Comparison of visual results after implantation of extended focus intraocular lenses (EDOF) in cataract surgery.

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ABSTRACT

Objective: To compare the visual results in the first month after the implantation of an EDOF intraocular lens.

Place: Ophthalmology Clinic Oftalmocor (private clinical practice), Córdoba (Spain).

Methods: This prospective, randomized study, masked by the examiner included 20 eyes of 20 patients 5 of them for each lens model. The average age was (67.96 ± 5.88 years of age). All patients underwent cataract surgery with implantation of an intraocular lens with Extended Depht of Focus (EDOF) technology. The studied lenses were MiniWell (SIFI), Precizon Presbyopic (Opthec), Symfony (J & J) and LARA (Zeiss) between May and July 2018. A monocular defocusing curve was made of each IOL evaluated one month after surgery.

Results: Of the ERV lenses, the CTF lenses (Precizon Presbyopic intraocular lens) achieved better postoperative AV: These visual acuities were found on average at distance with AVCC logMAR 0.05 ± 0.02, for intermediate vision AVCC logMAR 0.17 ± 0.04 and for near vision AVCC logMAR 0.38 ± 0.18.

Conclusion: The ERV LIOS are an alternative to the intervention of cataracts to have certain independence at distances of far, intermediate and near. Being the CTF the best solution to surgery offers in intermediate and close.

Keywords: Continuous transition lens; Extended focus lens; Multifocal lens; Presbyopia; IOL.

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Keywords: *Optometry, Protocol, Vision examination, School-age children, Dyslexic children*

INTRODUCTION

Cataracts surgery has evolved from a simple procedure to eliminate the opacified lens to a method that allows to compensate for refractive errors. In recent years the main objective of the implantation of intraocular lenses (IOL) is emmetropia for all distances. Theoretically, the latest IOLs are capable to compensate not only for spherical errors but also for astigmatism and presbyopia, providing complete restoration of visual function and patient's independence from optical aids.

Presbyopia is an Physiological ophthalmic condition in which the eye suffers a progressive degeneration resulting in losing the ability of focus objects clearly, particularly for near vision Due to loss of amplitude of accommodation. This is due to physiological changes usually caused by the aging of the eye. These changes are related to the decrease in elasticity of the lens that results in a lack of response to the contraction of the ciliary muscles, which results in the loss of lens accommodation [1]. Glasses and contact lenses have traditionally been used to correct presbyopia. However, the development of surgical techniques for the correction of presbyopia, such as intraocular lenses (IOL), have proven to be an attractive alternative. In search of total compensation, multifocal intraocular lenses (MIOL) are designed to reduce the dependency on glasses and to improve quality of life related aspects. As of this date there is scientific evidence that there is significant improvement in uncorrected near visual acuity (UNVA) after implantation of a MIOL as compared to monofocal IOLs, without a significant decrease in the levels of uncorrected far distance visual acuity (UDVA) [2]. However, there are still certain limitations associated with visual performance. Among these are glare and halos, reduced contrast sensitivity (CS) and the fixed distance focus these lenses offer. In the past designs were bifocal, which allowed the patient to have postoperatively functional distance and near visual function. Today, the massive use of electronic devices has changed patients' preferences on what distances need to be prioritized. The last generation of MIOL based on a diffractive platform delivers light to the retina with a predefined distribution of light at various foci.

The advantage of using IOL in patients in whom surgery to extract the lens is performed (cataracts) is that it is replaced by an artificial lens to restore vision. The first successful operation that implanted the first acrylic artificial lens was performed by Dr. Ridley [3]. Before this first surgery it was necessary to answer a series of questions related to the appropriate material and design for the IOL as well as the implementation of the surgical techniques as we know them today [4].

The introduction of a bifocal multifocal intraocular lens at the beginning of the 1980s offered patients the potential to reduce dependency on glasses. However, it was no devoid of secondary effects as dysphotopsias, halos, glare or loss of contrast sensitivity [5-9].

The next challenge was to conquer the intermediate range vision that is very important in the daily living of patients [10]. This changed with the introduction of the bifocal lens which combines two different structures to create three foci, near, intermediate and far-distance vision. [11, 12].

The psychological profile of patients is fundamental for the functional success of the MIOL implantation. A detailed preoperatory interview is necessary to achieve a real understanding of their character and the results they expect at the end of the process. It is necessary to obtain information on the daily activities of a patient before an IOL is selected as the most appropriate for them, with the advantages and disadvantages associated with the available products today. Complete information about the life-style of the patient is necessary. The most adequate questions to ask: At what distance do they read? Under what kind of light? and with what medium? Electronic devices, mobile phones and newspapers are read at various distances and today more newspapers articles are read on telephones than on paper. Do they drive? and more particulary, do they drive at night? What are their activities and hobbies?"

