Postoperative Results in Patients Implanted with a Novel Enhanced Depth of Focus Intraocular Lens

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Abstract

Purpose: A prospective study to evaluate the refractive and functional results, patient satisfaction and defocus curve after binocular implantation of an enhanced depth of focus intraocular lens (EDOF IOL).

Methods: In a pilot study, 14 eyes of 7 patients received binocular implantation of an extended depth of focus intraocular lens (EDOF IOL) AT LARA 829 (Carl Zeiss Meditech, Germany). Both eyes were targeted closest to emmetropia. Pre- and postoperative, monocular and binocular functional results (CDVA, UDVA, DCIVA [90 cm, 80 cm, 60 cm], DCNVA [40 cm], Defocus curve; [logMAR]) refractive outcome, Halo and Glare Simulator and patient satisfaction score were evaluated.

Results: Mean postoperative spherical equivalent was -0,06 +/- 0,31 D. Mean postoperative monocular UDVA, CDVA and DCNVA were 0.016 (±0.102), -0.031 (±0.072) and 0.383 (±0.172), respectively with binocular values of -0.034 (±0.076), -0.048 (±0.057) and 0.326 (±0.137). Monocular DCIVA in 90cm, 80cm and 60cm was 0.111 (±0.111), 0.078 (±0.097) and 0.109 (±0.117), respectively with binocular values of -0.022 (±0.144), 0.026 (±0.126) and 0.0252 (±0.103). Defocus curve analysis show a stable visual acuity from +0.5 to -1.5 D.

Conclusion: Binocular implantation of an EDOF IOL with a new diffractive pattern with the correction of chromatic aberration show a good refractive predictability. Functional results especially from distance to intermediate show excellent results with a slight increase comparing monocular to binocular visual function. Still binocular DCNVA in 40cm shows acceptable results offering a high degree of patient satisfaction.

Keywords: Cataract; Extended Depth of Focus; Intraocular Lens; Visual Acuity; Patient Satisfaction; Halo and Glare

Abbreviations

IOL: Intraocular Lens; EDOF: Extended Depth of Focus; UDVA: Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity; DCIVA: Distance Corrected Intermediate Visual Acuity; DCNVA: Distance Corrected Near Visual Acuity; ETDRS: Early Treatment of Diabetic Retinopathy Study; OSI: Objective Scattering Index; MTF: Modulation Transfer Function

Introduction

Change of daily habits from reading to more intermediate distance activities is one of the reasons for the latest developments in intraocular lens (IOL) optics [1].

Therefore, in cataract-refractive surgery, patients desire for spectacle independence after the surgery has become an important parameter to take into consideration when choosing an IOL [2-7].

Latest presbyopia correction options have provided patients with adequate visual acuity at far and near distances. This has been made possible by the principle of monovision, where one eye is targeted for emmetropia (usually dominant eye), and the other eye is targeted for near or intermediate distance vision correction. This principle, although not suitable for everyone, provides patients with pleased expectations when it comes to certain foci.

Another option is the use of multifocal intraocular lenses that usually create two to three focuses from distance to near [3-14]. However, the sharpness of vision is provided only for a limited zone around the targeted foci, leaving the patient with blurred vision in between. Especially in trifocal IOLs that still leads to a wide range of vision from distance to near, but with slightly reduced visual acuities in the intermediate distances. Moreover, these patients often experience degraded night vision due to halo and glare caused by light scattering induced by the diffractive optical structure of the IOLs, poor contrast sensitivity and optical quality [15].

Recently, Extended depth of focus (EDF) IOLs have been developed to combine the advantages of both monofocal and multifocal IOLs, hence providing a wider range of focus, more spectacle independence and reduced dysphotopsia, which is an interesting option for patients with an active lifestyle [2].

Methods

In this prospective, non-randomized, non-comparative, observational clinical pilot study, we included 7 patients. All patients have an active life style in common, and the desire of as much spectacle independency as possible in different intermediate distances, but were still willing to wear glasses for near distance activities, such as reading small characters. We excluded all patients with associated ocular pathologies, previous ocular surgeries and patients with unrealistic expectations. An uneventful cataract surgery was performed by the same experienced surgeon (FK) in all patients (14 eyes), and they were implanted with an EDOF IOL AT LARA 829 (Carl Zeiss Meditec, Germany) binocularly.

