AcrySof® IQ Vivity™ Extended Vision IOL

Clinical Science Compendium

Summary of presented research

Medical Affairs North America

Alcon

INTRODUCTION

At Alcon, our surgical medical device products, such as the AcrySof® IQ Vivity™ Extended Vision Intraocular Lens (IOL), are designed, manufactured and marketed with a body of science developed through rigorous bench research and clinical studies. As the body of knowledge behind Alcon's products grows, so does the challenge of making our customers aware of its depth. Our medical affairs organization is thus focused on both high-quality data generation and its communication to the clinical community. High-quality scientific publications are essential to convey the clinical community's knowledge and experience with new technology. This clinical science compendium provides a consolidated view of abstracts / presentations from U.S. and international congresses evaluating the pre-clinical and clinical characteristics of the AcrySof® IQ Vivity™ IOL*. In addition to exploring this compendium, we encourage you to visit Alcon's Medical Affairs website — AlconScience.com — to learn more about how medical science matters to us. Beyond scientific publications relating to Alcon's portfolio, you will find more information on independent medical education grants, teaching facility equipment placement, and areas of interest for investigator-initiated trials.

METHODOLOGY

This compendium includes papers and posters presented at U.S. and international ophthalmology congresses, involving the AcrySof® IQ Vivity™ IOL. The research included bench studies assessing the performance of the AcrySof® IQ Vivity™ IOL, as well as clinical studies examining outcomes in patients receiving surgical implantation of the IOL. Eighteen (18) total studies are included: 16 abstracts / presentations reporting clinical data (2 of which also include bench data) and 2 reporting bench data only.

*All studies were sponsored by Alcon Vision, LLC and / or authored by one or more Alcon employee investigators.

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Bench Performance

Optical Simulation and Bench Data of a Non-Diffractive Intraocular Lens Designed to Extend Depth of Focus and Minimize Visual Disturbances*

Schwiegerling J, Carson D†, Xu Z†, Choi M†, Lee S†, Milanovic Z†, Lane S†. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR

OVERVIEW

STUDY DESIGN
Bench study to evaluate the performance of a novel, non-diffractive extended vision IOL

STUDY SITE(S)
Bench testing and simulations at Alcon, Inc. (Fort Worth, TX, USA)

PATIENTS
N/A

METHODOLOGY
Through focus point spread function (PSF) and modulation transfer function (MTF) were used to evaluate light energy distribution and the range of vision; pinhole images were used to study halo propensity

IOL TYPE(S)
AcrySof® IQ Vivity™ Model DFT015 and AcrySof® IQ [Alcon Laboratories, Inc]; TECNIS Symfony® [Johnson & Johnson Vision]; AT LARA® EDoF [Zeiss]‡

KEY ENDPOINT(S)
Through focus PSF to show light energy distributions; MTF bench measurements to compare through focus performance; pinhole source images to demonstrate halo propensity

ANALYSIS AND CONCLUSIONS

Bench measurements and simulations show that a novel, non-diffractive extended vision IOL, Vivity™ Model DFT015 delivers a continuous depth of focus from distance to near and utilizes all available light without the energy losses.

In addition, Vivity® provides a monofocal-like halo profile

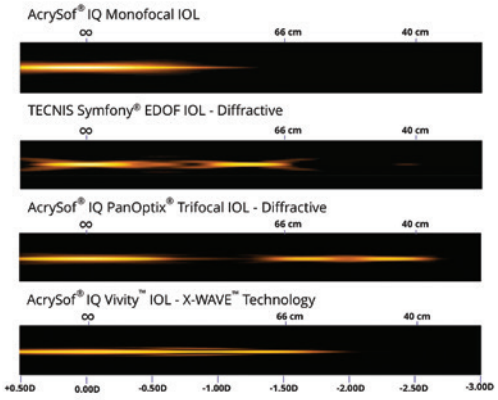
†This study was financially supported by Alcon. †Carson, Xu, Choi, Lee, Milanovic, and Lane are employees of Alcon.
‡The AT LARA® EDoF IOL is not FDA approved; data on non-FDA approved devices are not shown in results.

STUDY RESULTS

THROUGH FOCUS PSF

- The PSF through focus plots for Vivity™ (DFT015) show a continuous light energy distribution profile from distance to intermediate and towards near (**Figure 1**)

Figure 1. Simulated photopic through-focus point spread function.



MTF AND HALO PROPENSITY

- MTF measurements using polychromatic light at 3 and 4.5 mm pupil diameters show a greater depth of focus for Vivity™ DFT015 versus a monofocal IOL (**Figure 2**)
- The pinhole images demonstrate that Vivity™ DFT015 has a monofocal-like halo profile without the large diffractive rings characteristic of the presbyopia-correcting IOL tested (**Figure 3**)

Figure 2. Modular transfer function area for AcrySof® IQ monofocal and Vivity™ extended vision IOLs.

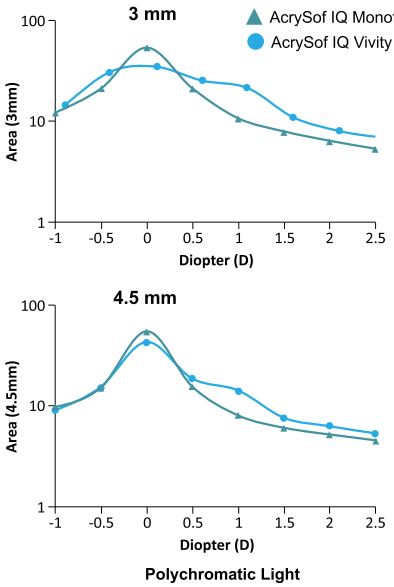
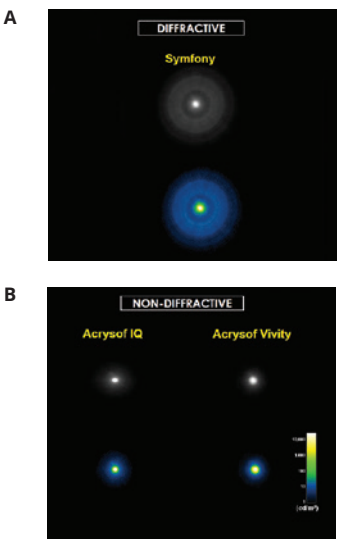


Figure 3. Pinhole images to simulate halo effects with diffractive (**A**) and non-diffractive (**B**) IOL designs.



Logarithmic scale images of halos around point source

Simulated Visual Acuity Performance of Monofocal and Extended-Depth-of-Focus Intraocular Lenses*

Schwiegerling J, Lemp-Hull J†, Lane S†, Baker K†. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

OVERVIEW

STUDY DESIGN
Bench study to predict the visual performance of various IOL designs

STUDY SITE(S)
Bench testing and simulations at Alcon, Inc. (Fort Worth, TX, USA)

PATIENTS
N/A

METHODOLOGY
Custom optical eye models were created for extended depth of focus (EDoF) and monofocal IOL design; simulated defocus curves were created by placing an appropriate trial lens in front of each custom IOL eye model and raytracing the system simulated optical performance measures were converted into clinical visual acuity (VA) estimates

IOL TYPE(S)
Monofocal and EDoF IOLs: AcrySof® IQ (SN60WF), AcrySof® IQ Vivity™ (DFT015), AcrySof® IQ ReSTOR® +2.5(SV25TO) [Alcon Laboratories, Inc]; AT LARA® (829MP)# [Zeiss]; TECNIS Symfony® (ZXR00) and Monofocal (ZCB00) IOL [Johnson & Johnson Vision]

KEY ENDPOINT(S)
Simulated defocus curve effects compared to clinical visual performance; simulated optical performance measures (area under the modulation transfer function [MTF] curve); clinical VA estimates; simulated retinal VA chart images

ANALYSIS AND CONCLUSIONS

Eye model simulation allowed predication of clinical visual acuity and low contrast sensitivity; the predicted visual acuity of Vivity™ was similar to that for diffractive EDoF IOL designs (e.g., Symfony®) when considering near and intermediate distances under photopic conditions, and was superior to monofocal IOLs (with an increase of -0.2 logMAR).

While well designed clinical trial data remains the gold standard for understanding visual performance, this validated modeling approach allows for prediction of IOL clinical performance, and provides confidence in the design stage of IOL development.

*This study was financially supported by Alcon. †Lemp-Hull, Lane and Baker are employees of Alcon.
#The AT LARA® (829MP) IOL is not FDA approved; data on non-FDA approved devices are not shown in results.

STUDY RESULTS

DEFOCUS CURVE PREDICTIONS

- A comparison of simulated defocus curve against the available clinical defocus curve demonstrates the accuracy and validity of the modelling and simulations
  - An exponential calibration function is fit to clinical VA data to enable prediction of acuity for different lens modalities and pupil sizes
    - Seven different clinical studies were used to derive calibration function from 4 IOLs (AcrySof® IQ (SN60WF), AcrySof® Vivity™ (DFT015), AcrySof® PanOptix® (TFNT00), AcrySof® IQ ReSTOR® +2.5 (SV25TO)
    - Calibration functions for pupil sizes ranging from 3 to 5.5 mm were developed
    - The fitted function's root mean square error (RMSE) difference was 0.037 logMAR, and the R2 correlation coefficient was 0.93
- Comparison of the 3 mm pupil defocus curves predictions for four different IOLs (Vivity™ (DFT015), TECNIS Symfony®(ZXR00), AcrySof® IQ (SN60WF), and TECNIS Monofocal (ZCB00) is shown in **Figure 1**
  - The two monofocal IOLs are predicted to have superior distance (0.0 D) VA over the 3 EDoF IOLs by ~ 0.08 logMAR
  - The two EDoF IOLs are predicted to be superior at intermediate (-1.5D) and near (-2.5D) VA over the monofocal IOLs by ~0.2 logMAR
  - All 2 EDoF IOL VA predictions are comparable to each other and within clinical VA measurement variability (~0.1 logMAR)

SIMULATED RETINAL IMAGES OF SMALL LETTER CONTRAST CHART

- Small letter contrast chart simulations of Vivity showed slightly better contrast compared to Symfony at both 3.5 and 5.5 mm pupil size‡ (**Figure 2**)

‡This is simulation bench data and does not establish the safety and efficacy of the device. Please refer to the DFU for complete safety and efficacy information for the device.

Figure 1. IOL defocus curve predictions, 3 mm pupil size.

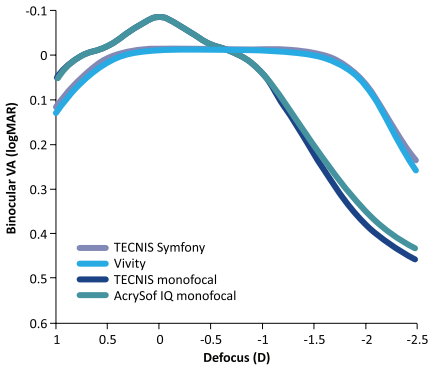
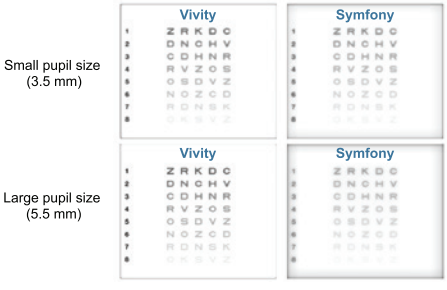


Figure 2. Small letter contrast chart simulations for small and large pupil sizes.



