Scientific Research Publishing

Journal of Biosciences and Medicines, 2025, 13(11), 291-302
https://www.scirp.org/journal/jbm
ISSN Online: 2327-509X
ISSN Print: 2327-5081

Clinical Application Analysis of Vivity Intraocular Lens

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How to cite this paper: Chen, Y., Wang, J.H. and Wu, B. (2025) Clinical Application Analysis of Vivity Intraocular Lens. *Journal of Biosciences and Medicines*, **13**, 291-302.
https://doi.org/10.4236/jbm.2025.1311020

Received: October 14, 2025
Accepted: November 11, 2025
Published: November 14, 2025

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Abstract

The demand for full-range visual quality in refractive cataract surgery has driven the development of non-diffractive extended depth of focus (EDOF) intraocular lenses (IOLs). Vivity achieves depth of focus extension through the X-Wave™ wavefront shaping technology (a 2.2 mm central dual smooth surface transition element). Its hydrophobic acrylate material reduces the incidence of posterior capsule opacification (PCO) and filters harmful blue light, while the modified L-haptic design ensures capsular bag centration. Clinical data shows that in both the cataract cohort and the refractive lens exchange (RLE) cohort with bilateral Vivity implantation, the uncorrected distance visual acuity (UDVA) and uncorrected intermediate visual acuity (UIVA) are excellent, while the uncorrected near visual acuity (UNVA) is adequate for daily needs. The spectacle independence rates for distance, intermediate, and near vision were 87.9%/86.6%, 77.6%/79.3%, and 46.1%/59.8% (cataract/RLE cohorts), respectively. Additionally, 91.8%/84.1% of patients reported no visual disturbances, and the satisfaction rate exceeded 85%. Clinical comparisons indicate that Vivity exhibits optical quality close to that of monofocal IOLs, a longer depth of focus than monofocal IOLs, fewer visual disturbances than diffractive multifocal IOLs, a relatively wide depth of focus range, and excellent resistance to tilt and decentration. However, Vivity has limitations, including insufficient fine near vision (most patients require low-power near vision add-ons), significant pupil dependence, and a lack of long-term data beyond 3 years. Strategies to optimize its application include adopting a micro-monovision design to improve near vision and adapting it for patients with mild epiretinal membranes and early age-related macular degeneration (AMD). Conclusion: Vivity is a recommended option for patients who require distance and intermediate vision and cannot tolerate optical disturbances from diffractive IOLs. However, in clinical practice, precise selection based on ocular parameters and visual needs is essential.

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Keywords

Vivity Intraocular Lens, Extended Depth of Focus Intraocular Lens (EDOF), Refractive Cataract Surgery, Visual Quality, Spectacle Independence Rate, Optical Disturbance, Clinical Application Optimization

1. Introduction

Against the backdrop of refractive cataract surgery entering the era of full-range visual quality optimization, the "visual blind spots" of traditional monofocal intraocular lenses (IOLs) and "optical disturbances" of diffractive multifocal IOLs have become clinical contradictions urgently to be resolved. As a non-diffractive wavefront reshaping extended depth of focus (EDOF) product, the Vivity IOL obtained marketing approval in 2023 through the Special Review Procedure for Innovative Medical Devices of the National Medical Products Administration (NMPA) of China. This article systematically sorts out the technical principles and clinical data of Vivity, conducts an in-depth analysis of its application advantages and limitations, and proposes targeted improvement strategies, aiming to provide references for precise decision-making in refractive cataract surgery.

2. Design Principles of the Vivity Intraocular Lens

The core breakthrough of Vivity lies in achieving depth of focus extension through non-diffractive wavefront modulation technology, and its design system covers three dimensions: optical principle, material properties, and structural optimization.

2.1. Optical Design: X-Wave™ Wavefront Shaping Technology

The design principle of Vivity is that in the central 2.2 mm zone of the anterior surface of the IOL, two smooth surface transition elements are used to effectively alter the propagation distance of light entering the eye, generating a continuously extended field of view from distance to functional near vision. The first element is a slightly elevated smooth flat top (approximately 1 μm in height), which stretches the wavefront to form a continuous extended depth of focus. The second element is a small curvature change within the entire 2.2 mm central optical zone, which ensures that most of the light energy is utilized. After light passes through the surface transition elements, the resulting wavefront shape is consistent with the anterior side of the IOL. The peripheral parts of the wavefront advance, while the central part of the wavefront is delayed, thereby generating a continuously extended focal length range. Notably, the very central portion of the wavefront reshaping technology is not elevated; instead, it adopts a design with small curvature variations. Therefore, even when the pupil diameter is less than 2.2 mm, light passing through the 2.2 mm curvature-variation functional zone at the center of the intraocular lens (IOL) can still be effectively reshaped, providing patients with a continuously extended depth of field. The optical advantages of this design are reflected in two aspects: first, it avoids light energy loss caused by diffractive structures, allowing more than 90% of incident light to be used for effective imaging, and its contrast sensitivity is close to that of monofocal IOLs; second, it eliminates the "optical break point" at the focal transition, and the defocus curve shows a smooth transition characteristic, so patients do not experience obvious visual jumps when viewing objects. Additionally, the dual-surface transition elements of Vivity further optimize the focusing efficiency of mid-distance light.