We analyzed demographic data (age, sex) of the 7 patients and preoperative and postoperative results in a follow up period over multiple visits from the first postoperative day to 3 months after the surgery. The collected data included preoperative and postoperative spherical equivalent (SE), uncorrected and corrected, monocular and binocular visual acuities in logMAR for distance vision (UDVA, CDVA), distance corrected intermediate vision (DCIVA) at 3 distances (90, 80 and 60 cm), distance corrected near visual acuity (DCNVA) at 40 cm and defocus curve analysis using the Early Treatment of Diabetic Retinopathy Study (ETDRS) charts (Precision Vision, Woodstock, IL). Furthermore, we used the HD Analyzer (Visiometrics, USA) to analyze optical quality using the OSI (Optical scattering Index), MTF cutoff (Modulation Transfer Function cutoff) and Strehl Ratio values, and the Halo and Glare simulator (Halo and Glare Simulator Software, Carl Zeiss Meditec, Germany) in order to study dysphotopsia in a comparative manner using the new strength function (developed by Hagen., *et al*. Dusseldorf) for the highest values of size and intensity of Halo and Glare. The function allows classifying halo and glare into 4 categories: none (0% - 25%), mild (25% - 50%), moderate (50% - 75%), severe (75% - 100%).

Finally, we analyzed patient satisfaction using the McAlinden questionnaire (McAlinden Skiadaresi., *et al*. 2013) evaluating the perception of photic phenomena, their severity, frequency and bother, the ability to perform daily activities without spectacles, spectacle independence at different distances and the satisfaction with the results of the surgery. We adopted a novel approach to the analysis of the questionnaire results using a score from 1 to 4 (1 for high satisfaction and 4 for unsatisfied) for questions from 1 to 10, for question 11 and 14 (the score was from 1 to 5) and Questions 12 and 13 (score was from 1 to 2). The higher the numbers, the less the patients were satisfied. Table 4 resumes patient's answers to the most relevant 7 questions to this study (Figure 2).

Results

Seven patients were included in the pilot study: 6 males (85,7%), 1 female (14,3%), mean age was 65 +/- 9,4 years, (range age from 52 to 77). All patients were targeted plano (closest postoperative SE from the myopic side) and the IOL power was calculated using the Barrett Suite with the IOLMaster 700 (Carl Zeiss Meditec, Germany).

The mean preoperative SE was +1,0 +/-1,77 D. The mean target spherical equivalent was -0,1 +/- 0,13 D, whereas the mean achieved postoperative SE was -0,06 +/-0,31 D, with 78,57% of patients with (-0,25 to +0,25 D) and 100% within (-0,75 to +0,75 D) (Figure 1). SE values are summarized in table 1.
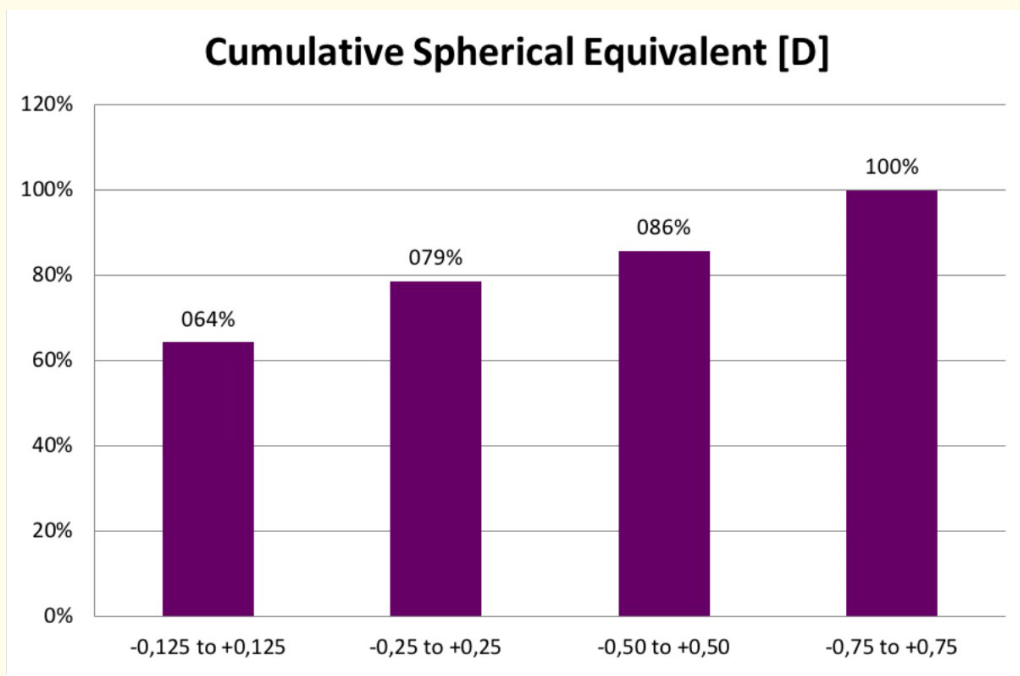
Figure 1: *Cumulative Spherical Equivalent (SE) [D].*