EXTENDED DEPTH OF FOCUS LENSES (EDOF)

Extended depth of focus lenses have been developed in recent years. The depth of focus is used every day during routine vision examinations, as well as in the prescription of ophthalmic lenses or contact lenses and the majority of refractive surgery with implantation of an intraocular lens. We define depth of focus as "the variation in the image distance of a lens or an optical system that may be tolerated without incurring an obvious loss of sharpness in focus" [13].

These lenses use diffractive (LARA and Symfony), refractive (MiniWell) and accommodative scales imbedded in the lens surface, which tend to extend in optical way the depth of focus and create a major range of uncorrected useful vision. The technology of negative dispersion refraction is also used for the chromatic adjustment and spherical aberration, improving the quality of the image on the retina.

Diffractive technologies were used with the extended vision Tecnis Symfony lens (Johnson & Johnson Vision, Santa Ana, CA, USA). A recent study in 176 eyes that compared ERV with monofocal intraocular lenses did not show significant differences between groups in far distance vision with uncorrected binocular VA, although intermediate and near VA were much better in the ERV group [14].

Bellucci et al introduced this requirement for theoretical and optic banks and computer simulations. The spherical aberration in the IOL central surface increases the depth of focus offering good MTF values in a wide dioptric range with a pupil opening of 3 mm and favoring far distance vision with a pupil opening of 4.5 mm. His specific worry was to introduce apodization to prevent distance problems under scotopic conditions. In addition, limited variation in spherical aberration should induce less halo and glare in eyes with implanted IOLs as compared to the variation extending beyond the central zone of 3 mm [15].

It must be taken into account that the MTF values they found are lower than those usually found with monofocal IOLs, but higher than those of multifocal IOLs [16].

Centering is considered very important of most the design in the majority of multifocal IOLs, like bi- and trifocal, since a decentered IOL relative to the visual axis can induce high level aberrations and decrease in postoperative visual function due to "looking through" IOL's refractive rings instead of the

central optical zone [17]. Consequently, decentralization could lead directly to a negative impact of the visual results. In addition, as a result of each focus with different IOL's properties, the severe changes of the transition points could have a negative impact in the patient's near vision? and this would probably result in optical distortion. At the same time, the diameter can also influence the additive power of near distance relation provided by the IOL. Patients with a small pupillary diameter (less than 3 mm) are not good candidates for the traditional asymmetric refractive MIOL, especially Lentis Mplus Toric (Oculentis GMBH, Berlin, Germany) [18]. In addition, patients with a large diameter are considered of greater risk of glare dysfunction, and may experiment optical aberrations, diffraction, or photic phenomena like glare and halos around the sources of light [19, 20].

The objective of our research is to compare the visual results, patient satisfaction and the rate of patient's independence through four intraocular lens designs with extended vision range. The lenses under study are MiniWell (SIFI Catania, – ITALY), Precizon Presbyopic (Opthec Groninge, The Netherlands), Symfony (Johnson y Johnson Visión, Santa Ana, CA, USA) and LARA (Carl Zeiss Meditec AG, Alemania).

Material and Methods

This is a prospective, randomized, masked for examiner study that included 20 eyes of 20 patients, 5 of each lens, with a mean age of 67.96 + 5.88 years. Each IOL had defocus curves performed at one month after surgery with lenses with extended focus in patients with cataracts.

The optometrist who performed the defocus curves did not know the type of EDOF the patient had inserted in order to prevent bias of the study results. The test was performed under the same office lighting keeping the optotype/patient distance equal for all monocular defocus curves.

For the analysis of the curves we used the mean and median values for each point of the curve. To calculate the area under the curve we used polynomial interpolation with free software from http://www.wolframalpha.com/ extracting the polynomial of tenth degree and integrating it between intervals +1.5 and -3.5D.

