Original Article

A prospective study of a new presbyopia pseudophakic intraocular lens: Safety, efficacy and satisfaction

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Purpose: To evaluate the safety, visual performance, and patient satisfaction of a new presbyopic pseudophakic intraocular lens (IOL). **Methods:** A prospective non-randomized case-series study was performed in Buenos Aires, Argentina. Patients included in the study underwent a programmed Femtosecond laser assisted cataract surgery (FLACS), performed between October and December 2020, with a 6-month follow-up period. The Intensity (Hanita Lenses) IOL was bilaterally implanted. Spherical equivalent (SE) refraction, uncorrected distance and near visual acuity (UDVA/UNVA), defocus curve, endothelial cell density (ECD), central corneal thickness (CCT), and a satisfaction questionnaire were evaluated. **Results:** A total of 56 patients (112 eyes), aged 65 ± 6.12 years were included. The mean ± SD of preoperative SE was 1.85 ± 2.24 D (range; −4.50 to 4.75), which had decreased 6 months after surgery to −0.08 ±0.32 D (range; −0.75 to 0.63). No eyes experienced a loss of lines of vision, and 94% obtained SE values between ± 0.50 D. Defocus curve for different additions was 0.03 LogMAR (logarithm of the minimum angle of resolution) for −3.0 D, −0.005 LogMAR for −1.5 D, and −0.07 LogMAR for 0 D. The ECD, CCT remained stable (*P*: 0.09 and 0.58, respectively) and all patients achieved their preoperative expectations, with a 6-month follow-up period. **Conclusion:** Patients who underwent a safe bilateral implantation with Intensity IOL achieved a high degree of spectacle independence and satisfaction, 6 months after surgery.

Access this article online

Website: www.ijo.in

DOI: 10.4103/ijo.IJO_2795_21

Quick Response Code:

Key words: Cataract surgery, multifocal intraocular lens, presbyopia, pseudophakic intraocular lens, refractive surgery

For most people worldwide, screentime has increased during the COVID-19 pandemic through numerous activities, such as homeworking, virtual education, social networks, and telemedicine consultations, which are made possible by smartphones, smart TVs, and computers.[1-5] In order to perform these activities, near and intermediate vision are mainly necessary. In order to help people with presbyopia, many options are being developed besides spectacles, including pharmacological treatments, corneal procedures, phakic and pseudophakic intraocular lenses (IOL) with different optical designs and therapeutic combinations, trying to achieve the best visual performance for all distances.[6-15]

When taking into account the needs of the patient and modern pseudophakic IOL options, choosing the best option in each case entails a summarization of factors, including the availability of the product in the region and budget, as well as its optical characteristics and surgeon preference. But undoubtedly, the expectations of patients after cataract surgery are increasing, and refractive results after cataract surgery are relevant.[16-19]

A new multifocal IOL, called Intensity (Hanita Lenses, Israel), became commercially available in Argentina in the second semester of 2020. The main author of this study has previous experience implanting a different multifocal IOL from the same company (FullRange®; Hanita Lenses, Israel), which has a similar platform.[20] Currently, there is a lack of information regarding non-sponsored real-life studies with clinical results of this new product. Therefore, the purpose of this study is to evaluate the visual performance obtained with the Intensity multicofal IOL, including safety aspects and the opinions of patients.

Methods

Study design

A single arm, single center, non-randomized prospective case-series study was designed to judge the refractive efficacy of the Intensity pseudophakic IOL in patients with a programmed Femtosecond laser assisted cataract surgery (FLACS), performed between October and December 2020, with a 6-month follow-up period after the second eye surgery. The study protocol and researchers adhered to the tenets of the Declaration of Helsinki, and the approval of the Clinica de Ojos Dr. Nano Institutional Review Board/Ethics Committee was obtained. Patients were informed about the characteristics of the study and the risks of the surgical procedure. Their written consent was obtained prior to participation.

