White Paper

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Optical Principles of Extended Depth of Focus IOLs

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Key Takeaways

- Depth of focus extension elongates the focal region to provide a continuous range of vision from distance to intermediate, with some functional performance at near.
- Small aperture IOLs increase the depth of focus of the eye, but dramatically reduce the amount of light entering the eye, and consequently are typically only implanted monocularly.
- Low add diffractive multifocal IOLs can provide similar acuity to extended depth of focus lenses, but are associated with the same visual disturbances, like halos, that are associated with all diffractive lenses.
- Wavefront shaping, a next generation optical principle, such as X-WAVE™ Technology, provides depth of focus extension that utilizes all of the light entering the eye while simultaneously reducing the halos and artifacts associated with diffractive lenses.

Introduction

Depth of focus extension is the desire to create sharp images over a continuous range of distances. Photographers are well acquainted with extending depth of focus. For example, when photographing a companion at the Grand Canyon, if the camera is focused on the canyon, then the subject is blurred. If the camera is focused on the subject, then the canyon is blurred. Photographers have learned to extend depth of focus by “stopping down” the aperture, that is making the pupil of the camera lens smaller. The smaller pupil now enables the subject and the canyon to be in focus simultaneously, but less light is entering the camera. Less light might be fine under bright lighting conditions, but may affect image quality under dimmer conditions.

In treating pseudophakic presbyopia, depth of focus extension is desirable. Creating an implant with the ability to create sharp images over the continuous range from distance to intermediate, and possibly even into the near vision region could dramatically reduce spectacle dependence and enable a flexible lifestyle for the patient. A variety of techniques have been tried to provide depth of focus extension in intraocular lenses (IOLs). The photographer’s technique of stopping down the aperture, as well as techniques such as increasing the spherical aberration of the eye and using low-add multifocal diffractive lenses have all been implemented. Each of these techniques have visual quality compromises associated with them. Wavefront shaping in IOLs is a next generation optical technology that can provide high quality depth of focus extension. Alcon’s X-WAVE™ technology is the first example of this technology in an IOL. Here, an overview of various depth of focus extension techniques is provided to illustrate their potential and differences.

The Ideal Extended Depth of Focus Lens

Prior to reviewing the properties of available Extended Depth of Focus (EDOF) lenses, it is useful to understand the properties of an ideal EDOF lens. While such lenses are physically impossible due to the limitations of the properties of light, this exercise is useful since as EDOF technology evolves, it should converge towards the ideal solution. Figure 1 compares the imaging properties of a monofocal lens to the desired properties of an ideal EDOF lens. For a monofocal lens viewing a distant object, the light is focused by the lens to a sharp point on the retina. Each point in the distant object is focused to a point on the retina, creating a crisp image. As objects come closer to the eye, the focal spot shifts further behind the retina. Instead of a sharp point on the retina, a blur circle is created. The closer the object, the bigger the blur circle. This leads to objects appearing progressively blurred as they come closer to the eye. The ideal EDOF lens would concentrate light down to a point, but then this point would remain focused over an extended range. In effect, the ideal EDOF lens concentrates the light to a line along the visual axis. Such a lens would then create a sharp image for distant objects. For near objects, the focal pattern again shifts behind the retina, but the light from the near object remains in focus on the retina. Furthermore, all objects in the range from distance to near would be in focus.