Clinical protocol Prior to surgery

All patients underwent an exhaustive preoperative ophthalmologic examination of overt refractive, optical biometry (IOLMaster 500, Carl Zeiss Meditec AG, Germany), pupilometry under mesopic and photopic conditions, biomicroscopy, topography (Pentacam Oculus, Germany). Goldmann applanation tonometry, dilated fundoscopy and Optical Coherence Tomography (OCT) (Topcon 3DOCT100, Japan). The power of the IOL and the refraction after the operation were based on the biometry data with the IOLMaster 500 biometric device (Carl Zeiss Meditec, Jena, Germany) and it is recommended to use the formula SRK-T, Holladay I or Hoffer- Q according to the axial length. The power of the IOL can be selected by a postoperative refraction of the plane and, therefore, selecting the option with the postoperative refraction closest to the emmetropia. In the postoperative period, patients were evaluated the day after surgery, 1 month after

surgery. Refraction, measurement of the blurring curve (only during the month's visit, evaluation by slit lamp, tonometry, and evaluation of the fundus with OCT. In the last postoperative visit, it is in addition to the previous tests: far Visual acuity without compensation (AVSC), far distance visual acuity with compensation (AVCC), near visual acuity without compensation (AVPSC) near visual acuity with distance compensation (AVPCC), intermediate distance without compensation (AVISC) and Intermediate visual guitar with far compensation (AVICC).

LENSES

MiniWell: Provides effective correction of presbyopia at all distances and a functional VA range for near distances, suggesting good visual acuity between 4 m and 50 cm. Achieving a widened focus depth, introducing different and controlled amounts of positive and negative spherical aberrations (SA), In two central sections within a diameter of 3 mm, in the central zone of the IOL. The peripheral section between 3- and 6-mm diameters is designed for achieving optimal distance vision at nighttime, and therefore has been given an aspheric profile without inducing any further SA.

Precizon Presbyopic: Has an optical design with neutral spherical aberration to retain the natural corneal residual SA to obtain fewer visual disturbances. The effects of this spherical design have been clinically evaluated {29]. It offers a complete vision range to patients without losing significant contrast sensitivity.

Technis Symfony: Is an extended range of vision IOL based on the combination of compensation of the chromatic aberration and primary spherical aberration [18, 30]. The IOL has an achromatic diffractive pattern that elongates the focus and compensates for the chromatic aberration of the cornea. With multifocal IOLs, is in focus while the out-of-focus image is suppressed (simultaneous vision), and this out-of-focus image generates halos. According to the manufacturer, halos are not expected with this IOL because it provides an elongated focal area rather than 1 or various individual focal points. The IOL has a biconvex wavefront-designed anterior aspheric surface and a posterior achromatic diffractive surface. The total diameter of the IOL is 13.0 mm, and the optic zone diameter is 6.0 mm. It is an ultraviolet– filtering hydrophobic acrylic material with a refractive index of 1.47 at 35°C. At present, the IOL is available in powers from +5.0 D to +34.0 D in 0.5 D increments. [33].

LARA: Uses patented Smooth Microphase (SMP) diffractive technology to minimize light dispersion, and therefore, possible undesired visual effects controlling the level of spherical or coma aberration. In conventional diffractive designs manufacturing technology is not able to create sharp angles. Hence, a certain amount of light is dispersed in undefined directions. On the other hand, the SMP technology incorporates the socalled phase zones in its optical design, which allows obtaining an ideal surface with much less acute angles that allow to minimize the scattering of light.

In all patients, lens surgery was performed without taking into account if it was for refractive lensectomy or cataracts with implantation of an intraocular lens with EDOP technology. The technique used was standard lens phacoemulsification without stitches and implant of all the types of IOL in

the capsular bag using the injection system qualified by the respective manufacturer. All surgeries were performed by the same experienced surgeon (Dr. Giménez de la Linde) at the Oftalmocor ophthalmology clinic (private practice), Córdoba (Spain), between May and September 2018.

This prospective, comparative, monocenter study included 20 eyes of 20 patients, 5 for each lens, aged between 60 and 80 years in whom cataracts surgery was performed with implantation of four different IOLs: MiniWell (SIFI), Precizon Presbyopic (Opthec), Symfony (J&J) y LARA (Zeiss).

The inclusion criteria included patients with or without monolateral cataracts who were looking for independence of optical aids that the ophthalmologist considered was the best optical solution and had persistent corneal astigmatism with less than 1.25D.

The exclusion criteria included amblyopia, patients with monocular vision, axial longitude of more than 25 mm, previous ocular surgery, chronic or recurrent uveitis, acute ocular disease or internal/external infection, diabetes, glaucoma or intraocular pressure (IOP) of 24 mm or more, pseudoexfoliation syndrome, pathologic myosis, intraoperative floppy iris syndrome (IFIS), choroidal hemorrhage, keratoconus and endothelial corneal dystrophy. All patients were informed about the study and provided informed consent to be submitted to clinical examinations in line with the principles of the Helsinki Declaration and the Good Clinical Practice protocols of the International Conference on Harmonization (ICH).