Inclusion/exclusion criteria

The patients seeking a presbyopia solution who were included were those who accepted the informed consent, and had

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Received: 06-Nov-2021 Revision: 06-Feb-2022
Accepted: 18-May-2022 Published: 26-Aug-2022

Cite this article as: Bianchi GR. A prospective study of a new presbyopia pseudophakic intraocular lens: Safety, efficacy and satisfaction. Indian J Ophthalmol 2022;70:3305-10.

cataracts classified as nuclear opalescence (NO) 1- nuclear color (NC) 1 to NO4-NC4, according to the Lens Opacities Classification System III (LOCS III),[21] with an indication for FLACS for both eyes. The only patients included were those who were programmed to have the same model of IOL (Intensity) implanted in both eyes. Among those excluded were patients who had cataracts classified as NO5-NC5 or NO6-NC6; as well as post-traumatic cataracts; patients with a preoperative endothelial cell density (ECD) count below 2000 cell/mm^2; patients with a corneal pathology (corneal scars, previous corneal refractive surgery); patients with pseudoexfoliation, pupil synechiae or small pupil, uveitis, and/or previous vitreoretinal surgeries and/or previous glaucoma surgery; patients with a history of phakic IOL and patients with intraoperative posterior capsular rupture with vitreous loss. Furthermore, patients with ocular surface disease, and/or history of corneal refractive surgery, and/or topographic astigmatism higher than 1.00 D were excluded, as well as cases with intraocular pressure (IOP) higher than 21 mm Hg.

Parameters and follow-up

All patients underwent a complete preoperative ophthalmic examination, including macular ocular coherence tomography (OCT). Ocular surface disease was evaluated to rule out patients with dry eyes (using vital dyes, tear break-up time, and the Schirmer test). Intraocular pressure (IOP) was measured at baseline and at the postoperative stage using Goldmann tonometry, whereas the Pentacam imaging system (Oculus, Wetzlar, Germany) was used for the preoperative evaluation of the cornea. The IOL power calculation was determined using the IOL-Master equipment, with SRK/T, Haigis and Holladay formulas, accordingly the axial longitude of the eye.[22] The target was emmetropia in both eyes, and manifest refraction spherical equivalent (SE) was evaluated 3 months and 6 months after surgery. The SE refractive accuracy was also evaluated. Postoperative uncorrected distance visual acuity (UDVA) on the Snellen chart, uncorrected near visual acuity (UNVA) on the Jaeger chart, and a defocus curve were evaluated during the final visit of each patient, 6 months after surgery. The logarithm of the minimum angle of resolution (LogMAR) was calculated to obtain the defocus curve with additions from −4.0 to +3.0 D. Uncorrected intermediate visual acuity (UIVA) was evaluated by the ability to see a computer screen at 70 cm.

Instead of reading and explaining what the informed consent contains, a preoperative talk with easy-to-understand terminology is carried out with every patient as part of the surgeon's routine practice (GB). The goal is to understand their needs and expectations, and also to explain the potential dysphotopsia effects they may experience at night, such as halos and glare. Also, the fact that it is not possible to guarantee that the patient will achieve successful and complete spectacle independence, but that it is a desired outcome with this kind of IOL, is emphasized. Postoperative evaluation of patient satisfaction is also a routine practice, and is conducted through a short "satisfaction questionnaire" previously developed and adapted to the cultural characteristics of the population, which is then published.[20] Patients respond to it anonymously in their homes following the last follow-up control of the study, which takes place 6 months after surgery. *Briefly*, there are three questions with multiple choice answers: 1 – Was spectacle independence obtained? 2 – Were the preoperative surgical expectations achieved? And 3 – Did the patient experience halos? Also, the presence of surgical complications was evaluated by slit lamp, as IOL decentration or posterior capsular opacification (PCO), 6 months after surgery. The corneal ECD, CCT, and IOP were registered preoperatively, 3 and 6 months postoperatively, using an electronic specular microscope (TOMEY EM4000).

