

## The Landscape of Presbyopia Correction with IOLs

Elizabeth Yeu, MD<sup>1\*</sup>

Andrea Petznick, Diplom-AO (FH), PhD<sup>2</sup>

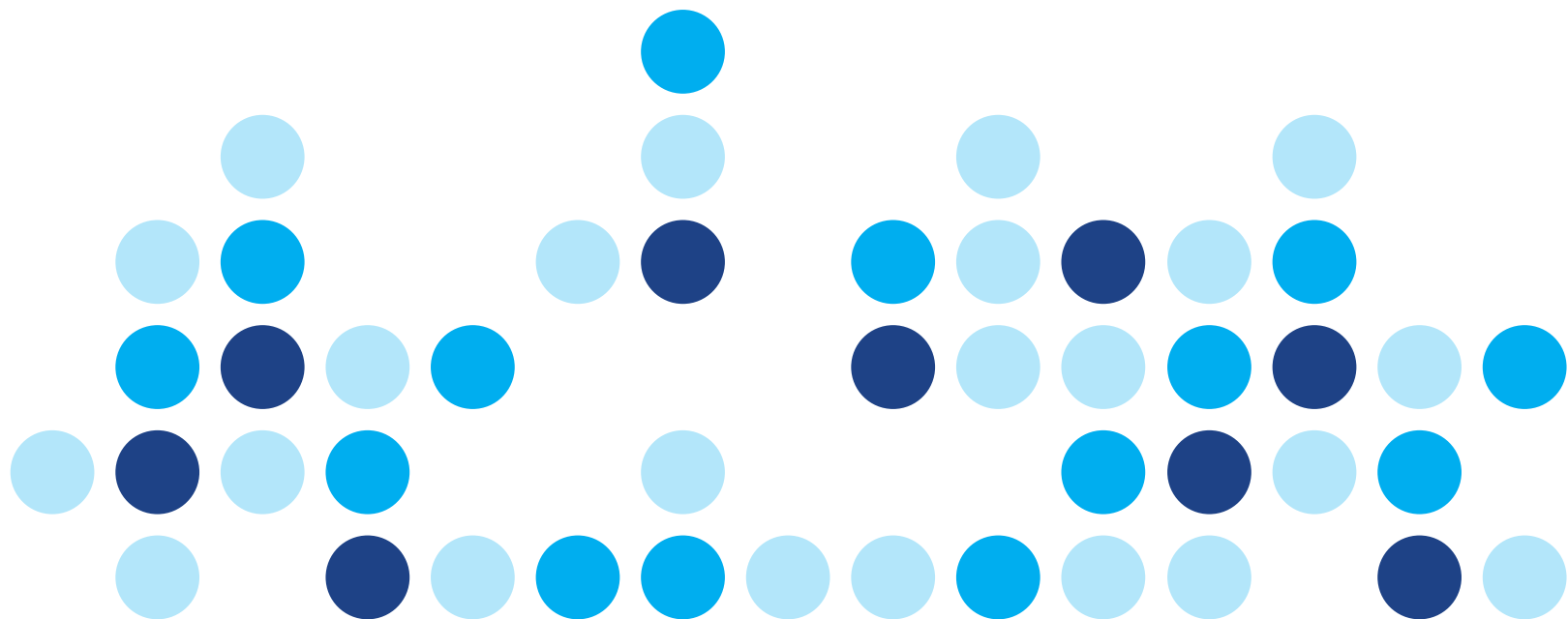
Xiaolin Gu, MD, PhD<sup>3</sup>

1. Virginia Eye Consultants, Norfolk, VA;  
Assistant Professor of Ophthalmology, Eastern Virginia Medical School, Norfolk, VA

2. Formerly of Alcon Medical Affairs, North America, Ft. Worth, TX

3. Alcon Medical Affairs, Fort Worth, TX

*\*Elizabeth Yeu is a paid consultant to Alcon.*



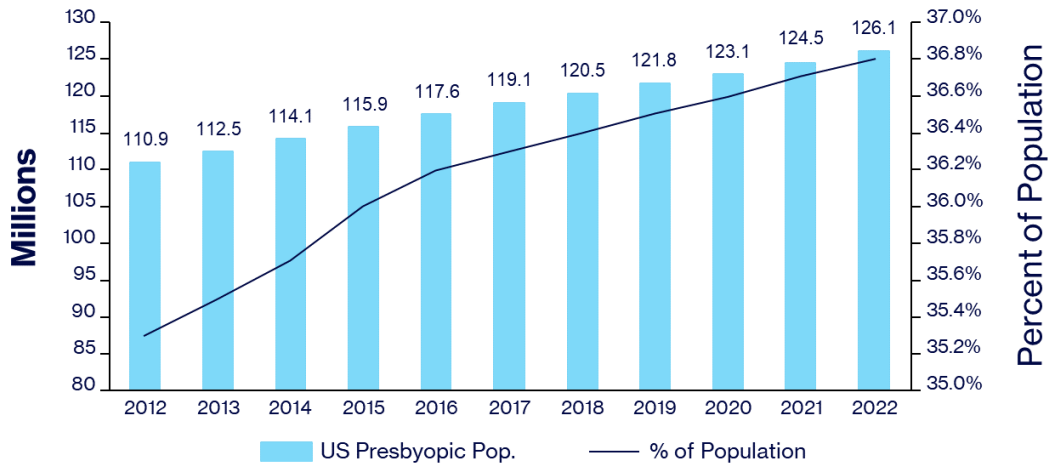
# Introduction

Surgeons have been able to offer presbyopia-correcting intraocular lenses (PCIOLs) for well over a decade. However, only 9% of current US cataract surgeries involved the use of PCIOLs, as assessed by the ASCRS 2018 survey of approximately 1000 US & non-US surgeons.<sup>1</sup> This presents an opportunity to further educate surgeons and patients on the availability and benefits of PCIOLs.