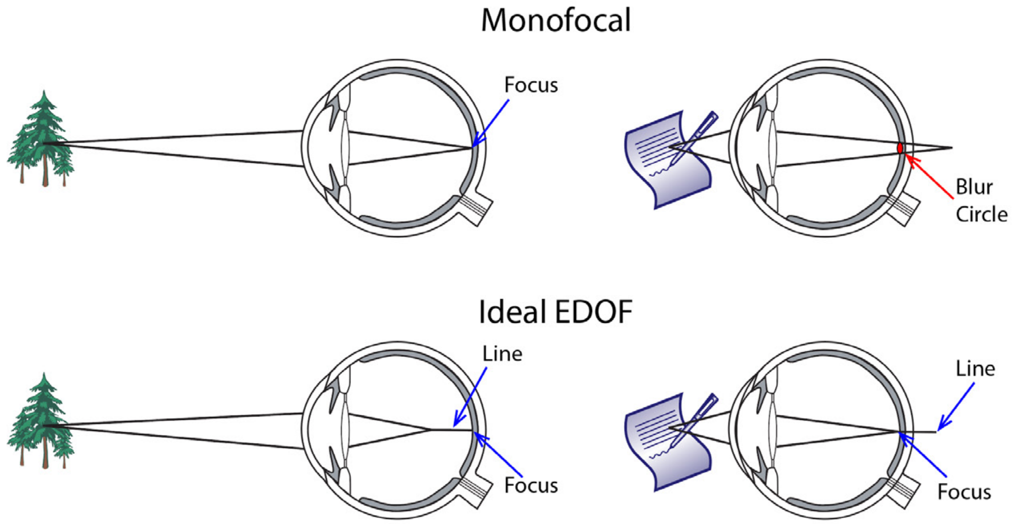

Figure 1: For distant objects, a monofocal lens focuses light to a sharp point on the retina. When looking at near objects, this focal point shifts behind the retina, leading to a large blur on the retina. The ideal EDOF lens would cause light to converge to a line, with one end of the line being on the retina for distant objects. When viewing near objects, the focal pattern again shifts, but the other end of the line is now on the retina. This ideal case would mean all objects from distance to near would be in focus simultaneously on the retina.

Unfortunately, the laws of physics preclude the creation of the ideal EDOF lens, but if the strict requirements of the line focus are reduced slightly, then some of the goals of depth of field extension can be achieved. Figure 2 illustrates these requirements. If the light entering the eye can be focused to a narrow channel that is stretched over an extended range, then some of the goals of the ideal EDOF lens can be achieved. The width of the channel dictates how tight the focus is, equating to the potential visual acuity. The length of the channel dictates the range of distances the EDOF lens provides a clear image. Light that is within the channel when it strikes the retina is in-focus and contributes to the perception of a sharp image. Light that is outside the channel is spread out when it strikes the retina, and may be perceived as either halos or blur.

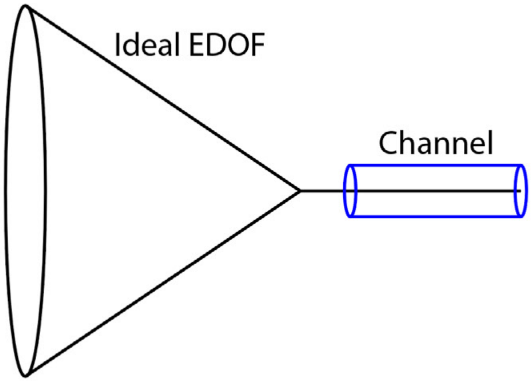

Figure 2: For a real EDOF lens, concentrating the light into a narrow channel would create good vision over an extended range of distances. The width of the channel dictates how sharp the images are and the length of the channel determines the range of distances the real EDOF would operate.

Figure 3 helps to illustrate the differences between halo and blur. The central image of Figure 3 shows a tightly focused spot. Most of the energy is concentrated within the central core of the spot and minimal energy is in the surrounding region. The right-hand image in Figure 3 shows a blurred spot of approximately 3D. The amount of energy within the blurred spot is the same as within the focused spot. Now, however, the energy is spread out over a larger area, so the peak intensity must be smaller. Here the energy is uniformly distributed, and the large size means the fine details in the image are smeared out. The left-hand image in Figure 3 shows a halo pattern which can be thought of as a combination of a focused spot of lower intensity and a blur pattern. Again, the amount of energy within the halo pattern and the focused spot is the same, but some of the energy from the focused spot has been redistributed into the halo. This type of pattern is typical for multifocal lenses where one foci creates the focused spot and the other foci create out-of-focus spots. The in-focus and out-of-focus spots are all superimposed to create simultaneous vision. In the halo pattern case, a smaller portion of the overall energy is concentrated within the central core of the spot, while the remainder of the energy is distributed into the surrounding region forming the halo. It is important to distinguish between halo and blur since perceptually they have different effects. Blur causes a reduction in acuity, whereas as halo causes a secondary ghost image and a reduction in contrast between the central and surrounding regions of the image.

