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# Efficacy, safety, and satisfaction in patients with a functional 5-focus pseudophakic lens 2 years after surgery

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***Abstract***

**Purpose:** To evaluate the safety, visual performance, and patient satisfaction of a new presbyopic pseudophakic intraocular lens (IOL).

**Methods:** An ambispective non-randomized study was performed in Buenos Aires, Argentina. Patients included in the study underwent a programmed femtosecond laser-assisted cataract surgery (FLACS), performed between October 2020 and September 2021, with a 24-month follow-up period. The Intensity SL (Hanita Lenses) IOL was bilaterally implanted. Uncorrected distance, intermediate, and near visual acuity (UDVA/UIVA/UNVA, respectively), and defocus curve as well as safety parameters were measured, and patient satisfaction was evaluated with the VF-14 QOL questionnaire.

**Results:** A total of 120 eyes of 60 patients (34 women and 26 men) aged 68.32 ± 8.9 years (54–85) were included. At the last follow-up, the mean monocular UDVA in eyes ($n = 120$) with an Intensity SL IOL implanted was 0.01 ± 0.07 logMAR, and the corrected distance visual acuity (CDVA) was −0.05 ± 0.06 logMAR. For 120 cm, mean UIVA was 0.06 ± 0.11 logMAR; for 80 cm, mean UIVA was 0.07 ± 0.07 logMAR; for 66 cm, mean UIVA was 0.05 ± 0.07 logMAR and for 40 cm, mean UNVA was 0.09 ± 0.08 logMAR (−0.1 to 0.2). The mean binocular UDVA in our patient group was −0.05 ± 0.05 logMAR. Glare and halo were rare phenomena. Patient satisfaction was high. The mean score value of the VF-14 QOL questionnaire 24 months postoperatively was 98.6.

**Conclusion:** Patients underwent safe bilateral implantation with Intensity SL IOL, achieving spectacle independence in most cases, and reported a high degree of satisfaction, refraction, and vision stability 24 months after surgery.

***Keywords:*** cataract surgery, multifocal intraocular lens, presbyopia, pseudophakic intraocular lens, refractive surgery

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## Introduction

A widely accepted axiom in current ophthalmology states that cataract surgery is almost always refractive surgery.[1] Undergoing the exchange of a more or less opaque natural lens for an intraocular lens (IOL) that serves the patient's individual visual needs is also an opportunity to treat an existing refractive disorder. In addition to myopia and hyperopia, which typically afflict patients since childhood or adolescence, presbyopia is a problem for the vast majority of cataract patients—globally the most common among individuals beyond the fifth decade of their lives[2] and many of them cherish the opportunity to have this visual problem solved in "one go" as they undergo IOL implantation.

For patients with presbyopia, several options exist to overcome this refractive condition. The expectations of the individual patient should play a

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decisive role in the planning of cataract surgery.[3] Many patients hope for—or outright, expect—postoperative spectacle independence for most, if not for all, visual distances.[4] Cataract surgery offers individuals with presbyopia the potential of spectacle independence with a wide array of premium intraocular lens options.[5] The subjective perception of surgical success is often shaped by achieving spectacle independence as well as by postoperative visual acuity, safety of the procedure, and other, more traditional factors[6,7]; this holds particularly true for the growing number of cataract patients who have previously undergone refractive surgery and thus place significant value on living their lives with as minimal reliance as possible on glasses.[8]

Today, there is a wide variety of presbyopic pseudophakic intraocular lenses[9–11] as well as phakic IOLs to treat this condition.[12] The main author has experience with different multifocal IOL designs[13] and in 2022 has published the results of a prospective non-randomized case series to evaluate the safety, visual performance, and patient satisfaction of a new multifocal IOL by the name of Intensity SL (Hanita Lenses, Israel). An emphasis was placed on the fact that these results were achieved under real-life conditions, which can be very different from the design, the settings, and the patient selection of sponsored clinical studies. The 6-month results documented the safety, efficacy, and high degree of patient satisfaction after bilateral implantation of the Intensity SL IOL.[14]

The purpose of this study is to evaluate the visual performance of the Intensity SL IOL over 2 years after surgery, in particular the visual acuity for far, intermediate, and near distance as well as its binocular defocus curve. In addition, the postoperative stability obtained between 6 and 24 months after surgery was compared, along with the evaluation of safety parameters and patient satisfaction.