|	Number of eyes	Spherical Equivalent (D)
-0,125 to +0,125	9	64,28%
-0,25 to +0,25	11	78,57%
-0,50 to +0,50	12	85,71%
-0,75 to +0,75	14	100%

Table 1: *Postoperative Spherical Equivalent distribution [D].*

The monocular and binocular UDVA, CDVA, DCIVA in different distances and DCNVA are summarized table 2 and figure 2.

	Monocular (n = 14)		Binocular (n = 7)	
	Mean	**Standard Deviation**	**Mean**	**Standard Deviation**
UDVA	0,016	0,102	-0,034	0,076
CDVA	-0,031	0,072	-0,048	0,057
DCIVA (90 cm)	0,111	0,111	-0,022	0,144
DCIVA (80 cm)	0,078	0,097	0,026	0,126
DCIVA (60 cm)	0,109	0,117	0,052	0,103
DCNVA	0,383	0,172	0,326	0,137

Table 2: *Visual Acuity at Far, Intermediate, and Near Distances Using ETDRS Charts.*

ETDRS: Early Treatment of Diabetic Retinopathy Study; VA: Visual Acuity; UDVA: Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity; DCIVA: Distance-Corrected Intermediate Visual Acuity; DCNVA: Distance-Corrected Near Visual Acuity, [logMAR]
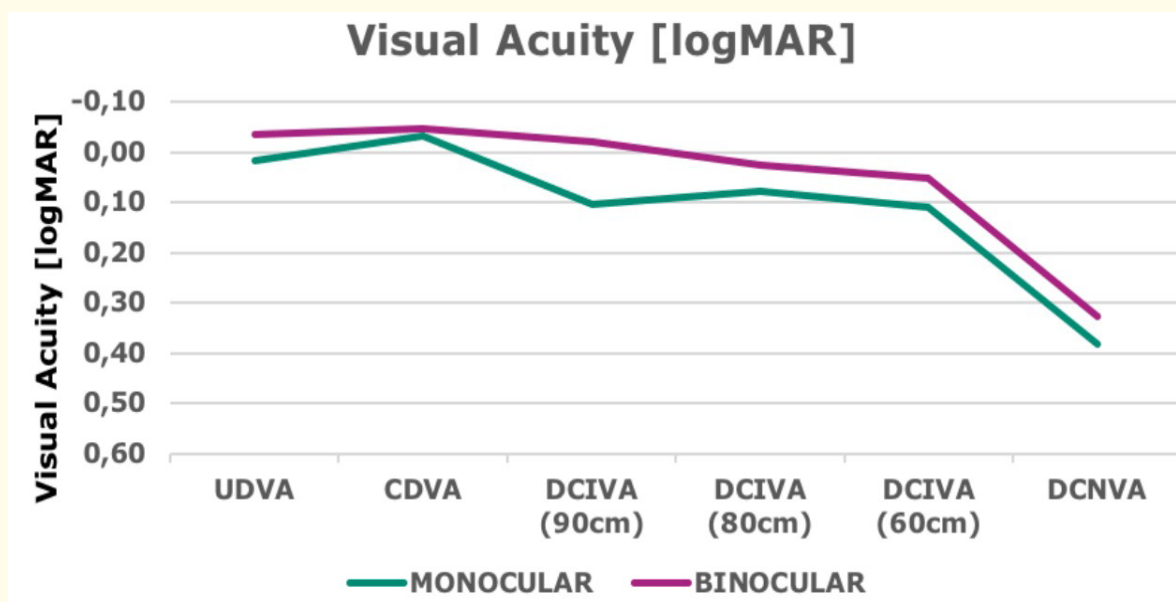