RESULTS

The graphs of the monocular defocus curves obtained one month after surgery are presented. We present the mean VA value for each patient as well as the median. The patients with a mean age of 67.96 + 5.88 years (n=20).

To evaluate the quality of the lens we have considered a 0.3 LogMAR as optimal vision for daily activities [56] which is above 2/3 of the optimal vision required to obtain a driving license, and this requirement at monocular level is necessary to apply the any state security position. In addition, the area under the curve for defocus curves for each lens was calculated.

The clinic surgeon asked in a subjective (questionnaire not validated) way the level of satisfaction and for the presence of dysphotopsias. For this the surgeon asked a series of questions per protocol at the one-month visit. Table 1 shows the mean VA for far, intermediate and near distances. The far distance is the mean of the VA in the 0 to +0.50 D range, for intermediate distance in the -1.00 to -1.50 D range and for near distances in the -2.00 to +2.50 D range.

Table 1:

Mean VA for far, intermediate and near distances (LogMAR)

	FAR VA ± SD	INTERMEDIATE. VA ± SD	NEAR VA ± SD
LARA (n=5)	0.06 ± 0.05	0.20 ± 0.10	0.63 ± 0.37
PRECIZON (n=5)	0.03 ±0.06	0.15 ± 0.06	0.22 ± 0.06
SYMFONY (n=5)	0.07 ± 0.09	0.19 ± 0.05	0.35 ± 0.07
MINIWELL (n=5)	0.03 ± 0.04	0.12 ± 0.05	0.30 ± 0.08
TOTAL N=20	0.05 ± 0,02	0.17 ± 0.04	0.38 ± 0.18

Figure 1 shows the defocus curve for the Precizon Presbyopic (Opthec) IOL. Considering <0.3 LogMAR VA as "good vision", we could say that this lens behaves satisfactorily for far distance vision (positive values), intermediate distance (values between -1.00 and -1.50) reaching for near distances to a cutoff point of approximately -1.75 D, which corresponds to reading at a distance of 60 cm. In relation to the functional results of this lens, we like to point out the patient's lack of complaints of halos and dysphotopsias. Subjectively the quality of the retinographic image could also be relevant due to its great quality making this an ideal lens for patients in whom retinal involvement is suspected (diabetics, history of retinal disease, etc…). The patients' comment when asked for their vision was that it was very natural with a high degree of subjective satisfaction (examined with an internal test not validated, with answers with an average of 4.6 on a scale of 5, being unsatisfied and 5 very satisfied). Since this is a new lens, more research is necessary. The stability and friability of the lens also needs to be verified. In our calculation of area under the curve, the IOL value was 3.51 (Table 2). Being this a figure comparable to that obtained at the Clínica Oftalmocor of Córdoba (Spain) for the defocus curves for trifocal lenses and superior to the one obtained with mono- and bifocal IOLs. This value is the best obtained among extended range vison lenses, which reinforces the manufacturer's idea of calling this a continuous transition focus lens.

Fig.1

Monocular defocusing curve of the Precizon Presbyopic lens (Opthec) VA LogMAR.

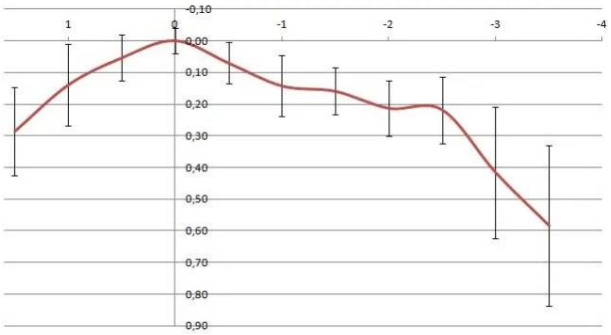


Figure 2 shows the defocus curve for the MiniWell (SIFI) IOL, were we see that this lens behaves in a satisfactory manner for far vision (positive values), intermediate distances (values between 0 and -1.50) reaching for near distances to a cutoff point of approximately -1.75 D, which corresponds to reading at a distance of 60 cm providing a significant depth of focus. With this lens patients don't mention presence of halos and dysphotopsias when asked at the next visit by the doctor. Only one patient complained about insufficient near vision, and this deficiency was solved by prescribing glasses for near vision of +1.00 D. In our calculation of area under the curve, the IOL value was 3.44 (Table 2). This value is very similar to that obtained with the Precizon lens.