Vision Outcomes of a Non-Diffractive Extended-Vision Intraocular Lens Implanted with Mini-Monovision*

Bench Performance | Visual Outcomes | Visual Acuity

Balachandran C, Lee S, Carson D†, Lemp-Hull J†. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

OVERVIEW

STUDY DESIGN

Post-hoc exploratory analysis of data from a prospective, randomized, assessor- and subject-masked clinical trial to evaluate the clinical outcomes in patients with emmetropia and mini-monovision after bilateral implantation of a novel non-diffractive extended vision IOL (AcrySof® IQ Vivity™ DFT015)

STUDY SITE(S)

Multiple centers in multiple countries; bench testing at Alcon, Inc. (Fort Worth, TX, USA)

PATIENTS

One hundred and fifty-one (151) patients; 19 subjects with mini-monovision (≥0.50 D absolute difference in manifest refraction spherical equivalent (MRSE) between eyes AND MRSE of -0.25 D or more myopic in at least one eye); 132 subjects non-monovision

METHODOLOGY

Post hoc analysis of visual outcomes of patients with emmetropia and mini-monovision after bilateral Vivity™ Model DFT015 implantation (6 months post-op); simulated binocular halo images with different myopic offsets

IOL TYPE(S)

AcrySof® IQ Vivity™ Model DFT015 (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

MRSE; binocular uncorrected distance visual acuity (UDVA); uncorrected intermediate visual acuity (UIVA); uncorrected near visual acuity (UNVA); spectacle use; halo profile from questionnaire (QoV) and bench

ANALYSIS AND CONCLUSIONS

This small dataset showed that mini-monovision following bilateral implantation of the Vivity™ DFT015 IOL resulted in improved near and intermediate vision compared with individuals with non-monovision, with no compromise in distance vision, and a halo profile that patients were not bothered by (no statistical analysis was conducted due to small number of mini-monovision patients)

Further studies specifically designed to evaluate the effect of targeting mini-monovision in bilateral recipients of the Vivity™ DFT015 IOL would be informative

*This study was financially supported by Alcon. †Carson, Xu, Choi, Lee, Milanovic, and Lane are employees of Alcon.

STUDY RESULTS

VISUAL ACUITY

- Compared to the non-monovision group, UIVA and UNVA improved approximately one line (-0.08 logMAR) with no meaningful change in UDVA (0.02 logMAR) in the mini-monovision group (**Figure 1**)

OTHER VISUAL OUTCOMES

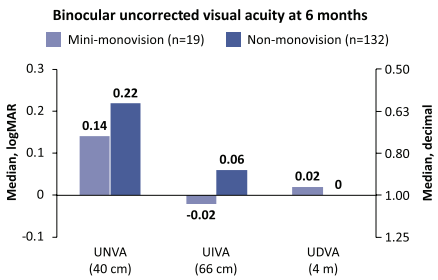
- Approximately twice as many patients reported never wearing spectacles for any purpose in the mini-monovision subgroup (53.3%) compared to the non-monovision subgroup (26.4%)
- The proportion of patients who reported never wearing spectacles for intermediate tasks was 93.3% in the mini-monovision group and 72.5% in the non-monovision group; the proportion for near tasks was 46.7% and 26.4%, respectively
- The proportion of subjects not bothered by visual disturbances remained high in the mini-monovision group (**Figure 2**)

BENCH DATA

- Spot images from a high dynamic range halo bench (4.5 mm aperture) were collected from simulated monovision of Vivity™ DFT015 with one IOL set to -0.25 D, -0.5 D
- Bench halos remained monofocal-like for the monovision simulations

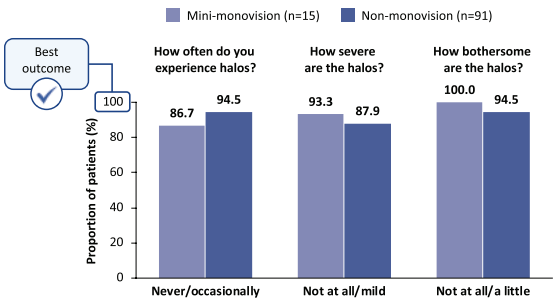
Figure 1. Manifest refraction spherical equivalent (MRSE) and binocular uncorrected visual acuity at 6 months post-AcrySof® IQ Vivity™ IOL implantation.

MRSE (D)		
Mini-monovision subgroup		
	Distance eye	Myopic eye
Mean (SD)	0.026 (0.311)	-0.586 (0.240)
Median	0.00	-0.50
Non-monovision subgroup		
	First eye	Second eye
Mean (SD)	-0.137 (0.293)	-0.148 (0.282)
Median	-0.125	-0.125



Exploratory analysis only; no statistical comparison conducted
MRSE, manifest refraction spherical equivalent; UDVA, uncorrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity

Figure 2. Patient-reported halo experience at six months post-AcrySof® IQ Vivity™ IOL implantation, assessed using the Quality of Vision (QoV) questionnaire. Exploratory analysis of a small data set — no statistical comparison conducted.



Clinical Outcomes of a New Extended Vision Intraocular Lens Implanted by Spanish Surgeons*¶

Visual Outcomes

Visual Acuity

Guarro M, Pedrell J, Peris C, Alvarez de Toledo Elizalde J, Poyales F. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

OVERVIEW

STUDY DESIGN

Subgroup analysis from a prospective, randomized, assessor- and subject-masked clinical trial to evaluate the clinical outcomes of a novel non-diffractive extended vision IOL (AcrySof® IQ Vivity™ DFT015) relative to an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)

Six sites in Spain

PATIENTS

Fifty-one (51) randomized subjects implanted with AcrySof® IQ Vivity™ DFT015 IOL; 38 control subjects implanted with AcrySof® IQ SN60WF monofocal IOL

METHODOLOGY

Evaluation of clinical outcomes 6 month after bilateral cataract removal and IOL implantation

IOL TYPE(S)

AcrySof® IQ Vivity™ Model DFT015 (Alcon Laboratories, Inc.); AcrySof® IQ monofocal IOL Model SN60WF (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Six months post-operatively: binocular defocus curve; binocular distance corrected visual acuities (VAs) at distance (BCDVA, 4m), intermediate (DCIVA, 66 cm), near visual acuity (DCNVA, 40 cm); visual disturbances

ANALYSIS AND CONCLUSIONS

In the Spanish subpopulation of a large clinical study, bilateral implantation of the non-diffractive extended vision IOL, Vivity™ Model DFT015, provided subjects with an extended range of vision from distance to functional near, without increasing the incidence of visual disturbances as compared to the monofocal IOL.

Results for patients across the six sites in Spain were similar to the overall study results.

*This study was financially supported by Alcon.

¶This is site-specific (country level) data and does not establish the safety and efficacy of the device. Please refer to the DFU for complete safety and efficacy information for the device.

STUDY RESULTS

VISUAL ACUITY

- Binocular BCDVA was better than 0.0 logMAR for both groups;
- At intermediate and near, the improvement in binocular distance corrected visual acuity for Vivity® DFT015 over AcrySof® IQ SN60WF was ≥ 0.1 logMAR (1 line) (**Figure 2**)

OTHER VISUAL OUTCOMES

- Similar to overall population, the Vivity™ DFT015 IOL binocular defocus curve demonstrated >0.5 D of extension over AcrySof® IQ SN60WF at 0.2 logMAR
- Sixty-nine percent (69%) or more subjects in the Vivity™ IOL group and 57% or more subjects in the AcrySof® SN60WF group were not at all bothered by either halos, starbursts and glare (**Figure 1**)

Figure 1. Subjects in the Spanish subpopulation reporting never being bothered by starburst, halos or glare at six months post-IOL implantation (safety analysis set; assessed using the Quality of Vision [QoV] questionnaire).

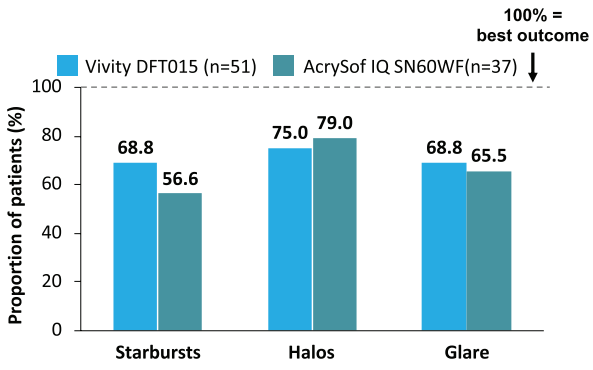
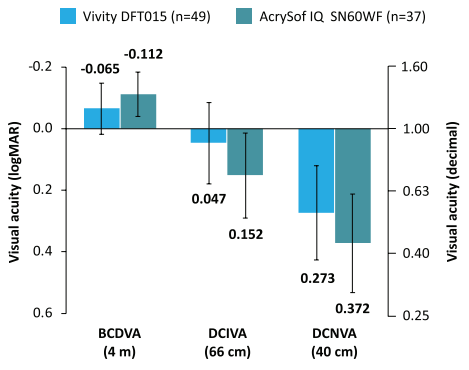


Figure 2. Binocular Distance Corrected Visual Acuity in Spanish subpopulation six months IOL implantation (all-implanted analysis set). Error bars represent standard deviation.



BCDVA, best-corrected distance visual acuity; DCIVA, distance-corrected intermediate visual acuity; DCNVA, distance-corrected near visual acuity

A Non-Diffractive Extended-Vision Intraocular Lens that Meets the Optical and Clinical Criteria for Extended-Depth-of-Focus IOLs*

Bench Performance
Visual Outcomes
Visual Acuity

McCabe C, Xu Z†, Lemp-Hull J†, Carson D†, Milanovic Z†. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

OVERVIEW

STUDY DESIGN

1) Alcon bench optical testing; 2) Prospective, randomized, assessor- and subject-masked clinical trial to evaluate the clinical outcomes of a novel non-diffractive extended vision IOL (AcrySof® IQ Vivity™ DFT015) relative to an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)

Bench testing at Alcon; multiple clinical sites in the United States

PATIENTS

One hundred and seven (107) patients with bilateral implantation of AcrySof® IQ Vivity™ Model DFT015 IOL; 113 patients with bilateral implantation AcrySof® IQ Model SN60WF IOL

METHODOLOGY

Bench Modulation Transfer Function (MTF) measurements and halo images; evaluation of clinical outcomes 6 month after bilateral cataract removal and IOL implantation

IOL TYPE(S)

AcrySof® IQ Vivity™ Model DFT015; AcrySof® IQ Model SN60WF (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Bench test: through frequency and through focus MTF; halo. Clinical study: monocular visual acuities, defocus curve; visual disturbance measured by patient-reported outcomes questionnaire

ANALYSIS AND CONCLUSIONS

Bench measurements and clinical study results demonstrate that the non-diffractive extended vision IOL (Vivity™ Model DFT015) meets the expectations for the extended depth of focus category by extending depth of focus beyond intermediate while maintaining distance vision that is non-inferior to an aspheric monofocal.

The non-diffractive extended vision IOL visual disturbance profile is shown to be comparable to the monofocal control.

