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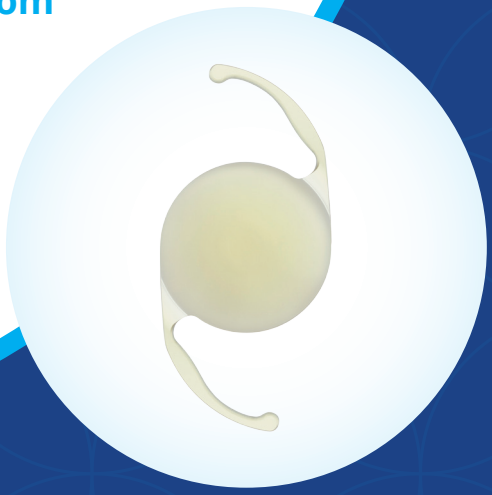
Extending Vision with **AcrySof®IQ Vivity™** IOL, the First and Only Extended Depth of Focus (EDoF) IOL with the Wavefront-Shaping **X-WAVE™ technology**

Real-world perspectives and clinical experience from the AcrySof®IQ Vivity™ Users Experience Meeting

AcrySof IQ Vivity
EXTENDED VISION IOL



October 2020

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This supplement solely reflects the views, opinions, and clinical practice experiences of presenters who participated in the AcrySof®IQ Vivity™ Users Experience Meeting in October 2020. Data presented are representative of each participating surgeon's own experience and do not arise from formal clinical studies.

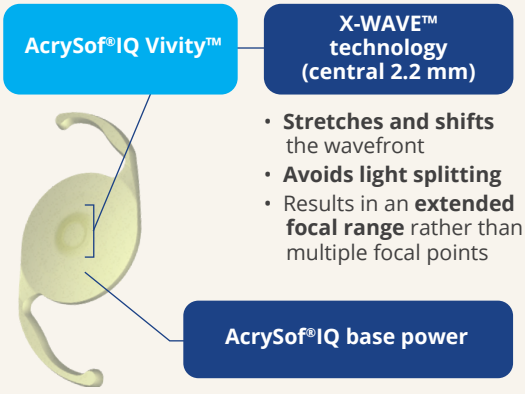
AcrySof®IQ Vivity™ answers the call for continuous range of vision, with an aspheric monofocal visual disturbance profile

Cataract surgery is one of the most frequently performed procedures worldwide, involving the removal of the opacified natural crystalline lens and subsequent replacement with an intraocular lens (IOL).[1] Traditional IOLs are monofocal and typically focused on distance vision.[2,3] However, because presbyopia is the most common refractive disorder in people over 40 years of age,[4] there is a need for IOLs that offer improved near and intermediate vision.

Presbyopia-correcting IOLs have been developed with the aim of mitigating the effects of presbyopia. Early examples of multifocal IOLs were designed to improve distance and near vision; more recently, there has been increasing demand for improved intermediate vision to accommodate patients' needs, such as driving and technical device use.[5] Trifocal IOLs have sought to bridge this gap by offering improved vision at intermediate distances.[5] Several technologies in this category have been employed, including refractive and diffractive lens optics, but many are associated with photic phenomena (such as glare and halo) and reduced contrast sensitivity,[3,6] thus compromising patients' quality of life. Extended depth of focus (EDoF) IOLs

Figure 1: Introduction to AcrySof®IQ Vivity™

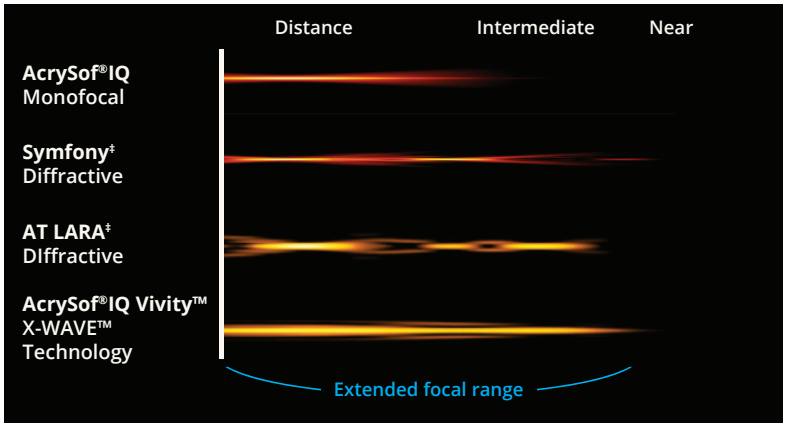
- AcrySof®IQ Vivity™ IOL is the First and Only Extended Depth of Focus (EDoF) IOL with the Wavefront-Shaping X-WAVE™ technology
- Intended benefit: continuous extended range of vision* with an aspheric monofocal visual disturbance profile (AcrySof®IQ)