Figure 2: *Visual Acuity in different distances [logMAR].*

The results of the HD Analyzer measurements showed a mean pupil size of 3,9 +/-0,83 mm (range 2,9 to 5,4 mm), following mean values for OSI of 1,75 +/- 1,04, MTF cutoff (c/deg) 35,42 +/- 10,95 and Strehl Ratio 0,16 +/- 0,04.

The mean strength value of Halo and Glare was 30,88% falling into the mild classification, with 4 patients reporting no halo and glare (43%), 2 patients reporting mild dysphotopsia and only one patient reported severe halo and glare (Table 3, Figure 3).

Strength interval	Percentage
None (0% - 25%)	43%
Mild (25% - 50%)	42,8%
Moderate (50% - 75%)	14,2%
Severe (75% - 100%)	0%

Table 3: *Halo and Glare Strength distribution (P Hagen., et al. Dusseldorf).*
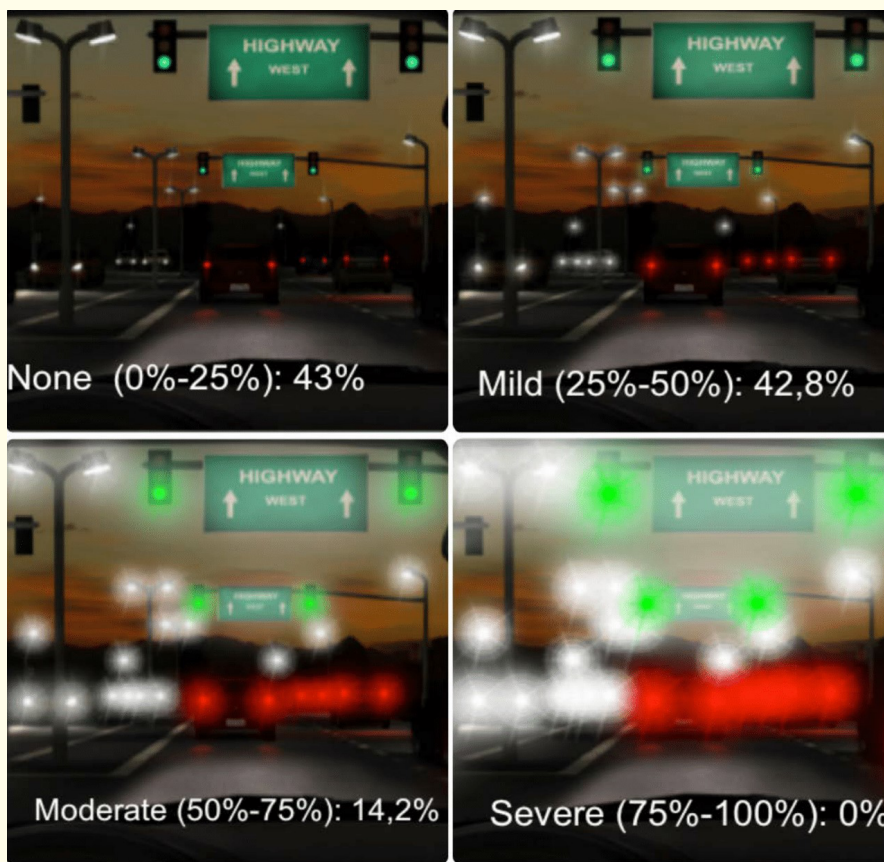
Figure 3: *Halo and Glare strength distribution adapted by P Hagen., et al. Dusseldorf.*