## Methods

### *Study design*

This was an ambispective single-arm, single-center, non-randomized study, performed to evaluate the clinical outcomes of patients implanted with the Intensity SL pseudophakic IOL 2 years after surgery, who underwent FLACS between October 2020 and September 2021 at the Clinica Nano (Olivos, Argentina). The patients were selected from the surgeon's clinical records. Cases operated on in the previously described period, who had also undergone a follow-up control 6 months after surgery, were identified. These patients were called and a visit was scheduled to evaluate their condition 2 years after surgery. Approval was obtained from the Institutional Review Board (Ethics Committee of the "Sociedad Argentina de Presbicia"; report number: 0001/23). 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*

Inclusion criteria consisted of patients who provided informed consent, underwent bilateral implantation of the Intensity SL IOL following cataract surgery performed with the FLACS technique, completed postoperative follow-up at 6 months, and attended a scheduled follow-up visit 2 years after surgery. Patients who did not have bilateral implantation of the same lens model (Intensity SL) were excluded. Also, patients who had cataracts classified as NO5-NC5 or NO6-NC6 (according to the Lens Opacities Classification System III), as well as post-traumatic cataracts, were excluded.[15] Patients at increased risk of postoperative endothelial decompensation (preoperative endothelial cell density $<2000$ cells/mm$^2$) were excluded, as well as patients with preoperative corneal pathology (corneal scarring, previous corneal refractive surgery) that resulted in a contraindication to multifocal lens implantation. Also were excluded patients with pseudoexfoliation, pupillary synechia or small pupil, uveitis, and/or previous vitreoretinal surgery and/or previous glaucoma surgery, or patients with a history of phakic IOL and patients with intraoperative posterior capsular rupture with vitreous loss. In addition, patients with severe ocular surface disease, and/or history of corneal refractive surgery, and/or topographic astigmatism greater than 1.00 D, as well as cases with perioperative intraocular pressure (IOP) greater than 21 mm Hg, were excluded.

### *Parameters assessed in the study*

To evaluate safety, visual, and refractive efficacy aspects, as well as patients' satisfaction, the following measurements were performed at 2 years.

Initially, all patients underwent a complete preoperative ophthalmic examination, including macular ocular coherence tomography (OCT). The 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 IOLMaster 700 equipment (Carl Zeiss Meditec, Jena, Germany), with SRK/T, Haigis, and Holladay formulas, accordingly to the axial length of the eye.[16] The pupil diameter was measured 2 years after surgery under photopic and mesopic conditions (measured with the Pentacam imaging system). Objective refraction was assessed using a Topcon KR-800 auto kerato-refractometer (Topcon Medical Japan Co., Ltd., Tokyo, Japan). The target was emmetropia in both eyes, and the manifest refraction spherical equivalent (SE) was assessed at 6 months and 2 years postoperatively. Postoperative uncorrected and corrected distance visual acuity (UDVA and DCVA) on the Snellen chart, uncorrected and corrected near visual acuity (UNVA) on a logarithmic reading chart, and a defocus curve were evaluated during the final visit of each patient. The logarithm of the minimum angle of resolution (logMAR) was calculated to obtain the defocus curve with additions from −4.0 to +1.0 D. Uncorrected and corrected intermediate visual acuity (UIVA and DCIVA) was evaluated with logarithmic charts at different distances, as at 120, 80, 66 cm, as well as for UNVA and 40 cm. Also, the presence of surgical complications was evaluated by slit lamp, as IOL decentration or posterior capsular opacification (PCO). To assess whether stable results were achieved regarding visual performance, some parameters were compared between 6 and 24 months postoperatively, such as UDVA, UIVA (66 cm), UNVA (40 cm), and objective and subjective refraction. In addition, the type and number of cases with complications at 6 and 24 months were descriptively evaluated.

