

# The Vivivity Extended Depth of Focus IOL: Our Clinical Experience



The Vivivity IOL provides an improved range of vision while maintaining a monofocal-like visual disturbance profile.

**IQBAL IKE K. AHMED, MD, FRCS, AND DEVESH K. VARMA, MD, FRCS**

## INTRODUCTION

Patient expectations for cataract surgery are growing exponentially as it increasingly becomes a procedure to address lifestyle demands beyond removing a cataract. Ophthalmologists are addressing presbyopia during cataract surgeries with monovision with monofocal intraocular lenses (IOLs) or utilizing one of the pseudo-accommodative or presbyopia-mitigating IOLs, most frequently with one of the diffractive multifocal, trifocal, or extended depth of focus (EDOF) IOLs available in North America. Recently, a novel non-diffractive EDOF IOL, the AcrySof IQ Vivivity (Alcon), was approved by both the US Food and Drug Administration (FDA) and Health Canada (HE). The Vivivity IOL provides an improved range of vision compared to the monofocal IOL while maintaining a monofocal-like visual disturbance profile.

## WHAT ARE THE MAJOR CONCERNS THAT HAVE PREVENTED MANY OPHTHALMOLOGISTS FROM ADOPTING PRESBYOPIA-MITIGATING IOLS?

**Iqbal Ike K. Ahmed, MD, FRCS:** Despite the rapid technology advancement in the area of presbyopia-mitigating IOLs in the past 20 years, the percentage of cataract procedures involving presbyopic IOLs is still hovering around 8% according to the 2019 ASCRS Clinical Survey.<sup>1</sup> One of the main reasons for surgeons not performing presbyopic IOL procedures is the concern over postoperative quality of vision. The ASCRS/ESCRS survey also reported that the most frequent complaint leading to explantation of one-piece hydrophobic acrylic multifocal IOLs is glare and optical aberration (>90%).<sup>2</sup> Current US marketed multifocal, trifocal, and diffractive EDOF IOLs showed greater visual disturbances compared to monofocal control IOLs in the clinical studies.<sup>3-6</sup> Importantly, clinical studies showed that the diffractive EDOF IOL had similar incidence and severity of visual disturbances to those of the diffractive trifocal IOL.<sup>7,8</sup>

## WHAT IS THE ACRYSOF IQ VIVITY EDOF IOL?

**Devesh K. Varma, MD, FRCS:** The AcrySof IQ Vivivity EDOF IOL uses patented non-diffractive X-WAVE (Alcon) technology to stretch and shift the light wavefront giving an extended depth of focus. Unlike diffractive technology, it does not split light, so all

available light is used throughout the entire range of focus, and it provides a monofocal-like halo profile (Figure 1).<sup>9</sup>

## WHAT IS THE CLINICAL PERFORMANCE WITH THE ACRYSOF IQ VIVITY EDOF IOL?

### Visual Acuity and Range of Vision

**Dr. Varma:** Two large prospective, multicenter, randomized controlled clinical studies of bilateral implantation of the AcrySof IQ Vivivity IOL versus the control AcrySof IQ monofocal have been completed, one within the United States (FDA registration study) and the other conducted in multiple countries outside of the United States, in which I was one of the principal investigators. The 6-month postoperative data from more than 250 Vivivity subjects across the two studies were very consistent. The Vivivity IOL (DFT015) provided excellent binocular distance, intermediate, and functional near visual acuity (Figure 2),<sup>10</sup> and the binocular defocus curve showed a superior range of vision versus the monofocal control from intermediate to near (Figure 3).<sup>11</sup>