Understanding the different types of PCIOLs and their different mechanisms of action is important to ensure proper patient selection and postoperative patient satisfaction. This white paper provides an overview of the various PCIOL technology options currently available in the United States.

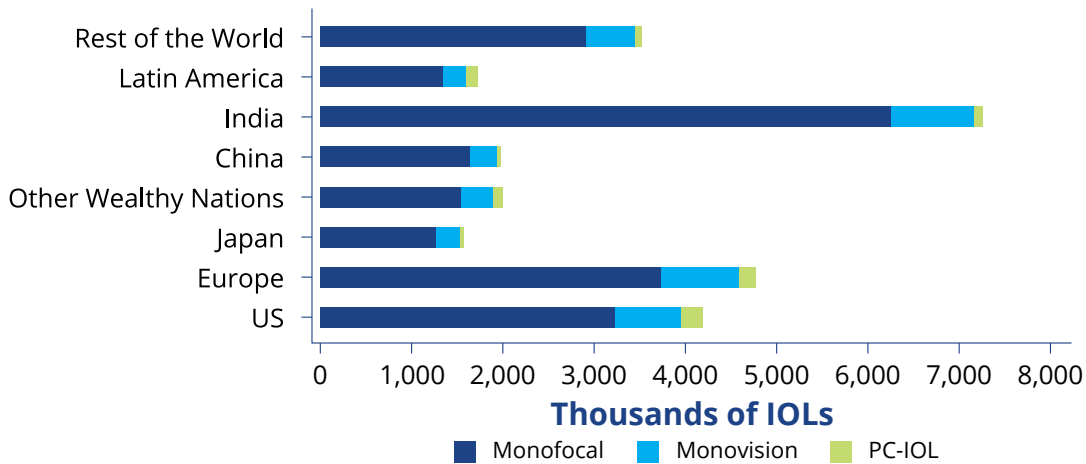
## Presbyopia

Presbyopia is an age-related condition in which the crystalline lens gradually loses the natural ability to accommodate and see near objects clearly. It represents an increasing medical challenge with more than 36% of the population affected by presbyopia in the US alone (Figure 1).



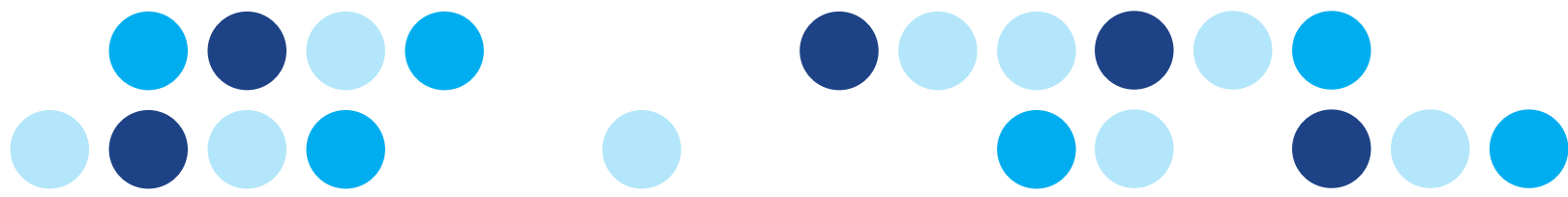
**Figure 1: An increasing trend of Presbyopia in the US population.**

After removal of a cataract, a monofocal IOL can be implanted to provide clear distance vision (if little or no astigmatism is present), but patients will require reading and/or computer glasses. PCIOLs offer the cataract and refractive surgeon an option to correct ametropia and presbyopia, thereby reducing patient dependence on spectacles following surgery. Even with this advanced option available to patients, the use of PCIOLs today is low (Figure 2).<sup>2</sup>



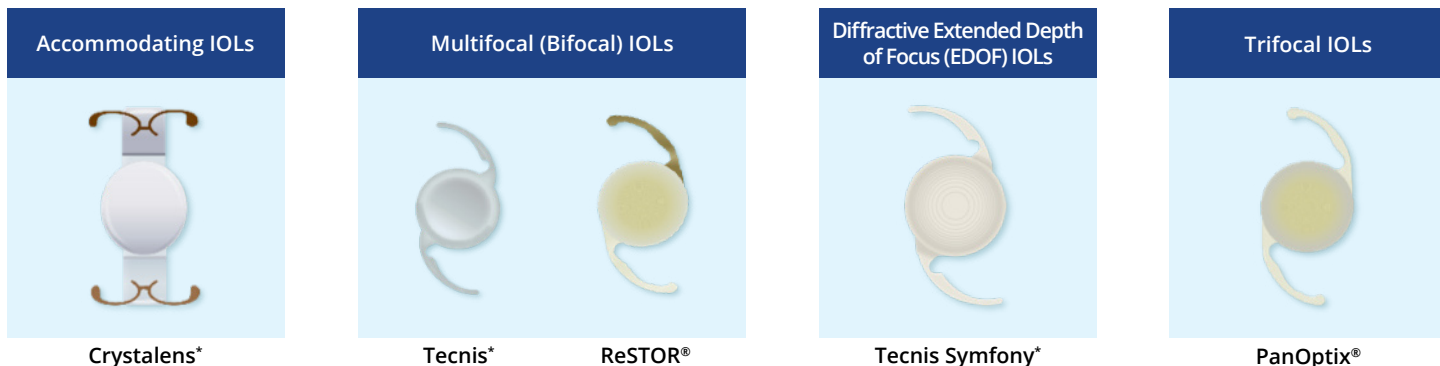
**Figure 2: Estimated monofocal, monovision and posterior chamber IOL (PCIOL) usage by country/region.<sup>2</sup>**

\*Trademarks are property of respective owners.



