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REVIEW

Axial movement of the dual-optic accommodating intraocular lens for the correction of the presbyopia: Optical performance and clinical outcomes

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Received 1 March 2014; accepted 3 June 2014

Available online 22 September 2014



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KEYWORDS

Accommodative intraocular lenses;
Dual optic intraocular lens;
Pseudophakic accommodation;
Presbyopia

Abstract Presbyopia occurs in the aging eye due to changes in the ciliary muscle, zonular fibers, crystalline lens, and an increased lens sclerosis. As a consequence, the capacity of accommodation decreases, which hampers to focus near objects. With the aim of restoring near vision, different devices that produce multiple focuses have been developed and introduced. However, these devices are still unable to restore accommodation. In order to achieve that goal, dual-optic accommodating Intraocular Lenses have been designed, whose anterior optic displaces axially to increase ocular power, and focus near objects. Although dual-optic accommodating IOLs are relatively new, their outcomes are promising, as they provide large amplitudes of accommodation and a greater IOL displacement than single-optic accommodating IOLs. The outcomes show comfortable near vision, higher patients' satisfaction rates, and minimal postoperative complications like Posterior Capsular Opacification and Anterior Capsular Opacification, due to their design and material.

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PALABRAS CLAVE

Lentes intraoculares acomodativas;
Lentes intraoculares de óptica dual;

Movimiento axial de las lentes intraoculares acomodativas de doble óptica para la corrección de la presbicia: rendimiento óptico y resultados clínicos

Resumen La presbicia se produce en el ojo envejecido debido a los cambios en el músculo ciliar, las fibras zonulares y el cristalino, y al incremento de la esclerosis del mismo. Como consecuencia, disminuye la capacidad de acomodación, lo que dificulta el enfoque de los objetos

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Acomodación
pseudofáquica;
Presbicia

cercanos. Con el fin de restaurar la visión de cerca, se han desarrollado e introducido diferentes dispositivos que producen múltiples focos. Sin embargo, dichos dispositivos no son aún capaces de restaurar la acomodación. A fin de lograr este objetivo, se han diseñado las lentes intraoculares acomodativas de doble óptica, cuya óptica anterior se desplaza axialmente para incrementar la potencia ocular, y enfocar los objetos cercanos. Aunque estas LIOs acomodativas son relativamente nuevas, sus resultados son prometedores, ya que aportan grandes amplitudes de acomodación y un mayor desplazamiento de la LIO que las LIO acomodativas de óptica simple. Los resultados muestran una visión de cerca cómoda, unos índices elevados de satisfacción del paciente y unas mínimas complicaciones postoperatorias, tales como la opacificación capsular posterior y posterior, debido a su diseño y material.

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Presbyopia is characterized by the difficulty of focusing objects in near vision, in persons over age 40, due to the progressive loss of accommodation.^{1,2} Accommodation occurs as a result of the contraction of the ciliary body and the consequent lowering of tension of zonular fibers, producing an increase in the curvature of the crystalline lens.^{3,4} However, in presbyopia, the capacity to accommodate is reduced due to the loss of contraction of the ciliary muscle,^{2,4} lessening of zonular fibers,^{2,5,6} changes in the thickness and elasticity of the crystalline lens capsule,²⁻⁸ increase of equatorial diameter,⁶ loss of elasticity of the Brück's membrane,⁹ and an increased lens sclerosis with age.¹⁰ Despite the loss of accommodation caused by the weakening of the ciliary muscle, it has been shown through pharmacological stimulation by instillation of pilocarpine and in vivo and in vitro studies using ultrasound biomicroscopy and Magnetic Resonance Imaging (MRI) that the function of the ciliary body persist over the years, even in pseudophakic patients.^{3,5,7} The persistence of the function of the ciliary body during presbyopia is expected, because each effort to focus on an object made by the presbyopic patient, even wearing reading glasses for near vision, will cause convergence and pupillary contraction, so it will activate the ciliary body.⁶

Monofocal intraocular lenses, despite providing good outcomes in distance vision after surgery, provide unsatisfactory near visual outcomes.¹¹ Due to the advances in cataract surgery with the introduction of the femtosecond laser and the micro-incision surgery (MICS), a large number of Intraocular Lenses have been introduced to restore the patient's vision.¹ Until relatively recently, among the corneal surgical alternatives that a patient had to improve his near vision, there were the techniques of monovision Near Vision Conductive Keratoplasty (Near-Vision CK) (Refractec, Irvine, CA),⁶ multifocal corneal refractive surgical procedures (AMO, Santa Ana, CA),⁶ and pinhole corneal inlay (AcuFocus, Irvine, CA), all of them aimed at increasing the depth of field.^{2,6} Cataract surgery allows the implantation of diverse types of Intraocular Lenses to correct presbyopia, like multifocal intraocular lenses (refractive, diffractive and hybrid), which provide simultaneous images to the visual system.^{2,3,6,9,12} However, despite the introduction of these devices that improve the near vision, the intermediate and distance vision are not sophisticated enough to restore the accommodation.¹

Because the action of the ciliary muscle persists over time, it has been found that pseudo-accommodation occurs after cataract surgery with implantation of monofocal intraocular lenses,⁷ which can induce approximately 2 Diopters of pseudo-accommodation.⁹ For this reason, accommodative intraocular lenses have been developed with the aim of avoiding the side effects induced with multifocal intraocular lenses, like halos, glares, etc.¹¹ In recent years, there has been a considerable research on the possibility of replacing the opacified crystalline lens by an intraocular lens that responds to the contraction of the ciliary body causing the accommodation.^{3,5} Therefore, accommodative lenses have been introduced to focus objects at all distances as the young crystalline lens would do in physiological conditions.^{1,3,7}

The aim of this review is to describe the different dual-optic accommodating Intraocular Lenses for the correction of presbyopia, as well as their optical performance and design. For that purpose, the movement and the amplitude of accommodation of the dual-optic accommodating IOL is analyzed, the visual outcomes published in recent scientific literature are compared, and the potential complications of these accommodative intraocular lenses are assessed.