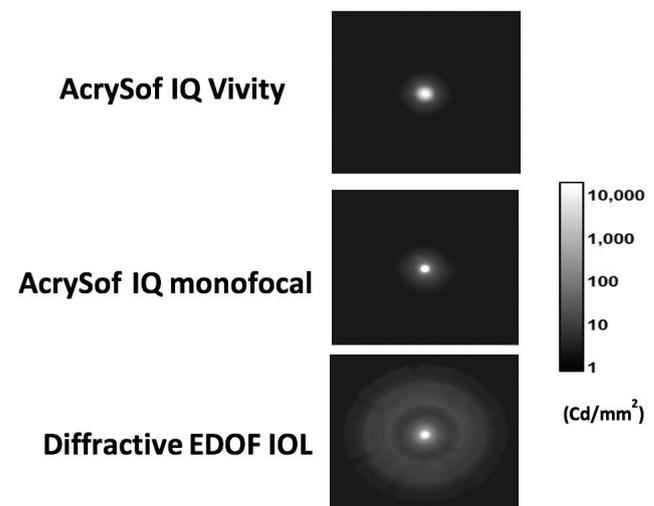


Figure 1. Simulated halo effects with pinhole images.

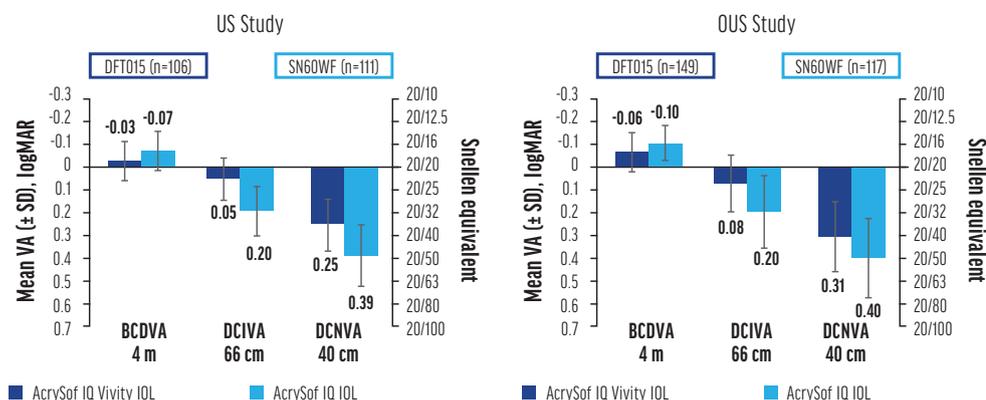


Figure 2. Vivity binocular distance corrected visual acuity at 6 months.

I have been using the Vivity lens in clinical practice for several months now. It has expanded the proportion of patients to whom I can offer a refractive cataract solution, which now includes patients who would have been unable to tolerate halos as well as those with certain pre-existing eye conditions who require better possible light transfer. While I counsel patients that they can expect functional near and may require a small near prescription for smaller print, I have been pleasantly surprised by the near performance many of my patients have achieved.

**Dr. Ahmed:** The most appealing aspect of this lens is of course the ability to provide a broader range of vision than a monofocal and similar visual disturbances.

If the clinical study data holds true in real-world use, I have no doubt this will be an important IOL option for our patients and our practices. Although many patients are keen for presbyopic IOL options, a significant group are non-candidates for the classic diffractive multifocal IOLs due to concerns for dysphotopsia or quality of vision.

I was fortunate to be one of the first surgeons in North America to implant the Vivity IOL in real-world conditions. Over the last 6 months, I have implanted the lens in over 60 cases. Although I certainly look to longer-term follow-up and more experience, thus far I have been thoroughly impressed at the performance of this innovative IOL design. My patients comfortably have achieved excellent