2.2. Material Properties: Biocompatibility Optimization of Hydrophobic Acrylate

The Vivity IOL is made of a hydrophobic acrylate/methacrylate copolymer, which can adhere closely to the lens capsule, reduce epithelial cell proliferation, and significantly lower the incidence of posterior capsule opacification (PCO). Moreover, the lens has a pale yellow tint that filters harmful blue light to prevent damage. It exhibits excellent biocompatibility, causes mild postoperative inflammatory responses, and is suitable for long-term implantation.

2.3. Structural Parameters: Detailed Design Adapting to Clinical Needs

The structural parameters of Vivity are optimized around surgical operation and visual effects: The optical zone diameter is 6.0 mm, which is compatible with the pupil size of most patients. It adopts a modified L-haptic design, which provides excellent intracapsular centration and good rotational stability, preventing the IOL from shifting or rotating after surgery and ensuring stable postoperative vision. This feature also enables the IOL to exhibit excellent rotational stability in astigmatism correction [1]. The edge of the optical zone is treated with a smooth transition to reduce the risk of glare caused by light scattering [2]. In addition, it offers a refractive power range from +10.00 D to +30.00 D in 0.5 D increments, accommodating a wide range of patients from high hyperopia to high myopia.

3. Product Advantages of the Vivity Intraocular Lens

Based on the aforementioned design features, the Vivity IOL demonstrates core advantages of "continuous vision, high-quality imaging, and high patient satisfaction" in clinical applications, with relevant data validated by multicenter studies.

3.1. Good Distance and Intermediate Vision, and Adequate Near Vision

A multicenter study (n = 885) showed that for patients with bilateral Vivity IOL implantation: In the cataract cohort, the mean ± standard deviation (SD) logMAR (Snellen) values for uncorrected distance visual acuity (UDVA), uncorrected intermediate visual acuity (UIVA), and uncorrected near visual acuity (UNVA) were 0.012 ± 0.102 (approximately 20/20), 0.088 ± 0.118 (approximately 20/25), and 0.256 ± 0.154 (approximately 20/40), respectively. In the refractive lens exchange (RLE) cohort, the corresponding values were -0.005 ± 0.088 (approximately 20/20), 0.054 ± 0.141 (approximately 20/25), and 0.213 ± 0.151 (approximately 20/32) [3]. Meanwhile, a non-interventional study reported that the mean binocular logMAR visual acuity was (−0.07 ± 0.07) at 4 meters, (0.00 ± 0.07) at 66 cm, and (0.07 ± 0.11) at 40 cm [4].

3.2. Contrast Sensitivity

The Vivity IOL exhibits excellent contrast sensitivity under different lighting conditions [5], meaning it provides better visual performance in low-contrast environments such as nighttime or rainy days.

3.3. Glasses Independence Rate

In the cataract cohort, the proportions of patients reporting glasses independence for distance, intermediate, and near vision were 87.9%, 77.6%, and 46.1%, respectively; in the RLE cohort, the rates were 86.6%, 79.3%, and 59.8% [3]. This significantly reduces patients' dependence on glasses.

3.4. Optical Disturbances

91.8% of patients in the cataract cohort and 84.1% in the RLE cohort reported no visual disturbances [3]. Over 95% of subjects reported that glare, halos, and starbursts were "not at all" or "slightly" bothersome [4]. The Vivity IOL performs best in terms of halo perception, producing the fewest halos [5].

3.5. Patient Satisfaction

The majority of patients in the cataract cohort (92.1%) and RLE cohort (85.4%) were satisfied with their postoperative vision [3].

4. Clinical Comparative Studies of the Vivity Intraocular Lens

By comparing the Vivity IOL with monofocal IOLs, diffractive multifocal IOLs, and other EDOF IOLs, its clinical positioning and applicable scenarios can be clearly defined.