Dual-optic devices

Recently, a variety of intraocular lenses that use the contraction and relaxation of the ciliary muscle have been introduced, to produce accommodation by moving the Intraocular Lens forward, causing a myopic refractive change, and improving the patient's near vision.^{2,12,13} Among the various devices that have been created single-optic accommodating IOLs stand out, as BiComFold (Morcher GmbH, Stuttgart, Germany), 1 CU (Human-Optics, Erlangen, Germany), Tetraflex (KH3500; Lenstec, St. Petersburg, FL, USA), and Crystalens (Bausch & Lomb, Rochester, NY, USA).¹⁴⁻¹⁸ Furthermore, there are other single-optic accommodating IOLs as Acuity C-Well (Or'Yehuda, Israel), Tekia TekClear (Irvine, CA, USA), and Bausch & Lomb OPAL (Rochester, NY), but their performance has not been intensively studied.^{6,16} Some single-optic accommodating IOLs have shown little movement,⁷ and in some cases backwards movement have been reported.^{6,9} With the aim of obtaining a greater movement of the lens in order to focus

near objects, spring-driven single-optic IOLs, magnet-driven active-shift systems and dual-optic accommodating IOL have been introduced.⁷ The shift of the single-optic accommodating IOL and dual-optic accommodating IOL occurs within the capsular bag. However, Preussner proposed a new concept based on the IOL-capsular bag shift to produce accommodation through a magnetic field.^{7,9,19,20} The magnet-driven active-shift systems are formed by two magnets that are implemented at 3 and 9 o'clock in the periphery of the capsular bag (inner magnets), while the other two pairs are sutured under the inferior and the superior rectus muscle insertions (outer magnets).^{7,9} In order to immobilize it correctly, a Capsular Tension Ring (CTR) has been developed, which also prevents capsular contraction, Posterior Capsular Opacification, and zonular distention.^{7,9}

The single-optic accommodating IOL is dependent on the dioptric power of the displaced lens,²¹ being the dual-optic accommodating IOL the one that provides better visual outcomes in near vision,¹¹ and greater changes in the refractive power.²² The concept of dual-optic accommodating IOLs dates back to the work of Hara et al. in 1990.^{4,6,7,9} More recently, the Synchrony accommodating IOL (Visiogen, Abbott Medical Optics, AMO, Santa Ana, CA, USA) and the Sarfarazi Elliptical Accommodative IOL have been developed in order to restore the accommodation after cataract surgery, and provide good visual quality at all distances.^{6,7,21,23}

The Synchrony accommodating IOL (Visiogen, Abbott Medical Optics, AMO, Santa Ana, CA, USA), is a silicone-made,^{1,5,7,9,11,12} single-piece IOL, that has a refraction index of 1.43,^{1,3} a dual optical system, and characteristic haptics that rest outside the capsular bag while the two optical lenses are located within the same.^{3,7,9,11,12,24} The design of the Intraocular Lens (IOL) inside the capsular bag has been performed according to the Helmholtz's theory of accommodation.²⁵ It combines a high power convergent optical lens with a divergent optical lens to achieve emmetropia,^{2,3,12,17,18,21,24,25} or some predetermined ametropia.² It is available in powers ranging from +16.00 Diopters to +28.00 Diopters in steps of +0.50 Diopters,^{11,21} with a total length of 9.5 mm and 9.8 mm wide.^{1,3-5,7} The anterior optical lens has a diameter of 5.5 mm with a fixed power of +32.00 Diopters,^{1,2} which is connected through the spring haptic to the negative powered optical lens of 6 mm in diameter.^{1,2,7,9} The diameter of the anterior optic is specifically designed to minimize the contact between the anterior capsule and the anterior surface of the Synchrony IOL,²⁵ facilitating the flow of aqueous humor.^{4,6} However, the power of the posterior optic can be varied depending on the dioptric power of each patient.¹ The diameter of the posterior optic is superior because it has been specifically designed with the aim of maintaining the stability within the capsular bag.²⁵

The spring haptics of the Synchrony IOL are located at 3 o'clock and at 9 o'clock while the stabilizing elements are located at 12 o'clock and at 6 o'clock.^{4,5} The length and the thickness of the spring haptics can change in order to produce a response range to the tension of the capsular bag.³ The haptics of the synchrony IOL were designed to permit a displacement of 1.5 mm of the anterior optic with the ciliary body contraction,^{4,5,23} reaching a total thickness of 2.2 mm when the device is compressed.^{1,3-5,16} The

Synchrony IOL was approved by the EC to be implemented in June 2006.⁶ Furthermore, the Synchrony IOL has the advantage that it can be preloaded in a cartridge, which enables the IOL to be injected into the capsular bag through a small incision ranging between 3.8 mm and 4.00 mm, depending on the dioptric power required by the patient.^{1,6,7,9,11,12}

The Sarfarazi Elliptical IOL is another type of dual-optic accommodating Intraocular Lens, formed by 2 optic lenses of 5 mm in diameter connected by 3 haptics,^{7,16} which, through the same operation of displacement of the anterior optic of the Synchrony IOL, produces the accommodation.⁷ Its elliptical shape has been designed in order to conform to the natural morphology of the crystalline lens capsule.⁷ It was designed by FM Sarfarazi of Shenasa Medical LLC (Carlsbad, CA, USA), but later, Bausch & Lomb (Rochester, NY, USA) acquired the rights of development, production and marketing in 2003.⁷ The Sarfarazi Elliptical Accommodative IOL has been implanted in vivo in primates, proving that it can induce an increase in accommodative amplitude of approximately 6 Diopters.²³ Using sophisticated models, the creators of the Sarfarazi Elliptical Accommodative IOL predicted that the amplitude of accommodation could reach 4 Diopters in humans, if a 1.9 mm movement of the optics was achieved.²³ Unfortunately, there are no studies in the literature showing the effectiveness of this IOL in humans.