Figure 4 illustrates binocular defocus curve analysis. A visual acuity of 0,3 logMAR or better was achieved between -2,5D and +1,25 D defocus, and 0,1 logMAR visual acuity was achieved in a range of -1,75 to +0,75 D.
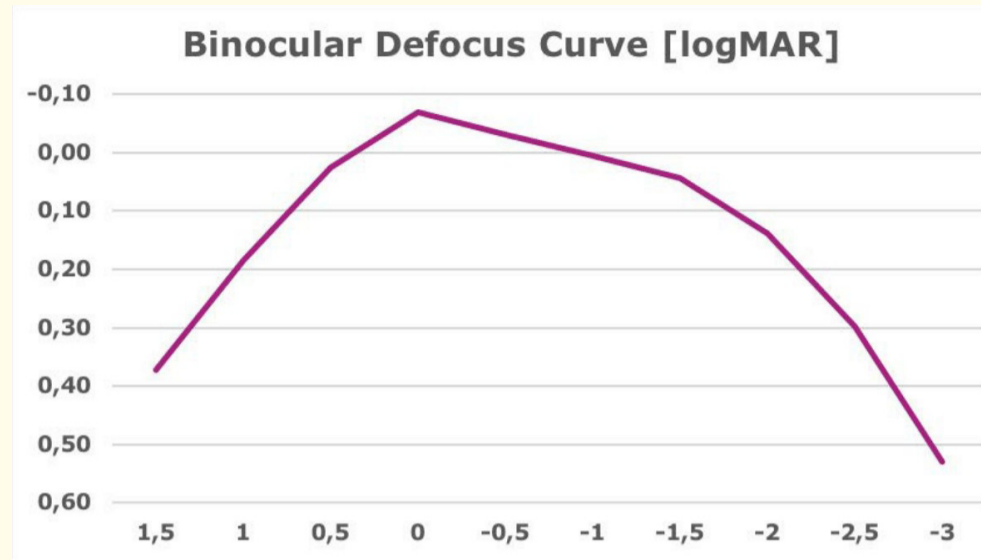
Figure 4: *Binocular defocus curve analysis.*

Furthermore, we evaluated patient satisfaction using the McAlinden questionnaire. The questions (Table 4) were about the frequency, severity and bothersome of various visual phenomena, spectacle independency and satisfaction of surgical outcome.

Question n°1	Question n°2	Question n°3	Question n°9
A: How often do you experience glare?	**A: How often do you experience haloes?**	**A: How often do you experience starbust?**	**A: How often do you experience focusing difficulties?**
Never	Never	Never	Never
Occasionally	Occasionally	Occasionally	Occasionally
Quite Often	Quite Often	Quite Often	Quite Often
Very Often	Very Often	Very Often	Very Often
B: How severe is the glare?	**B: How severe are the halos?**	**B: How severe are the starburst?**	**B: How severe are the focusing difficulties?**
Not at all	Not at all	Not at all	Not at all
Mild	Mild	Mild	Mild
Moderate	Moderate	Moderate	Moderate
Severe	Severe	Severe	Severe
C: How bothersome is the glare?	**C: How bothersome are the halos?**	**C: How bothersome are the starburst?**	**C: How bothersome the focusing difficulties?**
Not at all	Not at all	Not at all	Not at all
A little	A little	A little	A little
Quite	Quite	Quite	Quite
Very	Very	Very	Very

Question n°12	Question n°13		Question n°14
If you had to choose again, would you pick a multifocal intraocular lens again?	**Die the Surgery offer you spectacle independancy?**		**How often do you wear glasses?**
Yes	**A: Distance**		**A: Distance**
No	Yes		Never
Explanation if no	No		Seldom
	B: Intermediate		Half of the time
	Yes	Most of the time	
	No	Always	
	C: Near	**B: Intermediate**	
	Yes	Never	
	No	Seldom	
	Most of the time	Half of the time	
	Always		
	C: Near		
	Never		
	Seldom		
	Half of the time		
	Most of the time		
	Always		

Table 4: *McAlinden questionnaire (Questions 1, 2, 3, 9, 12, 13, 14).*

The analysis of the results revealed occasional glare perception, with no halo or starburst on average. The severity of photopic phenomena was described as mild, and a little bothersome. All patients reported never having any focusing difficulties, and 100% would pick the same IOL model again. One patient reported wearing glasses most of the time for all distances, 5 patients reported never wearing glasses in far and intermediate distances, 2 of them only rarely wear glasses for near distance (Table 5, Figure 5).