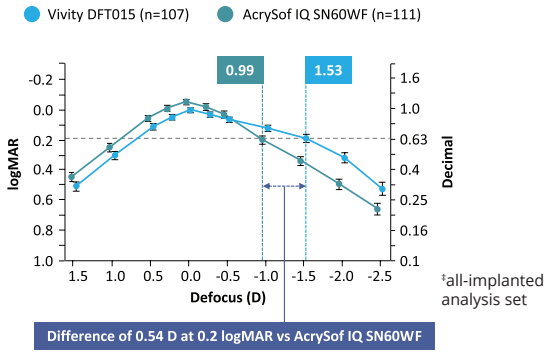
*This study was financially supported by Alcon. †Xu, Lemp-Hull, Carson, and Milanovic are employees of Alcon.

STUDY RESULTS

BENCH MEASUREMENTS

- Through frequency MTF measurements at 100 lp/mm spatial frequency (equivalent to 20/20) met the minimum ISO 11979-2 distance requirement for small aperture
- Through focus MTF area under the curve (AUC) spatial frequency analysis (small aperture, 3 mm, polychromatic light) extended vision 0.5 D greater than the monofocal control (AcrySof® IQ Model SN60WF) and beyond 1.5 diopters
  - Vivity™ DFT015 halo images at large aperture were comparable to halo images of the monofocal control (AcrySof® IQ Model SN60WF)

Figure 1. Monocular defocus curves at 6 months.‡

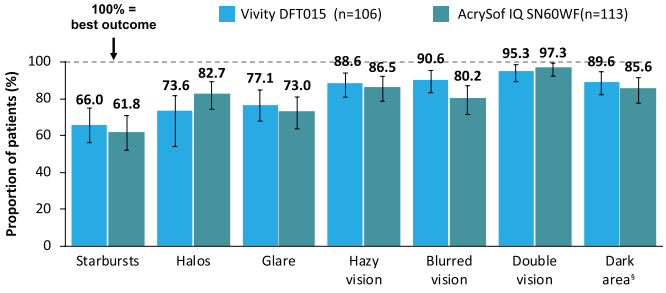


‡all-implanted analysis set

CLINICAL OUTCOME

- Vivity™ DFT015 provided mean photopic BCDVA that was noninferior to the monofocal control, and mean photopic DCIVA and DCNVA that was superior to the monofocal control
- Monocular defocus curve for Vivity™ DFT015 showed greater than 0.5 D extension of 20/32 vision when compared to AcrySof® IQ Model SN60WF and beyond 1.5 D (**Figure 1**)
- Patient-reported results showed that the visual disturbance profile of the Vivity™ DFT015 IOL was comparable to the monofocal profile (**Figure 2**)

Figure 2. Patients reporting **NO** visual disturbance (negative dysphotopsia) at six months after IOL implantation. Error bars = 95% confidence intervals.



§Negative dysphotopsia.
Error bars represent 95% confidence intervals. EDF, extended depth of focus

Visual Disturbance Profile of a Non-Diffractive Extended Vision Intraocular Lens from Two Pivotal Trials*

McCabe C, Bergdahl J, Lemp-Hull J†, Poyales F, Balachandran C. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.14-18, 2019; Paris, FR.

OVERVIEW

STUDY DESIGN

Two prospective, randomized, patient- and assessor-masked clinical trials to evaluate the rates of visual disturbances with a new non-diffractive extended vision IOL (AcrySof® IQ Vivity™ Model DFT015) relative to an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)

Study 1: 11 surgeons in the United States; Study 2: 19 surgeons in the UK, Spain, Australia, and Canada

PATIENTS

Study 1: 107 Vivity™ DFT015 patients; 113 AcrySof® IQ SN60WF patients. Study 2: 156 Vivity™ DFT015 patients; 120 AcrySof® IQ SN60WF patients

METHODOLOGY

Evaluation of clinical outcomes 6 month after bilateral cataract removal and IOL implantation

IOL TYPE(S)

AcrySof® IQ Vivity™ Model DFT015 (Alcon Laboratories, Inc.); AcrySof® IQ monofocal Model SN60WF (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Binocular defocus curves in both studies; Questionnaire for Visual Disturbances (QUVID) in Study 1, quality of vision [QoV] questionnaire in Study 2

ANALYSIS AND CONCLUSIONS

Analysis of data from two randomized, aspheric monofocal controlled, double-blind, pivotal trials found that bilateral implantation of this non-diffractive extended vision IOL, Vivity® Model DFT015, provided subjects with an extended range of vision from distance to functional near while maintaining a visual disturbance profile similar to a monofocal.

*This study was financially supported by Alcon. †Dr. Lemp-Hull is an employee of Alcon.

STUDY RESULTS

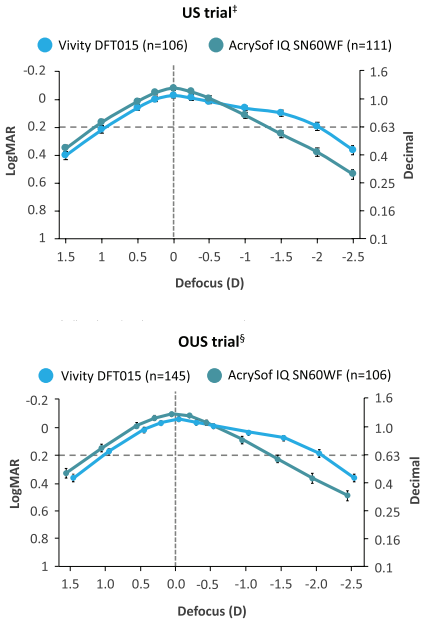
RANGE OF VISION

- Data from both trials showed that Vivity™ DFT015 had a greater negative range of binocular defocus (>0.50 D at 0.2 logMAR) compared with AcrySof® IQ SN60WF at six months (**Figure 1**)

VISUAL DISTURBANCE

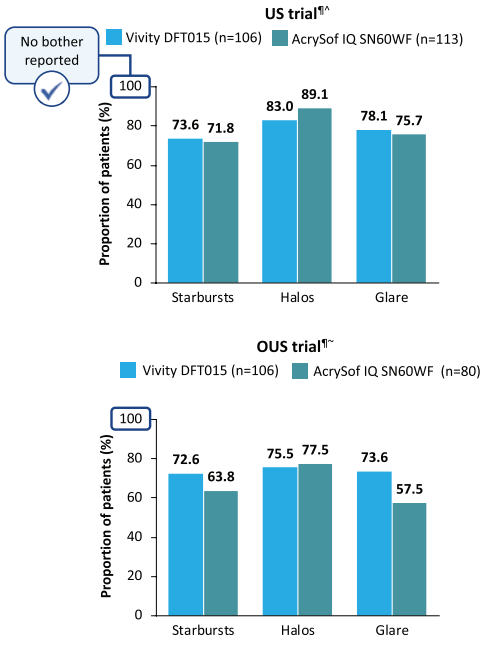
- In Study 1, at 6 months, there were no significant differences between the Vivity™ DFT015 and AcrySof® IQ SN60WF IOLs with respect to rates of six of the seven visual disturbances assessed; however, significantly more subjects reported never experiencing the visual disturbance of blurred vision with Vivity™ DFT015 compared to AcrySof® IQ SN60WF (90.6% vs. 80.2%; 10.4% difference (95% confidence interval 0.6, 20.1)
- The proportion of patients reporting free of starbursts, halos or glares were comparable between two group in both studies.
- In both studies, the majority of subjects in both groups reported not being bothered by starbursts, halos, or glare (**Figure 2**)

Figure 1. Binocular defocus curves at six months following bilateral IOL implantation. Bars represent 95% confidence interval.



‡ All-implanted analysis set; § Best-case analysis set. OUS, outside the US.

Figure 2. Patients **'not at all'** bothered by starbursts, halos or glare at six months post-IOL implantation.



¶Safety-analysis set. ^Assessed using the QUVID. ~Assessed using the QoV questionnaire. OUS, outside of the US; QoV, Quality of Vision; QUVID, Questionnaire for Visual Disturbance

Clinical Outcomes of a New Extended-Vision Intraocular Lens in the United Kingdom*¶

Mearza A, Bhermi S, Patton N, Kasaby H. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

OVERVIEW

STUDY DESIGN

Subgroup analysis of United Kingdom (UK) patients from a prospective, randomized, assessor- and subject-masked clinical trial to evaluate the clinical outcomes of a novel non-diffractive extended vision IOL (AcrySof® IQ Vivity™ DFT015) relative to an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)

Four centers in the UK that participated in a multi-site, multi-country study

PATIENTS

UK subset included 28 Vivity™ DFT015 patients and 21 AcrySof® IQ SN60WF patients

METHODOLOGY

Evaluation of clinical outcomes 6 month after bilateral cataract removal and IOL implantation

IOL TYPE(S)

AcrySof® IQ Vivity™ Model DFT015 (Alcon Laboratories, Inc.); AcrySof® IQ monofocal IOL Model SN60WF (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Binocular defocus curve, binocular uncorrected visual acuities (UCVAs) at distance (UCDVA, 4 m), intermediate (UCIVA, 66 cm) and near (UCNVA, 40 cm), and visual disturbances of haloes, glare and starbursts (QoV) were assessed at six months (post-2nd eye implant)

ANALYSIS AND CONCLUSIONS

Patients implanted with AcrySof® IQ Vivity™ extended vision IOL (DFT015) in the UK sites had similar outcomes to those in the overall multinational study.

Results in the UK demonstrated that bilateral implantation of this non-diffractive extended vision IOL (AcrySof® IQ Vivity™ Model DFT015) provided subjects with an extended range of vision compared with an aspheric monofocal IOL while maintaining a monofocal-like visual disturbance profile.

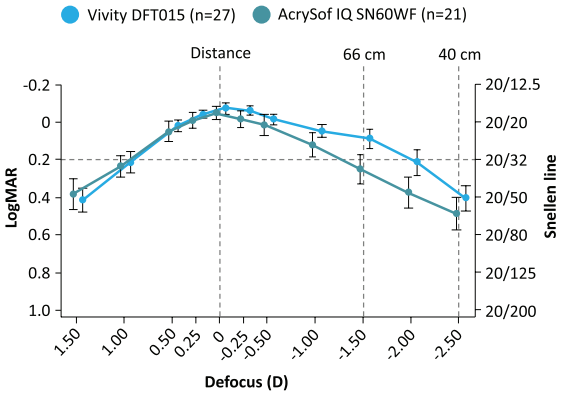
*This study was financially supported by Alcon.
¶This is site-specific (country level) data and does not establish the safety and efficacy of the device. Please refer to the DFU for complete safety and efficacy information for the device.

STUDY RESULTS

VISUAL ACUITY

- The Vivity™ DFT015 IOL provided 20/20 binocular UCDVA, >0.5 line improvement in UCIVA and >1 line improvement in UCNVA compared to the AcrySof® IQ SN60WF IOL in UK patients
- Binocular UCVAs for Vivity™ DFT015 at the UK sites were within two letters of those reported for the total study population

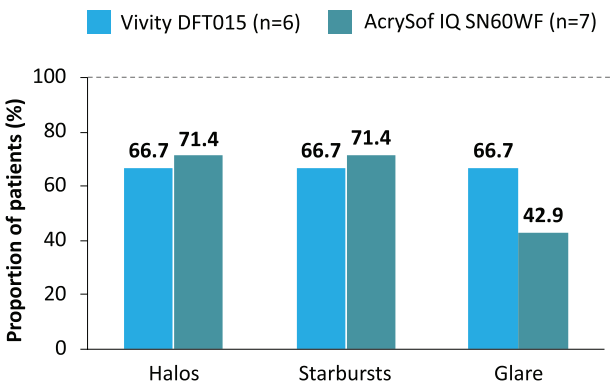
Figure 1. Mean defocus curves for UK patient data (best-case analysis set). Results were similar to those in the overall study population. Error bars represent 95% confidence interval



OTHER VISUAL OUTCOMES

- Binocular defocus curves overall and in the UK demonstrated >0.5 D extended range of vision with Vivity™ DFT015 over AcrySof® IQ SN60WF at 0.2 logMAR (**Figure 1**)
- The visual disturbance profiles of Vivity™ DFT015 and AcrySof® IQ SN60WF recipients in the UK were similar to those for all study patients (**Figure 2**)

Figure 2. Visual disturbance profile, UK patients (safety analysis set). Patients reporting non bother from visual disturbances.



