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Alcon Vivity, Extended Depth of Focus (EDoF) Lens Implants

The Vivity lens has the same basic shape and construction to that of the standard, monofocal Alcon IQ lens, which Mr Tanner has used for many years. The Alcon IQ monofocal lens is one of the most frequently implanted lenses worldwide and has an excellent safety profile. Like a monofocal lens, the purpose of the Vivity Extended Vision implant is to focus images clearly onto the back of your eye (retina) to allow clear vision after cataract removal. The Vivity lens has an additional, new, wavefront-shaping technology which allows a wider range of focused image than with a monofocal lens, helping decrease the need for glasses. The Vivity lens is also available in a toric version to help decrease astigmatism (oval rather than round cornea). The most benefit is gained from the Vivity lens when it is implanted in both eyes.

Clinical trial data, and Mr Tanner's own results, have meant that the Vivity lens is now Mr Tanner's preferred lens for patients undergoing cataract surgery who wish to reduce their spectacle requirement whilst avoiding most of the side effects associated with previous multifocal lens. The Vivity is the most commonly used extended depth of focus implant, with over million Vivity lenses implanted worldwide.

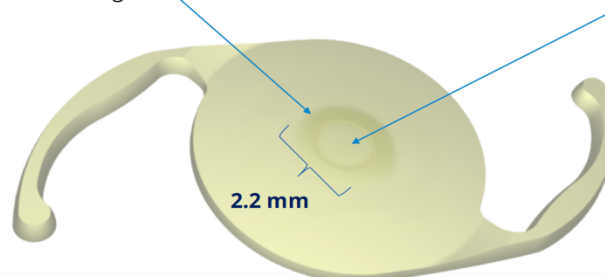
X-WAVE™ Technology consists of 2 smooth-surface transition elements that stretch and shift the wavefront^{3,8-9}

Surface Transition #1:

Slightly Elevated Smooth Plateau (~1 μ m high) **stretches** the wavefront, creating a continuous extended focal range

Surface Transition #2:

Small Curvature Change (across the ~2.2 mm region) **shifts** the wavefront to utilise all available light energy



Range of Vision Results

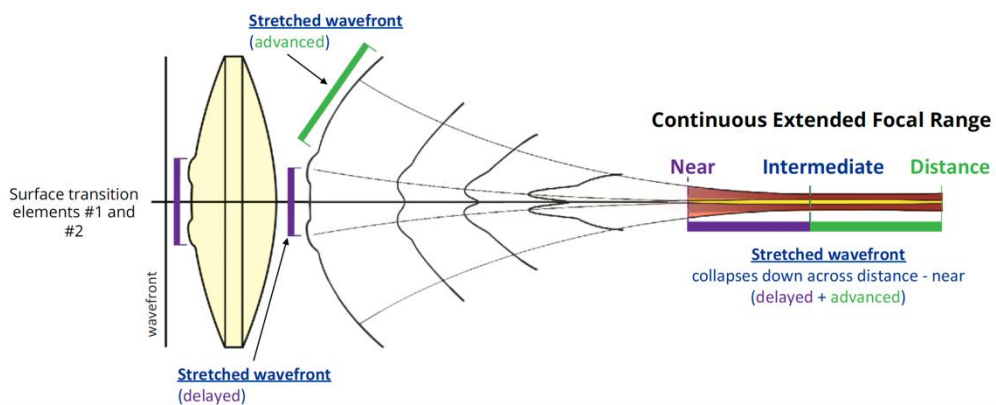
Patients in the study were also asked about how often they needed glasses to see distance, intermediate, and near objects overall, and in bright and dim light separately. A comparison of the rate of patients reporting “rarely” or “never” needing to wear glasses is presented below. Overall, Vivity IOL patients reported needing to wear glasses less than monofocal IOL patients, especially at intermediate distance and in brighter light.

Comparison of Patients Reporting “Rarely” or “Never” Needing to Wear Glasses

Condition and Distance		Rate of “Rarely” or “Never” Needing to Wear Glasses	
		Vivity IOL	Monofocal IOL
Bright Light	Distance	Almost all patients (94/100)	Almost all patients (92/100)
	Intermediate	Almost all patients (87/100)	More than half patients (58/100)
	Near	About half of patients (46/100)	Some patients (16/100)

Assuming a good outcome with first eye surgery, allowing excellent distance vision with no glasses, Mr Tanner may recommend “micro mono-vision”. This adjusts the outcome in second eye to further enhance ability to read without glasses but avoiding any significant imbalance between the eyes.