Optical performance of the dual-optic devices

The mechanism of action of the dual-optic accommodating IOL is produced due to the axial displacement of the positive power optic within the capsular bag,^{1,9,25} separating the axes of both optics a maximum of 4 mm.^{1,3,23} The divergent optic have a larger diameter than the convergent optic with the aim of preventing axial displacements.³ When both optics separate an increase of the dioptric power of the eye is achieved with the accommodative effort.^{7,9} In other words, in distance vision, in the absence of contraction of the ciliary body, the zonular tension remains, thereby increasing the tension produced in the capsular bag, and reducing the inter-optic separation.^{1,3,5,7,11,12} Nevertheless, in near vision, when the contraction of the ciliary muscle occurs (assuming that it could have a maximum force of 10 nN)⁴ zonule relaxes and reduces stress on the capsular bag.^{1,4,5,7} The lowering of tension on the capsular bag causes a reduction in the tension over the spring haptic of the dual-optic accommodating, allowing them to expand, and separate the convergent lens from the divergent lens, as a consequence of the displacement of the convergent lens in response to the contraction of the ciliary muscle.^{1,3,5,12} With the accommodative action, an aqueous humor exchange inside and outside the capsule is expected to occur. The silicone material of the dual-optic accommodative IOL makes that the difference between the refractive index of the aqueous humor and the intraocular lens considerably higher than the difference of refractive index between the aqueous humor and the anterior surface of crystalline lens in the phakic eye.⁶ This difference of the refractive indexes between both surfaces may cause the Purkinje III image to be displayed brighter on reflection from the anterior surface of the accommodative Intraocular Lens.⁶

Optical design: magnification of the image

The increment of the accommodative range produced by the movement of the anterior lens of the dual-optic accommodating causes that the distance between the retina and the image space nodal point is increased compared to the single-optic accommodating IOL.²⁶ The greater separation between the retina and the image space nodal point in the dual-optic accommodating IOL is produced by the higher magnification that it provides, in comparison to the single-optic accommodating IOL.²⁶ The fact that the cardinal points of the dual-optic accommodating IOL are displaced toward the center will cause an increment of the focal lengths and the magnification.⁴ The effects of the image magnification have been identified as a possible factor that influences in the optical performance of the dual-optic accommodating IOL.⁸ It has been found that an increase of the retinal image is produced with the dual-optic accommodating IOL: 1% in eyes with small axial length, 2.16% in eyes with intermediate axial lengths and 2.5% in eyes with high axial length.⁴

Cataracts often are not produced bilaterally, so implanting monocularly the dual-optic accommodating IOL may cause symptoms like diplopia, dynamic anisometropia or dynamic aniseikonia if the accommodative response is particularly strong.^{5,6,23,26} The tolerance of the aniseikonia, that allows to merge the images has been commonly determined to be between 4% and 5%,²⁶ although in some studies it is in the range of 5–8%.^{4,5} It is considered that stereopsis is harmed with a 1% difference between the images of both eyes.²⁶ However, the dual-optic accommodating IOL can be implanted monocularly or binocularly,⁴ being necessary, if it is implanted monocularly, to choose properly the combination of designs and customize them with the aim of achieving binocularity.²⁶ Glasser suggests that even if the dual-optic accommodating IOL is implanted bilaterally, the accommodative response may be different due to the differences in the surgery itself or postoperative recovery responses.⁶ McLeod et al. found that when a single-optic accommodative IOL is implanted in one eye and a dual-optic accommodative IOL in the other, the maximum range of magnification disparity was in the order of 2.5%.^{4,5} However, this 2.5% is considered to be below the level at which the aniseikonia may produce symptoms, not affecting the binocular vision.⁴ Ale et al. found that even when the accommodative intraocular lens is implanted binocularly, an aniso-accommodation of approximately 1 Diopter would induce a retinal image size disparity of approximately 6%, being enough to compromise the binocular vision.²⁶ They found that an aniso-accommodation less than 1 Diopter was not sufficient to produce diplopia, being enough to impair the stereopsis.²⁶ However, there are situations in which, for example, the Crystalens HD has been implanted in one eye and a multifocal intraocular lens in the other to achieve some level of binocularity at all distances, and the patient's satisfaction with this combination has been shown to be good.⁶

In addition to the above discussed aniso-accommodation and stereopsis, another important factor for clinical optometrists is astigmatism. Since Syncryny dual-optic accommodating IOL is not currently available in toric version, it cannot compensate the preoperative astigmatism.¹

According to the revised literature, a lot of studies use corneal astigmatism as an exclusion criterion when greater than 2.00 Diopters,^{4,12} or greater than 1.50 Diopters.¹ In fact, another study considers 1 Diopter or less as an appropriate preoperative corneal astigmatism value.²¹ It is worth to mention that one of the postoperative complications of IOL implantation is the induced astigmatism. Fortunately, the industry is moving toward microincisional surgery (MICS), which has improved the control of postoperative astigmatism.