# Presbyopia correcting IOLs (PCIOLs)

Patients undergoing cataract surgery have very high but mostly unmet visual expectations.<sup>3</sup> These expectations include a desire to reduce the need of spectacles after surgery. Since 2004, an array of PCIOLs have been introduced into the market that provide different ranges of vision. The following section is an overview of available PCIOLs in the US.



## Accommodating IOLs

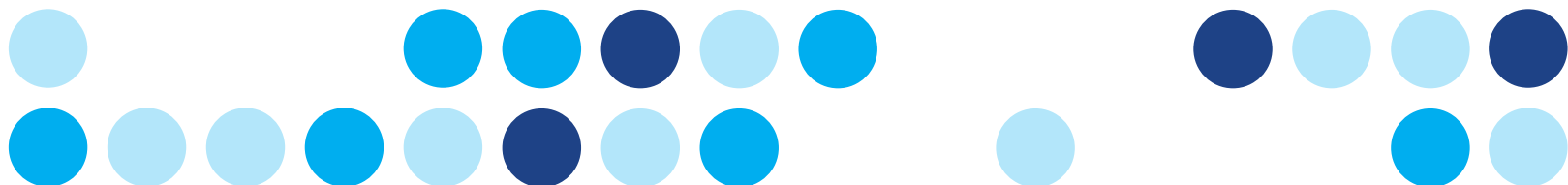
The first IOL labeled as accommodating, introduced to the US market in 2003, is a single-optic, plate haptic platform (Crystalens\*, Bausch + Lomb). The design of this IOL is hypothesized to allow it to move anteriorly or posteriorly depending on the accommodative forces of the eye, thus providing distance and some intermediate vision. The single-optic accommodating IOL potentially has an advantage over other PCIOLs in regard to the visual quality perceived by the patient.<sup>4</sup> However, both near and intermediate vision are limited with this type of lens and this option has not been widely adopted.

## Multifocal IOLs

The first multifocal IOL was launched in the United States in 2004. The light energy in a multifocal IOL is split into two focal points that are simultaneously presented to the retina. Different optical principles can be used to obtain two focal points: diffractive, refractive (which is no longer commonly used in the United States), and hybrid diffractive-refractive.<sup>5</sup> In the diffractive design, concentric rings with a small height bend the incoming light into the two focal points. In the hybrid diffractive-refractive platform, the lens typically has a diffractive central portion while the periphery is the refractive portion. The central portion may be apodized (ie, there is a gradual decrease in step height of the concentric rings from the center to the periphery) to redirect light energy to the distance focus in dim light conditions, thereby reducing optical phenomena. The peripheral refractive portion of the lens is intended to provide additional distance vision particularly in dim light. These IOLs are available in various add powers from low-add to high-add options (Table 1).

Multifocal IOLs with a higher add can provide clear near and far distance foci, but in doing so, may compromise intermediate vision. On the other hand, multifocal IOLs with lower-add power have fewer diffractive steps and can provide clear intermediate and far foci, but may compromise near vision. Another approach to achieve improved near vision with low-add multifocal IOLs is mini-monovision. This option targets the dominant eye for emmetropia and the nondominant eye for near vision by targeting -0.50D or -0.75 D. Lower-add multifocal lenses may have a lower halo profile than higher-add multifocal lenses and this has been shown in bench testing.<sup>6</sup>

\*Trademarks are property of respective owners.



Lower- and higher-add multifocal IOLs can be mixed and matched to tailor the patient's individual needs to provide near, intermediate and far vision, thereby maximizing functional vision. For example, a lower-add multifocal IOL can be implanted in the dominant eye to provide distance and intermediate vision, while the contralateral eye receives a higher-add multifocal IOL to provide distance and near vision. Mixing and matching of multifocal IOLs requires additional planning time during the preoperative patient work-up to determine eye dominance, refractive power targeting, mixed IOL design use and patient education time. Additionally, significant chair time is spent managing patient expectations after surgery.

## Extended Depth Of Focus IOLs

IOLs labeled as extended depth of focus (EDOF IOLs) entered the US market in 2016. The diffractive optic profile of these lenses is designed to split light into multiple foci, and an elongated focus area is created for increased depth of focus and a range of vision from distance to intermediate. EDOF IOLs currently available in the United States provide approximately +1.50 to +1.75 D of accommodative range.