Postoperative evaluation of patient satisfaction was conducted 2 years after surgery in two ways: (a) using as a basis the short questionnaire that was used for the study published in 2022, an extended and original questionnaire was developed, mainly oriented to learning about different visual phenomena, dysphotopsias and general patient satisfaction, and (b) with the VF-14 Quality of Life (VFQ-14) questionnaire.[17] To answer the questionnaire (a), patients respond to it anonymously in their homes following the last follow-up control of the study, which takes place 24 months after surgery. The complete questionnaire can be found as Supplemental Material 1. For questionnaire (b), the VFQ-14 was used which is a brief questionnaire designed to measure functional impairment in patients due to cataracts. It consists of 18 questions covering 14 aspects of visual function affected by cataracts. The VFQ-14 shows high internal consistency and is a reliable, valid instrument providing information not conveyed by visual acuity or general health status measures.[17] Scores on all activities that the person performed or did not perform because of vision were then averaged, yielding a value from 0 to 4. This value was multiplied by 25, giving a final score from 0 to 100. A score of 100 indicates the ability to do all applicable activities, such as driving, doing handwork, watching television, and reading, and a score of 0 indicates the inability to do all applicable activities because of vision.[17]

### *Intensity SL IOL characteristics*

The Intensity SL is a diffractive aspheric, foldable, one-piece lens designed for micro-incision cataract surgery through sub-2mm incisions and for implantation. The lens has an 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 that gives it a functional performance of 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*

All interventions were performed with a femtosecond laser (Femto LDV Z8®; Ziemer Ophthalmic Systems AG, Port, Switzerland) on both eyes (one week apart) and by the same experienced surgeon. The diameter of the anterior capsulotomy was 5.1 mm; following laser capsulotomy, the nucleus of the lens was 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°. For phacoemulsification, the INFINITI equipment (Alcon, Fort Worth, USA) was used. Viscoelastic substance (sodium 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. Topical treatment using gatifloxacin 0.03% and dexamethasone 0.1% four times per day was maintained over the next four postoperative weeks.

### *Statistics*

Descriptive statistics were reported as mean, standard deviation (SD), and range. The normality of the data was assessed using the Kolmogorov–Smirnov test. Single-factor analysis of variance (ANOVA) was employed to evaluate differences in the mean values of the primary outcomes. Statistical significance was defined as a $p$-value $< 0.05$. All statistical analysis was performed using the XLMiner Analysis ToolPak software (Frontline Systems Inc.). The data are available upon request to the corresponding author.

## Results

### *Demographic results and safety parameters*

A total of 120 eyes of 60 patients (34 women and 26 men) aged 68.32 ± 8.9 years (54–85) were included. The mean axial length of the eyes undergoing surgery was 25.97 ± 1.92 mm (21.5–30.2). The mean pupil diameter evaluated 2 years after surgery was 2.29 ± 0.13 mm (2.05–2.52) under photopic conditions and 2.82 ± 0.23 mm (2.38–3.25) under mesopic conditions. All surgeries were performed without intraoperative complications; on all follow-up visits, the IOL was successfully centered in all cases, and no change between that observed at 6 and 24 months. Two years after surgery, visually relevant PCO was observed in three eyes (2.5%); PCO was not registered in any eye at 6 months after surgery.

Two patients (4 eyes) developed postoperatively a mild dry eye symptom, which was detected in the control performed for the present study 2 years after surgery; in the clinical records of these patients, there was no record of dry eye at the 6-month postoperative control. No eye had intraocular pressure greater than 18 mmHg at 2 years after surgery. No cases of ocular hypertension were found in the control group performed 6 months after surgery. When examining the fundus, no clinically relevant condition was detected in the patient group during follow-up, and no patient developed retinal detachment. The retinal OCT showed normal macular thickness in all eyes after surgery; there was no case of visually relevant macular edema.