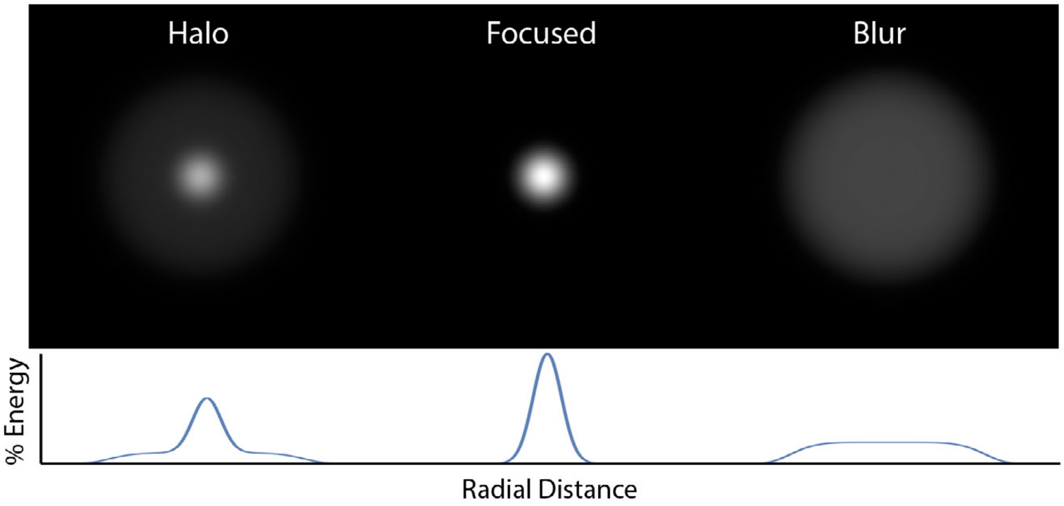

Figure 3: Comparison of halo and blur to an in focus spot. Blur tends more uniformly distributed over a spot, whereas halos have a portion of their energy concentrated in the center of the spot.

Designing EDOF lenses requires several (usually conflicting) goals. First, maximizing the length of the channel to give high performance for a broad range of object distances. Second, minimizing the width or diameter of the channel to give high acuity and minimal blur over the range of object distances. Finally, minimizing the amount of light outside of the channel when a significant portion of the light is concentrated within the channel to reduce the unwanted effects of halos. Below, various EDOF technologies are explored to illustrate where they meet or do not meet the above defined EDOF characteristic.

Small Aperture IOLs

Small aperture lenses extend depth of focus by using the photographer's trick of "stopping down" the pupil of the eye. Figure 4 shows the effect of a small aperture lens in relation to the EDOF channel. For a monofocal lens, the rays from a distant object are focused onto the retina. These rays are within the channel only when near the retina. In front of the retina, some of the light goes down the channel, but most of the light lies outside the channel and leads to blur for nearer object distances. Blur appears in this case because the energy is uniformly distributed over the retina for near objects like the right-hand image of Figure 3. In the small aperture lens, much of the light entering the eye is blocked by the aperture and only the small cone of light going through the center of the lens is allowed to pass. This has the effect of blocking the rays that would lie outside the EDOF channel. In other words, small aperture lenses do not increase the concentration of the light in the EDOF channel, but instead remove the light that would normally be outside the channel. This has the effect of increasing depth of focus at the expense of reduction of available light and contrast. The EDOF effect may work for bright lighting conditions, but will be diminished in dim lighting conditions. Furthermore, diffraction from the small aperture causes the focused beam to spread, leading to reduced acuity and loss of contrast. Due to these limitations, small aperture implants are typically only performed monocularly. To overcome this small-aperture effect, an ideal EDOF lens would instead concentrate all of the available light entering the eye into the EDOF channel.

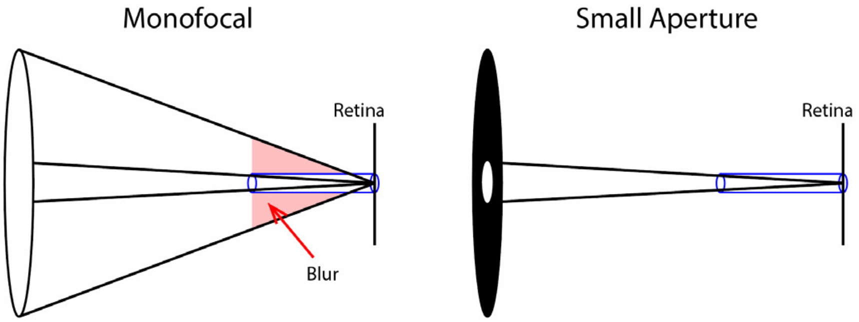

Figure 4: For a small aperture lens, an opaque mask is placed in the lens to artificially reduce the size of the eye pupil. This has the effect of concentrating the light into a narrow channel would create good vision over an extended range of distances. However, much of the light is blocked by the small aperture, so these lenses may be problematic under low lighting conditions.

