Visual Outcomes and Quality of Vision After Implantation of a New Presbyopia-Correcting Intraocular Lens with a Non-diffractive Design

Dr. Cathleen McCabe, MD

Eye Associates, Sarasota, Florida, USA

Dr. Aldo Martinez, PhD

Alcon Vision LLC, Fort Worth, Texas, USA

Financial disclosures:

Alcon: Consultant and Research

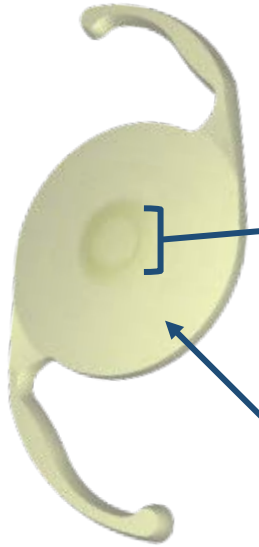
Consultant: Dompe, Imprimis, Novartis, Omeros, Science Based Health, Sight Sciences, Tarsus, Zeiss; Research: Glaukos, Johnson & Johnson Vision, Ora; Consultant and Research: Allergan, Bausch & Lomb, EyePoint Pharmaceuticals, Ivantis, Ocular Therapeutix; Consultant and Investor: Engage Technologies

Alcon: Employee

DFT015: Mechanism of Action

AcrySof IQ Vivity® IOL (model DFT015) is a non-diffractive extended depth of focus IOL with novel wavefront-shaping X-WAVE™ technology
Intended benefit: Continuous extended range of vision with a visual disturbance profile similar to that of an aspheric monofocal IOL (SN60WF)

DFT015



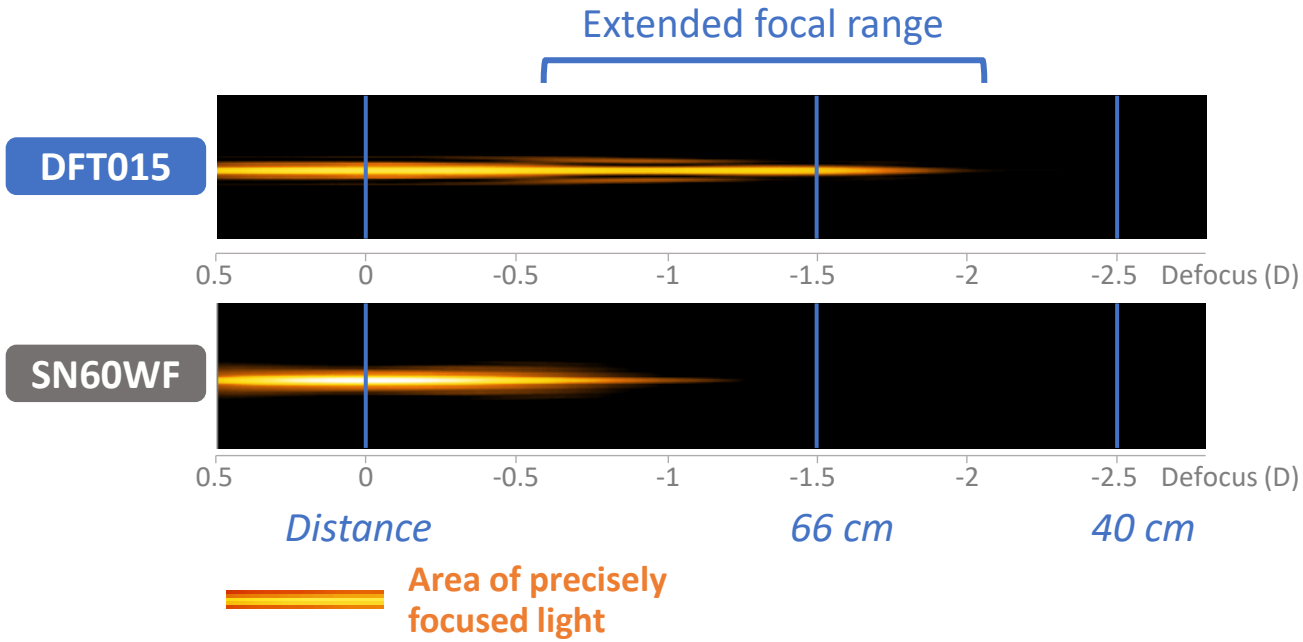
7x magnification of central element

2.2 mm wavefront-shaping optic (X-WAVE™ technology)