### *Visual and refractive outcomes*

Two years after surgery, the mean subjective refraction in eyes ($n = 120$) with an Intensity SL IOL implanted was −0.16 ± 0.26 D (−0.75 to 0.38), and the objective refraction was −0.29 ± 0.27 D (−0.88 to 0.38). The mean monocular UDVA was 0.01 ± 0.07 logMAR (−0.1 to 0.1), and the CDVA was −0.05 ± 0.06 logMAR (−0.20 to 0.1). For 120 cm, mean UIVA was 0.06 ± 0.11 logMAR (−0.2 to 0.2) and mean DCIVA was 0.01 ± 0.07 logMAR (−0.1 to 0.1). For 80 cm, mean UIVA was 0.07 ± 0.07 logMAR (−0.1 to 0.2) and mean DCIVA was 0.03 ± 0.05 logMAR (−0.2 to 0.1). For 66 cm, mean UIVA was 0.05 ± 0.07 logMAR (−0.1 to 0.2) and mean DCIVA was 0.03 ± 0.06 logMAR (−0.1 to 0.18). For 40 cm, mean UNVA was 0.09 ± 0.08 logMAR (−0.1 to 0.2) and mean corrected near visual acuity (CNVA) was 0.07 ± 0.07 logMAR (−0.1 to 0.2).

The mean binocular UDVA in our patient group was −0.05 ± 0.05 logMAR (−0.2 to 0.05), mean binocular UIVA was 0.009 ± 0.05 logMAR (−0.18 to 0.18), and mean binocular UNVA was 0.04 ± 0.06 logMAR (−0.1 to 0.2). To assess the stability in visual performance, Table 1 presents the results of UDVA, UIVA (66 cm), and UNVA (40 cm), along with the values of the SE obtained in the subjective and objective refraction measurements. It is observed that no statistically significant differences were found.

The defocus curve obtained 2 years after surgery is shown in Figure 1. Figure 2 shows the binocular defocus curve obtained 6 months after surgery and the curve obtained 2 years after surgery, where it can be seen that they are very similar at most defocus points.

**Table 1.** Comparison of the visual performance obtained in patients implanted with the Intensity lens between 6 months and 2 years after surgery.

| Parameters | 6 Months postop | 24 Months postop | *p* |
|---|---|---|---|
| UDVA LogMAR | 0.007 ± 0.14 (–0.1 to 0.1) | 0.01 ± 0.07 (–0.1 to 0.1) | 0.8 |
| UIVA (66 cm) LogMAR | 0.04 ± 0.03 (–0.1 to 0.2) | 0.05 ± 0.07 (–0.1 to 0.2) | 0.5 |
| UNVA (40 cm) LogMAR | 0.08 ± 0.03 (–0.1 to 0.2) | 0.09 ± 0.08 (–0.1 to 0.2) | 0.4 |
| Subjective refraction (D) | –0.18 ± 0.28 (–0.75 to 0.50) | –0.16 ± 0.26 (–0.75 to 0.38) | 0.6 |
| Objective refraction (D) | –0.30 ± 0.26 (–0.88 to 0.38) | –0.29 ± 0.27 (–0.88 to 0.38) | 0.9 |

D, diopters; UDVA, uncorrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity.