X-WAVE™ Technology: Surface Transition Elements Affect Speed of the Wavefront^{1,3}



- Surface transition element #1 alters the wavefront, stretching it
- Surface transition element #2 shifts the wavefront
- The simultaneous actions deliver a naturally occurring continuous extended focal range

Potential Side Effects Associated with AcrySof™ IQ Vivity™ ExtendedVision IOLs

There are some side effects that can be associated with the design of all implants that provide a broader range of vision, which may be worse than with a monofocal IOL. These side effects include visual disturbances such as glare, rings around lights, starbursts, and a decrease in ability to distinguish objects from their background, especially in dim lighting. These side effects may make it more difficult to see in some situations. The side effect profile of the Vivity is however very similar to that of the standard monofocal lens as summarized in the table below.

Rates of “Very Severe” Visual Disturbances, per 100 patients, 6 months After Surgery

Visual Disturbance	AcrySof IQ Vivity IOL Rate	Monofocal IOL Rate
	6 Months	6 Months
Starbursts	4 out of 100 patients	3 out of 100 patients
Halos	1 out of 100 patients	1 out of 100 patients
Glare	No (0) patients	No (0) patients
Hazy Vision	No (0) patients	No (0) patients
Blurred Vision	No (0) patients	No (0) patients
Double Vision	No (0) patients	No (0) patients
Dark Area	1 out of 100 patients	1 out of 100 patients

Contrast Sensitivity

Contrast sensitivity, an important measure of visual function, is the ability to distinguish objects from their background, especially in dim lighting. In the Vivity clinical study, contrast sensitivity in dim lighting was reduced in patients who received the AcrySof IQ Vivity IOL compared to those who received the Monofocal IOL.

- As with other IOLs, if there are unexpected results, there is a chance you may need to continue wearing eyeglasses or may need a second surgical procedure to reposition your IOL.
- After surgery, it may be more difficult to see well in dim or low-contrast situations, especially with a bright light shining in your eyes, than it would be with a monofocal IOL. Therefore, you should take extra care in situations like driving at night, especially if there is oncoming traffic.
- It is possible you could be bothered very much by visual disturbances, to the extent that you may request explant of the AcrySof IQ Vivity IOL. In the Vivity clinical study, two out of 100 Vivity patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances; however, no explants were reported. One in a hundred patients receiving a monofocal lens also reported similar symptoms.

Provide patients with monofocal-quality distance with excellent intermediate and functional near vision.¹¹ Vivity® expands visual possibilities.

By harnessing the power of non-diffractive X-WAVE™ Technology, the Clareon® Vivity® IOL helps your patients take advantage of enhanced vision where they need it most.



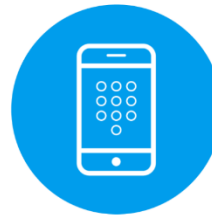
Monofocal-quality distance vision

Binocular Mean Uncorrected Distance Visual Acuity¹²
20/20



Excellent intermediate vision

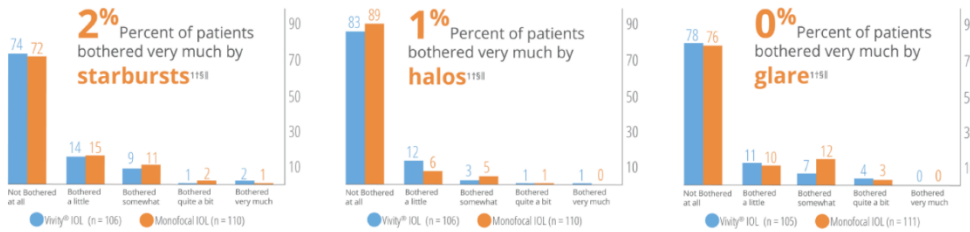
Binocular Mean Uncorrected Intermediate Visual Acuity (26 in)¹²
>20/25



Functional near vision

Binocular Mean Uncorrected Near Visual Acuity (16 in)¹²
20/32

Low levels of patient reported visual disturbances^{15§}



* Based on in vitro examinations of glisterings, surface haze and SSNGs.

[†] Results from a prospective, randomized, parallel group, subject- and assessor-masked, multisite trial of 107 subjects bilaterally implanted with the AcrySof® IQ Vivity® IOL and 113 with the AcrySof® IQ IOL with 6 months follow-up.

[‡] Snellen VA was converted from logMAR VA. A Snellen notation of 20/20-2 or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.

[§] Assessed using QUID questionnaire.

^{||} AcrySof® IQ Vivity® was tested. AcrySof® IQ Vivity® and Clareon® Vivity® are optically equivalent.