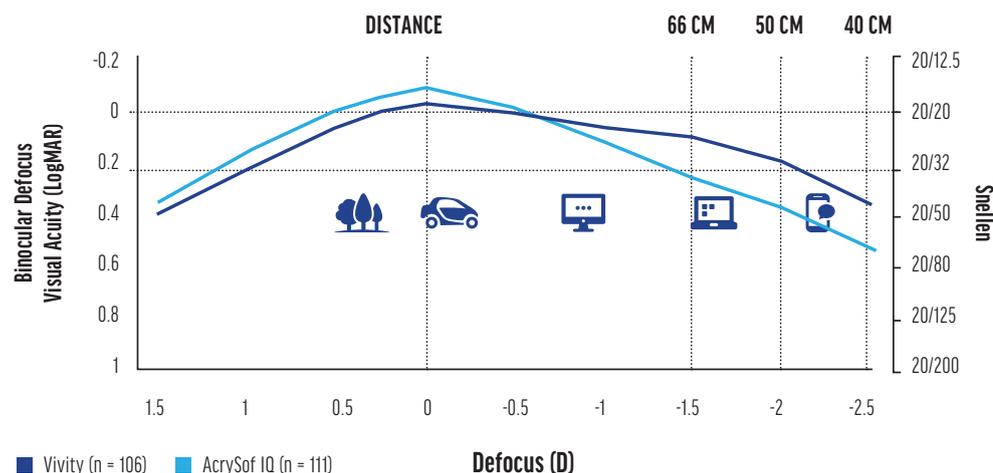


Figure 3. Vivity binocular defocus curve at 6 months.

distance and intermediate vision, and most are able to perform many near tasks as well. We are also exploring the “micro-monovision” approach in some patients to understand the range of vision and quality of vision.

I think another place for this lens is with those patients who choose to benefit from a monofocal toric IOL due to corneal astigmatism. With availability of the Vivity Toric, this is a chance for those patients who are seeking some spectacle independence to achieve a greater degree of uncorrected vision over an extended range of distances.

### Patient-Reported Outcomes

**Dr. Varma:** The most impressive finding from my site level data and the two Vivity registration studies is the patient-reported outcomes on visual disturbances. Similar levels of dysphotopsia were reported in both studies using the two different validated questionnaires: QUID (Alcon) in the FDA study and QoV (McAlinden) in the outside the United States Vivity registration study. Just as the bench study predicted, the majority of Vivity IOL-implanted patients reported not experiencing, or that they were not at all bothered by, starbursts, halos, and glare at similar levels compared to the AcrySof IQ monofocal control-implanted patients (Figure 4).<sup>10,11</sup> This finding sets this non-diffractive EDOF IOL apart from diffractive EDOF IOLs, which have shown more visual disturbances versus monofocal control.<sup>5,8</sup>

**Dr. Ahmed:** Thus far, in my early experience, I am happy to report that my patients are very satisfied. As they say, “there is no free lunch in optics,” and there is always some compromise with optical and light manipulation with presbyopic IOLs. However, I have been very pleased with the visual disturbance profile of Vivity. I have specifically asked patients and probed them for visual disturbance complaints, but I have not been able to elicit any significant issues thus far, similar to what is reported in

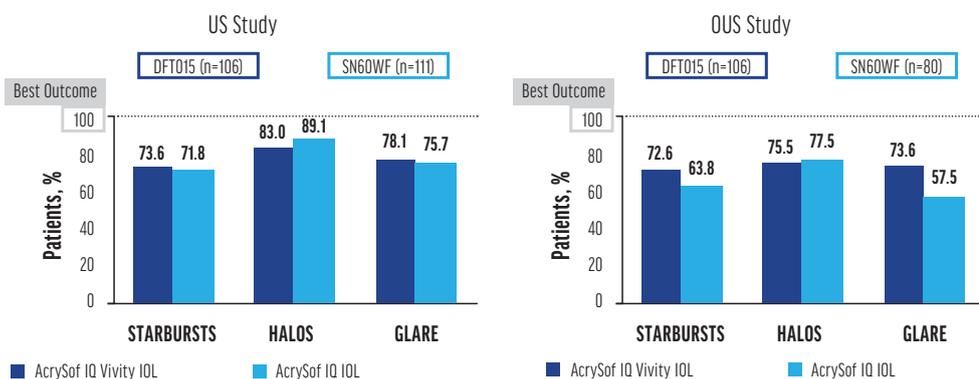


Figure 4. Percent of patients reporting "Not At All Bothered" by starbursts, halos, or glare at 6 months after bilateral implantation of Vivity or AcrySof IQ monofocal IOLs.

the clinical trials. This speaks to the novel design of light stretching and shifting the X-WAVE Technology, as opposed to light splitting approaches of diffractive EDOF IOL designs. I believe that, although there is a small amount of monocular contrast reduction compared to an aspheric monofocal IOL, I have not found this to be clinically significant in real-world use of Vivity. My patients experience excellent visual performance in both bright and dim lighting conditions across a variety of pupil sizes. We have also had early experience with eyes with comorbidities such as mild corneal epithelial issues, endothelial dystrophy, glaucoma, and macular pathology with success.