- **Stretches and shifts** the wavefront
- **Avoids light splitting**
- Results in an **extended focal range** rather than multiple focal points

SN60WF base power

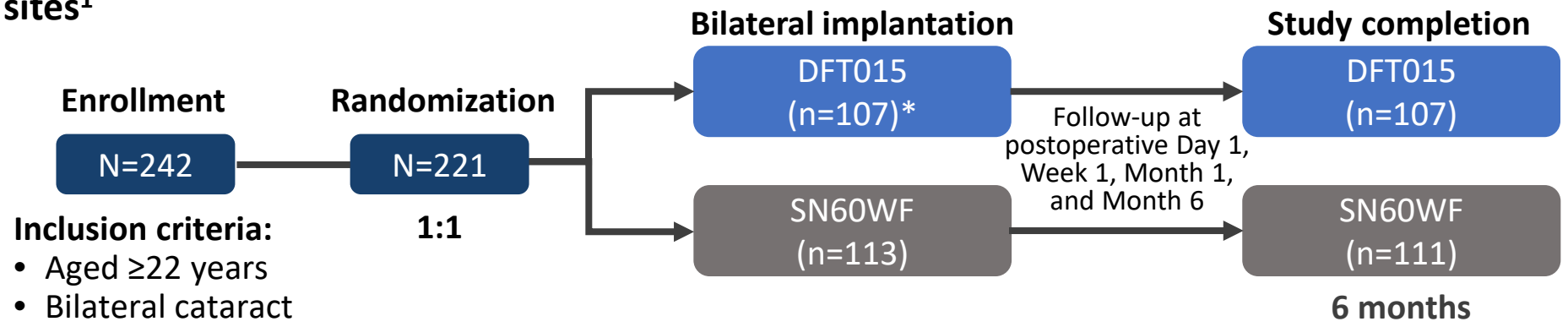
Point spread function analysis



Study Design

Objective: To evaluate the clinical outcomes of binocular implantation of a novel presbyopia-correcting IOL with a non-diffractive design (DFT015) versus a premium aspheric monofocal IOL (SN60WF) and demonstrate that DFT015 meets ANSI EDF IOL criteria

Prospective, multicenter, randomized, assessor- and patient-masked, parallel-group, controlled US clinical trial; 11 sites[1]



Inclusion criteria:
- Aged ≥22 years
- Bilateral cataract

Key outcome measurements based on the ANSI EDF IOL criteria[2]

- Monocular defocus curve: At least 0.5 D negative depth of focus at 0.2 logMAR versus monofocal control
- Monocular photopic distance-corrected visual acuity at:
  - Distance (BCDVA): Statistical non-inferiority to monofocal control
  - Intermediate (DCIVA, 66 cm): Median at least 0.2 logMAR and statistical superiority of mean versus monofocal control
  - Near (DCNVA, 40 cm; additional outcome)
- Patient-reported visual disturbances (validated QUVID questionnaire; additional outcome)