Technologies for analyzing the movement of the optic and the amplitude of accommodation

Prior to the implantation of a dual-optic accommodating IOL, it is necessary to check that the patient has a wide anterior chamber depth (ACD) in order to ensure that the intraocular space is enough for the Intraocular Lens displacement.^{1,12} The evolution of changes of the anterior chamber depth (ACD) with the contraction of the ciliary muscle may be used as an indicator of the accommodative ability on accommodative intraocular lens implanted eyes.⁷ Different techniques have been described to objectively determine the displacement of the anterior optic with the accommodative effort.⁴ Among those techniques the biometric techniques, which use high-frequency ultrasounds (UBM),⁴ partial coherence interferometry (Carl Zeiss, Jena, Germany), optical low coherence reflectometry (LenStar, Haag-Streit or Allegro Biograph, Wavelight), Scheimpflug imaging, and anterior segment optical coherence tomography (AS-OCT) need to be highlighted.⁷

The accommodation induced by accommodative Intraocular Lenses not only depends on the displacement of the IOL, but that also on the axial length of the eye, on the IOL power, and on the corneal power.^{4,5} Studies performed with Ray-tracing show that dual-optic accommodating IOLs produce greater change in the refractive power and greater amplitude of accommodation than single-optic accommodating IOLs,^{7,23,24} in eyes with high axial length (myopic) or eyes with axial lengths of 23–24 mm (normal eyes).^{2,8} However in eyes with short axial length (hyperopic), the dual-optic accommodating IOL provides lower amplitude of accommodation than the single-optic accommodating IOL.² It is important to note that the power of the IOL varies with corneal power and axial length. For this reason, depending on the preoperative ametropia, the power of the dual-optic accommodating IOL will be different, and it will produce more or less amplitude of accommodation. It is considered that the dual-optic accommodating IOL provides approximately the double of amplitude of accommodation than the single-optic accommodating IOL, so that, the latter provides limited visual outcomes in near vision.^{2,3,5,11} However, Langenbucher et al. found that in extremely short eyes (hyperopic) the amplitude of accommodation of the single-optic accommodating IOL was greater than the dual-optic lens.² Mathematical calculations show that a movement of 1 mm in a single-optic accommodating IOL of power of +19 Diopters produces a change of approximately 1.2 Diopters. On the other hand, as the dual-optic accommodating IOL is formed by two lenses of +32 Diopters and –12 Diopters separated by 0.5 mm, it can produce an

increase of approximately 2.2 Diopters/mm.^{3,4,6,9} Based on these calculations, McLeod et al. say that it is possible to achieve a greater variation in the refractive power by unit axial displacement choosing a higher potency of the anterior lens. Nevertheless, McLeod et al. specify that the benefits of the increased accommodative range with high-powered anterior lenses must be studied against the increase of the optical sensitivity of the system.³

The objective methods of measurement of the amplitude of accommodation as skiascopy, infrared optometer, and wavefront analysis,⁴ can provide, in theory, more approximate values than subjective methods.^{7,12} However, these have the disadvantage that the light sources of the autorefractometers, retinoscopic techniques or aberrometers, among others, can produce luminous effects in pseudophakic patients, complicating the measurements, particularly in elder patients with high refractive myopias or miotic pupils.^{4,6} Despite this limitation, some studies have used autorefractometers, retinoscopic techniques and aberrometers to measure the objective amplitude of accommodation of the pseudophakic patient because these devices are necessary to differentiate pseudoaccommodation from true accommodative response, although in the revised literature there are not many studies in this regard.⁶ According to the monocular outcomes obtained by Peris-Martínez et al. with the OQASTM (Visiometrics-System), the patients who had sufficient amplitude of accommodation did not require addition for 40 cm once the dual-optic accommodating IOL was implanted.¹ They found that the values of objective amplitude of accommodation were 2.25 ± 1.00 Diopters 1 month after the intervention, 2.17 ± 0.77 Diopters at 3 months and 2.25 ± 0.83 Diopters at 6 months, not being observed statistically significant changes in the amplitude of accommodation over time ($P=0.84$).¹ Therefore, Peris-Martínez et al. suggested that patients had the required amplitude of accommodation, but they needed some training to achieve the correct functioning.¹ However, there are other studies that demonstrate little benefit of the dual-optic accommodating IOL in near vision. Alió et al. proved that although the dual-optic accommodating IOL restored the visual function, the benefits in near vision were limited.¹¹ Likewise, Ehmer et al. found 54 months postoperatively, by dynamic stimulation aberrometry (DSA) device (Optana) attached to the WASCA aberrometer (Carl Zeiss Meditec AG), that after the implantation of the dual-optic accommodating IOL an accommodation of approximately 1.00 Diopters occurred for a pupil size of 3.00 mm and an accommodative stimulus of 3.00 Diopters.²⁷

Although the benefits of dual-optic accommodative IOLs in near vision are limited, the amplitude of accommodation and the shift of the single-optic accommodation IOL are even inferior. Marcos et al. analyzed the movement of the Crystalens HD accommodating IOL by means of spectral optical coherence tomography (OCT) using pilocarpine. They proved that the average displacement of Crystalens HD accommodating IOL was -0.02 ± 0.20 mm. They only noted in two cases a maximum shift of -0.52 mm in one eye and -0.49 mm in another eye.²⁸ In a recent study, Pérez-Merino et al. evaluated the objective accommodative response using laser ray tracing aberrometry in eyes implanted with the Crystalens accommodative IOL. They showed that the accommodative response was lower than 0.4 Diopters.²⁹