7× magnification of central element for illustrative purposes

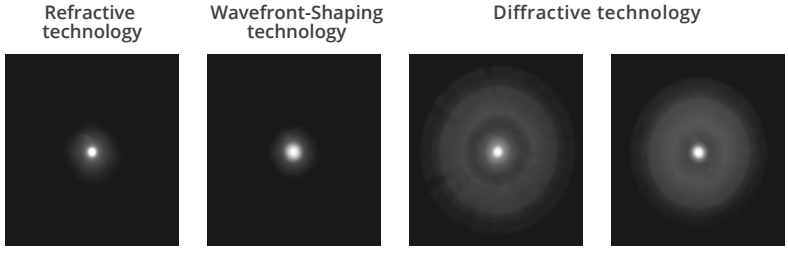
AcrySof®IQ Vivity™ EXTENDED VISION IOL

Light intensity distribution†



Area of precisely focused light

Halo profile§



*AcrySof®IQ Vivity™ demonstrated a mean monocular negative range of focus at 0.2 logMAR of 1.53 D compared to 0.99 D for the monofocal control IOL; †Simulated photopic through-focus point spread function (light intensity [energy]) – polychromatic; ‡Trademarks are the property of their respective owners; §Optical bench data of pinhole images to simulate halo effects (logarithmic scale images of halos around point source).

IOL, intraocular lens.

were intended to provide extended range of vision without the typical visual disturbances associated with diffractive trifocal and bifocal technologies.[5] However, many EDoF IOLs are still associated with photic phenomena and reduced contrast sensitivity;[2] and so, despite the numerous IOL options available to surgeons and patients, distinct unmet needs remain.[4]

AcrySof®IQ Vivity™ IOL is the First and Only Extended Depth of Focus (EDoF) IOL with the Wavefront-Shaping X-WAVE™ technology. It provides patients with a continuous extended range of vision from distance to functional near, thereby reducing their need for spectacles. X-WAVE™ technology stretches and shifts the wavefront rather than splitting it. This means it can utilize almost all of the light, like a monofocal, and hence has an aspheric monofocal visual disturbance profile, while the uniform light intensity distribution gives "more natural vision" (see **Figure 1**).[7–11]

Global perspectives on the real-world use of AcrySof®IQ Vivity™: Helping to translate clinical data to practice

Regulatory approval of IOLs in various countries often requires a research study (ie, clinical trial), in which participants are prospectively assigned to one or more interventions to evaluate safety and performance of the IOL. These results are usually compared with a concurrent control group and, collectively, this evidence forms the basis for supporting the safety and effectiveness of the device. Although these controlled studies provide a useful baseline for understanding the safety and performance of an IOL, clinical trials can sometimes be narrow in scope due to their practical challenges and carefully controlled target populations. Hence, case series utilizing real-world data can complement this evidence by providing information on a wider patient population that cannot be obtained through a traditional registration clinical trial alone.

In early October 2020, Alcon brought together key thought leaders in ophthalmology from Europe, Australia, and Canada to discuss their real-world experience with AcrySof®IQ Vivity™. This group of experts shared their clinical evidence and practice insights through case studies in key patient populations that may be particularly suited to receiving AcrySof®IQ Vivity™; these included those targeted for mini-monovision, post-laser-assisted *in situ* keratomileusis (LASIK) patients, and patients with mild glaucoma. Highlights of the discussion can be found in **Figure 2**.

Figure 2: Key highlights from the AcrySof®IQ Vivity™ Users Experience Meeting

- **AcrySof®IQ Vivity™** provides **very good distance and intermediate vision**, good near vision, and an **excellent visual disturbance profile** that is similar to a monofocal IOL
- Several of the group described **AcrySof®IQ Vivity™** as their "**default lens**," saying it is difficult to find reasons not to use it, including in patients with ocular pathologies
- Preliminary clinical experience data gathered from our patient cases suggest **AcrySof®IQ Vivity™** could be a **great IOL choice for mini-monovision, and potentially post-LASIK and mild glaucoma patients***
- **AcrySof®IQ Vivity™ is a "forgiving lens"** in terms of refractive error and targeting, which makes it an optimal choice when considering mini-monovision for patients

*Preliminary clinical experience is favorable but more data will be needed to confirm this in a larger population.