4.1. Comparison with Monofocal Intraocular Lenses

4.1.1. Equivalent Optical Quality to Monofocal IOLs

The central optical zone of the Vivity IOL features two symmetric height variations of approximately 1 μm. Compared with the SN60WF monofocal IOL, the Vivity IOL has smoother surface variations, which plays a key role in creating a continuous focal range while minimizing visual disturbances [2]. Clinical data indicate that, compared with monofocal IOLs, wavefront shaping technology achieves a continuous extended depth of focus while generating minimal halos—similar to aspheric monofocal IOLs [6].

4.1.2. Wider Depth of Focus, Resolving Intermediate Vision Blind Spots

In a laboratory study, light propagation visualization and intensity distribution of the AcrySof IQ SN60WF monofocal IOL (control group) showed a distinct focal point, whereas the AcrySof IQ Vivity IOL exhibited an extended focusing area [7]. In an experiment using optical metrology equipment, at a visual acuity level of 0.20 logMAR, the EDOF IOL (Vivity) had a depth of focus increased by at least 0.75 diopters (D) compared with the monofocal ZCB00 IOL [8].

4.1.3. Higher Glasses Independence Rate

Patients with bilateral implantation of the AcrySof IQ Vivity IOL showed a high rate of glasses independence for distance to intermediate vision [3].

Conclusion: The distance visual quality of Vivity is comparable to that of monofocal intraocular lenses. Meanwhile, its wide depth of field ensures excellent intermediate visual acuity, which significantly increases the spectacle independence rate and improves patients' quality of life.

4.2. Comparison with Multifocal Intraocular Lenses

4.2.1. Fewer Postoperative Visual Disturbances and Higher Satisfaction

Compared with the PanOptix group (69%, $p < 0.03$), ReStor 2.5 monovision group (75%, $p < 0.05$), or ReStor 2.5/3.0 group (71%, $p < 0.05$), patients in the Vivity cohort were less likely to notice glare and halos in low light (85% reported "none" or "only a little") [9].

4.2.2. Better Tolerance to Residual Refractive Errors

Compared with the monofocal AcrySof SA60AT group (0.24 ± 0.07 at 3 mm) and the EDOF AcrySof IQ Vivity group (0.23 ± 0.06 at 3 mm), the retinal image quality (point spread function [PSF] including light offset analysis [LOA]) of the AT LISA tri 839MP was most severely affected by such residual refractive errors (decreasing to 0.26 ± 0.06 at 3 mm; $p < 0.001$) [10].

4.2.3. Relatively Inferior Near Vision

The proportion of patients who achieve complete spectacle independence across all visual activities in the Vivity cohort is significantly lower than that in the PanOptix cohort, particularly in terms of near visual acuity [11].

Conclusion: Diffractive trifocal IOLs are marketed for "full-range vision" but at the cost of optical disturbances. This comparison highlights the "balanced advantage" of the Vivity IOL: it achieves better contrast sensitivity and fewer optical disturbances by making a slight compromise in near vision. It is suitable for patients who prioritize nighttime visual quality and can accept occasional glasses use for reading. For patients with extreme demands for near vision who can tolerate optical disturbances, PanOptix is more appropriate.

4.3. Comparison with Other EDOF Intraocular Lenses

4.3.1. Wider Depth of Focus

The full-focal-length modulation transfer function (MTF) of three IOLs—Tecnis Symfony (diffractive), wavefront-shaped AcrySof IQ Vivity, and LuxSmart Crystal IOL (all 22D)—was studied on an optical bench. All three IOLs showed two peaks in their full-focal-length MTF curves, representing the primary and secondary focal points, with the peaks of the Symfony being the most prominent. At a 3 mm aperture, the diopter differences between the far and intermediate focal points were 1.25 D (Symfony), 1.75 D (Vivity), and 1.5 D (LuxSmart) [12], indicating a wider depth of focus for the Vivity IOL.

4.3.2. Fewer Visual Disturbances

A laboratory comparison of the point spread functions (PSFs) of four IOLs—AcrySof IQ Vivity, Symfony ZXR00, AT Lara 829 MP, and AcrySof IQ SN60WF—revealed that the AcrySof IQ Vivity had less light diffusion outside the PSF center. Additionally, the transition of the Vivity IOL's extended focal range from distance to intermediate vision appeared smoother [7], which also confirms that the Vivity IOL is less likely to cause bothersome visual disturbances [13].

4.3.3. Stronger Tolerance to Tilt and Decentration

An optical bench comparison of AcrySof Vivity, LuxSmart Crystal, RayOne EMV, and Tecnis Eyhance (all 22 D) showed that tilt and decentration significantly reduced the performance of Eyhance, but had minimal impact on the performance of Vivity and LuxSmart [14].