Trifocals and full-range multifocal IOLs remain our choice for the full correction of vision at all distances: far, intermediate, and near. Nothing compares to the power of these lenses. However, a fair number

of patients are not ideal candidates for such diffractive lenses, particularly due to the concern for postoperative halos and glare or quality of vision. I also find we save time and effort with both pre- and postoperative counseling since the risk for visual dysphotopsia is not different than a monofocal. Although caution is needed when evaluating new technology, I believe the unique design of the Vivity IOL provides a very promising option for patients seeking presbyopic IOL benefits with low visual disturbance profile.

### SUMMARY

Our early experience with the AcrySof IQ Vivity EDOF IOL convinced us this novel non-diffractive optical design enabled patients to see well at distance, intermediate, and functional near. More importantly, it provides a monofocal-like visual disturbance profile. This IOL represents a revolutionary leap in IOL

technology. We, the ophthalmologists, should tell our patients about this lens and continue exploring its clinical usage in a broader patient population. ■

1. Presbyopia education. [ascrs.org](https://ascrs.org/clinical-education/presbyopia), <https://ascrs.org/clinical-education/presbyopia>. Accessed January 6, 2021.
2. Mavalis N, Bontu S, Kennedy S. ASCRS/ESCRS survey on foldable IOLs requiring explanation or secondary intervention 2019 update. Presented at: ASCRS Virtual Annual Meeting, May 2020.
3. TECNIS® Multifocal 1-Piece Intraocular Lens.
4. PanOptix DFL.
5. Symphony DFL.
6. K. G. Gunderson and R. Potvin, Comparative visual performance with monofocal and multifocal intraocular lenses. *Clin Ophthalmol*. 2013;7:1979-1985.
7. Escandón-García S, Ribeiro FJ, McAlinden C, et al. Through-focus vision performance and light disturbances of 3 new intraocular lenses for presbyopia correction. *Journal of Ophthalmology*. 2018;1-8.
8. Liu J, Dong Y, Wang Y. Efficacy and safety of extended depth of focus intraocular lenses in cataract surgery: a systematic review and meta-analysis. *BMC Ophthalmology*. 2019;19(198).
9. Schwiagerling J, Carson D, Xu Z, et al. Optic simulation and bench data of a non-diffractive IOL to extend depth of focus and minimize visual disturbances. Presented at: ESCRS, Sept. 2019, Paris, France.
10. Varma D, Bazan R, Martínez A. Clinical outcomes of a new non-diffractive presbyopia-correcting IOL from two large confirmatory studies. Presented at: AAO 2020 Virtual Annual Meeting, Nov. 2020.
11. AcrySof IQ Vivity DFL.

### IQBAL IKE K. AHMED, MD, FRCS

- Assistant Professor and Director of the Glaucoma and Advanced Anterior Surgical Fellowship, University of Toronto, Canada
- Chief Medical Editor, *Glaucoma Today*
- Financial disclosure: Consultant (Alcon, MicroSurgical Technology)

### DEVESH K. VARMA, MD, FRCS

- Glaucoma and Advanced Anterior Segment Surgeon, Prism Eye Institute, Mississauga, Ontario, Canada
- Assistant Professor, University of Toronto, Canada
- Member, *Glaucoma Today* Editorial Advisory Board
- [devesh.varma@prismeye.ca](mailto:devesh.varma@prismeye.ca)
- Financial disclosure: Consultant and research support (Alcon, Allergan/AbbVie)

#### AcrySof® IQ Vivity™ Family of Extended Vision IOLs IMPORTANT PRODUCT INFORMATION

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 IOLs 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 AcrySof® IQ 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 AcrySof® IQ 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 AcrySof® IQ Vivity™ IOL clinical study, 1% to 2% of AcrySof® IQ Vivity™ IOL 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.

© 2021 Alcon Inc. 01/21 US-ACM-2000008