Nowadays, a variety of accommodative intraocular lenses that produce greater amplitudes of accommodation have been introduced, for instance, optical systems that replace the lens by an elastic material in order to modify their curvature,^{7,30} or optical systems that by means of fluids produce accommodation.⁷ Optical systems that change their curvature can provide satisfactory refractive powers with minimal axial displacement.^{7,31} Some examples of this type of IOLs are NuLens (Herzliya Pituach, Israel), SmartIOL (Medennium Inc, Irvine, CA) and PowerVision FluidVision IOL (Belmont, CA).^{7,9} NuLens (Herzliya Pituach, Israel) has been the most studied one and it is the most promising one, as well. NuLens is formed by a flexible silicone gel that through the contraction of the ciliary muscle, the piston applies pressure on the flexible gel.^{6,7} The movement of the gel modifies the shape of the anterior surface, increasing or decreasing the optical power.⁷ According to theoretical calculations, it is estimated that the NuLens may produce a power change of 40 Diopters in the monkey's eye.^{7,32} There are already strong results that demonstrate the potential of this intraocular lens. Alió et al. showed that it can achieve even 10 Diopters of accommodation.³³ However, there is a lack of synergy between accommodation and vergence, necessary for maintaining binocular vision.^{6,7,34} In distance vision, when the visual axis are oriented to the infinite, accommodation and convergence would be maximal. Opposite to this, in near vision the visual axis would be in divergence. For this reason, it has been suggested that a period of adjustment would be required for the brain to adapt, and to learn to reverse relationship between accommodation and convergence.^{6,7}

Among the devices that use fluids for pseudo-accommodation, Liquilens (Vision Solutions Technologies Rockville, MD) highlights.⁷ It consists of two liquids that vary their refractive index to produce accommodation. According to the trading house, it is estimated that it can induce even 30 Diopters of refractive power change that could be very useful for low-vision patients.⁷ Nevertheless, some drawbacks have been reported so far: they do not provide true accommodation, and their behavior is similar to bifocal lenses, so the intermediate vision is not restored.⁷ Currently, there are no studies in the scientific literature showing the results in humans.

Clinical outcomes of the dual-optic devices

Correction independence vs refractive error

According to Peris-Martínez et al. in the prospective study in which they evaluated the Synchrony accommodating IOL (Visiogen Inc., a wholly owned subsidiary of Abbott Medical Optics, Inc.) the accommodative IOL only provided a minimal amount of accommodation, with most of their patients requiring additionally distance vision correction.¹ In addition, Peris-Martínez et al. observed a slight change of the myopic spherical equivalent (-0.84 ± 1.12 Diopters),¹ which had to be compensated with the aim of providing an adequate vision in intermediate and near distances.¹ They also found a slight tendency of the spherical myopic equivalent to compensate over time at all distances (40 cm, 70 cm, 2 m and 4.8 m), although only statistically significant differences were found at 2 m of distance in the postoperative period of

1 month and 6 months.¹ Ossma et al. also noted that the spherical equivalent was -0.52 ± 0.77 D after 6 months of the intervention.¹²

Visual acuity

The visual acuity in near vision with the distance correction is a good indicator of the accommodative effect of the intraocular lenses.²¹ Although it was originally thought that the pseudo-accommodation in patients with dual-optic accommodating IOLs was not expected to be higher than the one obtained with monofocal intraocular lenses,²¹ it has been found that the pseudo-accommodation of dual-optic accommodating IOLs allows to obtain better visual acuities in near and intermediate vision compared to those obtained with monofocal intraocular lenses.¹ Pseudoaccommodation improves near visual acuity by means of several factors such as depth of field, pupil size, ptotic eyelids, squinting, low magnitude myopia, against-the-rule myopic astigmatism and Higher Order Aberrations (HOA), mainly spherical aberration and coma.^{7,35,36} Furthermore, the pseudoaccommodation can occur due to the axial shift of the Intraocular Lens. For this reason, accommodative Intraocular Lenses have more amount of pseudoaccommodation than monofocal intraocular lenses.³⁶ After 6 months of the implantation of the dual-optic accommodating IOL Synchrony, Bohórquez & Alarcon found that the Uncorrected Near Vision Acuity (UNVA) and the Uncorrected Distance Visual Acuity (UDVA) was 20/40 or better.²¹ Ossma et al. found that at 6 months of the intervention, all eyes reached an Uncorrected Near Visual Acuity (UNVA) 20/40 (J3) or better, while 70.8% of eyes reached an Uncorrected Near Visual Acuity (UNVA) of 20/25 (J1) or better ($P < 0.001$).¹² McLeod, in a clinical essay where the Synchrony IOL was implanted, found that Uncorrected Near Visual Acuity (UNVA) improved from 0.11 LogMAR one month after surgery to 0.08 LogMAR 6 months postoperatively.⁴ In the same essay, McLeod found that the Distance Corrected Near Vision Acuity (DCNVA) remained stable, improving from 0.17 LogMAR one month after surgery to 0.14 LogMAR at 6 months postoperatively.⁴ In addition to the good outcomes obtained in near vision, it is considered that the visual acuity in intermediate vision is better with the dual-optic accommodating IOL than with some multifocal intraocular lenses.¹