Multi-Country Clinical Outcomes of a New Non-Diffractive Extended-Vision Intraocular Lens at Six Months Postoperatively*

Visual Outcomes

Visual Acuity

Safety

Poyales M, Mearza A, Varma D, Balachandran C, Lemp-Hull J†. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

OVERVIEW

STUDY DESIGN

Prospective, randomized, assessor- and subject-masked clinical trial to evaluate clinical outcomes of a novel non-diffractive extended vision IOL (AcrySof® IQ Vivity™ DFT015) relative to an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)

Nineteen (19) sites in Canada, United Kingdom, Spain, Australia

PATIENTS

One hundred and fifty-six (156) patients received AcrySof® IQ Vivity™ DFT015 IOL; 120 patients received AcrySof® IQ SN60WF IOL

METHODOLOGY

Evaluation of clinical outcomes 6 month after bilateral cataract removal and IOL implantation

IOL TYPE(S)

AcrySof® IQ Vivity™ Model DFT015 (Alcon Laboratories, Inc.); AcrySof® IQ monofocal IOL Model SN60WF (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Assessment of monocular best-corrected distance visual acuity (BCDVA, 4m), distance corrected intermediate (DCIVA, 66m) and distance corrected near visual acuity (DCNVA, 40 cm) and defocus curve; binocular uncorrected distance (UDVA), intermediate (UIVA) and near visual acuity (UNVA) and defocus curve along with quality of vision (QoV Questionnaire) and overall safe

ANALYSIS AND CONCLUSIONS

Bilateral implantation of the non-diffractive extended vision AcrySof® IQ Vivity™ Model DFT015 IOL improves near and intermediate vision without affecting distance vision while maintaining a monofocal-like visual disturbance profile, with an acceptable safety profile as compared to the aspheric monofocal AcrySof® IQ Model SN60WF IOL.

The AcrySof® IQ Vivity™ extended vision IOL (DFT015) is an effective and well-tolerated IOL for patients seeking an extended range of vision.

*This study was financially supported by Alcon. †Dr. Lemp-Hull is an employee of Alcon.

STUDY RESULTS

VISUAL ACUITY

- Monocularly, the Vivity™ DFT015 IOL demonstrated non-inferior BCDVA, superior DCIVA, superior DCNVA and >0.5D extended range of vision at 0.2 logMAR compared to AcrySof IQ® SN60WF (**Figure 1**)
- Binocularly, Vivity™ DFT015 provided 20/20 UCDVA, and >0.5 line improvement in UIVA and >1 line improvement in UNVA compared to the SN60WF IOL

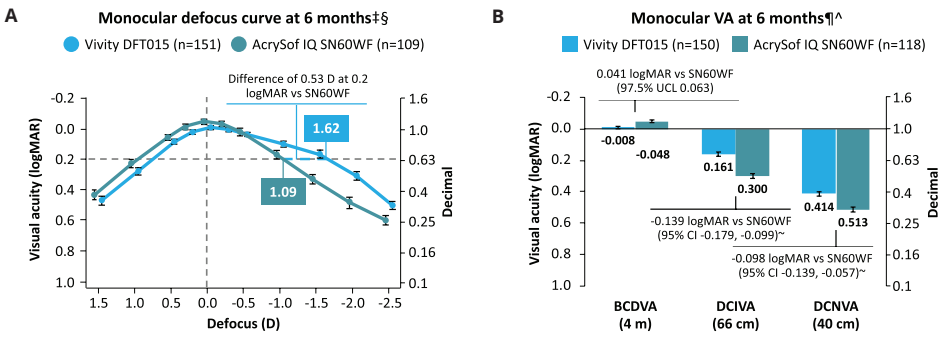
OTHER VISUAL OUTCOMES

- The majority of Vivity™ DFT015 implanted subjects were not at all bothered by starbursts, halos, and glare; reported rates of severe visual disturbances were <4% in both IOL groups

SAFETY

- The frequency of all adverse events (AEs) in Vivity™ DFT015 recipients remained lower than the pre-defined safety and performance endpoints limits
- Rates of posterior capsule opacification (PCO) or posterior capsulotomy were similar between the two IOL groups (Vivity® DFT015 and SN60WF)

Figure 1. Monocular defocus curve (**A**) and visual acuity (VA) (**B**) six months post-IOL implantation.



‡Best-case analysis set (first eye). §Error bars represent 95% confidence interval.
¶All-implanted analysis set (first eye). ^Error bars represent standard error. ~P<0.001.
BCDVA, best corrected distance visual acuity; DCIVA. Distance-corrected intermediate visual acuity; DCNVA, distance-corrected near visual acuity; UCL, upper confidence limit; VA, visual acuity

Multi-Country Functional Vision Outcomes of a New Non-Diffractive Extended-Vision Intraocular Lens*

Ruiz-Mesa R, Bhatt U, Kasaby H, Rabinovitch T, Lemp-Hull J†. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

OVERVIEW

STUDY DESIGN

Prospective, randomized, assessor- and subject-masked clinical trial to evaluate the clinical outcomes of a novel non-diffractive extended vision IOL (AcrySof® IQ Vivity™ DFT015) relative to an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)

Nineteen (19) sites in Canada, United Kingdom, Spain, Australia

PATIENTS

One hundred and fifty-six (156) patients received AcrySof® IQ Vivity™ DFT015 IOL; 120 patients received AcrySof® IQ SN60WF IOL

METHODOLOGY

Evaluation of clinical outcomes 6 month after bilateral cataract removal and IOL implantation

IOL TYPE(S)

AcrySof® IQ Vivity™ Model DFT015 (Alcon Laboratories, Inc.); AcrySof® IQ monofocal IOL Model SN60WF (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Binocular uncorrected distance (UDVA, 4m), intermediate (UIVA, 66cm), and near visual acuity (UNVA, 40cm), defocus curve, subjective assessment of spectacle use and visual disturbances (quality of vision (QoV)), reading speed (66cm) measured using MNREAD

ANALYSIS AND CONCLUSIONS

The non-diffractive extended vision Vivity™ Model DFT015 IOL, in comparison to the aspheric monofocal control IOL (AcrySof® IQ SN60WF), enhanced near and intermediate vision without affecting distance vision.

The Vivity™ IOL further improved visual outcomes by reducing the need for spectacles, allowing a functional reading speed at smaller font sizes, while maintaining a monofocal-like visual disturbance profile as compared to aspheric monofocal control IOL.

*This study was financially supported by Alcon. †Dr. Lemp-Hull is an employee of Alcon.

STUDY RESULTS

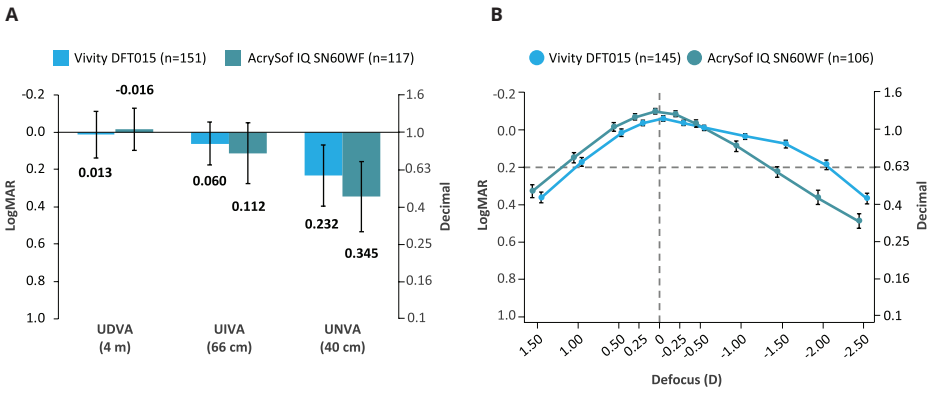
VISUAL ACUITY

- The AcrySof® IQ Vivity™ DFT015 IOL provided 20/20 binocular UDVA, > 0.5 logMAR line improvement in UIVA, and >1 line improvement in UNVA (**Figure 1A**)
- The Vivity™ IOL had a greater negative range of defocus (>0.5D at 0.2 logMAR) compared with the monofocal IOL (**Figure 1B**)

VISUAL OUTCOMES

- Significantly greater numbers of subjects implanted with Vivity™ DFT015 vs. monofocal never needed spectacles overall (30.2% vs 10.0%) and for intermediate (75.5% vs 53.8%) tasks
- Vivity™-implanted subjects achieved better than functional intermediate reading speeds (80 words/minute or better) at every font size tested down to 8 pt
- In the Vivity™ group, 73% or more subjects were not at all bothered by starbursts, halos, and glare compared to 58% or more in the monofocal IOL group.

Figure 1. Mean uncorrected binocular visual acuity at six months following IOL implantation (all-implanted analysis set) (**A**) and mean binocular defocus curve at six months (best-case analysis set) (**B**). Bars represent 95% confidence intervals.



UDVA, uncorrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity.

Multi-Country Clinical Outcomes of a New Non-Diffractive Extended Vision Intraocular Lens*

Balachandran C, Lemp-Hull J†. Presented at the American Society for Cataract and Refractive Surgery (ASCRS) Virtual Annual Meeting; May 16-17, 2020.

Visual Outcomes

Visual Acuity

Safety

OVERVIEW

STUDY DESIGN

Prospective, randomized, assessor- and subject-masked clinical trial to evaluate the clinical outcomes of a novel non-diffractive extended vision IOL (AcrySof® IQ Vivity™ DFT015) relative to an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)

Nineteen (19) sites in Canada, United Kingdom, Spain, Australia

PATIENTS

One hundred and fifty-six (156) patients received AcrySof® IQ Vivity™ DFT015 IOL; 120 patients received AcrySof® IQ SN60WF IOL

METHODOLOGY

Evaluation of clinical outcomes 6 month after bilateral cataract removal and IOL implantation

IOL TYPE(S)

AcrySof® IQ Vivity™ Model DFT015 (Alcon Laboratories, Inc.); AcrySof® IQ monofocal IOL Model SN60WF (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Monocular best-corrected distance visual acuity (CDVA, 4m), distance corrected intermediate visual acuity (DCIVA, 66m) and distance corrected near visual acuity (DCNVA, 40 cm), and defocus curve; binocular uncorrected distance visual acuity (UDVA), uncorrected intermediate visual acuity (UIVA), and uncorrected near visual acuity (UNVA) and defocus curve; reading speed, visual disturbances, and overall safety

ANALYSIS AND CONCLUSIONS

The non-diffractive extended vision IOL (AcrySof® IQ Vivity™ DFT015) improved near and intermediate vision without affecting distance vision while maintaining a monofocal-like visual disturbance profile, compared to the aspheric monofocal IOL.