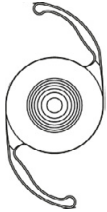

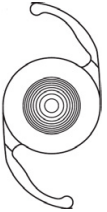

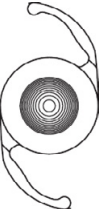
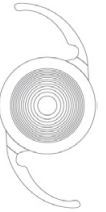
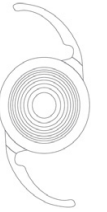
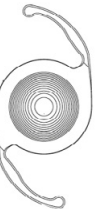
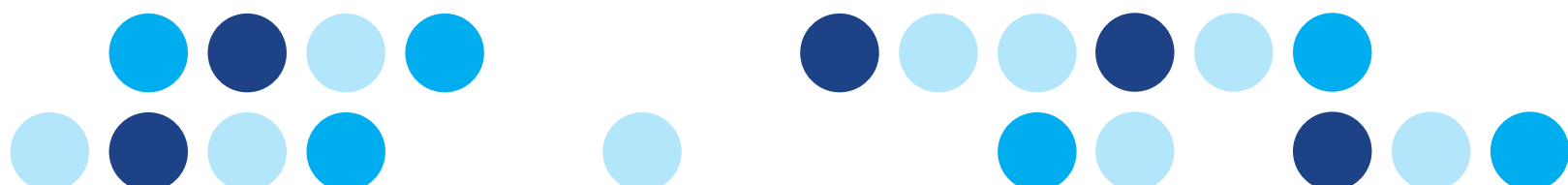
	High-add multifocal IOL		Multifocal IOLs		Low-add multifocal IOLs		EDOF IOL	Trifocal IOL
Name	ReSTOR® +4.0 D	TECNIS* +4.0 D	ReSTOR® +3.0 D	TECNIS* +3.25 D	ReSTOR® +2.5 D with Activefocus	TECNIS* +2.75 D	TECNIS* Symphony*	PanOptix®
								
Add Power (at the IOL Plane)	+4.0 D	+4.0 D	+3.0 D	+3.25 D	+2.5 D	+2.75 D	+ 1.75 D	+2.17D +3.25D
Peak Near/ Intermediate Performance	13 in (33 cm)	13 in (33 cm)	16 in (40 cm)	16.5 in (42 cm)	21 in (53 cm)	20 in (50 cm)	26 in (66 cm)	16 & 24 in (40 & 60 cm)
Diffractive Steps	12 steps Apodized	22 steps	9 steps Apodized	18 steps	7 steps Apodized	15 steps	9 steps referred to as echellettes	15 steps
Availability of Toric Technology	NO	NO	YES	NO	YES	NO	YES	YES

Table 1: PCIOLs in the US market. IOLs are not drawn to scale.

## Trifocal IOLs

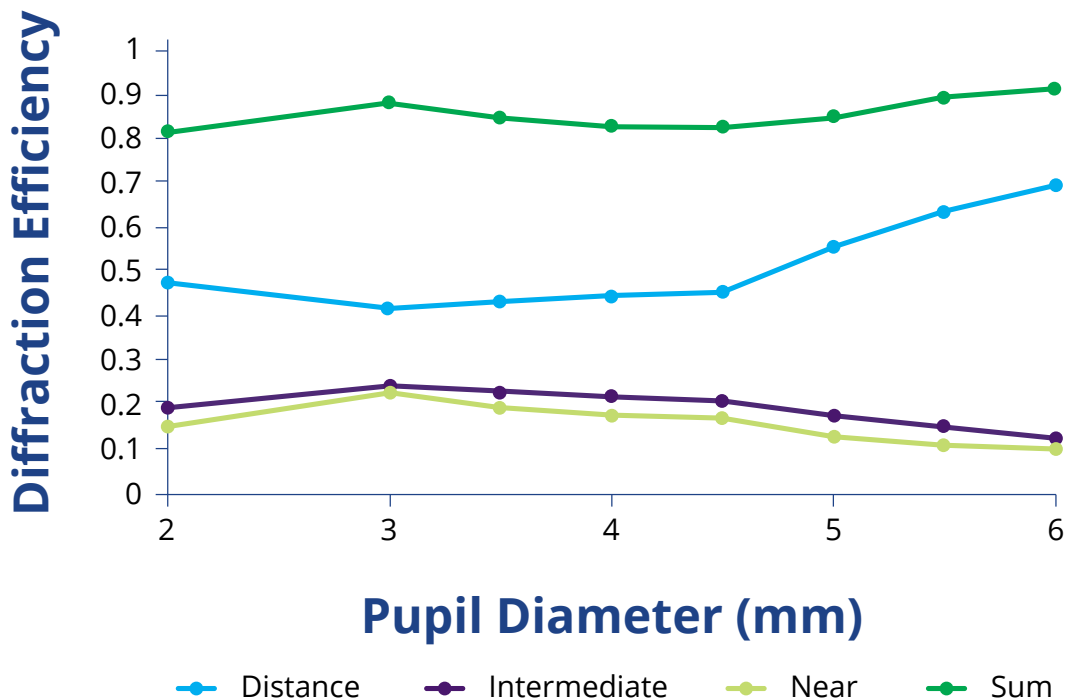
Trifocal IOLs are the latest addition to the US PCIOL landscape and represent an exciting opportunity to provide vision at distance, intermediate and near ranges. With the introduction of new technologies, such as the smartphone and the tablet, patients not only require good distance and near vision, but also good intermediate vision. In the trifocal platform, light energy is split into three focal points: near, intermediate, and far. Generally, trifocals incorporate a diffractive optical design and can be apodized or nonapodized. These IOL designs have been widely adopted by surgeons and patients in the global IOL market due to the range of vision they offer.

\*Trademarks are property of respective owners.