The dual-optic accommodating IOL does not produce the same effect in near vision in all patients. Peris-Martínez et al. found in a prospective study conducted in patients with a mean age of 74 ± 6 years old, that older patients who had been a long time without accommodating, required addition in order to obtain the Best Near Visual Acuity (BNVA) once the dual-optic accommodating IOL was implanted.¹ They have found that, the average addition for a distance of 40 cm one month after the intervention was 1.87 Diopters, 1.66 Diopters at 3 months and 1.5 Diopters at 6 months after the intervention.¹ This improvement is due to the fact that the ciliary muscle, like any other muscle in the body, needs a training period to recover its function,⁶ so that if the ciliary muscle has been some time without contracting, it needs some exercise to produce the optimum effect.¹ With the appropriate training, patients who were implanted with the dual-optic accommodating IOL could achieve large amplitudes of accommodation.¹

Due to the constriction of the pupil with age, the depth-of-field increases, allowing an improvement of the near visual acuity. The depth-of-field is defined as the range of distance in the object space that can be sharply focused. It is strongly related to the depth-of-focus – the amount by which the distance between the crystalline lens and the image can be varied without altering the image quality. The latter also enhances near vision. The depth-of-focus, in addition to being influenced by factors as the power of the eye or the axial length, it may be influenced also by the pupil size of the patient.^{7,13} However, there are other factors that influence on the depth of focus, as the lens power, implant position and the type of accommodating Intraocular Lens.¹³ Some studies have been conducted to determine whether dual-accommodating IOLs enhance the depth-of-field. Ale et al. studied a depth-of-field of a dual-optic accommodating IOL and the single-optic accommodating IOL through theoretical analyses using paraxial optic equations.¹³ They found that the depth-of-field in both accommodative Intraocular Lenses was increased with more posterior positioning of the accommodating Intraocular Lens,¹³ while the pseudophakic accommodation produced by the movement of the lens decreased.¹³ Ale et al. affirmed that despite the variation in the depth-of-field due to the depth of implantation of the IOL, pseudophakic accommodation and the combination of the two optics did not exceed 0.02 Diopters.¹³ However, studying the depth-of-field is mandatory, as it is strongly associated with the shape of the defocus curve.

The visual acuity in distance vision obtained with dual-optic accommodating IOLs is similar to that obtained with monofocal intraocular lenses.¹ Peris-Martínez et al. in a prospective study in which they implanted the Synchrony accommodating IOL (Visiogen, Abbott Medical Optics, AMO, Santa Ana, CA, USA) in 18 patients (36 eyes) found that the Best Distance Visual Acuity (BDVA) had improved significantly from 0.27 ± 0.17 LogMAR to 0.06 ± 0.21 LogMAR at 6 months postoperatively ($P > 0.05$).¹ Ivan et al. found that 6 months after implantation of a dual-optic accommodating IOL, no patient lost Best Corrected Visual Acuity (BCVA), with 79.2% of patients with Uncorrected Distance Visual Acuity (UDVA) of 20/40 or better.¹²

Few studies have been performed comparing the visual outcomes of a dual-optic accommodating IOL with a single-optic accommodating IOL. Alio et al. found that at 3 months after surgery, patients who have been implanted with the dual-optic accommodating IOL had better Uncorrected Distance Visual Acuity (UDVA) and Corrected Distance Visual Acuity (CDVA) than the patients who had been implanted the single-optic accommodating IOL ($P \leq 0.04$), not observing differences between both groups in intermediate and near vision ($P \geq 0.13$).¹¹

Defocus curves

The defocus curve is useful to evaluate the performance of intraocular lenses. It measures visual acuities simulating various distances with different levels of blur provoked by positive and negative lenses.^{11,12} The dual-optic accommodating IOL provides a better range of focus than monofocal intraocular lenses.^{4,12} McLeod studied the defocus curve 6

months after the implantation of the dual-optic accommodating IOL Synchrony, finding that the accommodative range was 3.22 ± 0.88 Diopters (range 1.00–5.00 D) with the dual-optic accommodating IOL in comparison with the 1.65 ± 0.58 Diopters (range 1.00–2.50 D) of standard monofocal intraocular lenses ($P < 0.05$).^{4,7,12,21} MacLeod claimed that the design of the dual-optic accommodating IOL might induce a multifocal effect or a greater depth-of-focus, which could explain these outcomes.⁴ Likewise, values of the defocus curve seems to be better with the dual-optic accommodating IOL than with the single-optic accommodating IOL.¹¹ Alió et al. implanted a single-optic accommodating IOL (Crystalens HD) in 27 eyes and a dual-optic accommodating IOL (Synchrony) in 26 eyes. They found that the defocus curve of both lenses were similar, with better visual acuities in the levels of blur of -3.50 Diopters and -3.00 Diopters ($P \leq 0.04$) that corresponded approximately to reading distances of 33 cm with the dual-optic accommodating IOL.¹¹ They also showed that the visual acuity in near vision was limited for the level of blur of -2.50 Diopters with the dual-optic accommodating IOL as well as with the single-optic accommodating IOL.¹¹ The defocus curves of the dual-optic accommodating IOL have only been compared with monofocal IOLs and single-optic accommodating IOLs. Nevertheless, currently there is a lack of studies that compare the defocus curve of dual-optic accommodating IOLs with multifocal IOLs. Although the defocus curve should be better with dual-optic accommodating IOLs than with monofocal IOLs or single-optic accommodating IOLs, the defocus curve may vary among studies because different criteria may be used to obtain it. The defocus curve can be measured in monocular or binocular vision, with the best distance correction in steps of 0.50 Diopters. Furthermore the power range used varies between studies. Alió et al. used a power range between -4.00 Diopters to $+2.00$ Diopters,¹¹ while MacLeod used a power range between -2.00 Diopters to $+2.00$ Diopters.⁴

Reading speed

Although visual acuity is often used as a measure of visual quality, the static conditions in which it is performed, and as isolated letters are used, it is a flawed test to explore dual-optic accommodating IOL performance.²¹ Reading speed tests (MNRead, Radner, charts in German and Portuguese), are increasingly common in clinical practice because they provide quantitative and qualitative measures of different components of reading ability.²¹ Three features can be evaluated: the smallest legible print size (in LogMAR units), the critical print size or the smallest print size where the reading speed starts to decline (also in LogMAR units), and, finally, the reading speed (words per minute – wpm).