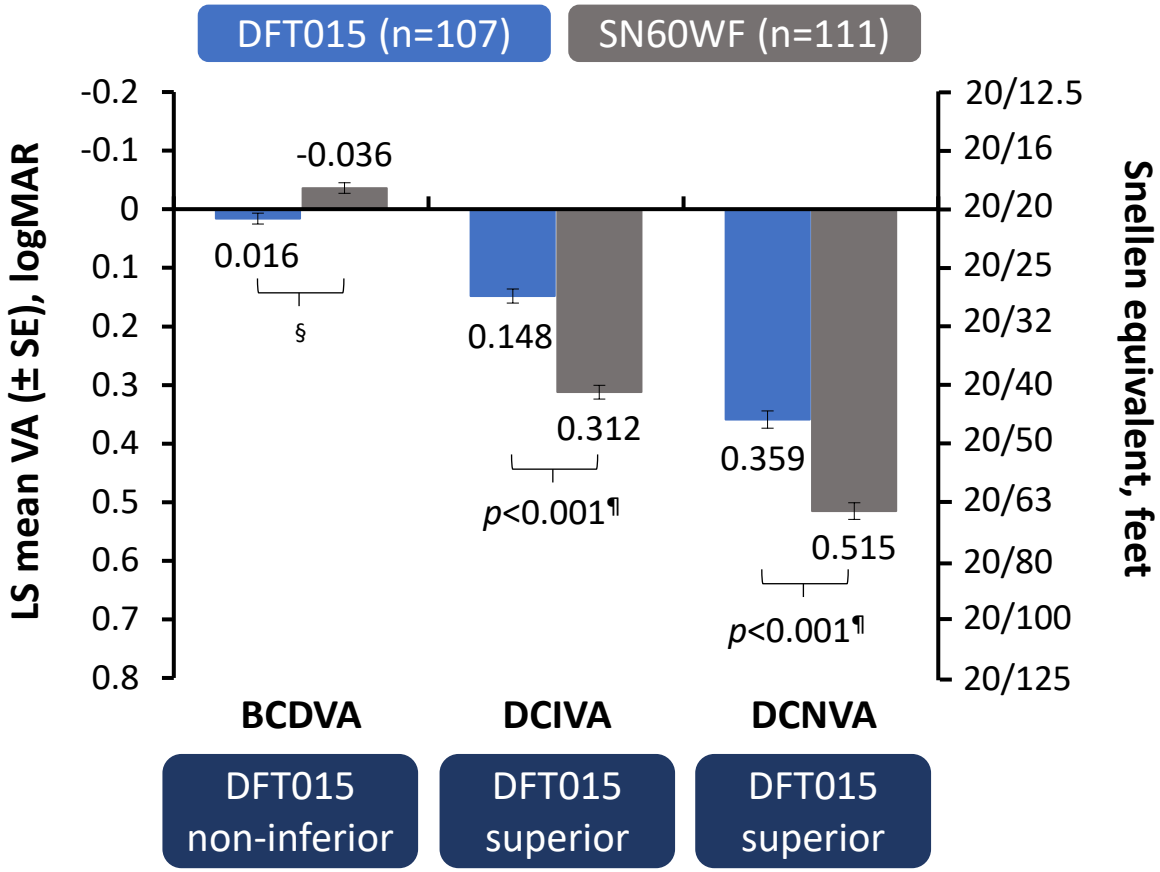
*One patient in the DFT015 group underwent unilateral implantation.

1. clinicaltrials.gov. NCT03274986 (accessed June 15, 2021); 2. American National Standard for Ophthalmics. ANSI Z80.35-2018: Extended depth of focus intraocular lenses. 2018. https://webstore.ansi.org/standards/vc%20(asc%20z80)/ansiz80352018 (accessed June 15, 2021)

DFT015 Provided Superior DCNVA and DCIVA, and Non-inferior* BCDVA, Compared with SN60WF