# Clinical Experience with PanOptix® Trifocal IOL

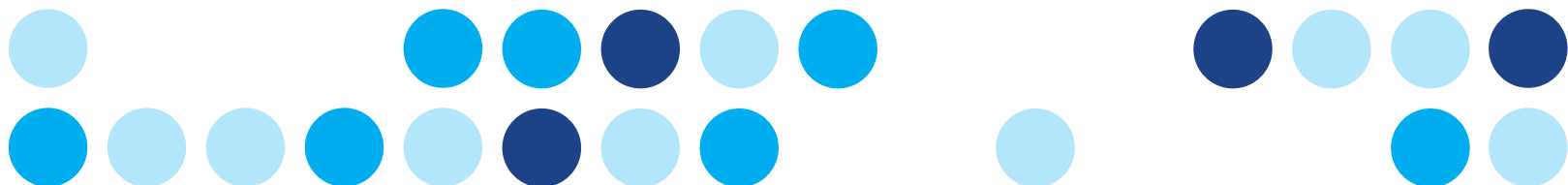
The PanOptix® Trifocal IOL creates 3 focal points: distance, intermediate at 60 cm and near at 40 cm. The central diffractive portion of the lens splits the light energy entering the eye so that about 50% of the available light is directed to distance, 25% to intermediate and 25% to near. The combination of the 4.5 mm non-apodized diffractive zone and the light energy distribution provides less dependence on pupil size and lighting conditions. Figure 3 shows a light utilization of 88% at a 3 mm pupil and consistent light energy distribution over a range of pupil diameters (i.e. up to 5.0 mm pupil diameter).<sup>7</sup>

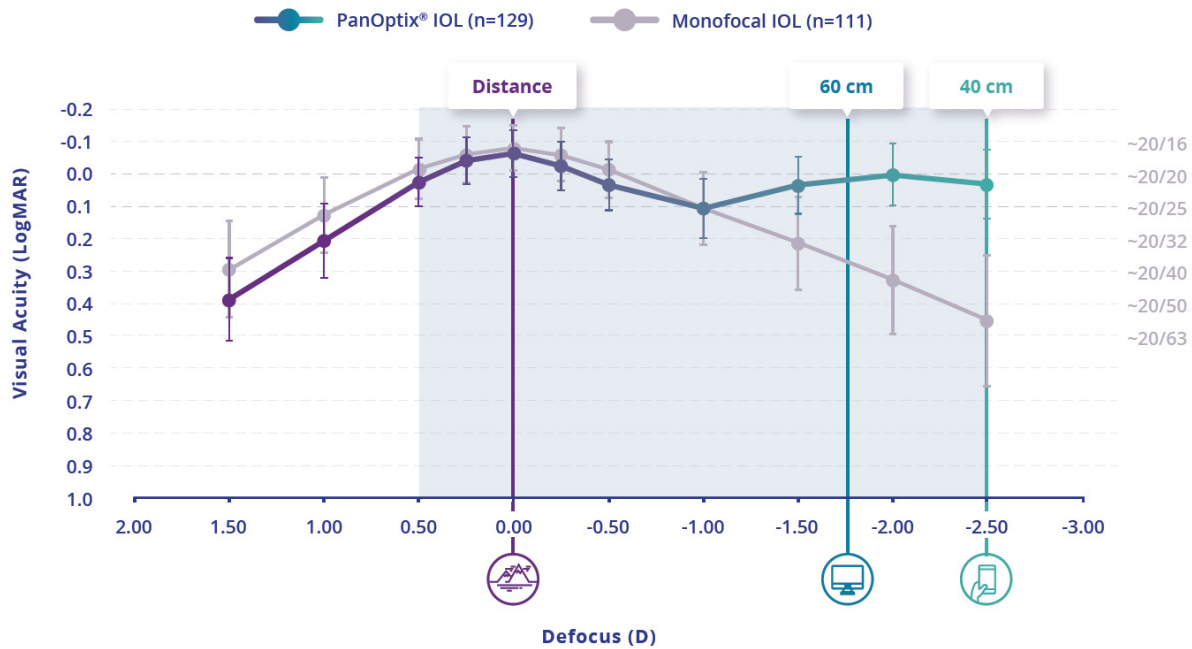


**Figure 3: Theoretical light distribution for distance, intermediate and near in relation to pupil size.<sup>7</sup>**

A prospective, multicenter (12 sites), bilateral eye study conducted in the US compared the implantation of the PanOptix® Trifocal IOL in 129 patients to the implantation of a monofocal IOL (SN60AT, Alcon) in 114 patients.<sup>8</sup> An important measure to assess the optical performance of an IOL is defocus curve testing. The defocus curve for the PanOptix® Trifocal IOL showed that the lens provided consistently a vision of 0.1 logMAR or better (approximately 20/25 or better) from +0.5D to -2.5D or from distance to near; more specifically a 20/25 or better vision was achieved at distance, intermediate and near focal points (Figure 4).