Spherical Aberration Lenses

Aspheric IOLs originally emerged as a means of reducing the positive spherical aberration introduced by the cornea. However, a class of aspheric lenses were developed which are “aberration-free” meaning the IOL itself does not have spherical aberration. This means that the pseudophakic eye with these lenses would have large amounts of spherical aberration due to the cornea. The argument for these lenses is that they provide increased depth of focus. Spherical aberration means that the power of the lens progressively changes from the center of the lens to the periphery. Figure 5 shows a case of a lens with positive spherical aberration. In the case of positive spherical aberration, rays passing through the center of the lens focus on the retina, while rays passing through the mid-periphery of the lens focus more myopically. Rays passing through the edge of the lens focus still further myopically. For negative spherical aberration lenses, the peripheral rays would be more hyperopically focused relative to the central rays. Most aspheric IOLs have negative spherical aberration to offset the positive spherical aberration from the cornea. However, aberration-free IOLs have no spherical aberration, leading to an eye that is dominated by positive spherical aberration from the cornea. As seen in Figure 5, depending on where the rays enter the lens, the light will converge to a point within the EDOF channel. As shown, the location of the foci within the channel become more myopic as the entry location of the rays move from the visual axis towards the periphery of the lens with positive spherical aberration. The downside to spherical aberration is that only a fraction of the light is concentrated into the channel for a given object distance and the remainder of the light is necessarily outside the channel leading to halos. Halos, like that shown in the left-hand image of Figure 3, appear in this case since some of the energy is concentrated into the channel by the spherical aberration and the remainder lies outside the channel. Different variations of the spherical aberration concept have been implemented to improve depth of focus. These variations include the aberration-free (or aberration neutral) type lenses where the corneal spherical aberration causes the effect, lenses where high spherical aberration is used over a small central zone of the lens,[1] as well as lenses that mix positive and negative spherical aberration across multiple zones.[2] In general, all of these lenses will suffer from the same effect of light expanding outside of the channel resulting in visual disturbances.

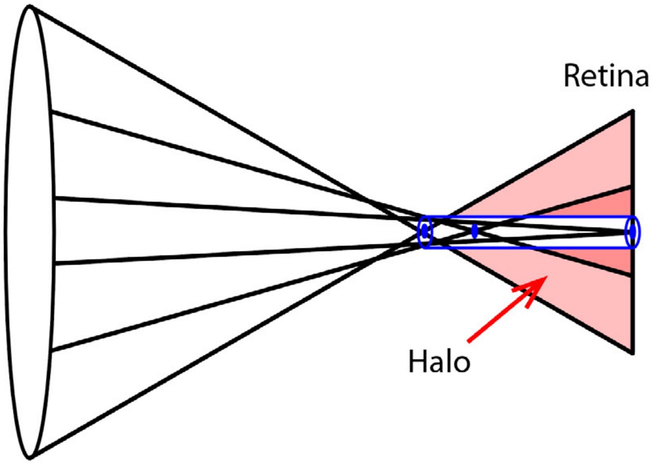

Figure 5: When spherical aberration is present, the power of the lens changes from its center to edge. In this case, the rays passing through the edge of the lens are myopic relative to the rays passing through the center of the lens (positive spherical aberration). While the rays come to focus within the EDOF channel, away from this point, the rays lay outside of the channel leading to halos.

Diffractive IOLs

In diffractive IOLs, a stepped structure is placed on the lens surface where the shape of the structure is chosen to split the light into distinct foci using diffraction. A typical diffractive multifocal lens consists of concentric annular zones created on the surface of the lens. The surface areas of the zones are equal, which means the separation between or width of each zone gets progressively smaller towards the edge of the lens. At the junction of each zone, an abrupt step appears. The area of each zone dictates the add power of the lens and the height of the step determines the relative amount of energy that goes into each focus. Figure 6 shows an example of a bifocal diffractive lens. Two distinct foci are created within the EDOF channel, but as was seen previously with spherical aberration type lenses, away from these foci, the rays expand outside of the EDOF channel leading to halos, image quality loss and visual disturbances. Furthermore, for the typical bifocal diffractive lens, only 82% of the light entering the eye reaches these two foci (41% into each foci).[3] The remaining 18% of the light goes into other foci well outside of the range of the EDOF channel and this light further contributes to halos and loss of contrast in the retinal image. Halos again appear in this technology because the diffraction is concentrating a portion of the energy into the central core of the spot like the left-hand image in Figure 3.