AcrySof® IQ Vivity™ DFT015 also allowed a functional reading speed at smaller font sizes compared with the aspheric monofocal IOL, and had a similar safety profile.

*This study was financially supported by Alcon. †Dr. Lemp-Hull is an employee of Alcon.

STUDY RESULTS

VISUAL ACUITY

- Monocularly, the AcrySof® IQ Vivity™ Model DFT015 demonstrated non-inferior BCDVA, superior DCIVA, superior DCNVA and >0.50 D extended range of vision at 0.2 logMAR compared to AcrySof® IQ Monofocal IOL Model SN60WF
- Binocularly, the Vivity™ Model DFT015 had a greater negative range of defocus (≥0.50 D at 0.2 logMAR) compared with the monofocal IOL Model SN60WF
- The Vivity™ Model DFT015 provided 20/20 binocular UDVA, as well as >0.5 line improvement in UIVA and >1 line improvement in UNVA compared with the monofocal IOL
- Patients receiving the Vivity™ Model DFT015 achieved an above functional reading speed down to the lowest tested 8 point font (**Figure 1**)

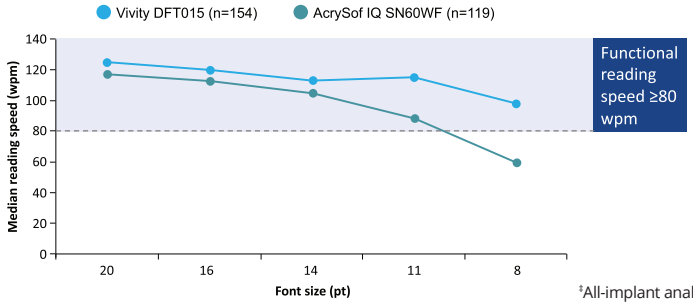
PATIENT-REPORTED OUTCOMES

- The majority of subjects in both groups were not bothered by starbursts, halos, and glare (**Figure 2**)
- Reported rates of severe visual disturbances were low (<4%) for both groups

SAFETY

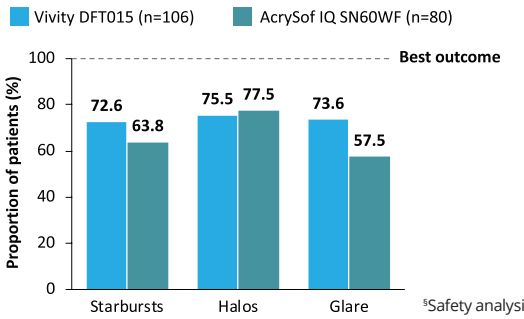
- Rates of adverse events and clinically non-significant or significant posterior capsule opacification (PCO) and PCO requiring yttrium aluminum garnet (YAG) were low and similar between group

Figure 1. Distance corrected reading speed at 6 months. The dotted line at 80 wpm represents the functional reading speed limit, indicating that Vivity™ patients had better than functional reading speed.‡



‡All-implant analysis set

Figure 2. Proportion of patients who reported being not at all bothered by starbursts, halo or glare at 6 months based on QoV Questionnaire.§



§Safety analysis set

Visual Outcomes of a New Non-Diffractive Extended Vision Intraocular Lens at a Single US Site*¶

Baartman B, Berdahl J, Lemp-Hull J†. Presented at the American Society for Cataract and Refractive Surgery (ASCRS) Virtual Annual Meeting; May 16-17, 2020.

OVERVIEW

STUDY DESIGN
Subgroup analysis of a prospective, randomized, assessor- and subject-masked clinical trial to evaluate the clinical outcomes of a novel non-diffractive extended vision IOL (AcrySof® IQ Vivity™ DFT015) relative to an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)
Single center in the United States

PATIENTS
Twenty (20) patients (10 Vivity® DFTO15 and 10 SN60WF)

METHODOLOGY
Evaluation of clinical outcomes 6 month after bilateral cataract removal and IOL implantation

IOL TYPE(S)
AcrySof® IQ Vivity™ Model DFT015 (Alcon Laboratories, Inc.); AcrySof® IQ monofocal IOL Model SN60WF (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Binocular uncorrected distance (UDVA, 4m), intermediate (UIVA, 66cm), and near visual acuity (UNVA, 40cm), defocus curve, subjective assessment of spectacle use and visual disturbances (quality of vision (QoV)), reading speed (66cm) measured using MNREAD

ANALYSIS AND CONCLUSIONS

The non-diffractive extended vision IOL (Vivity™ DFT015) improved near and intermediate vision without affecting distance vision.

This improvement was achieved while maintaining a monofocal visual disturbance profile and reducing spectacle need, compared to an aspheric monofocal IOL.

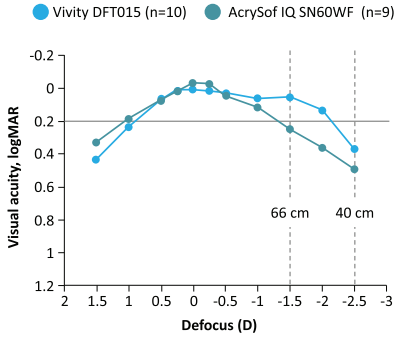
*This study was financially supported by Alcon. †Dr. Lemp-Hull is an employee of Alcon.
¶This is site-specific (country level) data and does not establish the safety and efficacy of the device. Please refer to the DFU for complete safety and efficacy information for the device.

STUDY RESULTS

VISUAL ACUITY

- The Vivity™ DFT015 IOL binocular defocus curve demonstrated visual acuity of 0.1 logMAR or better from distance to -1.5 D, and also showed greater than 0.5 D extension at 0.2 logMAR compared with AcrySof® IQ SN60WF (**Figure 1**)
- Vivity™ DFT015 provided similar distance vision compared with AcrySof® IQ SN60WF (both IOLs provided best-corrected distance visual acuity better than 20/20), but allowed for greater improvement in intermediate and near vision (providing >1 line of improvement for binocular distance-corrected visual acuities at both distances relative to SN60WF)

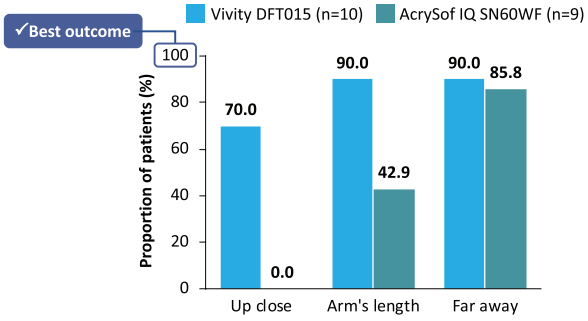
Figure 1. Binocular defocus curves at 6 months for the Vivity™ DFT015 IOL compared to the monofocal AcrySof® IQ SN60WF IOL.



VISUAL OUTCOMES

- The majority of subjects in both groups were "not at all bothered" by starbursts, halos, and glare, and no patients were "bothered very much"
- Rates of starburst, halos and glare were similar for the Vivity™ DFT015 and monofocal AcrySof® IQ SN60WF groups
- Vivity™ DFT015 reduced the need for spectacles compared with AcrySof® IQ SN60WF, and also improved quality of vision without spectacles at near and intermediate distances (**Figure 2**)

Figure 2. Percentage of subjects reporting "good" or "very good" vision without spectacles.



Single Site Clinical Outcomes of a New Non-Diffractive Extended Vision Intraocular Lens*¶

McCabe C, Foster B, Lemp-Hull J†. Presented at the American Society for Cataract and Refractive Surgery (ASCRS) Virtual Annual Meeting; May 16-17, 2020.

OVERVIEW

STUDY DESIGN
Subgroup analysis of a prospective, randomized assessor- and subject-masked clinical trial to evaluate the clinical outcomes of a novel non-diffractive extended vision IOL (AcrySof® IQ Vivity™ DFT015) relative to an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)
Single center in the United States

PATIENTS
Nine (9) patients implanted with AcrySof® IQ Vivity™ DFT015 IOL; nine 9 patients implanted with monofocal AcrySof® IQ SN60WF IOL

METHODOLOGY
Evaluation of clinical outcomes 6 month after bilateral cataract removal and IOL implantation

IOL TYPE(S)
AcrySof® IQ Vivity™ Model DFT015 (Alcon Laboratories, Inc.); AcrySof® IQ monofocal IOL Model SN60WF (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Six months post-operatively: manifest refraction spherical equivalent (MSRE) prediction error; binocular uncorrected; best-corrected distance (UDVA, BCDVA, 4m), intermediate (UIVA, DCIVA, 66 cm), near visual acuity (UNVA, DCNVA, 40 cm); quality of vision (Questionnaire for Visual Disturbances [QUVID])

ANALYSIS AND CONCLUSIONS

Data from this single study site show that the novel non-diffractive extended vision IOL, Vivity™ Model DFT015, improved near and intermediate vision without affecting distance vision while maintaining a monofocal visual disturbance profile, compared to aspheric monofocal IOL.

*This study was financially supported by Alcon. †Dr. Lemp-Hull is an employee of Alcon.
¶This is site-specific data and does not establish the safety and efficacy of the device. Please refer to the DFU for complete safety and efficacy information for the device.

STUDY RESULTS

VISUAL ACUITY
- Binocular UDVA was 20/20 or better in both the Vivity™ DFT015 and AcrySof® IQ SN60WF groups (**Figure 1**)
- Binocular UIVA was 20/25 or better and UNVA was ~20/32 for Vivity™ DFT015, with >1 line of improvement over AcrySof® IQ SN60WF (**Figure 1**)
- Binocular distance-corrected visual acuities also showed >1 line of improvement at intermediate or near, with no clinically relevant difference for distance (**Figure 2**)

OTHER VISUAL OUTCOMES
- 100% of eyes implanted with Vivity™ DFT015 and 89% of eyes implanted with AcrySof® IQ SN60WF achieved an absolute MRSE prediction error of 0.5 D or less (**Figure 1**)
- The majority of subjects, in both groups, were "not at all bothered" by starbursts, halos and glare, and rates were similar between groups

Figure 1. Binocular uncorrected visual acuity at 6 months for the Vivity™ DFT015 IOL compared to the monofocal AcrySof® IQ SN60WF IOL.

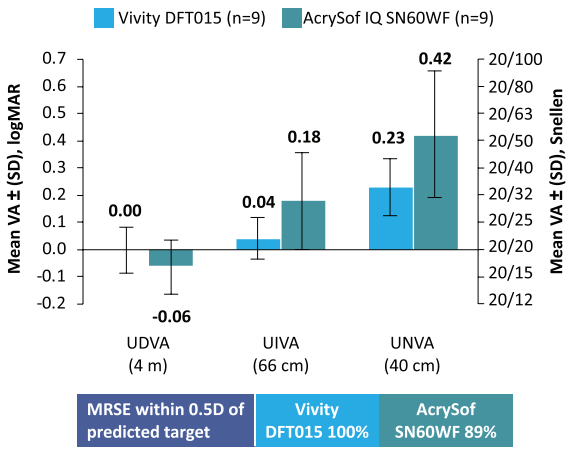
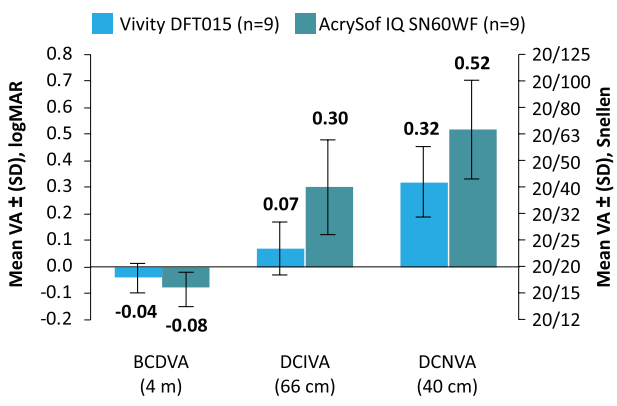


Figure 2. Binocular distance-corrected visual acuity at 6 months for the Vivity™ DFT015 IOL compared to the monofocal AcrySof® IQ SN60WF IOL.