IOL, intraocular lens; LASIK, laser-assisted *in situ* keratomileusis.

Several of the group described Vivity as their "default lens," saying it is difficult to find reasons not to use it.

A/Prof. Chandra Bala, PersonalEyes, and Macquarie University, Sydney, Australia and Dr. Michael Lawless, Vision Eye Institute and University of Sydney, Australia.

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AcrySof®IQ Vivity™ is a "forgiving" IOL with versatile applications in different target populations

Real-world insights reveal that AcrySof®IQ Vivity™ is a versatile lens that surgeons consider to be a go-to lens

The group agreed that AcrySof®IQ Vivity™ provides excellent distance visual acuity, with extended range of vision to intermediate and functional near, combined with a visual disturbance profile similar to that of a monofocal lens. Personal clinical experience of using AcrySof®IQ Vivity™ that was discussed during the meeting reflected the results of a registration study carried out in the United States (US), which demonstrated excellent distance, intermediate, and functional near visual acuities for AcrySof®IQ Vivity™ (see **Figure 3**).[8,10] AcrySof®IQ Vivity™ was also described as the default lens for many, even in the presence of eye pathologies (see **Figure 4**).

Figure 3: Binocular mean photopic corrected and uncorrected visual acuity at Month 6 for AcrySof®IQ Vivity™ from the US registration study*[8]

- 91.6% of AcrySof®IQ Vivity™ patients (first eyes) achieved MRSE within 0.5 D of emmetropia†

Patients (N)	106
Binocular VA	**Mean logMAR (SD)**
BCDVA	-0.028 (0.084)
UCDVA	0.035 (0.102)
DCIVA	0.054 (0.093)
UCIVA	0.058 (0.083)
DCNVA	0.253 (0.118)
UCNVA	0.208 (0.104)

*Visual acuities were measured at distance, intermediate (66 cm), and near (40 cm); †Surgeons were instructed to select the lens power that targeted emmetropia (closest to 0.0 D) and mean ± SD MRSE in first eyes at 6 months was 0.049±0.345 D for AcrySof®IQ Vivity™.

BCDVA, best-corrected distance visual acuity; D, diopters; DCIVA, distance-corrected intermediate visual acuity; DCNVA, distance-corrected near visual acuity; logMAR, logarithm of the minimum angle of resolution; MRSE, manifest refraction spherical equivalent; SD, standard deviation; UCDVA, uncorrected distance visual acuity; UCIVA, uncorrected intermediate visual acuity; UCNVA, uncorrected near visual acuity; VA, visual acuity.

AcrySof®IQ Vivity™ is a "forgiving" lens that can tolerate residual refractive error

AcrySof®IQ Vivity™ was described as a "forgiving" lens because patients could tolerate some residual refractive error, which encouraged many of the group to feel confident in adopting a mini-monovision approach with patients. Additionally, it was argued that the "forgiving" attributes of AcrySof®IQ Vivity™ could benefit post-LASIK patients, in whom IOL calculations may be difficult.

"Vivity provides excellent distance visual acuity, with extended range of vision to intermediate and functional near, combined with an aspheric monofocal visual disturbance profile."

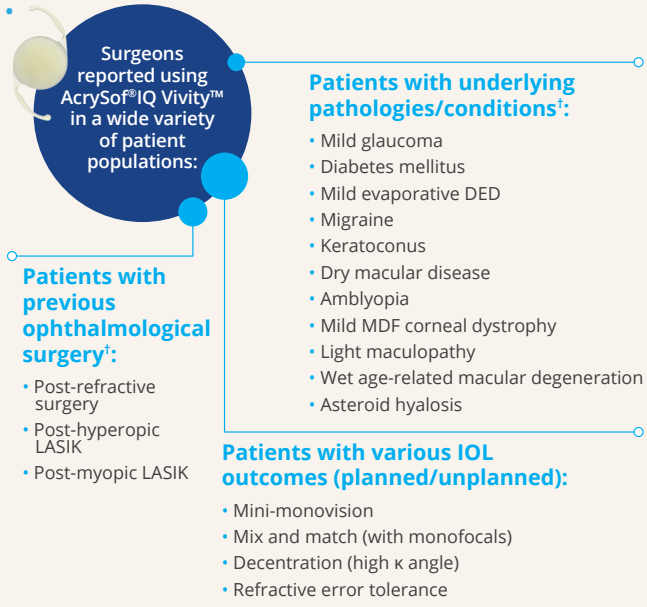
Dr. Francesco Carones, Carones Ophthalmology Center, Milan, Italy.