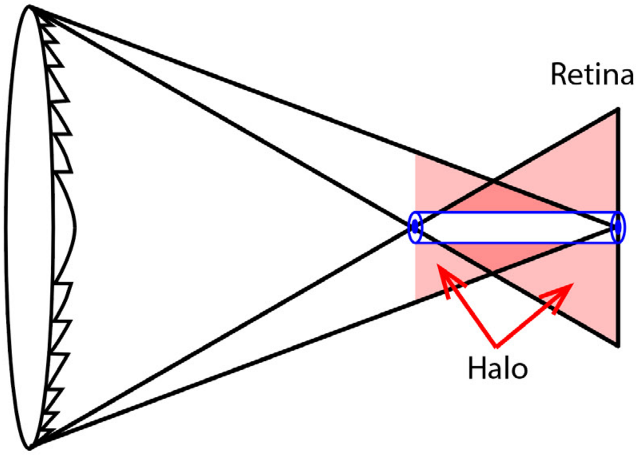

Figure 6: Diffractive lenses split the light into two or more foci. Here, a bifocal diffractive lens creates two distinct foci within in channel. While these rays again come to focus within the EDOF channel, away from these points, the rays lay outside of the channel leading to halo.

A specific diffractive IOL, the TECNIS Symfony® IOL, is designed to split light using a diffractive echelette optic design to create an elongated focus from distance to intermediate.[4] Similar to other diffractive IOL designs, this diffractive IOL design is also associated with increased halos, image quality loss and visual disturbances compared to its monofocal control.[5] In the case of diffractive trifocal lenses, now three distinct foci appear within the EDOF channel. The lenses concentrate more of the light within the channel compared to their bifocal counterparts.[6] However, trifocal lenses still exhibit similar behavior with light away from the various foci expanding outside of the channel creating halos. Furthermore, roughly 10% of the light still focuses outside the EDOF channel contributing to halos and contrast loss.[6]

Wavefront Shaping Optical Principle

Wavefront shaping is a unique means for providing depth of focus extension applied for the first time in IOL technology. This technology differs from refractive multifocal lenses and diffractive lenses by how it enables EDOF imaging. To better understand wavefront shaping, it is useful to examine other fields where this technology has had an impact. One such area is laser manufacturing, where a common application is to use a high-powered laser to drill a hole in a metal plate. Typically, the beam emerging from a laser has a Gaussian profile. This means that the beam is brighter in the center and its intensity falls off away from the beam center much like the falloff seen in the Gaussian or "bell-shaped" curve from statistics. In Figure 7, the Gaussian beam creates an undesirable tapered shape.

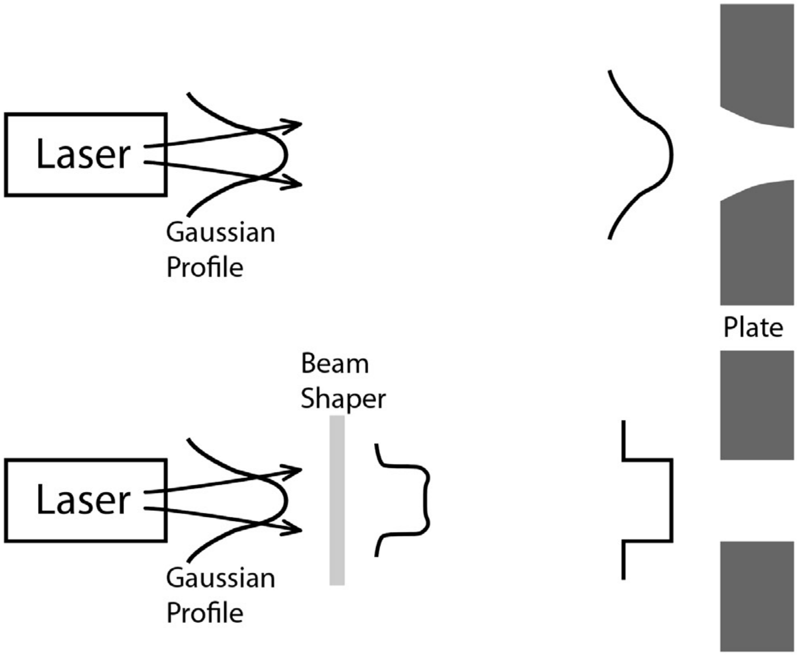

Figure 7: (Top) In laser manufacturing, a Gaussian laser beam would propagate to a metal plate and drill a hole that has tapered sides. (Bottom) Wavefront shaping technology can pre-distort this Gaussian beam so that when it arrives at the metal plate it has a square profile and creates a uniform hole.