Fig.2

Monocular defocus curve of the MiniWell lens (SIFI) VA LogMAR.

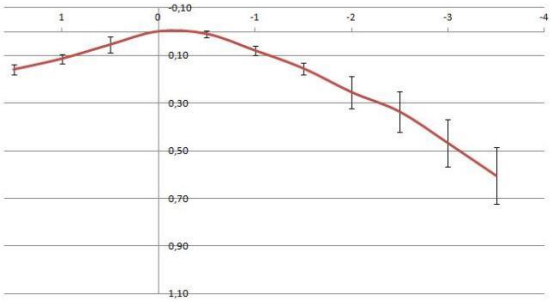


Figure 3 shows the defocus curve for the Symfony (J&J) IOL. The curve shows that the lens allows good far distance vision (positive values) intermediate distances (values between 0 and -1.50) with a mean VA inferior to Precizon and MiniWell. For near distance vision, there is considerable decrease as confirmed by the patients at the visit. In our calculation of area under the curve, the IOL value was 2.93 (Table 2). This value is inferior to the previous lenses, in agreement with the slope of the defocus curve and the patients' comments. This lens is based on a previous design by the manufacturer providing stability and safety in its eye-lens interaction. We find that the highest degree of patient satisfaction is when we implanted a bifocal lens by the same manufacturer (mix and match) in the other eye. In conclusion, we could say that the Symfony (J&J) lens provides sufficient intermediate and far distance vision after cataracts surgery lacking good near distance vision.

Fig.3

Monocular defocus curve of the Tecnis Symphony lens (J & J) VA LogMAR.

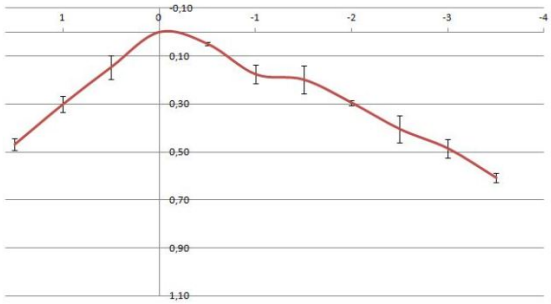


Figure 4 shows the defocus curve for the LARA (Zeiss) IOL. The main characteristic that the curve shows is the steep slope as compared to the other three previous lenses. This lens behaves in satisfactory manner for far distances (positive values). For intermediate distances, the data are inferior but for the patient they can be considered acceptable (values between 0 and -1.25 D). Near distance vision is insufficient. This was resolved prescribing glasses for near vision of +1.00 and 1.50 D. During follow-up visits, no patient complained of presence of halos and dysphotopsias. In our calculation of area under the curve, the IOL value was 2.59 (Table 2). This number is below those found with this type of lenses and similar to those of bifocal lenses. In conclusion, we could say that the LARA lens provides intermediate and far distance vision but insufficient near distance vision.

Fig.4

Monocular defocus curve of the At-Lara lens (Zeiss) VA LogMAR.

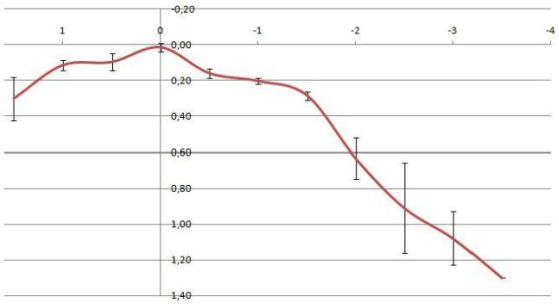


TABLE 2:

Calculation of the area under the curve by polynomial interpolation for the studied lenses

	Area under the curve
PRECIZON PRESBYOPIC (OPTHEC)	
MINIWELL (SIFI)	
SYMFONY (J&J)	
LARA (ZEISS)	

DISCUSSION

At the present time, the concept of ERV-IOL is more frequently used among ophthalmologists. This is due to the physical properties of IOLs, which that generate a wide focus area where the optical quality is minimally affected with fewer number of optical phenomena. The basis for this is the new IOL technology, where the combination the correction of the corneal chromatic aberration and corneal spherical aberration has been demonstrated by previous theoretical and in vitro studies [18-35]. In the context of optical simulations, it was capable of improving the retinal image quality as compared to spherical/aspherical IOLs for aberrometric correction, but without reduction in field depth [18-35]. ERV-IOLs have behaved with optimal performance for far distance vision, comparable to monofocal lenses. As of this moment there are few clinical data about postoperative results after ERV-IOL implantation with this type of lens one month after surgery.