Mini-monovision using AcrySof®IQ Vivity™

Excellent mini-monovision outcomes achieved with AcrySof®IQ Vivity™

The US registration study demonstrated that AcrySof®IQ Vivity™ extends the range of vision, with improved intermediate and functional near visual acuity compared with a monofocal control.*[9] Although the US registration trial was limited to targeting emmetropia, many in this users experience meeting have utilized a mini-monovision approach with AcrySof®IQ Vivity™ to enhance the benefit of the Wavefront-Shaping X-WAVE™ technology and extend their patients' vision further into the near range, while maintaining monofocal-quality distance visual acuity. Clinical experience from three surgeons' case series, including 62 patients in total, demonstrated that a mini-monovision approach using AcrySof®IQ Vivity™ resulted in excellent distance to near visual acuity (see **Figure 5**). Furthermore, patient satisfaction, as observed by the surgeons in their routine clinical practice, was reported to be high, with no visual disturbances or night vision problems reported in the majority of patients. Spectacle independence has also been reported to be high (see **Figure 6**), although it was noted that it cannot be guaranteed; reading books or newspapers, especially in dim light, or activities involving delicate hand–eye coordination may require spectacle use in some patients (see **Figure 6**).

Figure 4: AcrySof®IQ Vivity™ with Wavefront-Shaping X-WAVE™ technology potentially expands the patient population for presbyopia correction



†The safety and effectiveness of AcrySof®IQ Vivity™ has not been substantiated in clinical trials in patients with certain pre-existing conditions and/or intraoperative conditions, including uncontrolled glaucoma or previous refractive surgery, as these patients were excluded from the clinical studies.[8,9]

DED, dry eye disease; IOL, intraocular lens; κ angle, angle kappa; LASIK, laser-assisted *in situ* keratomileusis; MDF, map-dot-fingerprint.

*AcrySof®IQ Vivity™ provided mean photopic monocular distance-corrected intermediate visual acuity and distance-corrected near visual acuity superior to the monofocal control IOL.

Figure 5: AcrySof®IQ Vivity™ provides excellent visual acuity across distances for patients targeted for mini-monovision

Binocular uncorrected VAs in patients with pristine eyes targeted for mini-monovision

	Dr. Carones	Prof. Bala	Dr. Gundersen
Patients (n)	20	20	22
Mean target MRSE (non-dominant)	-0.47 D	-0.58 D	-0.35 D
VA	Binocular (mean logMAR)	Binocular (mean logMAR)	Binocular (mean logMAR)
UCDVA	-0.08	-0.04	-0.04
UCIVA	0.00 (60 cm)	0.01 (60 cm)	0.00 (100 cm)
UCNVA	0.05 (45 cm)	0.04 (40 cm)	0.01 (50 cm)

All eyes were within ±0.50 D of target MRSE

D, diopters; logMAR, logarithm of the minimum angle of resolution; MRSE, manifest refraction spherical equivalent; UCDVA, uncorrected distance visual acuity; UCIVA, uncorrected intermediate visual acuity; UCNVA, uncorrected near visual acuity; VA, visual acuity.

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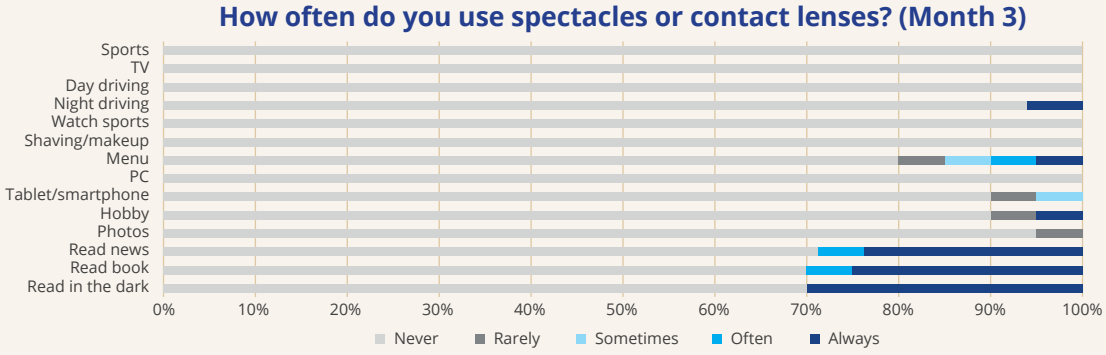
Figure 6: In patients with pristine eyes, mini-monovision using AcrySof®IQ Vivity™ yields high spectacle independence (consecutive case series; n=20*)



*Spectacle independence data from Dr. Carones, collected in their routine clinical practice.