Dual-optic accommodating IOLs provide an improvement in those three components over time.²¹ Mean reading acuity has shown to improve at least one line with a dual-optic accommodating IOL (0.07 LogMAR versus 0.15 LogMAR, $P < 0.01$), critical print size to increase 2 lines (0.28 LogMAR versus 0.48 LogMAR, $P < 0.01$), and reading speed to be faster for 0.3–0.1 LogMAR print sizes ($P < 0.01$).²¹ However, these authors failed to find statistical differences in reading speed for 0.4 LogMAR print sizes (180.5 wpm versus 184.2 wpm, $P = 0.90$), equivalent to newspaper print size of 20/50.

Moreover, the percentage of patients whose reading speed was more than 80 wpm – the minimum necessary for a comfortable reading – was higher at 2 years.²¹ However Alió et al. claimed that dual-optic accommodating IOLs did not differ from single-optic accommodating IOLs in terms of reading acuity (0.60 ± 0.15 LogRAD vs. 0.67 ± 0.12 LogRAD, respectively; $P = 0.13$) or reading speed (95.83 ± 8.17 wpm versus 98.56 ± 12.38 wpm; $P = 0.46$).¹¹

According to Bohórquez & Alarcon, dual-optic accommodating IOLs render an acceptable functional near vision, with comfortable reading speeds and visual acuities better than 20/32, suggesting that the mechanism of action by which the optic of the dual-optic accommodating IOL moves forward is effective.²¹

Contrast sensitivity

The dual-optic accommodating IOL Synchrony provides better outcomes in terms of contrast sensitivity than the single-optic accommodating IOL Crystalens HD. Specifically, Alió et al. found that the Synchrony dual-optic accommodating IOL provided better contrast sensitivity in photopic conditions (85 Cd/m^2) and scotopic conditions (3 cd/m^2) for spatial frequencies of 18 cycles/degree ($P = 0.02$).¹¹

Optical quality

The Strehl ratio derived from wavefront aberrometry seems to be better in patients who have been implanted with dual-optic accommodating IOLs than those who have been implanted with single-optic accommodating IOLs.¹¹ Alió et al. found that the mean ocular Strehl ratio obtained with dual-step systems in the Synchrony dual-optic accommodating IOL was 0.12 ± 0.04 , while in the Crystalens single-optic accommodating IOL was 0.10 ± 0.02 ($P = 0.05$).¹¹

The estimated ocular Modulation Transfer Function (MTF) values of the single-optic accommodating IOL seems to be similar to the obtained with that dual-optic accommodating IOL. Alió et al. found that the estimated MTF cutoff spatial frequency of the group of eyes implanted with the dual-optic accommodating IOL was 18.83 ± 9.06 cycles/degree, while that of the group of eyes implanted with the single-optic accommodating IOL was 14.58 ± 4.96 cycles/degree ($P = 0.08$).¹¹

It is well known that the human eye has a small amount of positive spherical aberration in far focus, while with the accommodation, the aberration is progressively reduced and can change to negative.²³ Optical aberrations have been identified as possible factors influencing on in the optical performance of accommodative Intraocular Lenses.⁸ Laboratory studies have shown that an increase of the positive spherical aberration is produced with the dual-optic accommodating IOL during accommodation.²³ Nevertheless, it is observed that total and High Order Aberrations (HOA) root mean square (RMS) with the dual-optic accommodating IOL are lower than those with the single-optic accommodating IOL. Alió et al. found that at 6 months postoperatively, the total RMS was better in the group of the dual-optic accommodating IOL than in the group of the single-optic accommodating IOL ($1.21 \pm 0.37\text{ }\mu\text{m}$ versus $1.72 \pm 0.44\text{ }\mu\text{m}$; $P = 0.01$).¹¹ They also found that the High-Order

Aberrations RMS (HOA) was better in the group of the dual-optic accommodating IOL than in the group of the single-optic accommodating IOL ($0.50 \pm 0.11 \mu\text{m}$ versus $0.69 \pm 0.23 \mu\text{m}$; $P \leq 0.01$).¹¹ Peris-Martínez et al. found that in the group of patients who were implanted the dual-optic accommodating IOL nobody complained of halos, glares or other visual defects.¹