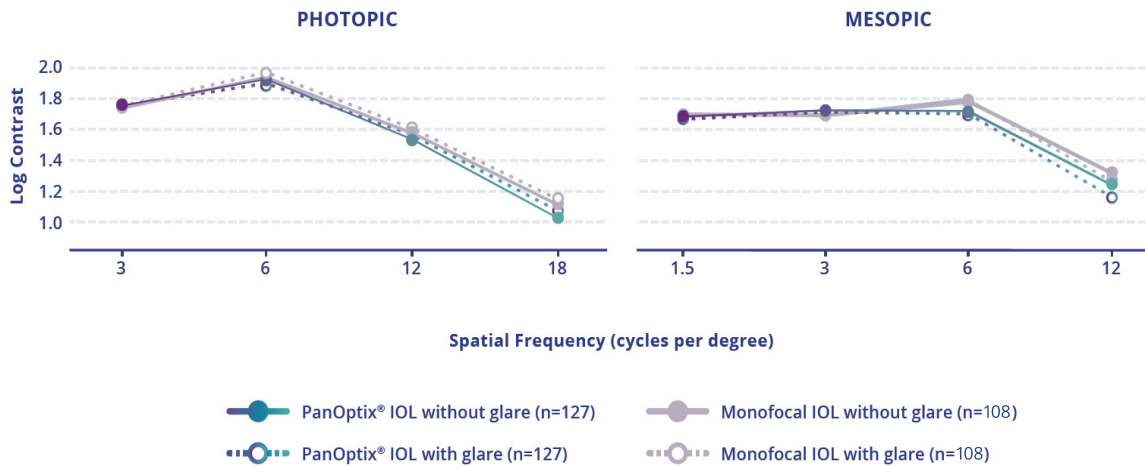
\*Trademarks are property of respective owners.





**Figure 4: Binocular best-corrected defocus curve of the PanOptix® Trifocal IOL as compared to a monofocal IOL at 6 months post-implantation.**

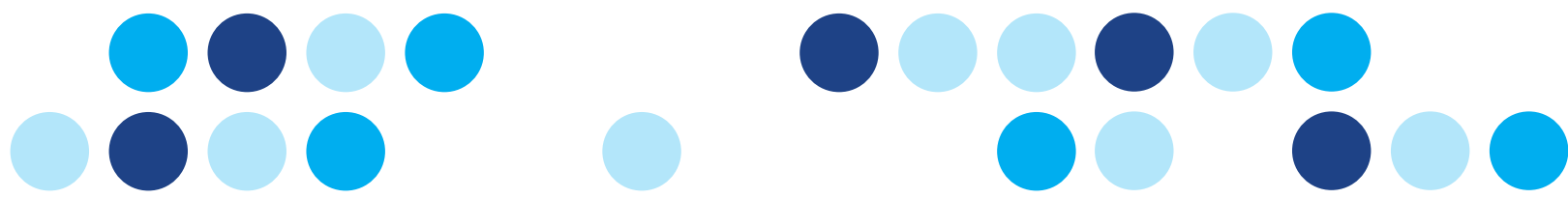
Additionally, the contrast sensitivity assessments under photopic and mesopic conditions described a mean contrast sensitivity that was not clinically significantly different between the PanOptix® Trifocal IOL and monofocal IOL implant (Figure 5)

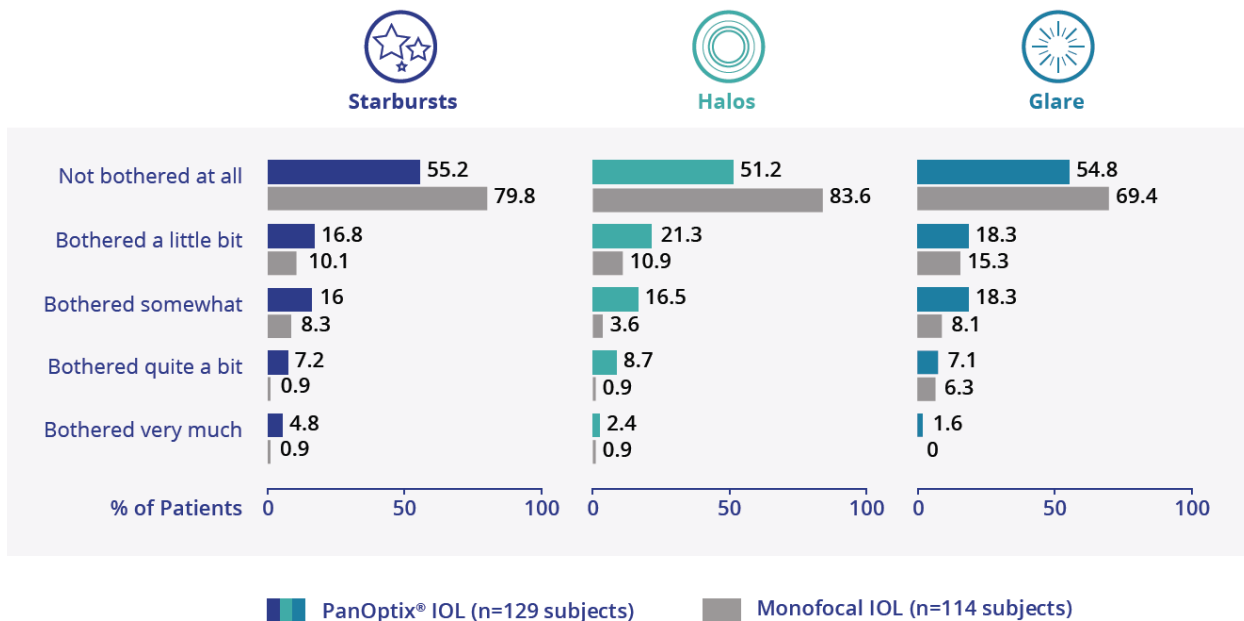


**Figure 5: Binocular photopic and mesopic contrast sensitivity with and without glare of the PanOptix® Trifocal IOL as compared to a monofocal IOL at 6 months post-implantation.**