n/4	n/4	n/4	n/4	n/4	n/4	n/4	n/4	n/4	n/4	n/4	n/4	n/2	n/2	n/2	n/2	n/5	n/5	n/5
lA	1B	1C	2A	2B	2C	3A	3B	3C	9A	9B	9C	12	13A	13B	13C	14A	14B	14C
1	1		1	1		1	1		1	1		1	1			1	1	1
2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	4
1			1	1		1			1			1	1			1	1	2
2	2	2	2	2	2	2	2	2	1	1	1	1	1	1	2	4	4	4
2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2	2	2	3	3	2	2	3	2	1	1	1	1	1	1	1	2	2	2
3	3	3	3	3	3	3	3	3	1	1	1	1	1	1	1	1	1	1

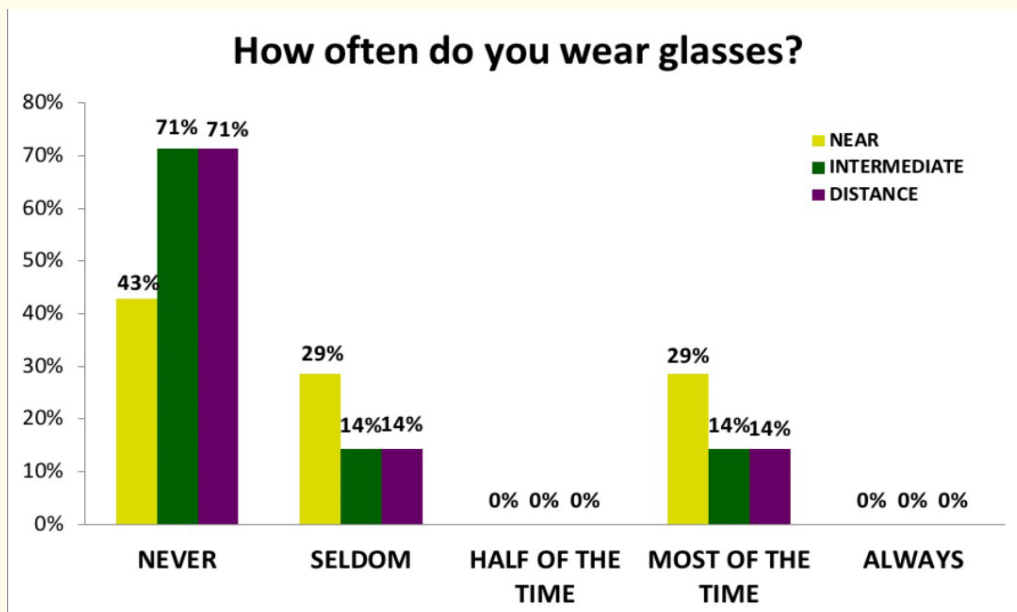*Table 5: MacAlinden Questionnaire results.*

Figure 5: Percentages of patients frequency of wearing glasses in different distances.

Discussion

The concept of extended depth of focus IOLs aims to enhance near and intermediate vision without compromising far distance vision and without inducing as many dysphotopic phenomena as it might be experienced with typical diffractive multifocal IOLs. However, patients must be aware that for true near vision they might still need to use spectacles after EDOF IOL implantation.

The AT LARA 829MP is one of few extended depth of focus IOLs available on the market. It features a light bridge optical design, a diffractive optical pattern that improves vision within the inter-focal distance between the far and intermediate foci. To achieve this light bridge optical design, the IOL has two focus additions of 1,9D and 0,95D, for intermediate and far-intermediate distances. While maintaining continuous range of sharp vision at this depth of focus, it also provides less dysphotopic phenomenon, such as halo, glare and starbursts. Moreover, it results in optimized contrast sensitivity due to its aberration neutral and chromatic aberration correcting optical design. Thus, making it an attractive option for people with an active life style, requiring good vision from near and intermediate to far distances.