Complications

The Posterior Capsule Opacification (PCO) is one of the main complications after cataract surgery. In the dual-optic accommodating IOL is not only important the prevention of the Posterior Capsule Opacification (PCO), but also the prevention of the Anterior Capsule Opacification (ACO) because of the functional loss that it could provoke.²⁵ The Posterior Capsule Opacification (PCO) occurs as a result of the proliferation or regeneration of the "E" cells (LECs). The "E" cells are equatorial lens epithelial cells (LECs) left in the capsular bag that can migrate after the surgery for cortex regeneration.^{7,9,25} As "E" cells' proliferation can produce capsular fibrosis, it is mandatory a proper capsule polishing in the intervention.⁷ The Anterior Capsule Opacification (ACO), nevertheless, occurs as a consequence of the fibrous metaplasia of the residual cells "A" linked to the inner surface of the anterior capsule where it makes contact with the anterior optic of the IOL.²⁵ The material and the design of the intraocular lens in the capsular bag influence on the formation of PCO and ACO.⁴ Studies performed in postmortem pseudophakic human eyes found that the incidence of ACO is lower in 3-piece silicone lenses than with 1-piece plate silicone lenses, because in 3-piece lenses there is less contact between the material of the haptics and the anterior capsule.²⁵ Studies performed in animals and in humans show that the incidence of Posterior Capsule Opacification (PCO) in dual-optic accommodating IOL is relatively low, due to the silicone material and dual-optics,^{5,12,21,24,25} with no regeneration or proliferative capsule fibrosis material among both optics.^{4,21} Werner et al. in a study performed in rabbits, found a slight tendency to Soemmering's ring formation between the components of the dual-optic accommodating IOL at the periphery, not being noticeable at central level.²⁵ Nevertheless, the formation of Soemmering's ring is not expected to occur in human eyes, because the human eye has not the same regeneration and proliferation ability as the rabbit's eyes, and the cortical cleaning and capsule polishing is better conducted in humans.²⁵ Werner et al. found in rabbit eyes that the incidence of Anterior Capsule Opacification (ACO), Posterior Capsule Opacification (PCO) and the formation of Soemmering's ring was lower in the eye implanted with the Synchrony IOL than in the eye with a control IOL (1-piece plate silicone IOL with large fixation holes).²⁵ The decline of the Posterior Capsular Opacity is due to the material of the dual-optic accommodating IOL and its 1-piece design. It has been found in the rabbit model as well as in humans that the incidence of Posterior Capsular Opacity is lower in the dual-optic accommodating IOL than in the single-optic accommodating IOL.⁵ Alió et al. found that the incidence of posterior capsular opacity in the dual-optic accommodating IOL was lower than that of

the single-optic accommodative IOL at 3 months postoperatively (11.5% versus 40.7% respectively; $P < 0.01$). At 3 months, 7.9% of patients with the dual-optic accommodative IOL required Nd:YAG laser capsulotomy. In contrast, 18.5% of patients with single-optic accommodative IOL required Nd:YAG laser capsulotomy.¹¹

Although there are not scientific studies that indicate the presence of post-operative refractive surprises secondary to the Capsular Opacification in dual-optic accommodating IOLs, the fibrotic deformation could cause hyperopic refractive changes, as it has been documented for 1 CU single-optic accommodating IOLs.⁹ However, single-optic accommodating IOLs are more robust against postoperative refractive surprises, because they have less capacity of movement.⁶ Based on that assumption, the ability of dual-optic accommodating IOLs to displace could provoke unexpected refractive outcomes. Unfortunately, the studies in the scientific literature neither corroborate nor evaluate that complication.

In addition to the actions of contraction and relaxation of the ciliary body and the zonule, there are certain hydraulic and mechanical influences produced by the vitreous humor and the iris that can affect the positioning of the dual-optic accommodating IOL.²³ Studies performed in rabbit eyes show complications after the implantation of the dual-optic accommodating IOL. Werner et al. found in rabbit eyes, that when the capsulorhexis diameter was higher than the diameter of the dual-optic accommodating IOL, a partial or total dislocation was produced into the anterior chamber.^{24,25} They found that the capsular bag-IOL complex pushed the iris forward when the capsulorhexis did not cover 360° of the optic. When capsulorhexis diameters were smaller than the dual-optic accommodating IOL diameter, the IOLs were properly set within the capsular bag.²⁵ Still, some complications took place, like pupillary margin – anterior surface of the IOL synechia, inadequate pupillary dilatation and iris bombe.²⁵ Nevertheless, the dislocation of some IOLs into the anterior chamber and pupillary block syndrome observed in rabbit eyes cannot be extrapolated to human eyes, because they are probably caused by the higher pressure of the vitreous humor in the rabbit eyes and that the dual-optic accommodating IOL was relatively bigger compared to the anterior segment of the rabbit eyes.²⁵ The dislocation into the anterior chamber and pupillary block syndrome observed in the rabbit eyes were solved by iridectomy.²⁴ If such complications occur in human eyes, the vast majority of situations could be prevented with intraoperative iridectomy.²⁵ Nevertheless, McLeod reported a clinical essay where a patient was implanted with Synchrony IOL, and because the capsulorhexis was higher than usual, the IOL decentred and its explantation was required.⁴

Nowadays, there is a lack of studies assessing the stability of dual-optic accommodating IOLs in the capsular bag in human eyes, but it has been done in rabbit eyes. Werner et al. found that after the implantation of the dual-optic accommodating IOL in the capsular bag in rabbit eyes, the location of the IOL did not change significantly (less than 1 clock hour).²⁵ To the best of our knowledge, there are no studies in the scientific literature that associate dual-optic accommodating IOLs with Intraocular Pressure (IOP) changes

or infection rates. For this reason, it could be interesting to conduct studies in this line.

Conclusions

Dual-optic accommodating IOLs present a greater axial displacement in the capsular bag than single-optic accommodating IOL. However, more studies are required to corroborate this greater shift of the dual-optic accommodating IOLs. The dual-optic accommodating IOL also provides larger accommodating capacity, optical quality and higher patients' satisfaction rates. Nevertheless, the visual outcomes in near vision are still limited. Furthermore, its design and material significantly reduces the formation of Posterior Capsular Opacification and Anterior Capsular Opacification, so few postoperative complications are observed.

Conflicts of interest

The authors have not proprietary or commercial interest in the medical devices that are involved in this manuscript.

Acknowledgement

To Manuel Alejandro Amaya Alcaraz for the collaboration in the revision of this manuscript.

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