Single-site Binocular Visual and Refractive Outcomes with a Novel Non-Diffractive Extended Vision Intraocular Lens*¶

Newsom T, Lemp-Hull J†. Presented at the American Society for Cataract and Refractive Surgery (ASCRS) Virtual Annual Meeting; May 16-17, 2020.

OVERVIEW

STUDY DESIGN
Subgroup analysis of data from a prospective, randomized, assessor- and subject-masked clinical trial to evaluate the clinical outcomes of AcrySof® IQ Vivity™ DFT015 relative to an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)
Single site in the United States

PATIENTS
Eleven (11) randomized subjects implanted with Vivity™ DFT015; 11 control subjects implanted with SN60WF

METHODOLOGY
Evaluation of clinical outcomes 6 month after bilateral cataract removal and IOL implantation

IOL TYPE(S)
AcrySof® IQ Vivity™ Model DFT015 (Alcon Laboratories, Inc.); AcrySof® IQ monofocal IOL Model SN60WF (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Six months post-operatively: uncorrected and distance corrected photopic binocular visual acuities (UCVA, DCVA) at distance (4 m), intermediate (66 cm) and near (40 cm); binocular defocus curve; patient-reported visual disturbance

ANALYSIS AND CONCLUSIONS

These data from a single site in the United States showed that the non-diffractive extended vision IOL (Vivity™ DFT015) provided an extended range of vision from distance to functional near.

Compared to the aspheric monofocal IOL, Vivity™ DFT015 improved near and intermediate vision without affecting distance vision while maintaining a monofocal visual disturbance profile.

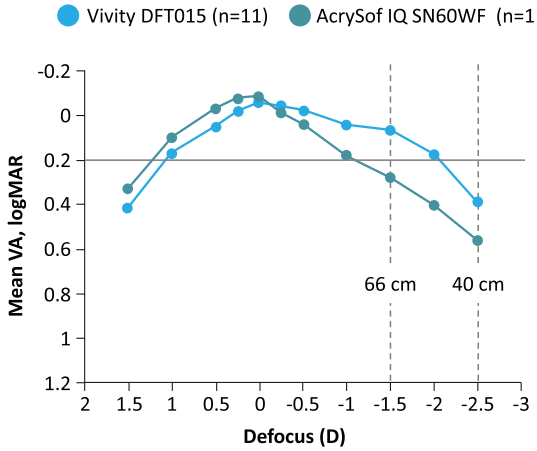
*This study was financially supported by Alcon. †Dr. Lemp-Hull is an employee of Alcon.
¶This is site-specific data and does not establish the safety and efficacy of the device. Please refer to the DFU for complete safety and efficacy information for the device.

STUDY RESULTS

VISUAL ACUITY

- The Vivity™ DFT015 IOL binocular defocus curve established better than 20/32 visual acuity from distance to -2.0D (50 cm) (**Figure 1**)
- Binocular uncorrected and distance corrected visual acuities were 20/20, 20/25, and 20/32 or better for Vivity™ DFT015 at distance, intermediate and near, respectively; and 20/20, 20/32, and 20/50 or better for AcrySof® IQ SN60WF

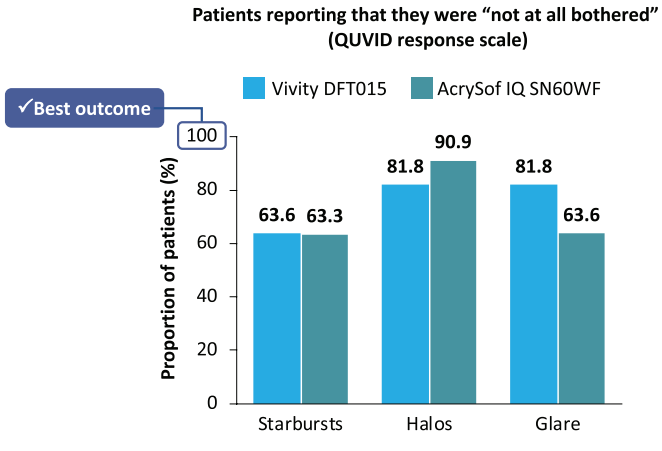
Figure 1. Binocular defocus curves for the Vivity™ DFT015 IOL compared to the monofocal AcrySof® IQ SN60WF IOL.



VISUAL OUTCOMES

- The majority of subjects in both groups were "not at all bothered" by starbursts, halos, and glare, and no patients were "bothered very much" (**Figure 2**)
- Rates of starburst, halos and glare were similar for the Vivity™ DFT015 and monofocal AcrySof® IQ SN60WF groups

Figure 2. Patient-reported visual disturbances were similar for the Vivity™ DFT015 IOL and the monofocal AcrySof® IQ SN60WF IOL.



Clinical Outcomes of a New Non-Diffractive Presbyopia-Correcting Intraocular Lens in a Multicenter US Study*

Berdahl J, Baartman B, Thompson V, Martinez A†. Presented at American Academy of Ophthalmology (AAO) 2020 Virtual; November 13-15, 2020.

OVERVIEW

STUDY DESIGN
Prospective, multicenter, randomized, assessor- and patient-masked, parallel-group, controlled, confirmatory clinical trial to evaluate visual outcomes with a new non-diffractive presbyopia-correcting IOL (AcrySof® IQ Vivity™ DFT015) versus an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)
Eleven (11) sites in the United States

PATIENTS
Two hundred twenty (220) patients with bilateral cataract; age ≥22 years

METHODOLOGY
Evaluation of clinical outcomes 6 months after bilateral cataract removal and IOL implantation

IOL TYPE(S)
AcrySof® IQ Vivity™ Model DFT015, AcrySof® IQ monofocal Model SN60WF (Alcon Vision, LLC)

KEY ENDPOINT(S)
Uncorrected distance, intermediate and near visual acuity (UCDVA, UCIVA, and UCNVA), absolute manifest refraction spherical equivalent (MSRE); spectacle use (Intraocular Lens Satisfaction [IOLSAT]) and patient-reported visual disturbances (Questionnaire for Visual Disturbances)

ANALYSIS AND CONCLUSIONS

In this large-scale US clinical study, Vivity™ DFT015 improved intermediate and near visual acuity compared with an aspheric monofocal IOL (AcrySof® IQ SN60WF), without affecting distance vision.

Vivity™ DFT015 also demonstrated a visual disturbance profile similar to that of AcrySof® IQ SN60WF, and improved quality of vision without spectacles

*This study was financially supported by Alcon. †Dr. Martinez is an employee of Alcon.

STUDY RESULTS

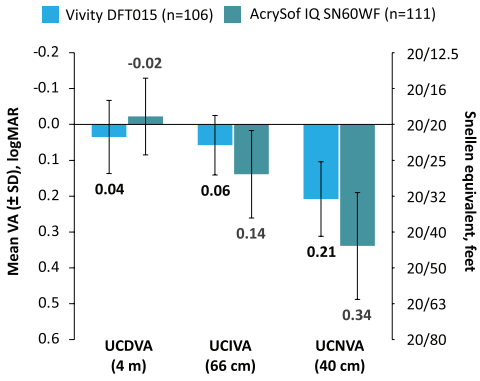
VISUAL ACUITY

- Mean binocular between-group difference in UCDVA was within 1-line for Vivity™ DFT015 vs AcrySof® IQ SN60WF (**Figure 1**)
- Vivity™ DFT015 provided a ~1-line improvement in binocular UCIVA and a >1-line improvement in binocular UCNVA vs AcrySof® IQ SN60WF (**Figure 1**)

OTHER VISUAL OUTCOMES

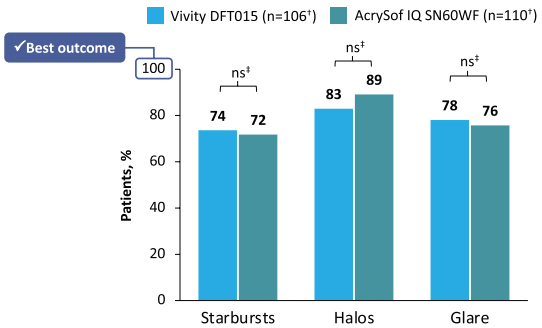
- Overall, 92% and 87% of first eyes achieved absolute MRSE ≤0.5D of emmetropia with Vivity™ DFT015 and AcrySof® IQ SN60WF, respectively
- 94%, 92% and 57% of subjects reported "good" or "very good" vision without spectacles at distance, intermediate and near with Vivity™ DFT015 (n=96), versus 92%, 63% and 25% with AcrySof® IQ SN60WF (n=89)
- Most patients reported never being bothered by visual disturbances; <2% in each group reported very bothersome starbursts, halos, and glare at 6 months (**Figure 2**)

Figure 1. Binocular uncorrected visual acuity at 6 months.*



*All-implanted analysis set

Figure 2. Proportion of patients reporting that they were "not at all bothered" by visual disturbances at 6 months.*



*Safety analysis set, assessed using the validated QUVID questionnaire; †for glare, DFT015 n=105, and SN60WF n=111; ‡95% confidence interval for the estimated difference between groups (DFT015–SN60WF) included zero, which indicates no significant difference (ns)

Visual Outcomes Under Bright and Dim Light Conditions with a New Non-Diffractive Presbyopia-Correcting Intraocular Lens*

Foster B, McCabe C, Foster G, Martinez A†. Presented at American Academy of Ophthalmology (AAO) 2020 Virtual; November 13-15, 2020.

OVERVIEW

STUDY DESIGN

Prospective, multicenter, randomized, assessor- and patient-masked, parallel-group, controlled confirmatory clinical trial to evaluate the effects of pupil size and lighting conditions on visual outcomes with a new non-diffractive presbyopia-correcting IOL (AcrySof® IQ Vivity™ DFT015) versus an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)

Eleven (11) sites in the United States

PATIENTS

Two hundred twenty (220) patients with bilateral cataract; age ≥22 years

METHODOLOGY

Evaluation of visual outcomes 6 months after bilateral cataract removal and IOL implantation

IOL TYPE(S)

AcrySof® IQ Vivity™ Model DFT015, AcrySof® IQ monofocal Model SN60WF (Alcon Vision, LLC)

KEY ENDPOINT(S)

Binocular defocus curve, best-corrected distance visual acuity (BCDVA), distance-corrected intermediate visual acuity (DCIVA), and distance-corrected near visual acuity (DCNVA); patient-reported quality of vision without spectacles in bright and dim lighting conditions (Intraocular Lens Satisfaction [IOLSAT] questionnaire)

ANALYSIS AND CONCLUSIONS

This large-scale US clinical study demonstrated that, compared with an aspheric monofocal IOL (AcrySof® IQ SN60WF), Vivity™ DFT015 improved near and intermediate vision, without affecting distance vision, at all pupil sizes.