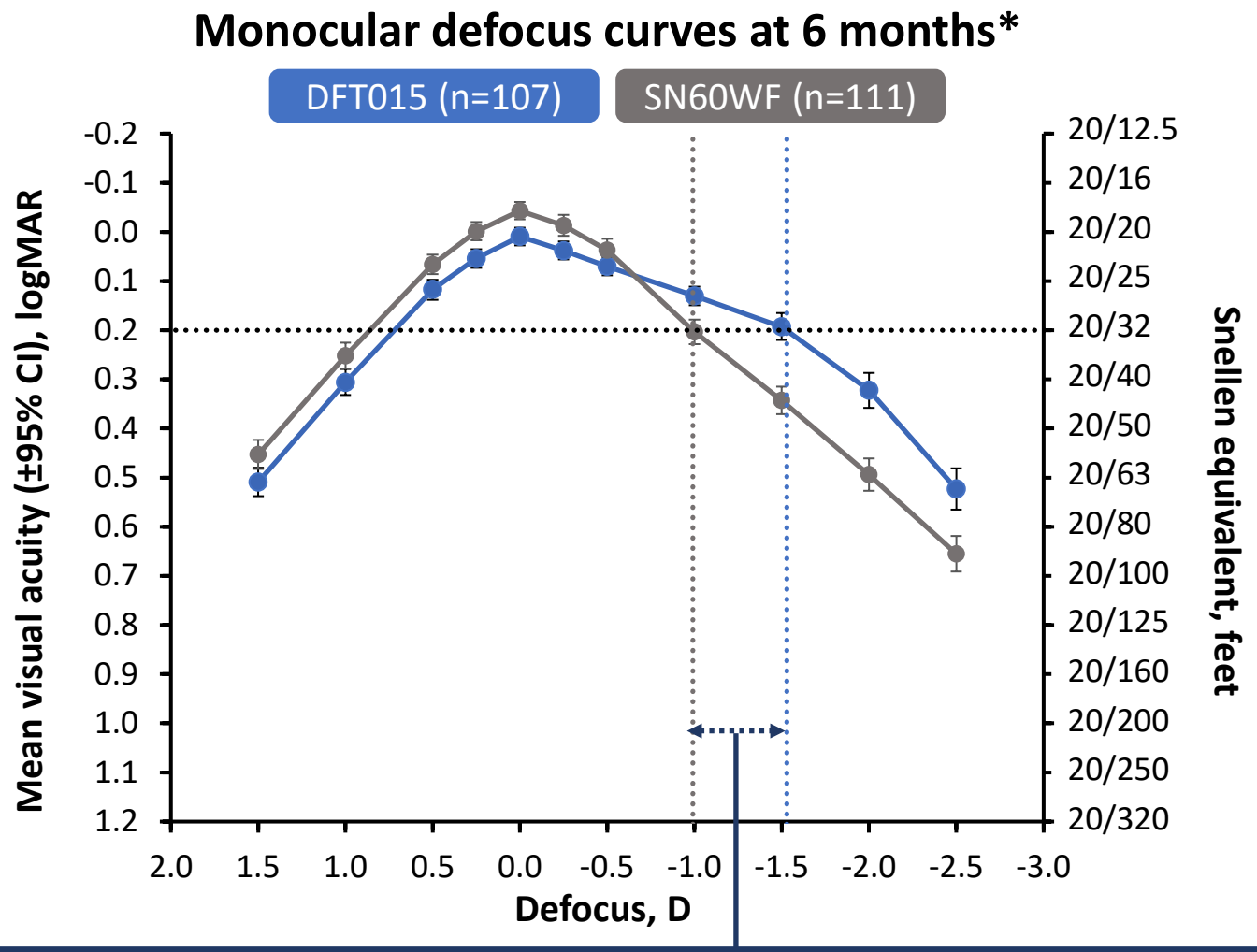
- 91.6% and 86.5% of first eyes implanted with DFT015 and SN60WF, respectively, achieved an MRSE ≤0.5 D of emmetropia
- Superiority of DFT015 to SN60WF in mean photopic monocular DCIVA (difference of -0.164 logMAR, $p<0.001$) and DCNVA (difference of -0.156 logMAR, $p<0.001$) was demonstrated†
- DFT015 also showed non-inferiority in monocular BCDVA (95% upper confidence limit of the difference was <0.1 logMAR margin)
- 72.9% and 25.2% of first eyes implanted with DFT015 and SN60WF, respectively, achieved a monocular DCIVA of 0.2 logMAR or better

Monocular photopic corrected VA at 6 months‡



*Defined as within <0.1 logMAR of SN60WF recipients' BCDVA; †Two-sided *p*-value <0.05 from a two-sample t-test; ‡All-implanted analysis set; §First eye: 95% upper confidence limit was less than the non-inferiority margin of 0.1 logMAR; ¶First eye.
clinicaltrials.gov. NCT03274986 (accessed June15, 2021)