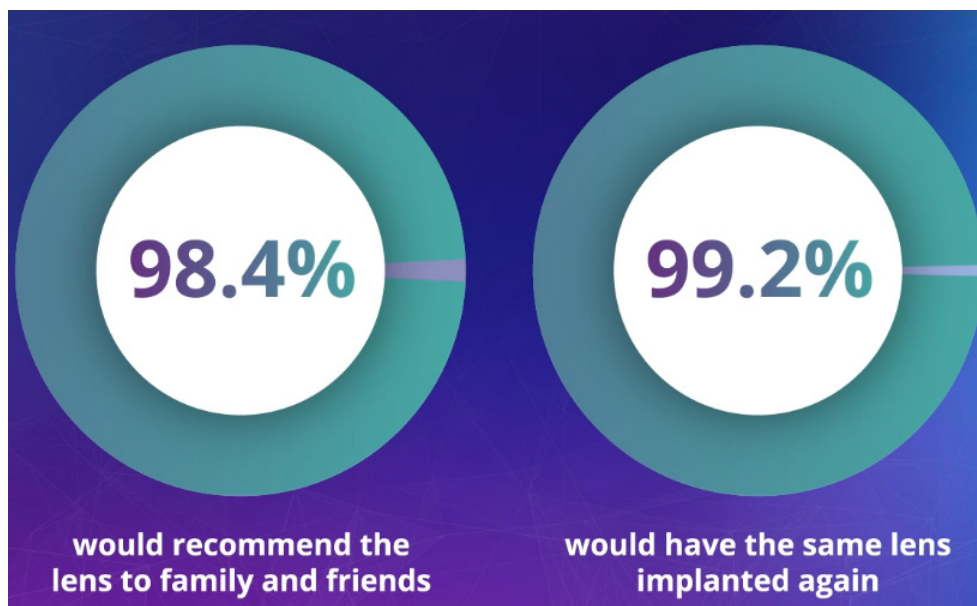
The study evaluated patient reported outcomes with specifically developed and validated questionnaires. One assessed the frequency, severity and bothersomeness of visual phenomena. As one would expect when comparing diffractive versus non-diffractive technology, a higher proportion of patients experienced starbursts, halo and glare with the PanOptix® Trifocal IOL as compared to the monofocal IOL (Figure 6). However, the majority of patients implanted with the PanOptix® Trifocal IOL reported that they were not bothered by each of these symptoms (Figure 6). Additionally, patient satisfaction levels were assessed and patients implanted with the PanOptix® Trifocal IOL were overwhelmingly very satisfied with their vision (Figure 7).

\*Trademarks are property of respective owners.





**Figure 6: Patient reported phenomena with the PanOptix® Trifocal IOL as compared to a monofocal IOL at 6 months post-implantation (Alcon Data on file). Note: up to 1D of corneal astigmatism and no enhancements were allowed.**



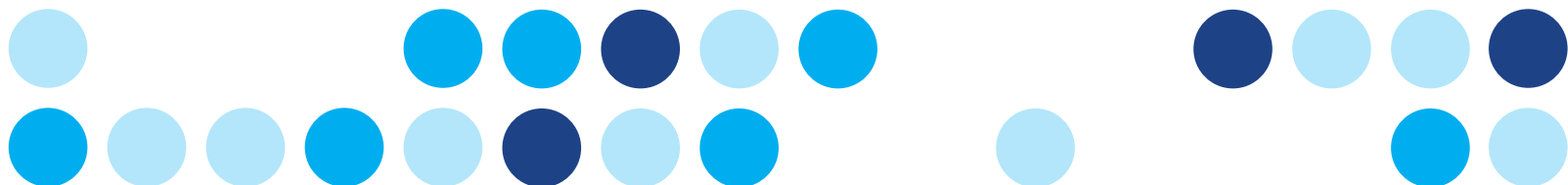
**Figure 7: The level of satisfaction in patients implanted with the PanOptix® Trifocal IOL (n=129) (Alcon Data on file).**

## Summary

In summary, it is an exciting time in refractive cataract care. Patient lifestyles are evolving, visual demands are changing, and technology is adapting to meet those demands.

The PanOptix® Trifocal IOL is a great option in the US to deliver excellent near and intermediate vision without compromising distance, with a single IOL design. A single lens reduces the complexities for surgeons and patients associated with mixing and matching of different IOLs or having to provide mini-monovision.

\*Trademarks are property of respective owners.



# AcrySof® IQ PanOptix® Family of Trifocal 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 PanOptix® Trifocal IOLs include AcrySof® IQ PanOptix® and AcrySof® IQ PanOptix® Toric and are indicated for primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia in adult patients, with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity with a reduced need for eyeglasses, compared to a monofocal IOL. In addition, the AcrySof® IQ PanOptix® Toric Trifocal IOL is indicated for the reduction of residual refractive 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. Physicians should target emmetropia, and ensure that IOL centration is achieved.

For the AcrySof® IQ PanOptix® Toric Trifocal IOLs, the 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.

Some visual effects may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or starbursts, as well as other visual symptoms. As with other multifocal IOLs, there is a possibility that visual symptoms may be significant enough that the patient will request explant of the multifocal IOL. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients and may be more prevalent in low lighting conditions. Therefore, patients implanted with multifocal IOLs should exercise caution when driving at night or in poor visibility conditions.

Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning).