Vivity™ DFT015 also improved quality of vision without spectacles in bright and dim lighting conditions.

*This study was financially supported by Alcon. †Dr. Martinez is an employee of Alcon.

STUDY RESULTS

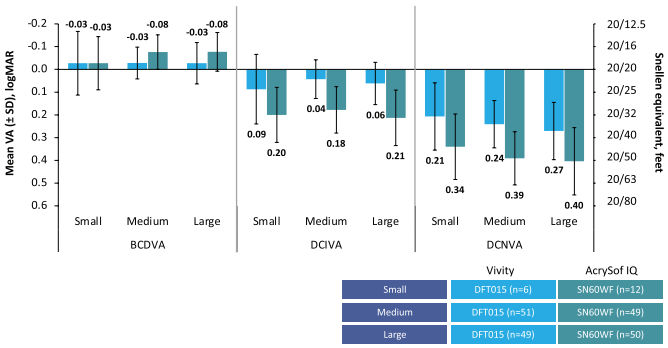
VISUAL ACUITY

- At 6 months, 92% of first eyes had medium (3-4 mm) or large (>4 mm) photopic pupil sizes, while 8% had small (<3 mm) pupil sizes
- Vivity™ DFT015 provided comparable BCDVA and improved binocular DCIVA and DCNVA (>1 line) compared with AcrySof® IQ SN60WF at all pupil sizes (**Figure 1**)

OTHER VISUAL OUTCOMES

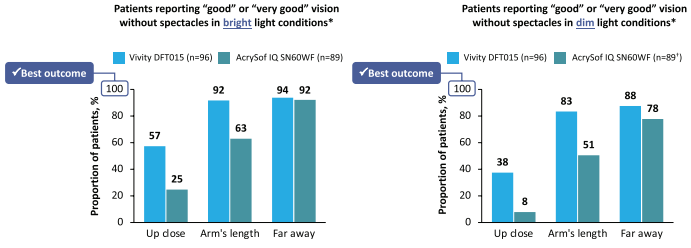
- Vivity™ DFT015 showed a greater negative range of defocus compared with AcrySof® IQ SN60WF, but had decreased depth of focus at 0.2 logMAR with increased pupil size
- For DFT015, about 30% more patients reported "good" or "very good" quality of vision without the use of spectacles, at intermediate and near distances, in both bright and dim light (**Figure 2**)

Figure 1. Binocular-corrected visual acuity by pupil size at 6 months.*



*All-implanted analysis set; pupil size = photopic pupil size for the first eye at 6 months

Figure 2. Patient-reported quality of vision in bright and dim lighting conditions.



*All-implanted analysis set, assessed using the IOLSAT questionnaire.
†SN60WF "Far away" n=90.

Clinical Outcomes of a New Non-Diffractive Presbyopia-Correcting Intraocular Lens in Canada*¶

Holland S, Martinez A†, Petrik M†. Presented at American Academy of Ophthalmology (AAO) 2020 Virtual; November 13-15, 2020.

OVERVIEW

STUDY DESIGN

Prospective, multicenter/ multicountry, randomized, parallel-group, assessor- and patient-masked study to evaluate clinical outcomes of a new non-diffractive presbyopia-correcting IOL (AcrySof® IQ Vivity™ DFT015) versus an aspheric monofocal IOL (AcrySof® IQ SN60WF) at investigational sites in Canada

STUDY SITE(S)

Multiple sites in Canada

PATIENTS

Seventy-five (75) patients with bilateral cataract; age ≥22 years

METHODOLOGY

Evaluation of clinical outcomes 6 months after bilateral cataract removal and IOL implantation; 1 patient underwent unilateral implantation

IOL TYPE(S)

AcrySof® IQ Vivity™ Model DFT015, AcrySof® IQ monofocal Model SN60WF (Alcon Vision, LLC)

KEY ENDPOINT(S)

Binocular best-corrected distance visual acuity (BCDVA), distance-corrected intermediate visual acuity (DCIVA), and distance-corrected near visual acuity (DCNVA); reading speed; quality of vision (QoV) questionnaire

ANALYSIS AND CONCLUSIONS

This Canadian subpopulation analysis found that Vivity™ DFT015 improved intermediate and near visual acuity compared with an aspheric monofocal IOL (AcrySof® IQ SN60WF), without affecting distance vision, and achieved functional reading speed (>80 words/minute) with as small as 8 point size at intermediate distance.

Vivity™ DFT015 was also associated with low rates of severe visual disturbances, with the majority of patients (≥70%) reporting not being bothered at all with starbursts, halos, or glare.

*This study was financially supported by Alcon. †Drs. Martinez and Petrik are employees of Alcon.
¶This is site-specific (country level) data and does not establish the safety and efficacy of the device. Please refer to the DFU for complete safety and efficacy information for the device.

STUDY RESULTS

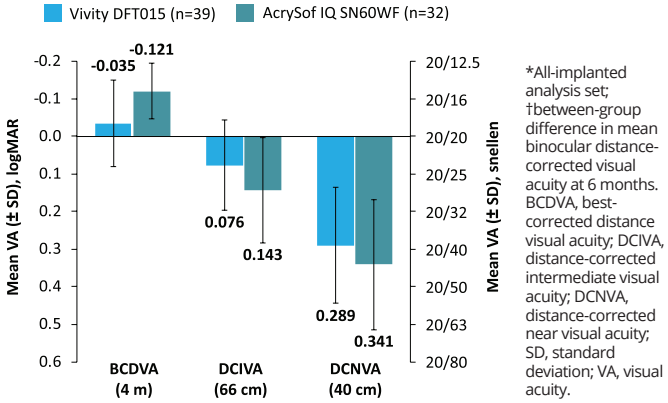
VISUAL ACUITY

- Mean binocular BCDVA was better than 20/20 with both Vivity™ DFT015 and AcrySof® IQ SN60WF (**Figure 1**)
- Vivity™ DFT015 showed improved intermediate and near vision over AcrySof® IQ SN60WF, allowing patients to achieve mean DCIVA of ~20/24 and DCNVA of ~20/39 (**Figure 1**)
- Vivity™ DFT015 demonstrated visual acuity of 0.1 logMAR or better from distance to –1.5 D on the binocular defocus curve

OTHER VISUAL OUTCOMES

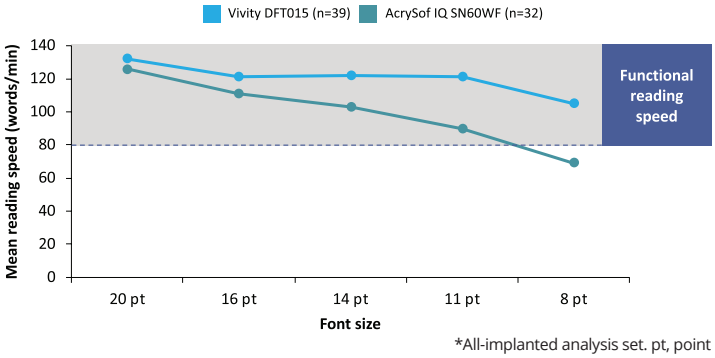
- Vivity™ DFT015 recipients achieved a functional reading speed with as low as 8 point font at intermediate distance (66 cm) (**Figure 2**)
- More Vivity™ DFT015 recipients indicated they were "not at all" bothered by starbursts and glare vs AcrySof® IQ SN60WF recipients
- Rates of severe visual disturbances were low and similar for Vivity™ DFT015 vs AcrySof® IQ SN60WF groups: starbursts (0% vs 3.7%), halos (0% in both groups), and glare (3.3% vs 3.7%)

Figure 1. Binocular uncorrected visual acuity at 6 months.*



*All-implanted analysis set; †between-group difference in mean binocular distance-corrected visual acuity at 6 months. BCDVA, best-corrected distance visual acuity; DCIVA, distance-corrected intermediate visual acuity; DCNVA, distance-corrected near visual acuity; SD, standard deviation; VA, visual acuity.

Figure 2. Distance-corrected reading speed at 6 months.*



*All-implanted analysis set. pt, point

US Multicenter Study of the Visual Outcomes of a New Non-Diffractive Presbyopia-Correcting Intraocular Lens*

McCabe C, Reiser H, Martinez A†. Presented at American Academy of Ophthalmology (AAO) 2020 Virtual; November 13-15, 2020.

OVERVIEW

STUDY DESIGN

Prospective, multicenter, randomized, assessor- and patient-masked, parallel-group, controlled confirmatory clinical trial to evaluate distance-corrected visual outcomes with a new non-diffractive presbyopia-correcting IOL (AcrySof® IQ Vivity™ DFT015) versus an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)

Eleven (11) sites in the United States

PATIENTS

Two hundred twenty (220) patients with bilateral cataract; age ≥22 years

METHODOLOGY

Evaluation of visual outcomes 6 months after bilateral cataract removal and IOL implantation

IOL TYPE(S)

AcrySof® IQ Vivity™ Model DFT015, AcrySof® IQ monofocal Model SN60WF (Alcon Vision, LLC)

KEY ENDPOINT(S)

Binocular defocus curve, best-corrected distance visual acuity (BCDVA), distance-corrected intermediate visual acuity (DCIVA), and distance-corrected near visual acuity (DCNVA); patient-reported visual disturbances (Questionnaire for Visual Disturbances)

ANALYSIS AND CONCLUSIONS

In this large-scale US clinical study, Vivity™ DFT015 extended range of vision compared with an aspheric monofocal IOL (AcrySof® IQ SN60WF), improving near and intermediate vision without affecting distance vision.

Vivity™ DFT015 also demonstrated a visual disturbance profile similar to that of AcrySof® IQ SN60WF.

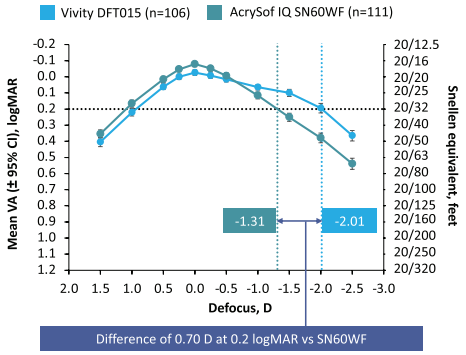
*This study was financially supported by Alcon. †Dr. Martinez is an employee of Alcon.

