Clinical Outcomes of a Novel Non-Diffractive Extended Vision IOL

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FINANCIAL DISCLOSURES: CONSULTANT AND INVESTIGATOR FOR ALCON
EDF IOLS ARE DESIGNED TO PROVIDE CONTINUOUS VISION FROM DISTANCE TO INTERMEDIATE

EDF IOL¹

Functional near

Intermediate

Distance

Continuous vision²

EDF, extended depth of focus; IOL, intraocular lens
EDF IOLS ARE DESIGNED TO ADDRESS VISION QUALITY ISSUES ASSOCIATED WITH MULTIFOCAL IOLS

Multifocal IOLs are associated with:

- Photic phenomena, such as glare and halo\(^1,2\)
- Reduced contrast sensitivity\(^2\) *Compared with monofocal IOLs*
ANSI CRITERIA TO DEFINE EDF IOLS HAVE RECENTLY BEEN DEVELOPED\textsuperscript{1,2}

<table>
<thead>
<tr>
<th>Depth of focus</th>
<th>( \geq 0.5 ) D greater than monofocal control</th>
</tr>
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<tbody>
<tr>
<td>DCIVA</td>
<td>Superior to a monofocal</td>
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<td>Achieve 0.2 logMAR or better in 50% of eyes</td>
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<td>BCDVA</td>
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There are no criteria regarding visual disturbances for EDF IOLs

ANSI, American National Standards Institute; BCDVA, best-corrected distance visual acuity; DCIVA, distance-corrected intermediate visual acuity
ACRYSOFT IQ VIVITY EXTENDED VISION IOL HAS BEEN DESIGNED TO EXCEED THE CRITERIA FOR EDF IOL’S

Vivity design intends to provide:

- An extended range of vision (>1.5 D)
- Superior intermediate and near vision, and comparable distance vision to AcrySof® IQ Monofocal IOL
- Preserved mesopic contrast sensitivity
- Monofocal visual disturbance profile
THE SURFACE PROFILE OF VIVITY IS RELATIVELY FLAT AND SMOOTH, SIMILAR TO THAT OF A MONOFOCAL IOL
VIVITY UTILIZES A NON-DIFFRACTIVE WAVEFRONT-SHAPING TECHNOLOGY TO STRETCH AND SHIFT THE WAVEFRONT

AcrySof® IQ Vivity (DFT015) Wavefront-Shaping Technology

Acrysof IQ (SN60WF) IOL Base Power

Non-Diffractive Wavefront-Shaping (2.2 mm)

Surface transition 1
Slightly elevated smooth plateau (~1 µm) stretches the wavefront resulting in an extended focal range

Surface transition 2
Small curvature change shifts the wavefront creating an extended negative focal range

Diffractive EDF IOL

Diffractive elevated rings contribute to halos

Elevation is 2.5× greater

Alcon
PINHOLE HALO SIMULATIONS

Logarithmic scale images of halos around point source

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SAFETY AND EFFECTIVENESS OF VIVITY HAS BEEN ASSESSED IN TWO CLINICAL STUDIES

Randomization | Bilateral Implantation | Follow-up
--- | --- | ---
US study\(^1\) (N=221) 1:1 | AcrySof\(^\text{®} \) IQ Vivity IOL (n=107)* | 6 months
| | AcrySof\(^\text{®} \) IQ Monofocal IOL (n=113) |
OUSSudy\(^2\) (N=282) 5:4 | AcrySof\(^\text{®} \) IQ Vivity IOL (n=156)\(^\dagger\) | 6 months\(^\ddagger\)
| | AcrySof\(^\text{®} \) IQ Monofocal IOL (n=120)\(^\ddagger\) |

*Vivity was only implanted in first eye of one patient; \(^\dagger\)Vivity was only implant in first eye of two patients; \(^\ddagger\)monofocal was only implanted in first eye of one patient; \(^\ddagger\)an interim analysis was conducted at 3 months

OUS, Outside United States
ANSI CRITERIA TO DEFINE EDF IOLS HAVE RECENTLY BEEN DEVELOPED ¹,²

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<th>Criteria</th>
<th>Requirement</th>
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**All 4 criteria plus a monofocal visual disturbance profile demonstrated in 2 large, pivotal trials**

ANSI, American National Standards Institute; BCDVA, best-corrected distance visual acuity; DCIVA, distance-corrected intermediate visual acuity.
Data from two large clinical trials showed that DFT015 had a greater negative range of binocular defocus compared with SN60WF at 6 months.