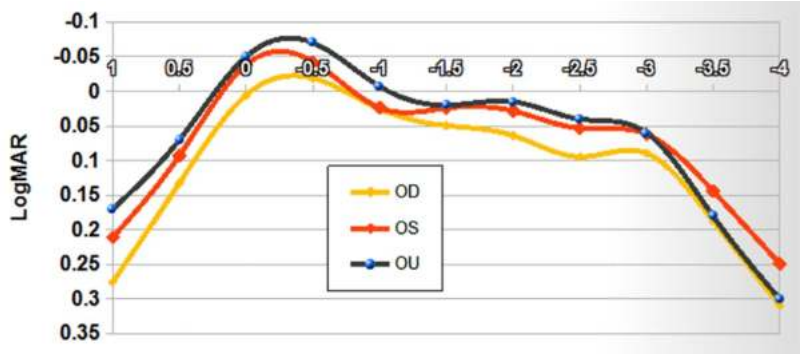


**Figure 1.** The monocular and binocular best corrected defocus curve, 2 years after surgery, in eyes implanted with Intensity SL (120 eyes, 60 patients).
OD, right; OS, left eye; OU, both eyes.

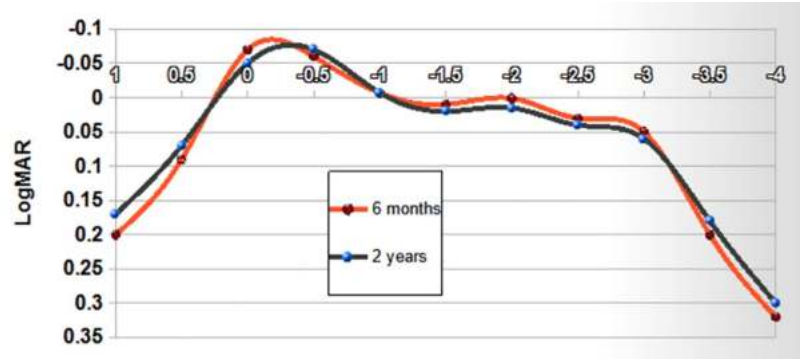


**Figure 2.** Binocular defocus curve, 6 and 24 months after Intensity SL (120 eyes, 60 patients) implantation.

*Psychometric results*

Patient satisfaction was high as is documented in Figure 3. The mean score value of the VF-14 QOL questionnaire 21 to 24 months postoperatively was 98.6 with the majority of the patients ($n = 46$) reaching the best possible score of 100 (Figure 2). Blurred vision for larger distances was reported by six patients and described as mild, blurred near vision was reported by eight patients (7 mild, 1 moderate). Evaluating other visual phenomena, 47 patients did not notice any halos (11 reported mild and 2 moderate halos), and 57

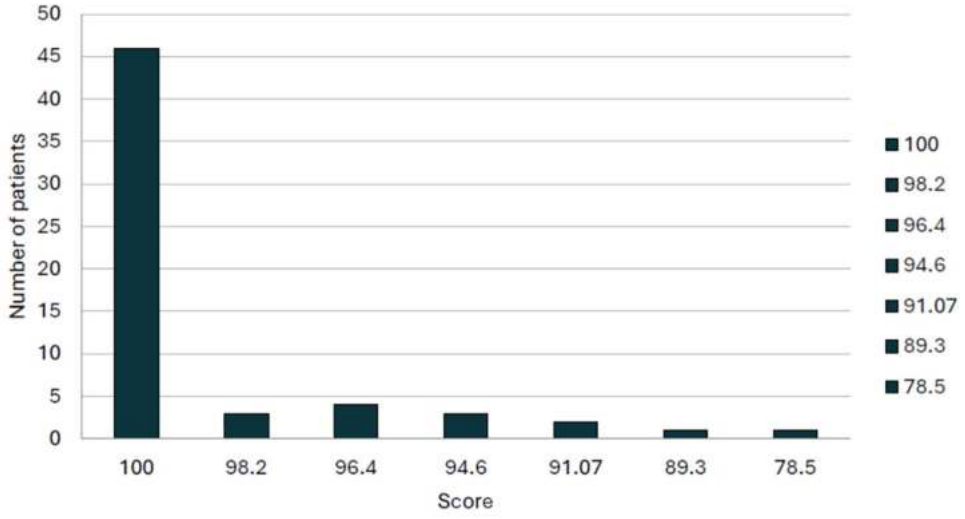


**Figure 3.** Patient satisfaction using VF-14 QOL Questionnaire, in patients implanted with Intensity SL, 2 years after surgery.