DFT015 Provided a Greater Negative Range of Defocus



DFT015 showed a greater range of monocular defocus compared with SN60WF: difference of 0.54 D at 0.2 logMAR

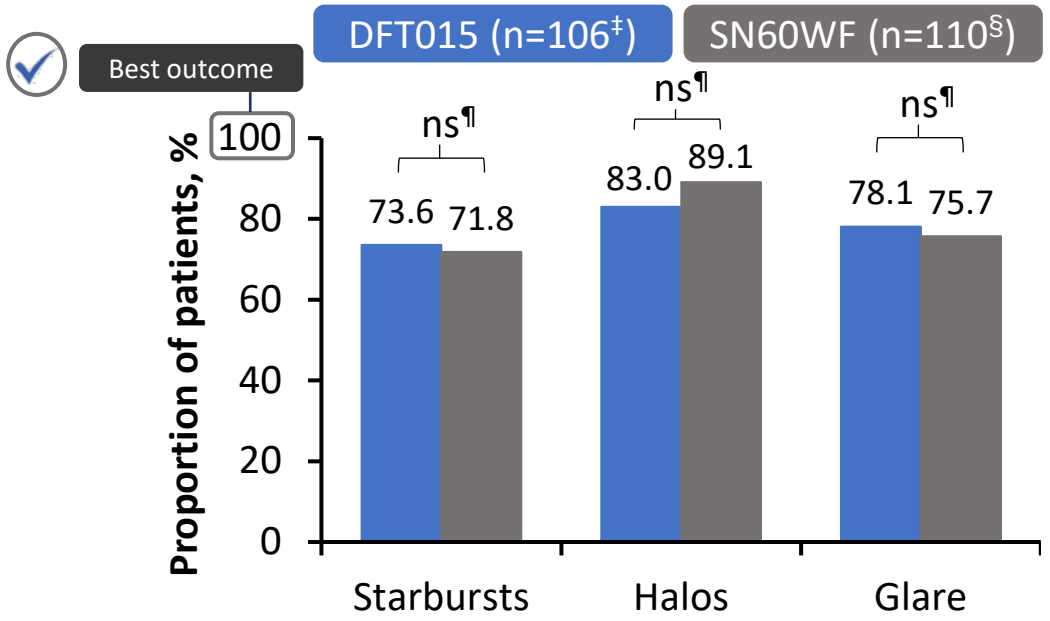
*First eye, all-implanted analysis set.
clinicaltrials.gov. NCT03274986 (accessed June 15, 2021)

Patient-Reported Visual Disturbances Were Similar Between DFT015 and SN60WF Recipients

Patients reporting experiencing "severe" starbursts, halos, or glare at 6 months*†

	Starbursts	Halos	Glare
DFT015 (n=106‡)	3.8%	0.9%	0.0%
SN60WF (n=110§)	2.7%	0.9%	0.0%

Patients reporting that they were "not bothered at all" by starbursts, halos, or glare at 6 months*†



The frequency of "severe" visual disturbances was low for both groups

Most patients in both groups reported being "not bothered at all" by visual disturbances

*Safety-analysis set; †Assessed using QUVID; ‡n=105 for DFT015 glare; §n=111 for SN60WF glare; ¶95% confidence interval for the estimated difference between groups (DFT015 - SN60WF) included zero, which indicates no significant difference.
clinicaltrials.gov. NCT03274986 (accessed June 15, 2021)

Conclusions

The results from this large, multicenter, randomized study demonstrate that DFT015 met the required ANSI EDF criteria. Compared with a premium aspheric monofocal IOL SN60WF, the novel, non-diffractive, presbyopia-correcting IOL DFT015:

- Provided patients with superior distance-corrected intermediate and near vision, a greater range of vision, and non-inferior distance vision
- Demonstrated a similar visual disturbance profile