Conclusion: Compared with other EDOF IOLs, the Vivity IOL offers a wider depth of focus and demonstrates greater advantages in controlling optical disturbances and tolerating tilt and decentration.

5. Product Shortcomings and Clinical Limitations of the Vivity Intraocular Lens

Despite its excellent performance, existing clinical data still reveal shortcomings of the Vivity IOL in terms of design characteristics, indication coverage, and long-term efficacy, which require clinical attention.

5.1. Inferior Near Vision

A prospective interventional single-center study indicated that the AcrySof IQ Vivity is a well-tolerated and effective IOL, achieving optimal refractive outcomes for distance and intermediate vision, but requires a slight spherical add to obtain optimal near vision [15]. A prospective observational study at an Indian hospital showed that after Vivity IOL implantation, distance and intermediate vision were good, but most near-distance activities required the use of near-vision add glasses, although the required add power was relatively low [16]. Research by Arrigo A *et al*. demonstrated that the AcrySof® IQ Vivity® IOL is a well-tolerated option for correcting distance and intermediate vision, but glasses are needed to optimize near vision [17].

5.2. Significant Pupil Dependence

A study of four IOLs (Lentis Comfort, MiniWell, LuxSmart, and Vivity) using optical metrology equipment found that MiniWell, LuxSmart, and Vivity exhibited more obvious pupil dependence, while Lentis showed more consistent performance across different apertures [8]. Analysis of uncorrected near vision (UNVA) after AcrySof Vivity IOL implantation suggested that eyes with smaller pupils may benefit in terms of UNVA [18].

5.3. Insufficient Follow-Up Data beyond 3 Years

Currently, the longest follow-up data available is 3 years. Although no obvious safety risks have been identified, uncertainties remain regarding long-term IOL capsular bag stability (e.g., whether delayed tilt occurs) and the impact of material aging on optical performance (e.g., decreased light transmittance).

6. Clinical Application Improvement Strategies for the Vivity Intraocular Lens

6.1. Precision Surgical Design: Micro-Monovision Design

Bilateral implantation of AcrySof® IQ Vivity IOLs using the micro-monovision approach can provide excellent distance and intermediate vision, as well as good near vision, resulting in high patient satisfaction [11]. Bansal M *et al.* adopted a micro-monovision strategy, achieving glasses independence rates of 100%, 94.7%, and 94.7% for distance, intermediate, and near vision, respectively. All defocus curves were smooth and broad, with uncorrected defocus curves (using the micro-monovision strategy) outperforming corrected defocus curves. The AcrySof IQ Vivity IOL demonstrated excellent subjective and objective visual performance [19]. A clinical institution in the United States reported that implanting the AcrySof IQ Vivity IOL in the non-dominant eye with a mild myopic target (an increase of 0.45 D in spherical equivalent refractive error) is a feasible method to improve near vision, albeit with a slightly increased risk of visual disturbances [20]. An ambulatory surgical center at the University of São Paulo in Ribeirão Preto, Brazil, compared the visual performance and glare disturbances of Symfony and Vivity using a micro-monovision design. Results showed no significant differences between the two IOLs in terms of distance vision, defocus curves, Patient-Reported Index of Spectacle Independence (PRISC), contrast sensitivity, or reading speed. Both exhibited good micro-monovision tolerance, and the Vivity IOL had a lower likelihood of causing bothersome visual disturbances [13]. Meanwhile, clinical data also indicate that better visual outcomes are achieved when the degree of monovision is limited to within −0.50 diopters. This not only ensures good distance visual acuity and satisfactory near visual acuity but also minimizes visual disturbances caused by anisometropia [18].

6.2. Adaptability: Breaking Indication Limitations of Traditional Functional IOLs

A study compared 45 eyes with mild epiretinal membrane (ERM) implanted with the Vivity IOL and 50 age-matched control eyes implanted with the Vivity IOL without ERM. Eyes with mild ERM showed comparable outcomes to those without ERM after Vivity implantation. Implantation of this newly developed low-add EDOF IOL may benefit eyes with mild, reversible ERM confined to the inner retinal layer [21]. The Vivity IOL provides a satisfactory range of vision for patients with early age-related macular degeneration (AMD) while maintaining a certain level of contrast sensitivity [22]. Furthermore, study results indicate that both non-astigmatic and astigmatic versions of the Vivity IOL can provide excellent distance and intermediate vision, as well as functional near vision, for eyes with long axial lengths (≥24.5 mm). High rates of glasses independence for distance and intermediate vision, high patient satisfaction, and minimal visual disturbances were also observed [23]. For patients sensitive to optical disturbances—who may experience severe halos or glare and fail to adapt to diffractive IOLs—the Vivity IOL can reduce optical disturbance symptoms and improve visual satisfaction. For patients with abnormal pupils: the Vivity IOL can still provide partial depth of focus for patients with pupils smaller than 2.2 mm [6].