Intensity IOL characteristics (obtained from the official brochure).[23] A 25% hydrophilic acrylic, foldable single-piece IOL, with 1.45 refractive index and −0.13 µ of spherical aberration. It has a similar platform as the SeeLens AF® (Hanita Lenses), with a different optic design, because it has a aspheric diffractive posterior surface and a spherical anterior surface, with an optimized pupil aperture design and a "dynamic light utilization technology" based on the Hanita Lenses proprietary algorithm. One of its main characteristics is the special smooth profile with 5 foci, distributed symmetrically around the zero order, which is directed to the intermediate vision and 12 steps at different heights, which vary along the lens radius with a maximum step height of 3.6 microns. It has a central ring of 1.0 mm and a sharp 360° square edge, effective against PCO, along with a wide-angle contact with the capsular bag. It also has a natural yellow violet filter, with an optic diameter of 6.0 mm, and an overall length of 13.0 mm. It is designed to be implanted from a 1.8 mm incision. Smooth diffractive steps are localized in the 4.0 mm central zone, enhancing photopic vision, and from 2.5 to 5.2 mm diameter for mesopic and scotopic vision, suiting pupil sizes in different lighting conditions.

Surgery. FLACS (Femto LDV Z8®; Ziemer Ophthalmic Systems AG, Port, Switzerland) were performed in both eyes, with 1 week apart between surgeries. All surgeries were performed by the same surgeon (German Bianchi [GB]), using a technique previously described with this laser equipment,[24] but the anterior capsulotomy was programed for 5.1 mm diameter. The nucleus of the lens was then laser-fragmented in eight pieces. Two corneal incisions were created, one of 2.8 mm located at 130°, and another one of 1.1 mm located at 35°. An INFINITI phacoemulsification equipment (Alcon, Forth Worth, USA) with "OZil burst" mode (parameters: 60 limit; 70 on ms, 300 vacuum and 30 rate) was used. Viscoelastic substance (sodium

Table 1: Refractive efficacy and safety outcomes, in the preoperative stage, and up to 6 months after the Intensity multifocal intraocular lenses implantation in 56 patients (*n*=112)

Safety outcomes	Preop	3 months	6 months	*P*
SE (D)	1.85±2.2 (−4, to 45)	−0.08±0.31 (−0.75 to 0.63)	−0.08±0.32 (−0.75 to 0.63)	<0.001
ECD (cells/mm^2)	2452.4±176.0 (2102–2926)	2416.7±179.1 (2084-2911)	2401.3±183.2 (2015-2912)	0.09
CCT (mm)	538.6±30.0 (458-618)	542.5±32.1 (450-620)	542.4±32.0 (450-622)	0.58
PIO (mm Hg)	14.1±2.0 (11-20)	14.0±1.8 (11-18)	14.0±1.8 (11-18)	0.84

hyaluronate 1.6%; Amvisc Plus®), was injected, the IOL cartridge was introduced, and the IOL was placed in the capsular bag. Finally, an intracameral antibiotic (cefuroxime) was injected and the surgery was concluded. A topical treatment using gatifloxacin 0.03% and dexamethasone 0.1% four times per day was maintained over the next 4 postoperative weeks.

Statistics. Descriptive statistical results were presented as mean, standard deviation (SD) and range. Data normality was checked using the Kolmogorov–Smirnov test. Analysis of variance (ANOVA, single factor) was used to compare the differences between the mean of the main outcomes. A P value of <0.05 was considered a statistically significant result. Statistical analysis was performed with the XLMiner Analysis ToolPak software (Frontline Systems Inc.). The data are stored at the "Clínica de Ojos Dr. Nano" and are available upon request to the corresponding author.

Results

A total of 112 eyes of 56 patients (25 women and 31 men), aged 65 ± 6.12 years (57–78) were included. All surgeries were performed without intraoperative complications. The IOL was successfully centered, and 6 months after surgery there were no signs of capsular opacification in any cases.