Wavefront shaping can be applied to the hole drilling analogy to create improved effects. As shown in the bottom of Figure 7, the wavefront shaper pre-distorts the beam so that when the beam propagates to the metal plate, the beam now has a rectangular profile when it reaches the plate. In this manner, the hole drilled in the plate has the desirable property of square side walls. Note that simply putting an aperture in front of the laser beam will not achieve this effect. The wavefront shaper needs to accomplish two tasks. First, it needs to redistribute the intensity of the beam and change the shape of the wavefront so that when the beam reaches the plate, the wavefront is uniform and the intensity profile has the desired rectangular shape. Fortunately, a wavefront shaping profile can be created that utilizes all of the energy from the laser beam and creates the desired intensity pattern at the plate surface.

The AcrySof® IQ Vivity™ IOL utilizes X-WAVE™ technology (wavefront shaping) to create an EDOF effect. In the eye, the incident beam now has a uniform intensity over the pupil of the eye. The goal of the wavefront shaper is to now convert this beam in such a manner so that when it reaches the retina, the light is confined to a region within the EDOF channel. As shown in Figure 8, the wavefront shaping profile is placed on the anterior surface of the AcrySof® IQ Vivity™ IOL shapes the beam of light entering the eye so that as it propagates to the retina, the light is mostly confined to the EDOF channel. Similar to all EDOF technologies used in presbyopia mitigating IOLs when the available light is used to achieve a broader range of vision compared to a monofocal, there may be a reduction in image contrast at distance that may lead to a reduction in contrast sensitivity. AcrySof® IQ Vivity™ IOL was associated with a reduction in mesopic monocular contrast sensitivity in most patients, particularly at higher spatial frequencies compared to a monofocal IOL in the US clinical study.[7] In a different clinical study, binocular mesopic contrast sensitivity with AcrySof® IQ Vivity™ showed no clinically meaningful differences compared to the same monofocal control.[8] Furthermore, patients reported good quality of vision with AcrySof® IQ Vivity™ at all distances in dim or bright light conditions.[7] In fact, 83% or more patients implanted with the AcrySof® IQ Vivity™ IOL reported good quality distance and intermediate vision without spectacles compared to only 51% or more patients for a monofocal control in dim light.[7] Importantly, the presence of halo, glare and other visual symptoms with AcrySof® IQ Vivity™ were similar to a monofocal.[7] The AcrySof® IQ Vivity™ IOL provides a range of vision from distance through intermediate and some functional near vision, while maintaining a visual disturbance profile similar to that of a monofocal intraocular lens.[7]

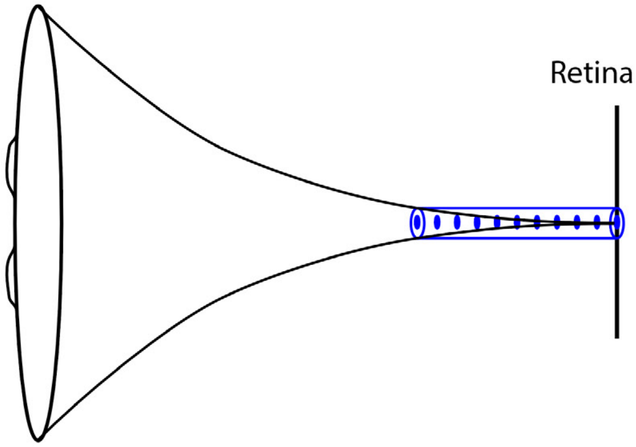

Figure 8: Wavefront shaping in the AcrySof® IQ Vivity™ IOL lens leads to light that is mainly confined to the EDOF channel with a halo profile similar to that of a monofocal lens.