This optical design allows to obtain excellent optical and visual results for far and intermediate distances, and a functional VA range for near distances [31]. These data can be confirmed with our study as well as various clinical studies that have corroborated recently these findings.

In general terms, we observed a similar quality image among these lenses. However, refractive multifocal lenses are more tolerant to defocus than diffractive IOLs in intermediate and near distances.

In this study, no measured the centered anatomical position of the lenses. However, previous studies have described that the inclination and decentralization have an impact on the visual performance of the various IOL designs [36, 37]. Therefore, more studies should evaluate the impact of different degrees of inclination and decentralization in the quality of these lenses. In addition, these studies can help understand better the impact of incorrect centering of this type of lenses.

FAR DISTANCE VISION

Our results show that the values for far distance VA are good and comparable to monofocal lenses [38, 39]. At the same time, the results for far distance vision and contrast

sensitivity obtained with the LARA EDOF IOL were consistent with those reported for other types of EDOF IOLs [38-44].

In a clinical study that reported clinical results with the LARA EDOF IOL [34], far distance visual acuity with this EDOF at 1 month postoperatively obtained values of the same magnitude and comparable among them, being the LARA IOL a lens that provides good far distance vision.

In the Tecnis Symfony group our value was comparable with other studies as Pilger et al reported, with minor differences in far distance vision with the monofocal IOL group [45]. These minor differences are due to developing the curves in binocular form while we did it monocular. It can be said that the Symfony (J&J) lenses provide sufficient far distance vision after cataracts surgery.

The Precizon Presbyopic (Opthec) is a lens that provides sufficient far distance vision after cataracts surgery with halos and dysphotopsias not significative for the patient in habitual conditions of illusion of their daily life.

The MiniWell IOL is a lens that provides sufficient vision after surgery for cataracts for far distance vision with absence of halos and dysphotopsias.

From the clinical point of view, refractive ERV-IOLs can benefit those activities that require good far distance vision in scotopic conditions, like nocturnal driving [46] that is reflected in the values we obtained (see Table 2) with the best of this type of lenses for far distance vision.

Consequently, we can say EDOF intraocular lenses do not affect the far distance vision, which is reflected in the high level of general satisfaction in patients with distance vision for activities of daily living and the absence of prescription of any optical aid.

INTERMEDIATE DISTANCE VISION

The intermediate distance vision measured one-month after surgery (at approx. at 80 cm or -1.25D) in our study is comparable to the results obtained by Dr Poyales [34], confirming the excellent performance of the EDOF IOL for intermediate distance vision. Savini et al [40] reported a mean value in 20 eyes implanted with a refractive intraocular EDOF lens based on the control of induced spherical aberration. These levels of intermediate distance visual acuity achieved with the intraocular EDOF lens are consistent with or even better than those provided by trifocal diffractive intraocular lenses [42, 43].

NEAR DISTANCE VISION

We found that near distance visual performance was more limited, BCVA comparable to other studies, for all types of EDOF IOLs [38-44]. In the study of Dr Poyales [34], (this is not clear in the Spanish version. It appears part of the sentence is missing) they reported a mean value of BCVA (40 cm) of logMAR AVCC (40 cm) de 0,30 ± 0,08, Savini et al., [40] also reported a similar mean value for implanted eyes with a specific model of refractive EDOF IOL. Similarly, it was reported a mean decimal UCVA in the multicenter study. Concerto who evaluated the Technis Symfony EDOF IOL [48], found values that were too distant from for the value obtained this study for this lens. Savini et al., [40] reported a logRAD BCVA mean value (40 cm) for eyes implanted with a specific model

of refractive EDOF IOL. In this study, it was obtained gave us a mean value for refractive lenses (Table 2) near another refractive CTF lens that provided a mean logMAR BCVA value (Table 2), being the best value of all studied lenses.

We especially mention the LARA EDOF IOL since it gave a logMAR BCVA values very much lower than those provided by the manufacturer.

The activities with near distance vision are performed in photopic conditions; refractive ERV-IOLs have a mean MTF similar to trifocal IOLs with near distance focus [46] This level of near distance vision is lower than that provided by multifocal intraocular lenses [38, 42, 43, 49].