Safety outcomes measured as ECD, CCT, and IOP remain stable without any statistically significant differences, as is shown in Table 1. The mean ± SD of preoperative SE was 1.85 ± 2.24 D (range; −4.50 to 4.75); 6 months after surgery, this

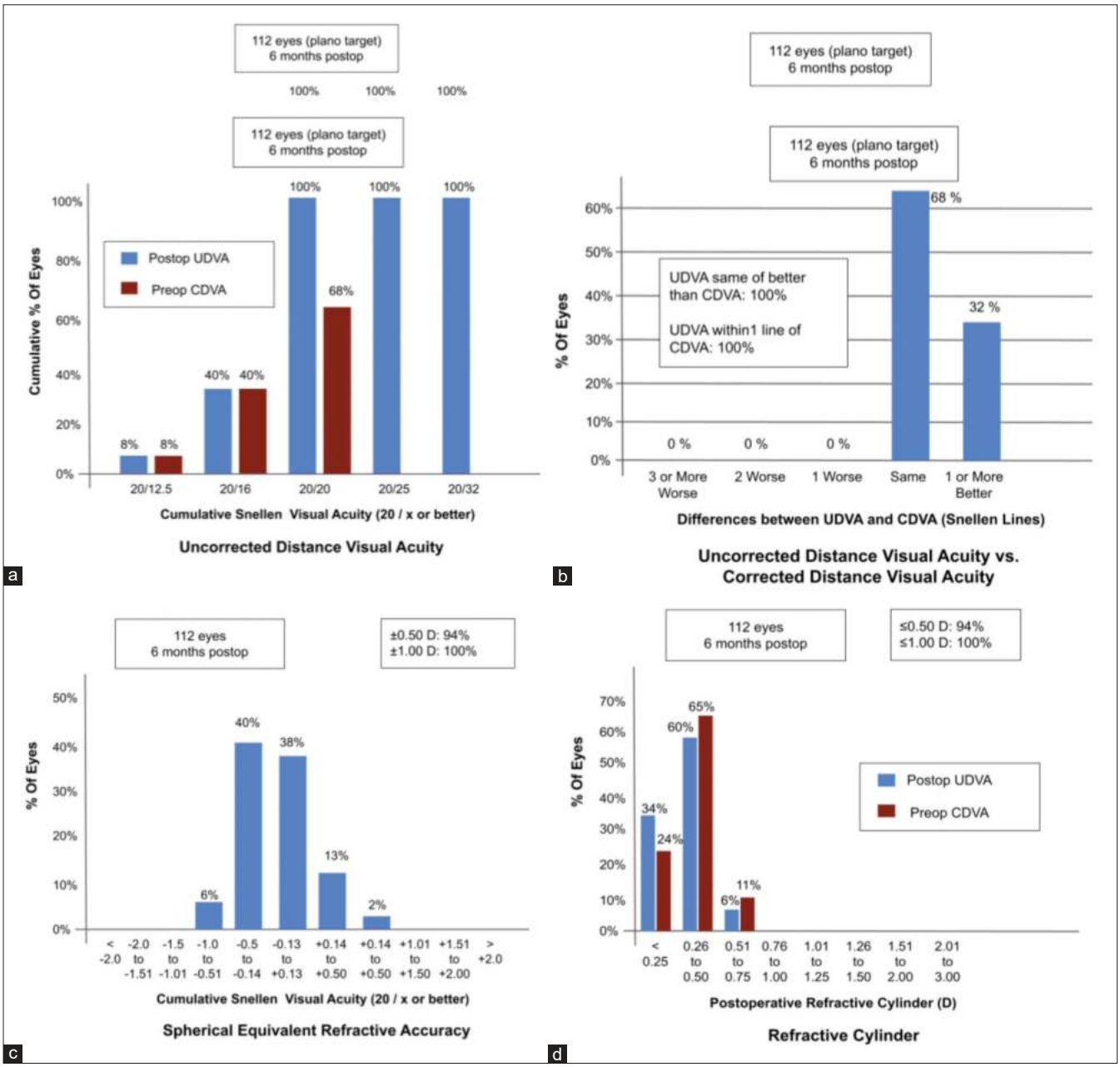

Figure 1: Standard graphs for reporting refractive outcomes for intraocular lens-based procedures in a cataract population. a: UDVA. b: UDVA versus CDVA. c: SE refraction accuracy. d: Postoperative refractive cylinder