In a study by Pedrotti E., *et al*. [16], in which the extended range of vision Tecnis Symfony IOL (Abbott Medical Optics, Inc.) was implanted in 25 patients, the mean monocular visual acuity was 0,08 +/- 0,12, -0,04 +/- 0,08, 0,19 +/- 0,09 and 0,33 +/- 0,10 for UDVA, CDVA, DCIVA (60 cm) and DCNVA respectively. The binocular mean visual acuities were 0,00 +/- 0,09, -0,08 +/- 0,07, 0,10 +/- 0,09 and 0,21 +/- 0,07 for UDVA, CDVA, DCIVA (60 cm) and DCNVA respectively. Postoperative spherical equivalent was within ± 1.00 diopters in 94%.

In comparison, results in our group of AT LARA patients show better spherical equivalence (100% patients within ± 0,75D), better monocular and binocular UDVA and DCIVA (60 cm), whereas the CDVA and DCNVA remain better in the Tecnis group both monocularly and binocularly.

In a comparative study by Ramón Ruiz-Mesa., *et al.* [17] including 68 eyes of 34 patients, 14 patients were implanted with the same IOL Tecnis Symfony IOL compared to 20 patients with Alcon's PanOptix IOL. The Symfony IOL group's postoperative results were binocular: CDVA -0,02 +/- 0,03 logMAR, DCIVA (80 cm) 0,06 +/- 0,04 logMAR, DCIVA (60 cm) 0,05 +/- 0,04 logMAR DCNVA 0,20 +/- 0,07 logMAR. In comparison, the binocular postoperative VA of AT LARA patients in our group showed better CDVA, DCIVA (80 cm) and similar values in DCIVA (60 cm).

And in another comparative study by the same author, Ramón Ruiz-Mesa., *et al*. [18] including 20 patients in each group, the visual outcomes of the FineVision (group 1) and the Symfony IOLs (group 2) were analyzed, comparing the results after 1 year of the surgery. The mean binocular value of UDVA for the Symfony group was 0.01 ± 0.02 logMAR, which is still inferior to the mean value achieved in our study (-0,034 +/- 0,076 logMAR). Defocus curves were similar in a range of -2,5 to +1,00 D where both groups showed a visual acuity of 0,3 logMAR or better. Comparatively, the defocus curve in our study showed a wider range of focus of -2,5 to +1,25 D where visual acuity was 0,3 logMAR or better.

In a study by Günther G., *et al* [19] analyzing the small-aperture IC-8 IOL, which contains a centrally located opaque annular mask creating a central aperture of 1,36mm. The study included 12 patients, in whom they implanted the IOL monocularly, aiming for a myopic target of -0,75 to extend the range of vision. The results at 3 months postoperatively revealed a monocular UDVA 0,05 +/- 0,09 logMAR, CDVA -0,01+/- 0,06 logMAR, DCIVA (80 cm) 0,04+/-0,07 logMAR and DCNVA 0,14 +/-0,15 logMAR, which prove better values compared to our study for the monocular DCIVA at 80cm and the DCNVA. However, we found better results for the UDVA and CDVA. Whereas the monocular defocus curve in Günther G., *et al*. study shows 0,1 logMAR or better between -1D and +0,5D, we found the same VA or better in a wider range between -1,75D to +0,75D for AT LARA patients in this study. The authors used a survey to rate patients satisfaction and quality of vision. They reported a significant decrease in glare at 12 months postoperatively with a slight increase in halo perception.

In another study by Kretz F., *et al*. [4] using the Lentis-313MF15 IOL, which is a refractive multifocal IOL with an add power of 1,5D on the lens plane, 30 patients were bilaterally implanted, with target refraction closest to emmetropia in all 60 eyes. The results showed a postoperative spherical equivalent of -0,07 +/- 0,35D, a binocular UDVA of 0,0 +/- 0,09 logMAR, CDVA of -0,08 +/- 0,09 logMAR, DCIVA (80 cm) -0,02 +/- 0,107 logMAR and DCNVA (40 cm) 0,385 +/ -0,20 logMAR. The monocular defocus curve revealed a functional visual acuity of 0,3 logMAR or better over a range of more than 2D. Subjective questionnaire results were collected, showing a high satisfaction amongst all patients, with no halo or glare reported. In our study, 57% of the patients reported halo and glare of different strengths, and the CDVA and DCIVA in 80cm were less than the ones reported in the Lentis-313MF15 study. However, the spherical equivalent in our study was closer to target, and the UDVA and DCNVA were better.