Three out of the five patients recounted near distance vision problems. This was resolved by prescribing glasses for near vision + 1.00 and 1.50 D. One patient complained of halos in nocturnal vision which was negatively surprising since one of the main values of these lenses is the absence of halos.

ERV & MULTIFOCALS

It has been demonstrated that light distribution in the ERV intraocular lens is homogeneous and less dependent on the distances in poor lighting conditions in comparison with other multifocal intraocular lenses. Hamis and Sokwala [43] found significantly better BCVA results with an EDOF IOL based on diffraction and two models of trifocal IOLs (AT.LISAtri and FineVision). In contrast, other studies that compared diffractive EDOF and trifocal IOLs have demonstrated significant differences in the performance in intermediate distances [13, 28].

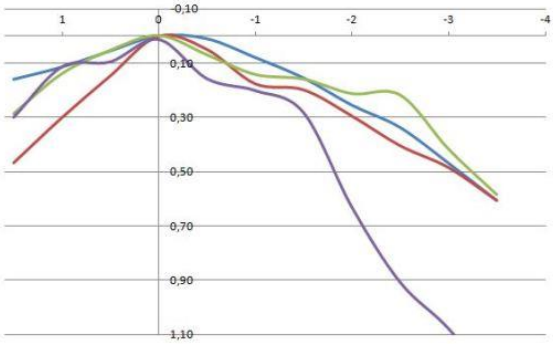
Felipe et al., [50] performed a study to determine the minimal change in optical quality to produce a significant difference in visual acuity. These authors evaluated optical quality for multifocal IOLs by mean MTF and intermediate distance corrected visual acuity. In that study patient's visual acuity was probably not affected by the mean MTF decreasing by 15%. On the one hand, the MiniWell IOL showed reduction in this measurement, that was less than 9% for both openings between intermediate and near visual foci. On the other hand, both trifocal intraocular lenses showed a maximum reduction of 40% in mean MTF in the same visual range for both openings. Consequently, with the data based on Felipe et al., [50] and those obtained in this study, it seems that the MiniWell IOL is more tolerant to defocus than trifocal IOLs for intermediate and near vision. These results may be related with a soft transition between intermediate and near foci obtained with the MiniWell IOL, and the steeper slope obtained with both trifocal lenses. However, the mean MTF of each IOL was significantly reduced for an opening of 4.5 mm in the far distance vision focus, which may be related with focus peaks of near distances. These results suggest that the MiniWell IOL can provide a depth of focus of approximately 0.50D for both openings in intermediate and near distance vision. However, this depth of focus is decreased for a 4.5 mm opening at far distance vision focus.

In the same way, in our study it is observed that the refractive lenses have a greater tolerance to the defocus than the diffractive lenses, since it maintained a good vision even with a defocus of 1.00 D, how can be observed in the figure 5. This can be Due to the transition between the far, intermediate and near the refractive lenses, it is of a

continuous form whereas in the diffractive lenses this transition occurs at a power.

Fig. 5

Comparison of the four defocus curves of the study lenses.



The optical quality of the MiniWell Ready is similar to that of AT LISA and Finevision IOLs for certain conditions; for example, intermediate distance vision. However, the optical quality of the MiniWell Ready intraocular lens for far distance vision with openings seems to be even better than with trifocal IOLs [51].

It is expected that in comparison with trifocal IOLs, the ERV IOL will show the ability of offering a clear vision in an extended range for various distances (that is to say, from far distance to 60 cm). Consequently, it should not have a discrete number of foci but a continuum of foci.

DEFOCUS CURVES

All these visual results were confirmed by the defocus curve that showed a very progressive decrease in visual acuity when the negative level of defocus increased to -2.00D. The decrease in visual acuity is significantly more pronounced for defocus levels greater than -2.00D. This shape of the defocus curves has also been reported for other type of EDOF IOLs [38, 40, 42, 44, 49]. Previous comparative studies have demonstrated that near distance visual performance level with EDOF IOLs compared to multifocal IOLs is more limited but within functional range [38. 40, 41, 49], which allows patients to perform daily activities without difficulties. This is reflected by the patient's high level of satisfaction for near distance vision. Ruiz-Mesa et al., [42, 49] found in two studies that the IOL's centrthe al surface increases the depth of focus, offering good MTF values in a wide dioptric range with a pupillary opening of 3 mm and favoring far distance vision with a pupillary opening of 4.5 mm. His specific preoccupation was to introduce apodization to prevent vision problems under escotopic conditions at certain distances. In addition, the limited spherical aberration variation should introduce less halos and glare in eyes with implanted IOLs than if the variation would extend beyond the central zone of 3 mm [15].