out of 60 patients did not notice any glare (3 patients had mild glare). There was no case of monocular or binocular diplopia and no difficulties with depth perception or color vision. Completely spectacle independent for distant vision were 55 patients, for intermediate vision 58 patients, and for reading 56 patients. Asked about all treatment-related items, 57 of 60 patients were "very satisfied with the results" and 3 patients were "satisfied with the results," none of the patients expressed dissatisfaction. Being asked whether they would choose the same treatment again, all 60 patients answered in the affirmative.

## Discussion

A frequent question from patients who have an intraocular lens implanted is how long it lasts or if it needs to be changed at some time. The surgeon's spontaneous answer is that the lens should last its lifetime if there are no problems—which are infrequent and unexpected—such as a loss of transparency of the material. As surgeons, the usual minimum follow-up time is 3 months,[18] after which the patient is discharged, and an annual check-up is recommended. However, the time factor is sometimes what reveals potential problems in intraocular lenses.[19] As surgeons, it is important to check the performance over time of the lenses we implant.

Presbyopia-correcting IOLs will certainly play an increasing role in cataract surgery with the number of seniors leading an active life—in which devices such as laptops, tablets, and smartphones seem to become indispensable, irrespective of age—growing and with it the patient's expectations for a high vision-related quality of life and for spectacle independence for most, if not for all activities. For the numerous IOL designs on the market or about to be introduced in the near future, currently, no standard exists for measuring their optical properties and clinical success rates. This makes it extremely difficult to compare results. In this study, we measured UIVA at different distances such as 120, 80, 66, and 40 cm—distances which are important for most daily indoor activities.

The 2-year results confirm the findings of an earlier study in which the safety and efficacy of the Intensity SL IOL were evaluated over a follow-up period of 6 months.[14] The visual performance achieved has allowed most patients to be spectacle independent, as was reported by more than 90% of the patients; 55 out of 60 for distant vision and 58 out of 60 for intermediate vision. This emphasizes that the results reported in our previous study reflect the findings of the present report, 2 years after surgery. Also, our present results confirm that the visual performance achieved 6 months after surgery remained stable 2 years after surgery. The safety outcomes were good with no adverse retinal conditions, no unphysiological loss of ECD, or significant IOP rise. Intraoperative complications did not occur, the only noteworthy postoperative adverse events were two cases of mild dry eye.

Recently Bellucci et al.[20] have published a very interesting study where they evaluated and compared objective and subjective visual outcomes of both the Intensity lens and the Finevision lens. Bellucci's study evaluated the results at the time of surgery. They found that the subjective value was −0.18 (similar to our study, which obtained the same result at 6 months postoperatively and −0.16 at 2 years postoperatively). But Bullucci highlighted the difference found with the objective value, which was −1.33, while we had an objective value of −0.29 at 2 years. The difference between the objective refraction reported by Bellucci et al and that found in our study may be due to several factors, mainly related to the methodologies adopted. This is a very interesting aspect to take into account for clinical practice, which in turn emphasizes the relevance of subjective refraction in patients with diffractive implants of this kind. The visual results obtained by Bellucci C et al and those of the present study were similar, although Bellucci's follow-up was 1 month.

A major problem with multifocal IOLs is visual dysphotopsias such as halos, glare, and starburst. Up to 67% of patients may experience positive dysphotopsia immediately after surgery, and about 2.2% of the patients have persistent symptoms up to a year postoperatively.[21] The incidence of negative dysphotopsias is up to 26% of all patients; by 1 year postoperatively, the symptoms usually persist in 0.13% to 3% of patients.[21] This problem is not unique to multifocal lenses; a recent meta-analysis found no statistical differences between multifocal and monofocal IOLs regarding contrast sensitivity, glare, or halos.[22] These phenomena are a major cause for patient dissatisfaction[23,24] and even explantation of an IOL,[25] although they currently seem to rank behind spontaneous late IOL in-the-bag dislocations as an indication for explantation.[26]