Table 6 summarizes results of the studies above.

		AT LARA		Pedrotti E., *et al.* [16] Tecnis Symfony		Ramon Ruiz-Mesa., *et al.* [17] Tecnis Symfony		Ramon Ruiz-Mesa., *et al.* [18] Tecnis Symfony		Günther G., *et al.* [19] IC-8		Kretz F., *et al.* [4] Lentis-313MF15	
		Mean	+/- SD	Mean	+/- SD	Mean	+/- SD	Mean	+/- SD	Mean	+/- SD	Mean	+/- SD
Monocular (logMAR)	UDVA	0,016	0,102	0,08	0,12					0,05	0,09		
	CDVA	-0,031	0,072	-0,04	0,08					-0,01	0,06		
	DCIVA (90 cm)	0,111	0,111										
	DCIVA (80 cm)	0,078	0,097							0,04	0,07		
	DCIVA (60 cm)	0,109	0,117	0,19	0,09								
	DCNVA	0,383	0,172	0,33	0,1					0,14	0,15		
Binocular (logMAR)	UDVA	-0,034	0,076	0	0,09			0,01	0,02			0	0,09
	CDVA	-0,048	0,057	-0,08	0,07	-0,02	0,03					-0,08	0,09
	DCIVA (90cm)	-0,022	0,144										
	DCIVA (80cm)	0,026	0,126			0,06	0,04					-0,02	0,107
	DCIVA (60cm)	0,052	0,103	0,1	0,09	0,05	0,04						
	DCNVA	0,326	0,137	0,21	0,07	0,2	0,07					0,385	0,2
Spherical Equivalent (D)		-0,06	0,31									-0,07	0,35
		78,57% between -0,25 and +0,25 D		94% between -1 and +1 D									
Defocus Curve		100% between -0,75 and +0,75 D											
		0,3 logMAR or better (-2,5 D to +1,25 D)						0,3 logMAR or better (-2,5 D to +1,00 D)				0,3 logMAR or better (over a range of 2 D)	
		0,1 logMAR or better (-1,75 D to +0,75 D)								0,1 logMAR or better (-1 D to +0,5 D)			

Table 6: Monocular and binocular corrected and uncorrected visual acuity in different distances, Spherical equivalent and defocus curve results of different extended depth of focus IOLs.

According to the comparative analysis of the results of studies mentioned herein, the AT LARA 829MP seems to always provide better UDVA and a wider range of focus where visual acuity is 0,3 logMAR or better.

When compared to the Symfony groups, it achieves closer spherical equivalent to target refraction and better visual acuities at far and intermediate (60 cm) distances. In comparison to the small-aperture IC-8, better CDVA values were found in addition to UDVA in which achieved values were higher than all the groups discussed above. We also found closer spherical equivalent to target when compared to the Lentis-313MF15 group.

However, the DCNVA (40 cm) was better in all groups, except for the Lentis-313MF15, in which almost similar values were found, with DCNVA (40 cm) values of 0,385 +/- 0,195 logMAR compared to 0,326 +/- 0,137 logMAR in our group. The DCIVA at 80cm was not measured in the Tecnis Symfony studies, but it was better in the IC-8 IOL and Lentis313-MF15 studies compared to our group. The patient satisfaction and amount of dysphotopsia reported could not be compared accurately because of the new approach we used to measure the Halo and Glare, but it is worthy to note that in the IC- 8 study patients reported significant decrease in dysphotopsia at 12 months postoperatively, and in the Lentis313-MF15, no halo or glare were reported in a group of 30 patients.

We collected data at 3 months postoperatively for our study. Further observation of functional and visual results in longer periods, with larger groups of patients is necessary to evaluate the outcomes of the new EDOF AT LARA 829MP.

Conclusion

In conclusion, the new Extended Depth Of Focus (EDOF) IOL AT LARA 829MP seems to provide good visual acuity from near, intermediate to far distances, to yield satisfying optical quality, and to result in less dysphotopic phenomena in this particular group of patients, who conduct an active life style, with high need of intermediate to far distance vision.

However, near distance activities, such as reading in small characters, will most likely still require spectacles.

As this is a new IOL, more comparative studies with larger number of patients and longer follow-up periods are required to assess its outcomes in the long term.

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