6.3. Cost-Effectiveness Optimization

A private health fund in Australia evaluated the cost-effectiveness of the AcrySof IQ Vivity IOL (DFT015) compared with the standard aspheric monofocal IOL (SN60WF). Assessing IOL costs, postoperative glasses dependence, and the disutility of wearing glasses, the AcrySof IQ Vivity IOL was found to be a highly cost-effective treatment strategy, delivering vision-related quality of life improvements for patients undergoing cataract surgery for presbyopia [24].

6.4. Enhanced Long-Term Follow-Up

Establish a standardized follow-up protocol at 1, 3, 6, 12, 24, 36, and 60 months postoperatively. Key monitoring items include material light stability, corneal endothelial cell density, IOL position, and capsular bag stability. Early intervention should be provided for posterior capsule opacification (PCO) and macular edema.

7. Future Outlook

As a representative product of wavefront reshaping-type extended depth of field (EDOF) intraocular lenses, Vivity can advance the further upgrading of refractive cataract surgery by focusing on three core development directions: "technological iteration, indication expansion, and intelligent adaptation".

7.1. Product Technological Iteration: Overcoming Existing Performance Limitations

Optical design optimization: The next-generation Vivity IOL is expected to adopt a "variable depth of focus" design. By adjusting the surface curvature of the optical zone, it will achieve personalized balance between near and intermediate vision. Additionally, a large optical zone version will be introduced to accommodate high myopic patients with large pupils.

Material innovation: Develop composite materials with both hydrophobic and hydrophilic properties to further reduce PCO incidence. Integrate dual UV and blue light filtering technology to enhance retinal protection.

Function expansion: Develop an adjustable Vivity IOL driven by capsular bag contraction force to move the optical zone, achieving an accommodation amplitude of over 1.00 D to address the shortcoming of insufficient near vision.

7.2. Indication Expansion: Covering More Complex Ocular Conditions

High astigmatism correction: Launch high-astigmatism correction versions combined with personalized axis marking technology to accommodate patients with severe astigmatism.

Adaptation for patients with fundus diseases: Conduct multicenter studies on the Vivity IOL in patients with moderate AMD and stable diabetic macular edema to clarify its impact on disease progression and expand indication scope.

Application in pediatric cataracts: Develop a small-sized pediatric version of the Vivity IOL using materials with better biocompatibility to adapt to the developmental needs of children's eyes and address the shortage of functional IOLs for children.

7.3. Intelligent and Precise Application

AI-assisted adaptability system: An artificial intelligence model trained on big data will integrate patients' ocular parameters, visual needs, and lifestyle habits to automatically generate Vivity adaptability scores and surgical plan recommendations, with a target accuracy of over 95%.

Personalized optical design: Combine wavefront aberration measurement data to customize the optical zone of the Vivity IOL, compensating for individual spherical and chromatic aberrations and improving contrast sensitivity by an additional 10% - 15%.

Integration with surgical robots: Achieve full-automated operations (capsulorhexis, phacoemulsification, and IOL implantation) through in-depth collaboration with cataract surgical robots, reducing IOL decentration to <5% and further optimizing visual outcomes.

8. Conclusion

With its X-Wave™ wavefront shaping technology, the Vivity IOL demonstrates excellent performance in continuous vision coverage, contrast sensitivity, glasses independence rate, optical disturbance control, and patient satisfaction. Its prominent advantages in distance and intermediate vision, combined with broad indication compatibility, make it the preferred option for most cataract patients who do not require precise near vision and cannot tolerate optical disturbances caused by diffractive IOLs. Although limitations such as insufficient near vision and restricted adaptation to special pupils exist, these drawbacks can be effectively addressed through personalized surgical techniques and precise indication matching. In the future, with the iterative upgrading of product technology and the establishment of intelligent adaptability systems, the Vivity IOL is expected to overcome current performance boundaries, cover more patients with complex ocular conditions, and further consolidate its core position in the field of functional IOLs. Clinicians should fully understand its design characteristics and clinical data, and make precise selections based on individual patient needs to maximize its clinical value.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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