It must be taken into account that the MTF values obtained are lower than those usually found with monofocal IOLs, but higher than for multifocal IOLs [16]. Even though the reduction of MTF in comparison with monofocal IOLs is obvious in the laboratory, in clinical practice the presence of a certain slope, defocus and astigmatism will be different, and probably lower. In this regard, the ability of this IOL design to maintain a good MTF, even with a slope of 2.5 and decentering of 0.5 mm, is of great importance. These amounts of IOL malposition are frequently found in clinical practice because the eye is a centered optical system [16].

Since the best results of ERV lenses (Figure 5) are obtained in the 0 to +0.50D side of the defocus curve, using the value recommended by the IOL Master 500, to obtain a better post-surgical result it would be convenient a good choice of the power in relation to this defocus curve, leaving the patient with a refractive error between -0.25 and -0.50D.

PHOTIC PHENOMENA AND PATIENT SATISFACTION

The incidence of photic phenomena was minimal (only in two cases). In the study during follow up visits none of the patients referred the presence of halos and dysphotopsias, as we found in the literature [34] in the evaluation of patients driving at night after surgery and the difficulties associated with halos as well as for subjective evaluation to postsurgical adaptation of the patients under photic and mesopic conditions [34]. This confirms one of the potential advantages of EDOF IOLs, the generation of less perturbing photic phenomena. Hamid and Sokwala [43] reported in a comparative study that the perception of halos with a trifocal intraocular lens was more disturbing compared to EDOF IOLs. However, other authors like Escandón-García et al., [52] found in a series of prospective studies that objective dysphotopsia measured with a light distortion analyzer was not reduced in eyes implanted with EDOF IOLs compared to trifocal IOLs. Possibly, in some patients with specific characteristics, tolerance to the double halo generated by trifocal intraocular lenses [53] is similar to that associated with halos of lesser magnitude generated by EDOF IOLs. Future studies should investigate this in greater detail.

The study by Concerto included 411 patients who were implanted bilaterally with this ERV IOL. These authors reported high level of satisfaction for visual restoration at all distances (more than 91% would recommend this procedure), independence of glasses (85.6% said it was not necessary to use glasses frequently) and absence of photic phenomena (more than 90%) [54]. In our study we had somewhat lower percentages, but we understand this could be due to the low number of patients studied.

MIX AND MATCH

Micro-monovision has been proposed as a viable alternative with the limitations of the ERV IOL for near distance vision. Ganesh et al., treated 25 patients with emmetropic dominant eye and -0.75 D in the non-dominant eye. Only 4 patients needed near distance glasses and did not show any contrast sensitivity limitation [55]. In our study, we found the greatest degree of satisfaction of patients implanted diffractive EDOF lenses when a bifocal lens from the same manufacturer was implanted in the other eye. For refractive ERVs, we choose always the first negative value or, if the patient had a complaint about near distance vision, in small monovision leaving the second eye -0.5 myopic.

CONCLUSION

ERV intraocular lenses provide do not affect vision quality, which is also reflected by the high levels of general satisfaction for far distance vision. The assessed intermediate distance visual acuity achieved with the ERV intraocular lens are consistent with or even

better than those provided by diffractive trifocal intraocular lenses.

IOLs for the treatment of presbyopia provide total independence in most of cases with a far to near distance transition vision without the need to prescribe any optical aid for activities of daily living. These values are confirmed by the tendency of the defocus curves, which show that when the patient is left with a refractive error between -0.25 and 0.50D it allows better intermediate and near distance vision, without excessive interference of this small graduation residual on far distance vision, although it was corrected for the realization of the defocus curve.

We could say that the MiniWell lens is a lens that provides sufficient vision after cataracts surgery for far vision as well as near vision at 60 cm with halos and dysphotopsias. The low slope of the defocus curve suggests the concept of a progressive lens with continuous multifocality that coincides with the idea of the main design by the manufacturer.

The Precizon Presbyopic (Opthec) is a lens that provides sufficient vision after cataracts surgery for far as well as near distance vision at 60 cm with absence of halos and dysphotopsias. CTF IOLs are those that show better numbers for near and intermediate distances (Table 1), providing patients with a better natural and comfortable vision. The incidence of photic phenomena was minimal. Most patients did not express the presence of halos and dysphotopsias during visits.

Patients have total independence from optic aids, with continuous focus from far to near distances, reducing undesirable photic effects.

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