STUDY RESULTS

VISUAL ACUITY

- Both groups achieved mean binocular BCDVA <0.0 logMAR
- BCDVA ≥20/25 was achieved by 97.2% of subjects in the Vivity™ DFT015 group and 98.2% in the AcrySof® IQ SN60WF group
- DCIVA ≥20/25 was achieved by 87.7% of patients in the Vivity™ DFT015 group and 34.2% in the AcrySof® IQ SN60WF group
- Vivity™ DFT015 provided a >1-line increase in DCIVA and DCNVA compared with AcrySof® IQ SN60WF

Figure 1. Binocular defocus curve at 6 months.*

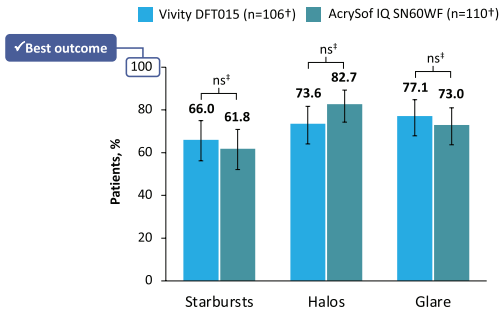


*All-implanted analysis set. CI, confidence interval; D, diopter

OTHER VISUAL OUTCOMES

- The binocular defocus curve for Vivity™ DFT015 showed a ≥0.5 D greater negative range of defocus, compared with AcrySof® IQ SN60WF (**Figure 1**)
- There were no significant differences between Vivity™ DFT015 and AcrySof® IQ SN60WF in percent of patients experiencing starbursts (66.0 vs 61.8), halos (73.6 vs 82.7), or glare (77.1 vs 73.0) (**Figure 2**)

Figure 2. Proportion of patients reporting "no" to experiencing visual disturbances in the past 7 days*



*Safety analysis set, assessed using the validated QUVID questionnaire; †for glare, DFT015 n=105, and SN60WF n=111; ‡95% confidence interval for the estimated difference between groups (DFT015–SN60WF) included zero, which indicates no significant difference (ns)

Clinical Outcomes of a New Non-Diffractive Presbyopia-Correcting Intraocular Lens from Two Large Confirmatory Studies*

Varma D, Bazin R, Martinez A†. Presented at American Academy of Ophthalmology (AAO) 2020 Virtual; November 13-15, 2020.

OVERVIEW

STUDY DESIGN
Two prospective, multicenter, randomized, controlled clinical trials to evaluate clinical outcomes with a new non-diffractive presbyopia-correcting IOL (AcrySof® IQ Vivity™ DFT015) versus an aspheric monofocal IOL (AcrySof® IQ SN60WF)

STUDY SITE(S)
Multiple centers in the United States and outside the United States (OUS, Australia, Canada, Spain, and the UK)

PATIENTS
Two hundred seventy-three (273) patients OUS, 219 in the United States with bilateral cataract; age ≥22 years

METHODOLOGY
Evaluation of clinical outcomes 6 months after bilateral cataract removal and IOL implantation

IOL TYPE(S)
AcrySof® IQ Vivity™ Model DFT015, AcrySof® IQ monofocal Model SN60WF (Alcon Vision, LLC)

KEY ENDPOINT(S)
Binocular defocus curve, best-corrected distance visual acuity (BCDVA), distance-corrected intermediate visual acuity (DCIVA), and distance-corrected near visual acuity (DCNVA); patient-reported visual disturbances (Questionnaire for Visual Disturbances)

ANALYSIS AND CONCLUSIONS

Two large-scale, independent confirmatory trials demonstrated that Vivity™ DFT015 extended range of vision compared with an aspheric monofocal IOL (AcrySof® IQ SN60WF), improving near and intermediate vision without affecting distance vision.

Vivity™ DFT015 also demonstrated a visual disturbance profile similar to that of AcrySof® IQ SN60WF.

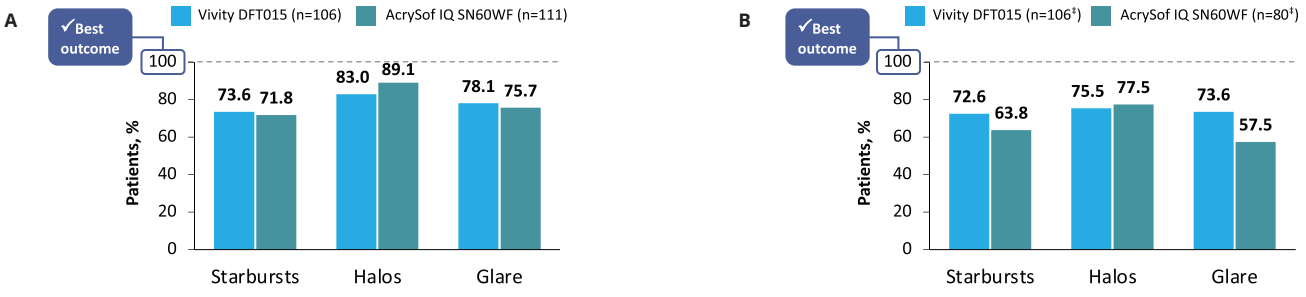
*This study was financially supported by Alcon. †Dr. Martinez is an employee of Alcon.

STUDY RESULTS

VISUAL ACUITY
- Both groups achieved mean binocular BCDVA <0.0 logMAR
- Vivity™ DFT015 provided an improvement of ~1 line or better in DCIVA and DCNVA compared with AcrySof® IQ SN60WF

OTHER VISUAL OUTCOMES
- Vivity™ DFT015 provided similar distance vision and a superior range of vision (binocular defocus ≤0.2 logMAR) in the intermediate vision range (-1.5 to -2.0 D) compared with AcrySof® IQ SN60WF at 6 months
- Patients reporting that they were not at all bothered by starbursts, halos, or glare at 6 months (**Figure 1**)
  - US study: for Vivity™ DFT015 and AcrySof® IQ SN60WF groups, 73.6% vs 71.8% of patients reported starbursts; 83.0% vs 89.1% reported halos; and 78.1% vs 75.7% reported glare
  - OUS study: for Vivity™ DFT015 and AcrySof® IQ SN60WF groups, 72.6% vs 63.8% of patients reported starbursts; 75.5% vs 77.5% reported halos; and 73.6% vs 57.5% reported glare

Figure 1. Proportion of patients reporting that they were "not at all bothered" by visual disturbances at 6 months in (**A**) the US study and (**B**) the OUS study.*‡



*Safety-analysis set; †US trial assessed using the QUVID questionnaire, OUS trial assessed using the QoV questionnaire; ‡Patients who had not exited the study by the Month 6 visit were asked to complete the QoV questionnaire, which was added as a protocol amendment.

AcrySof® IQ Vivity™ Family of Extended Vision IOLs

CAUTION

Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS

The AcrySof® IQ Vivity™ Extended Vision IOLs include AcrySof® IQ Vivity™ and AcrySof® IQ Vivity™ Toric and are indicated for primary implantation for the visual correction of aphakia in adult patients with <1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof® IQ Vivity™ IOL is intended for capsular bag placement only. In addition, the AcrySof® IQ Vivity™ Toric IOL is indicated for the reduction of residual refractive astigmatism in adult patients with pre-existing corneal astigmatism.

WARNINGS/PRECAUTIONS

Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling.

This lens should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation.

Most patients implanted with the Vivity™ IOL are likely to experience significant loss of contrast sensitivity as compared to a monofocal IOL. Therefore, it is essential that prospective patients be fully informed of this risk before giving their consent for implantation of the Vivity IOL. In addition, patients should be warned that they will need to exercise caution when engaging in activities that require good vision in dimly lit environments, such as driving at night or in poor visibility conditions, especially in the presence of oncoming traffic.

It is possible to experience very bothersome visual disturbances, significant enough that the patient could request explant of the IOL. In the Vivity™ clinical study, 1% to 2% of Vivity™ patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances; however, no explants were reported.

Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with the AcrySof® IQ Vivity™ IOLs.

ATTENTION

Reference the Directions for Use labeling for each IOL for a complete listing of indications, warnings and precautions.

References

Baartman B, Berdahl J, Lemp-Hull J. **Visual Outcomes of a New Non-Diffractive Extended Vision Intraocular Lens at a Single US Site**. Presented at the American Society for Cataract and Refractive Surgery (ASCRS) Virtual Annual Meeting; May 16-17, 2020.

Balachandran C, Lee S, Carson D, Lemp-Hull J. **Vision Outcomes of a Non-Diffractive Extended-Vision Intraocular Lens Implanted with Mini-Monovision**. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

Balachandran C, Lemp-Hull J. **Multi-Country Clinical Outcomes of a New Non-Diffractive Extended Vision Intraocular Lens**. Presented at the American Society for Cataract and Refractive Surgery (ASCRS) Virtual Annual Meeting; May 16-17, 2020.

Berdahl J, Baartman B, Thompson V, Martinez A. **Clinical Outcomes of a New Non-Diffractive Presbyopia-Correcting Intraocular Lens in a Multicenter US Study**. Presented at American Academy of Ophthalmology (AAO) 2020 Virtual; November 13-15, 2020.

Foster B, McCabe C, Foster G, Martinez A. **Visual Outcomes under Bright and Dim Light Conditions with a New Non-Diffractive Presbyopia-Correcting Intraocular Lens**. Presented at American Academy of Ophthalmology (AAO) 2020 Virtual; November 13-15, 2020.

Guarro M, Pedrell J, Peris C, Alvarez de Toledo Elizalde J, Poyales F. **Clinical Outcomes of a New Extended Vision Intraocular Lens Implanted by Spanish Surgeons**. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

Holland S, Martinez A, Petrik M. **Clinical Outcomes of a New Non-Diffractive Presbyopia-Correcting Intraocular Lens in Canada**. Presented at American Academy of Ophthalmology (AAO) 2020 Virtual; November 13-15, 2020.

McCabe C, Xu Z, Lemp-Hull J, Carson D, Milanovic Z. **A Non-Diffractive Extended-Vision Intraocular Lens that Meets the Optical and Clinical Criteria for Extended-Depth-of-Focus IOLs**. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

McCabe C, Reiser H, Martinez A. **US Multicenter Study of the Visual Outcomes of a New Non-Diffractive Presbyopia-Correcting Intraocular Lens**. Presented at American Academy of Ophthalmology (AAO) 2020 Virtual; November 13-15, 2020.

McCabe C, Bergdahl J, Lemp-Hull J, Poyales F, Balachandran C. **Visual Disturbance Profile of a Non-Diffractive Extended Vision Intraocular Lens from Two Pivotal Trials**. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

McCabe C, Lemp-Hull J. **Single Site Clinical Outcomes of a New Non-Diffractive Extended Vision Intraocular Lens**. Presented at the American Society for Cataract and Refractive Surgery (ASCRS) Virtual Annual Meeting; May 16-17, 2020.

Mearza A, Bhermi S, Patton N, Kasaby H. **Clinical Outcomes of a New Extended-Vision Intraocular Lens in the United Kingdom**. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

Newsom T, Lemp-Hull J. **Single-site Binocular Visual and Refractive Outcomes with a Novel Non-Diffractive Extended Vision Intraocular Lens**. Presented at the American Society for Cataract and Refractive Surgery (ASCRS) Virtual Annual Meeting; May 16-17, 2020.

Poyales M, Mearza A, Varma D, Balachandran C, Lemp-Hull J. **Multi-Country Clinical Outcomes of a New Non-Diffractive Extended-Vision Intraocular Lens at Six Months Postoperatively**. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

Ruiz-Mesa R, Bhatt U, Kasaby H, Rabinovitch T, Lemp-Hull J. **Multi-Country Functional Vision Outcomes of a New Non-Diffractive Extended-Vision Intraocular Lens**. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

Schwiegerling J, Carson D, Xu Z, Choi M, Lee S, Milanovic Z, Lane S. **Optical Simulation and Bench Data of a Non-Diffractive Intraocular Lens Designed to Extend Depth of Focus and Minimize Visual Disturbances**. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

Schwiegerling J, Lemp-Hull J, Lane S, Baker K. **Simulated Visual Acuity Performance of Monofocal and Extended-Depth-of-Focus Intraocular Lenses**. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 14-18, 2019; Paris, FR.

Varma D, Bazin R, Martinez A. **Clinical Outcomes of a New Non-Diffractive Presbyopia-Correcting Intraocular Lens from Two Large Confirmatory Studies**. Presented at American Academy of Ophthalmology (AAO) 2020 Virtual; November 13-15, 2020.

Alcon