To further illustrate the optical performance of the AcrySof® IQ Vivity™ IOL, the simulation in Figure 9 shows the through-focus Point Spread Functions (PSFs) for the AcrySof® IQ monofocal lens[9], the TECNIS Symfony® EDOF IOL[9], the AcrySof® IQ PanOptix® trifocal IOL[9] and the AcrySof® IQ Vivity™ IOL[9]. The AcrySof® IQ monofocal IOL provides high quality distance vision, but its depth of focus is limited. The light energy distribution profiles for different monofocal lenses will vary depending upon their specific design parameters, but in general, they will all have limited depth of focus. The halo profile of any monofocal IOL is minimal but still present. The Vivity™ IOL has a much broader depth of focus but has a halo profile comparable to the AcrySof® IQ monofocal lens.[7] When compared to diffractive IOLs, the light energy distribution profile of the Vivity™ IOL[9] using X-WAVE™ Technology demonstrates a continuous range from distance to intermediate (60cm) and towards near. The TECNIS Symfony® EDOF IOL[9] similarly demonstrates a range of light energy distribution to intermediate (60cm) but relies on diffractive technology, and the simulation below shows a reduction in light energy beyond intermediate with only some energy distributed to near. Finally, the PanOptix® Trifocal IOL[9] light shows a light energy distribution profile with peaks at near (40 cm), intermediate (60 cm) and distance, corresponding to the full range of vision possible with a trifocal IOL.

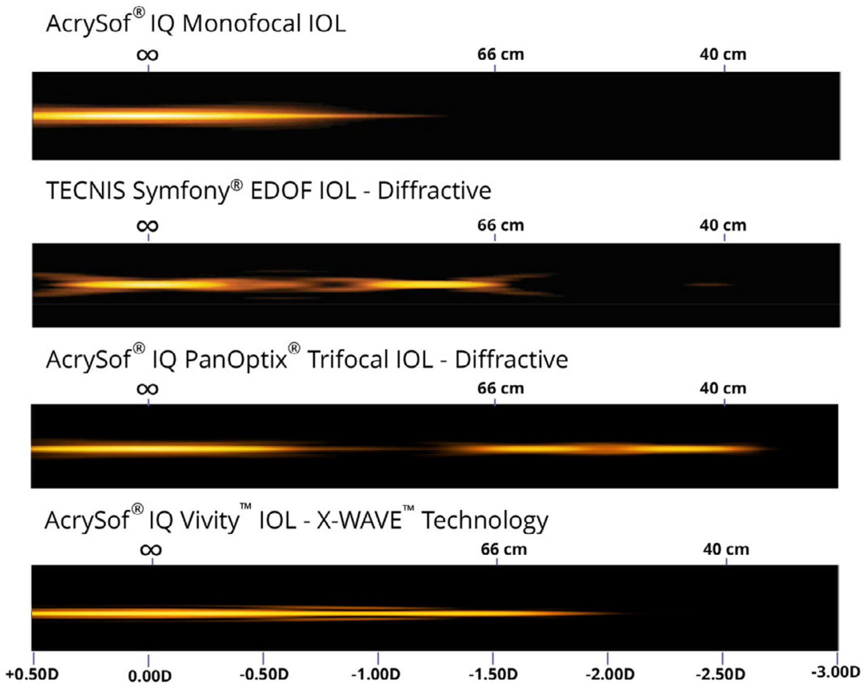

Figure 9: Simulated polychromatic through-focus point spread functions (light intensity [energy]) for AcrySof® IQ monofocal, TECNIS Symfony® EDOF IOL, AcrySof® IQ PanOptix® Trifocal IOL and AcrySof® IQ Vivity™ IOL.[9]

X-WAVE™ Technology

Alcon's X-WAVE™ Technology employs the wavefront shaping optical principle to create a unique EDOF profile. Figure 10 shows in more detail how this technology is incorporated into the AcrySof® IQ Vivity™ IOL. In the lens design, two anterior surface transition elements are used: surface transition element #1, a slightly elevated plateau (~1um) that stretches the wavefront resulting in a continuous extended focal range and surface transition element #2, a small curvature change that shifts the wavefront so that all the energy is usable. The two surface transition elements work synergistically and simultaneously to create a continuous extended focal range.

The emergent wavefront mimics the anterior lens surface shape after light passes through the surface transition elements. The wavefront is delayed when it passes through the central part of the surface transition elements and advanced when passing outside of the central part. The delayed part of the wavefront travels slower and focuses closer to form an image towards the near end of the extension and the advanced part of the wavefront travels faster and focuses further to form an image at the far end of the extension. As the wavefront propagates, it collapses down resulting in the wavefront being stretched forward and backward thereby creating a continuous extended focal range.