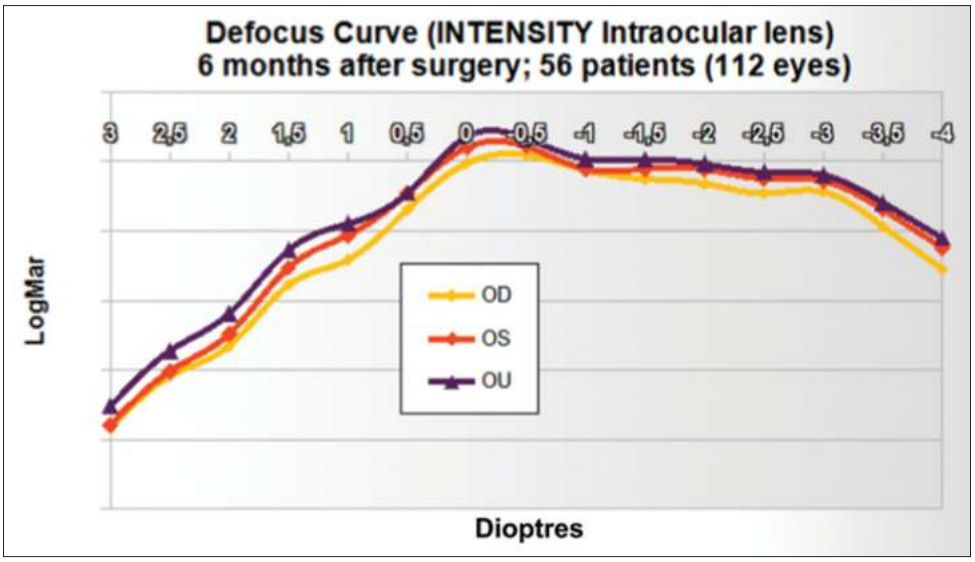

Figure 2: Binocular defocus curve from Intensity multifocal Intraocular Lens, 6 months after surgery (n: 56 patients; defocus addition from +3.0 to −4.0 D). Abbreviations: OD: right eye; OS: left eye; OU: both eyes

Table 2: Satisfaction questionnaire of 56 patients six months after the Infinitiy® pseudophakic multifocal intraocular lens were implanted

Questions	Answers
Did you obtain spectacle independence?	94.6% (53), yes 1.8% (1), I sometimes need spectacles to read 1.8% (1), I sometimes need spectacles for driving/watching television 1.8% (1), I sometimes need spectacles for digital screens, but not always
Did the surgical outcome meet your preoperative expectation?	100% (56), yes 0%, not at all
Do you perceive "halos"?	85.7% (48), no 0%, yes, always, and they do bother my visual activities
If yes, tell us if they bother your visual activities, daily life or not (e.g. for night driving)	1.8% (1), sometimes, and they do bother my visual activities 12.5% (7), sometimes, but they don't bother my life

Answers are expressed as percentages and number of patients

had dropped to − 0.08 ± 0.32 D (range; −0.75 to 0.63), a fact that is also presented in Table 1. Fig. 1 shows the standard for reporting refractive outcomes of IOL-based refractive surgery. Most eyes obtained SE values between ± 0.50 D. None of them showed loss of lines of vision, and patients achieved a UDVA between 20/20 and 20/12.5. In Fig. 2, we can see optimal outcomes that were obtained for different defocus additions, with 0.03 LogMAR for −3.0 D (near sight), −0.005 LogMAR for −1.5 D (intermediate sight), and −0.07 LogMAR for 0 D (distance sight).