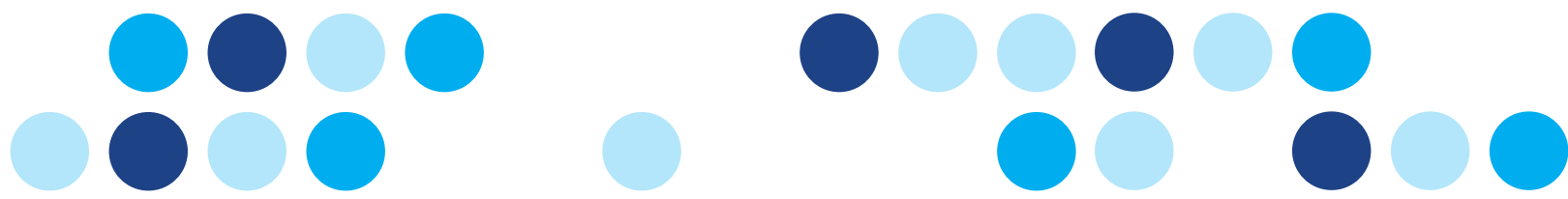
As with other multifocal IOLs, patients may need glasses when reading small print or looking at small objects. Posterior capsule opacification (PCO), may significantly affect the vision of patients with multifocal IOLs sooner in its progression than patients with monofocal IOLs. Prior to surgery, physicians 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 PanOptix® Trifocal IOLs.

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

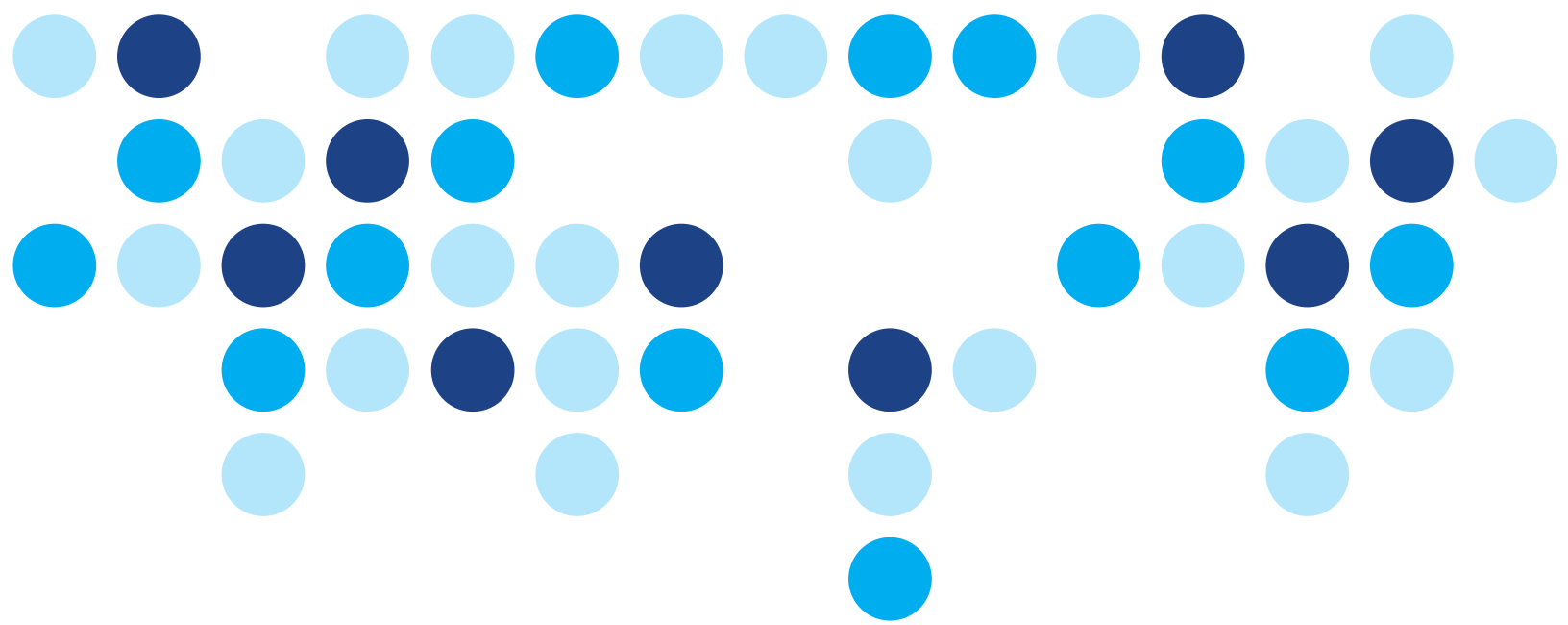
## References

1. ASCRS clinical survey. 2018.
2. Marketscope. 2017 IOL Report: A global market analysis from 2016 to 2022.
3. Pager CK. Expectations and outcomes in cataract surgery: a prospective test of 2 models of satisfaction. Arch Ophthalmol. 2004;122(12):1788-92.
4. Tomas-Juan J, Pinero D, A. M-GL. Single-optic positional accommodating intraocular lenses: a review. Expert Rev Ophthalmol. 2014;9(6):503-14.
5. Auffarth GU, Rabsilber TM, Kohnen T, Holzer MP. [Design and optical principles of multifocal lenses]. Ophthalmologe. 2008;105(6):522-6.
6. Carson D, Xu Z, Alexander E, Choi M, Zhao Z, Hong X. Optical bench performance of 3 trifocal intraocular lenses. J Cataract Refract Surg. 2016;42(9):1361-7.
7. Alcon data on file
8. Alcon data on file

\*Trademarks are property of respective owners.







# Alcon Medical Affairs