Figure 7: Opinion point: Is this mini-monovision with AcrySof®IQ Vivity™?

Monovision using traditional monofocal IOLs corrects distance vision in the dominant eye, while the non-dominant eye focuses intentionally on near to mid-range vision.[12] "Mini-monovision" requires a smaller interocular refractive error difference than traditional monovision, but typically still in the range of -0.75 and -1.75 D.[12]

With the extended vision gained from AcrySof®IQ Vivity™, an even smaller difference between the eyes (-0.25 D to -0.75 D for the non-dominant eye) could be used to achieve sufficient near vision for some patients, and each eye provides a range of focus in itself, which would potentially increase with binocular summation.

Considering that the patient will not likely perceive a difference between their eyes, the group argued that more patients could tolerate this approach and that the lens will give patients "more natural vision."

Perhaps it's time for new terminology?

AcrySof®IQ Vivity™
EXTENDED VISION IOL

D, diopters; IOL, intraocular lens.

Small refractive offsets can make big visual improvements with AcrySof®IQ Vivity™

Some of the surgeons reported that they have used AcrySof®IQ Vivity™ successfully for mini-monovision, with a refractive target between -0.25 D and -0.75 D for the non-dominant eye bolstering success. The experience using mini-monovision with AcrySof®IQ Vivity™ extends to patients with an array of ocular pathologies, who also stand to benefit from similar outcomes, such as patients with map-dot-fingerprint corneal dystrophy, asteroid hyalosis, dry macular disease, keratoconus, mild amblyopia, glaucoma, post-LASIK correction (myopia and hyperopia), diabetes, and light maculopathy. However, the group also considered whether the term "mini-monovision" was appropriate for AcrySof®IQ Vivity™, or if it should be considered a new treatment paradigm for presbyopia correction (see **Figure 7**).[12]

"Vivity was described as a "forgiving" lens because patients could tolerate some residual refractive error, which encouraged many of the group to feel confident in adopting a mini-monovision approach."

Dr. Merce Guarro, Valles Oftalmologia Recerca, Barcelona, Spain.

Using AcrySof®IQ Vivity™ in post-LASIK eyes

Preliminary clinical experience with AcrySof®IQ Vivity™ in post-LASIK eyes shows early promise

Post-LASIK patients are typically more challenging to treat, given the difficulty of IOL power calculations inherent in the post-LASIK eye due to alterations in the cornea.[13] Furthermore, these patients have high expectations of treatment and are keen to protect their investment in LASIK by retaining or restoring freedom from spectacle use.[13,14] Despite this, promising results have been observed in the limited number of post-LASIK patients who have received AcrySof®IQ Vivity™ (see **Figure 8**).

Although these early results suggest that AcrySof®IQ Vivity™ is an appropriate lens for myopic and hyperopic post-LASIK eyes, success is likely to depend on the degree of corneal irregularities in the post-LASIK eye. Further studies are required to determine the types of corneal irregularities that AcrySof®IQ Vivity™ can tolerate, including safe thresholds for coma and other higher order aberrations.

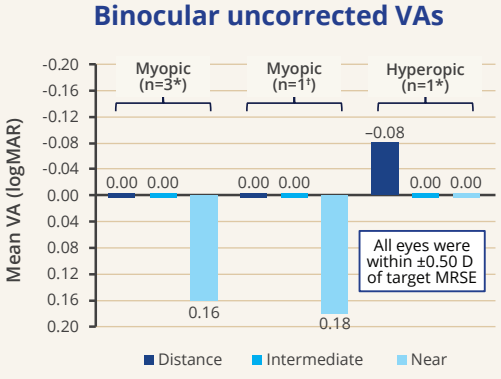
Using AcrySof®IQ Vivity™ in patients with glaucoma

Initial clinical experience in patients with preperimetric and mild glaucoma

Both glaucoma and cataract are common causes of blindness worldwide, and frequently coexist in the elderly population.[15] Therefore, it was of particular interest to understand how AcrySof®IQ Vivity™ performs in patients with glaucoma. Initial experience from 2 patient cases shows both cases achieved good visual outcomes at all distances (see **Figure 9**).