Regarding the questionnaire, most patients reported being satisfied, having achieved a high percentage of surgical expectations and obtaining spectacle independence; only a low percentage reported perceiving halos 6 months after surgery, as we can see in Table 2.

Discussion

The present study shows the efficacy and safety results of a new multifocal IOL called Intensity, with a follow-up period of 6 months. The majority of patients obtained spectacle independence, and all of them achieved their preoperative surgical expectations. Of the 56 participants, 8 of them reported experiencing the visual phenomenon of halos, albeit on occasions, and none of them stated that it was constant.

Modern cataract surgery has created demanding patients who pressure surgeons to deliver successful results. Even though surgeons can never guarantee this outcome, patients expect to achieve spectacle independence after surgery. In this globalized world, patients seek information online and ask friends and family for their opinions. Not only do they look to see where and when they can be operated, but they also try to learn about different IOL models and options. Because of this, surgeons needs to work with medicine-based evidence concepts, without bias and/or commercial interest, in order to suggest the most suitable option for every patient. When the Intensity multifocal IOL product became available, there was a need to evaluate its performance in clinical studies. Up until the elaboration of this study, the only clinical information available was provided by the Intensity's manufacture company (Hanita Lenses), which Prof. Assia describes on his website.[25] It is an interesting initial clinical study, but it has not been published in a peer-reviewed journal. It is a single arm, single center open label study, with 20 patients (40 eyes), and a 3-month follow-up period. The SE achieved was −0.24 D, and patients achieved similar visual performance as we see in the present study, even when the SE of the present series was −0.08 D.

Regarding binocular defocus curve, the Prof. Assia study and the present one show similar results, for 0.0 D of defocus (−0.10 and −0.07 LogMAR, respectively), and for −3.0 D of defocus (0.02 and 0.04 LogMAR, respectively). However, there is a difference for −1.5 D of defocus, (−0.05 and 0.00 LogMAR, respectively). Another difference is noted at the beginning of the defocus curve: whereas Prof. Assia observed − 0.02 LogMAR for a +0.50 D of defocus, we obtained

0.09 LogMAR. Likewise, at the end of the defocus curve, a similar behavior is observed at −3.5 D of defocus (0.13 and 0.11 LogMAR, respectively). The subjective opinions of patients were evaluated by nine questions with very good outcomes, as is the case in the present study, with a different questionnaire. The very good contrast sensitivity results reported by Prof. Assia in his study under different light conditions, which were not evaluated in the present study, are an interesting discovery. In general terms, the visual performance of the 3 month study reported by Prof. Assia is similar to what is being reported in this study, 6 months after surgery, with a large series of patients.

To the best of our knowledge, this is the first study reporting results of an Intensity multifocal IOL, with a 6-month follow-up period. It is interesting to compare the present results with another IOL of the same company, called SeeLens MF (FullRange optics). A large series was evaluated and published[20] (240 patients, 480 eyes followed over the course of 1 year), showing good outcomes with different defocus additions, achieving 0.04, 0.09, and 0.03 LogMAR for −3.0 D, −1.5 D, and 0.0 D of defocus, respectively. Intensity results in the present series were similar, with 0.03, −0.005, and −0.07 LogMAR for −.0 D, −1.5 D, and 0.0 D of defocus, respectively. A difference was however discovered for intermediate and distance vision, where Intensity performance seems to be better. Even when both lenses from the same company are very similar, their optical design is different (as the company itself states on its website): whereas SeeLens MF has a diffractive apodized aspheric, Intensity has an aspheric-diffractive posterior surface, with a spherical anterior surface posterior surface with pupil aperture optimized, with potent 5 foci for the intermediate vision, which is also efficient for near vision.