Bars represent 95% confidence interval. *All-implanted analysis set; †best-case analysis set. OUS, outside the US.
VIVITY HAS IMPROVED DISTANCE-CORRECTED AND UNCORRECTED INTERMEDIATE AND NEAR VISUAL ACUITY

**US Trial**

Vivity provides improved distance-corrected intermediate and near visual acuity, while maintaining monofocal distance vision.

<table>
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<tr>
<th>6mo</th>
<th>Mean MRSE</th>
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<tr>
<td>DFT015</td>
<td>.049 D</td>
</tr>
<tr>
<td>SN60WF</td>
<td>.081 D</td>
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</table>

### Graphs

#### Binocular distance-corrected visual acuity (logMAR)

- **BCDVA** (4m)
- **DCIVA** (66cm)
- **DCNVA** (40cm)

#### Binocular uncorrected visual acuity (logMAR)

- **UCDVA** (4m)
- **UCIVA** (66 cm)
- **UCNVA** (40 cm)

### Notes

- BCDVA, best corrected distance VA, DCIVA, distance corrected intermediate VA, DCNVA, distance corrected near visual acuity
- UCDVA, uncorrected distance visual acuity; UCIVA, uncorrected intermediate visual acuity; UCNVA, uncorrected near visual acuity

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**Alcon**

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**AcrySof.IQ Vivity**

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**Advancing Cataract Surgery**
No visual disturbance reported

A higher proportion of DFT015 recipients reported not experiencing blurred vision compared with SN60WF recipients (10.4% difference; 95% CI 0.6, 20.1)

The proportions of DFT015 recipients free of each visual disturbance at 6 months were comparable to those of SN60WF recipients

*Safety-analysis set; †assessed using the QUVID questionnaire; ‡negative dysphotopsia; §percent difference between DFT015 minus SN60WF
QUVID, Questionnaire for Visual Disturbance
In two large-scale, independent trials, the proportions of patients not at all bothered by starburst, halo, and glare were comparable between the DFT015 and SN60WF groups at 6 months.

*Safety-analysis set; †assessed using the QUVID; ‡assessed using the QoV questionnaire* OUS, outside the US; QoV, Quality of Vision; QUVID, Questionnaire for Visual Disturbance McAlinden C et al. Invest Ophthalmol Vis Sci 2010;51:5537
No clinically relevant differences were observed for monocular mesopic contrast sensitivity.

**OUS Trial**

**Without glare**
- Clinically meaningful drop in contrast sensitivity*

**With glare**
- Clinically meaningful drop in contrast sensitivity*

*Per ISO 11979-7  
**cpd**, cycles per degree
**VIVITY ALLOWS PATIENTS REDUCED SPECTACLE DEPENDENCE AT NEAR AND INTERMEDIATE**

US Trial

Patients experienced less spectacle dependence at near and intermediate distances in bright and dim conditions with Vivity.

![Bar chart showing reduced spectacle dependence]

- **Bright light**
  - Up close: 46, 39
  - Arm’s length: 58, 53
  - Far away: 94, 84

- **Dim light**
  - Up close: 16, 11
  - Arm’s length: 87, 84
  - Far away: 92, 93

Data based off results from IOLSAT questionnaire response.

*Alcon*
PATIENTS REPORTING GOOD/VERY GOOD VISION IN BRIGHT AND DIM LIGHT

US Trial

Vivity maintained enhanced vision quality without spectacles in bright and dim lighting conditions

Patients reporting good/very good vision in bright and dim light:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Bright Light</th>
<th>Dim Light</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up close</td>
<td>52%</td>
<td>38%</td>
</tr>
<tr>
<td>Arm's length</td>
<td>63%</td>
<td>51%</td>
</tr>
<tr>
<td>Far away</td>
<td>94%</td>
<td>88%</td>
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Data based off results from IOLSAT questionnaire response

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VIVITY ENABLES FLUENT READING AT A RANGE OF FONT SIZES

OUS Trial

With Vivity, patients maintain a fluent reading speed across a wide range of font sizes at intermediate (66 cm)

Distance-corrected reading speed (words/min)

Fluent reading speed

Font size

20 pt  16 pt  14 pt  11 pt  8 pt

20 pt  16 pt  14 pt  11 pt  8 pt

DFT015 (n=151)
SN60WF (n=117)
CLINICAL DATA SHOW THAT ACRYSOF® IQ VIVITY IS AN EFFECTIVE EDF IOL

Safety and effectiveness of Vivity have been assessed in two randomized, controlled, multicenter clinical studies.

Compared to an apheric monofocal, Vivity provides continuous vision, with non-inferior distance, and superior intermediate and near vision.*

Vivity maintains a visual disturbance profile comparable to an aspheric monofocal.*