Another consideration in glaucoma patients is contrast sensitivity, which has been suggested in this target population to be linked to subjective complaints

Figure 8: Preliminary visual acuity data at distance, intermediate and near in post-LASIK eyes implanted with AcrySof®IQ Vivity™

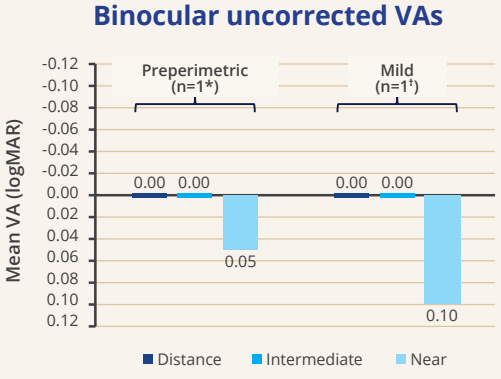


Target MRSE in non-dominant eye was approximately -0.5 D.

*Dr. Carones's patient cases, with VA measured at distance, intermediate (60 cm), and near (45 cm); †Prof. Braga-Mele's case study, with VA measured at distance, intermediate (60 cm), and near (40 cm).

D, diopters; LASIK, laser-assisted *in situ* keratomileusis; logMAR, logarithm of the minimum angle of resolution; MRSE, manifest refraction spherical equivalent; VA, visual acuity.

Figure 9: Visual acuity data from individual patients with preperimetric or mild glaucoma (n=2)



*Dr. Gundersen's case study, with VA measured at distance, intermediate (100 cm), and near (50 cm); †Prof. Kohnen's case study, with VA measured at distance, intermediate (66 cm), and near (40 cm).

LogMAR, logarithm of the minimum angle of resolution; VA, visual acuity.

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of blurred vision.[16] In the US registration study, reported outcomes in AcrySof®IQ Vivity™ patients (albeit without ocular comorbidities) were similar or better than monofocal controls for hazy and blurred vision, despite observed reductions in monocular mesopic contrast sensitivity with increasing spatial frequency.*[8,9] It would be important to study this further and understand if glaucoma patients report similar results.

On reflection of the available data, the group agreed that AcrySof®IQ Vivity™ could be considered in patients with preperimetric and mild glaucoma. However, further research is required to determine the performance of AcrySof®IQ Vivity™ in individuals with glaucoma.

*The proportion of patients who reported that they did not experience hazy vision was 88.6% and 86.5% for AcrySof®IQ Vivity™ and monofocal, respectively (95% CI -7.2, 11.3). Significantly more AcrySof®IQ Vivity™ patients (90.6%) than monofocal patients (80.2%) reported that they did not experience blurred vision (95% CI 0.6, 20.1).[9]

“A mini-monovision approach using Vivity resulted in excellent distance to near visual acuity, with no visual disturbances or night vision problems reported in the majority of patients.”

Dr. Kjell Gunnar Gundersen, Ifocus Øyeklinikk AS, Haugesund, Norway.

Summary

AcrySof®IQ Vivity™ IOL is the First and Only Extended Depth of Focus (EDoF) IOL with the Wavefront-Shaping X-WAVE™ technology, which provides a continuous extended range of vision from distance to functional near, reduces patients' reliance on spectacles, and has an aspheric monofocal visual disturbance profile. Early clinical experience suggests that AcrySof®IQ Vivity™ is a versatile technology that can be used in pristine eyes, as well as those with certain ocular pathologies. As clinical experience and confidence in the IOL grows, surgeons may gradually expand their use of AcrySof®IQ Vivity™ to other patient groups. In the meantime, Alcon remains committed to ongoing research to help guide how best to use AcrySof®IQ Vivity™ in practice.

Based on initial observations of these real-life patient cases:

Mini-monovision: AcrySof®IQ Vivity™ was considered a great choice for mini-monovision by advisors

Post-LASIK: Many surgeons have extended the application of AcrySof®IQ Vivity™ to post-LASIK eyes

Glaucoma: AcrySof®IQ Vivity™ may be considered for patients with preperimetric or mild glaucoma

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