The safety outcomes of the Intensity were good, observing that ECD, CCT, IOP remained stable and intra/postoperative complication did not occur, up to 6 months of follow-up. Considering scientific levels of evidence, the main limitation of the present study is its design. Furthermore, in this single central study, quality of vision was not objectively assessed. A comparative group would be necessary to improve the present evidence, and a randomized masked multicentric clinical study must be performed, also evaluating objective quality of vision measurement, as well as contrast sensitivity function, including the patient's pupil diameter under different light conditions. However, performing an ideal study design is very difficult to achieve, especially in Latin American countries, where most independent research has no economical support. A better study can be performed, and a prospective case series study design (like the present one) can offer valuable information to confirm or refute what the company has shared and published on its website.

Moreover, and in addition to objective results, the opinions of patients matters. In this study, that feature was assessed through a questionnaire specifically developed to evaluate spectacle independence, postoperative expectations, and if patients were experiencing halos that affected their daily activities. It was carried out through a short and easy questionnaire, which was previously used and published by the author of this work.[20] However, it is important to emphasize that patient satisfaction can be highly influenced by the patient–surgeon relationship.[26-28] This subjective aspect can be biased by a good (or not so good) preoperative patient communication, and a postoperative relationship with the physician. Many questionnaires have been developed and validated to evaluate the opinions of patients, and one of the better options is the National Eye Institute Visual Functioning Questionnaire-25 (NEI VFQ-25), followed by a shorter one, the Visual Function Index-14 (VF-14).[29] The very short questionnaire used in the present study is possibly weaker than the ones previously mentioned (NEI VFQ-25, VF-14), or even than the short questionnaire called Catquest-9SF.[30] However, it was chosen because it is culturally adapted to the Argentinian population, and easy to understand for patients, as was previously confirmed.[20]

Achieving safety and refractive efficacy do not guarantee that dissatisfaction will not appear after multifocal IOL implantation. Dissatisfaction is mainly associated with visual dysphotopsias, such as halos, starburst and/or glare, and also related to patient personality.[31-34] In the study published by Hovanesian *et al*.,[34] the PanOptix Trifocal IOL, ReSTOR 2.5 Active Focus, and ReSTOR 3.0-Add Multifocal Lenses were compared. And even when the incidence of glare and halos were higher for PanOptix (10% of patients answered that they noticed "extremely"), they finally found that overall results of visual performance and satisfaction were better with the PanOptix multifocal IOL. In our series, 14.3% of patients reported halos but only 1.8% mentioned that just sometimes they do bother their visual activities. Nevertheless, more studies will be necessary to confirm that, comparing Intensity lenses with other similar IOLs, in a prospective and masked study design. Also, in the present study, a low percentage of eyes have postoperative astigmatisms between 0.51 and 0.75 D and none of them were higher than that. And this can be in part the cause of halos in our patients. However, in a recent study, it was described that the effect of residual astigmatism on visual performance and satisfaction was more evident at the 0.75 to 1.00 D.[35] Finally, the authors conclude that corneal astigmatism of 0.50 or higher must be considered to be included and managed in the surgical plan. It is an interesting point, but in our case, we have not managed that: limbal relaxing incisions were not performed and the toric option was not available when the study was conducted. One more interesting aspect to take into account for future studies with Intensity multifocal IOL is to see if patient satisfaction, and particularly dysphotopsias, changes over time, as was reviewed by Zamora-de La Cruz D *et al*.,[33] which is related to neuroadaptation. However, visual neuroadaptation after surgery is still a special area to research and understand, which will be very useful clinically in the future if that information can be managed at the preoperative stage.[36]

Conclusion

Finally, the objective information obtained in the present series shows that patients bilaterally implanted with Intensity IOL were satisfied, achieving a high degree of spectacle independence, with a 6-month follow-up period. Procedures were safe and efficient. The best visual performance observed was for near and intermediate vision. However, more information must be gathered from more independent researchers, performing comparative studies in a population with a wide range of characteristics.

Acknowledgments

To Rodrigo M Torres, MD PhD. for his scientific assistance.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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