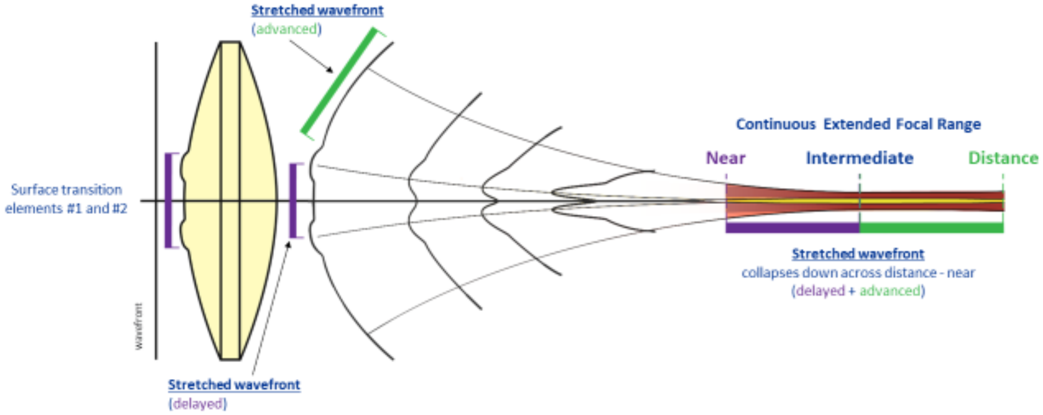

Figure 10: The X-WAVE™ technology provides a continuous extended focal range.

Summary

The Food and Drug Administration (FDA) has created a category for IOLs with extended depth of focus based on the recommendations of a task force from the American Academy of Ophthalmology.[10] Additional details regarding the definitions, requirements and testing protocols for EDOF lens can be found in ANSI Standard Z80.35-2018.[11] The summary of the clinical endpoints required for an EDOF lens are:

CLINICAL ENDPOINTS	EDOF EFFECTIVENESS CRITERIA
Monocular depth of focus at 0.2 logMAR	At least 0.5 D greater than monofocal control
Mean monocular photopic DCIVA (66 cm) at 6 months	Achieve in ≥50% of eyes
% of eyes with monocular photopic DCIVA (66 cm) of 0.2 logMAR or better	Monocular depth of focus at 0.2 logMAR
Mean monocular photopic BCDVA	Non-inferiority vs. monofocal control

DCIVA: distance corrected intermediate visual acuity;
BCDVA: Best corrected distance visual acuity

It is important to note here that these guidelines for classifying IOLs to the EDOF category are based on clinical outcomes and make no recommendations of the methods (diffractive or wavefront shaping optical principles) for achieving these outcomes, and critically provide no requirements for limiting visual disturbances. This strategy fosters flexibility for current and future technologies to use the EDOF descriptor, but an understanding of how various current technologies achieve these clinical endpoints gives insight into the potential side effects that patients will perceive. As shown above, small aperture lenses will reduce light levels entering the eye and likely have issues in low light conditions. Furthermore, spherical aberration-based technologies and diffractive technologies will concentrate some of the light into the EDOF channel, but suffer from visual disturbances much larger than what are seen with monofocal IOLs. For example, diffractive EDOF IOLs such as the TECNIS Symfony®, although classified as an EDOF using the clinical criteria above[10,11], have similar visual disturbance profiles typical of other diffractive presbyopia mitigating IOLs.[12] Interestingly, although similarity in frequency and severity of dysphotopsia complaints ($p>0.05$) was reported for TECNIS Symfony® and PanOptix®, a greater degree of bothersomeness for photic phenomena ($p<0.05$) is observed with TECNIS Symfony®, demonstrating variability in photic phenomena complaints even within the diffractive IOL category.[12] The TECNIS Symfony® IOL was shown to have worse reports of bothersome visual disturbances compared to a monofocal control in a large controlled clinical trial.[5] These findings highlight that not all IOLs classified as EDOF lenses are clinically similar, and that surgeons should carefully evaluate overall performance of EDOF lenses including dysphotopsia profiles.

Wavefront shaping is a next-generation optical principle that opens new possibilities in intraocular lens design. The AcrySof® IQ Vivity™ is the first presbyopia mitigating lens to use a wavefront shaping optical principle to meet the goals of EDOF category and simultaneously provide a visual disturbance profile similar to a monofocal IOL.

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 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 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 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 Vivity™ clinical study, 1% to 2% of Vivity™ 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.

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