomized IOL selection, Tecnis or SA60AT (Alcon)
- Same IOL in both eyes
- Aged 50-75 years
Photopic Contrast Sensitivity

Contrast Sensitivity

Spatial Frequency (c/deg)

Contrast Sensitivity vs Spatial Frequency for Tecnis and SA60AT lenses.

*P < 0.05

Bellucci et al.
Photopic/Glare Contrast Sensitivity

Contrast Sensitivity

Spatial Frequency (c/deg)

- *P < 0.05

- Tecnis
- SA60AT
Mesopic Contrast Sensitivity

![Graph showing mesopic contrast sensitivity. The X-axis represents spatial frequency (c/deg) with values 1.5, 3, 6, 12, and 18. The Y-axis represents contrast sensitivity with values ranging from 0 to 200. Two lines are depicted: one for 'Tecnis SA60AT' and another for a comparison group. The graph shows statistical significance marked by asterisks (*) indicating a P value less than 0.05.](image)
Mesopic/Glare Contrast Sensitivity

Contrast Sensitivity

Spatial Frequency (c/deg)

Contrast Sensitivity

TECNIS™
SA60AT

*P < 0.05
The Contrast of Age

Contrast Sensitivity in 5 Age Groups. 6 cd/m²
Dominant Eye

Contrast Sensitivity (Log units)

Spatial Frequencies

20-29
30-39
40-49
50-59
60-69
Z9000/Bellucci
SA60AT/Bellucci
Study Design - Packer, et al.

- Randomized implantation of Tecnis IOL or AR40e IOL (AMO) following cataract extraction in one eye of each subject
- $n = 30$
- Initial interim results published in *Journal of Refractive Surgery* Nov-Dec 2002
Preoperative Characteristics

• Tecnis
  – n = 15
  – 8 male, 7 female
  – Age 66.8 Years
  – 9/15 Dominant Eye
  – 0.50 BCVA

• Control
  – n = 15
  – 7 male, 8 female
  – Age 70.3 Years
  – 11/15 Dominant Eye
  – 0.57 BCVA
Postoperative Measurements

• Tecnis
  – 1.02 (20/20) BCVA
  – Tilt/Decentration = 0

• Control
  – 0.98 (20/20) BCVA
  – Tilt/Decentration = 0
Stereo Optical VT1600X
Postoperative Mesopic Contrast Sensitivity

Mesopic (low light) Log Contrast Sensitivity

Log Contrast Sensitivity

Spatial Frequency (c/deg)

Z9000

Control

*
Postoperative Photopic Contrast Sensitivity

Photopic Log Contrast Sensitivity

Log Contrast Sensitivity

Spatial Frequency (c/deg)
Peak Mesopic Contrast Sensitivity

- Tecnis provides a 0.19 log unit (52.4 %) gain in peak contrast sensitivity at 3 cpd compared with control.
Bilateral Subgroup Analysis

- All bilaterally implanted patients
  - Tecnis, $n = 7$ patients
  - AR40e, $n = 9$ patients
“Each Eye” Analysis

Mesopic Log Contrast Sensitivity

Spatial Frequency (c/deg)

Log Contrast Sensitivity
“Each Eye” Analysis

Photopic Log Contrast Sensitivity

Log Contrast Sensitivity

Spatial Frequency (c/deg)

Z9000
AR40

*
“Average of Eyes” Analysis

Mesopic Log Contrast Sensitivity

Spatial Frequency (c/deg)

Log Contrast Sensitivity

Z9000
AR40

*
“Average of Eyes” Analysis

Photopic Log Contrast Sensitivity

Log Contrast Sensitivity vs. Spatial Frequency (c/deg)

- Z9000
- AR40

* indicates a significant difference.
Study Design – US FDA Multicenter Trial

- Randomized implantation of Tecnis IOL, SA60AT IOL (Alcon) following cataract extraction in both eyes, n=78
- Wavefront Aberrometry (WASCA), Night Driving Simulation Subset, n=29
The VSRC Night Driving Simulator tests patients in rural and city nighttime visibility conditions.

Rural Scene

City Scene

Modified from: Ginsburg A, Kelly M; Functional vision testing: night driving simulator studies (1995) ASCRS ASOA Symposium of Cataract, IOL and Refractive Surgery, San Diego, California, April 1-5, 1995
Driving Identification Distance

- Tecnis Intraocular Lens
  - 45 feet average increased identification distance
  - prevents impact at 16 mph


(for pedestrian, 55 mph, rural night driving with glare)
One Patient’s Perspective

• “I had cataract surgery several years ago in one eye, but the Tecnis IOL used for my second eye surgery gave me a stark improvement in contrast, color and brightness.”
Will Every Patient Recognize the Difference?

- **Corneal SA Variation**
  - 93%

- **Refraction**
  - Lower Order Aberrations

- **Centration**
  - Capsulorhexis, Cortical Clean Up

- **CME**
  - Early, Late

- **Pupil Size**
  - >2.8 mm
Vision Need Not Deteriorate with Age

• Reducing total optical spherical aberration improves functional vision in the aging eye.
Thank You!