In our patient group, these sometimes-disturbing optical phenomena were rare and mild, having no influence on a high degree of patient satisfaction. The results from our questionnaire showed that 95% of patients were very satisfied and the remaining 5% were satisfied with the treatment and its outcomes, surpassing even the 83.4% of patients reported by Yotsukura et al. who were satisfied with the surgical results.[27] In turn, when comparing these aspects of the present study with the data published 6 months after surgery, we found a similarity in the patients' responses, expressing their stability over time. Likewise, to make an adequate comparison of these parameters over time, another type of study should be designed and a follow-up of the same patients should be performed, with the same methodology, to know if the patient's perception changes, something that will be very interesting to evaluate in the long term, for example at 5 years after surgery. For the present study, we used two different psychometric tools compared to those used in the 6-month study. In that study, the questionnaire was a simple one with few questions, used solely for internal quality control purposes. In the current study, in addition to the VFQ-14, we employed a longer questionnaire to investigate the presence of various dysphotopsias and visual phenomena, along with overall patient satisfaction. The Intensity SL is a new IOL design, thus there are hardly any major studies on the Intensity SL. Assia et al. have reported results similar to ours with an average uncorrected visual acuity for distance, intermediate, and near of 0.03, 0.09, and −0.22 logMAR in a smaller patient population (20 individuals = 40 eyes). They also documented a high degree of patient satisfaction.[28]

The limitations of this study are based on its design as a single-center study. A comparative study or a study involving different centers and multiple surgeons (perhaps comparing FLACS vs phaco-only surgical techniques) would be helpful to improve the present evidence. Moreover, as this was an ambispective study with a descriptive design aimed at evaluating the status of various parameters in patients implanted with the Intensity lens 2 years post-surgery, no specific sample size calculation was performed during the protocol design phase. We identified patients who underwent surgery between October 2020 and September 2021, had completed a 6-month postoperative follow-up, and attended their 2-year follow-up appointment after surgery. In a complementary analysis, a comparison was conducted on several parameters, primarily to assess whether vision remained stable. The number of eyes evaluated for the visual acuity parameter was 120. If the sample size had been calculated initially to detect a 0.2 LogMAR change in uncorrected distance visual acuity, assuming an SD of 0.5, a confidence interval of 95%, and a statistical power of 80%, a total of 98 eyes would have been required. Although the number of cases evaluated in our study exceeded this threshold, it remains a limitation of our work that the sample size calculation was not considered during the protocol design phase. This would have ensured the inclusion of

the minimum number of cases required to verify postoperative visual stability effectively. However, given that the minimum sample size was surpassed, we can confirm that patients demonstrated visual stability between 6 and 24 months post-surgery.

Nevertheless, with a reasonably long follow-up, our data seems to give a clear picture of the visual performance and the safety of the Intensity SL IOL, as well as—not the least important aspect—of the remarkable patient satisfaction it has generated.

## Conclusion

The present study has shown that the far, intermediate, and near vision obtained by the patients operated with the intensity IOL allows most of them not to use spectacles, reporting a high level of satisfaction, without having detected relevant complications. These data allow us to highlight the stability of results achieved 2 years after surgery.

Likewise, it is necessary to gather more information from other clinical centers that perform comparative studies under real conditions and to continue evaluating the evolution of these patients with a longer follow-up time.

## Declarations

### *Ethics approval and consent to participate*

The study protocol and the researchers adhered to the tenets of the Declaration of Helsinki. Approval was obtained from the Clinica de Ojos Dr. Nano Institutional Review Board and the Ethics Committee of the "Sociedad Argentina de Presbicia." (number: 0001/23). Patients were informed about the characteristics of the study and the risks of the surgical procedure. Their written consent was obtained prior to participation.

### *Consent for publication*

The patients who participated gave their informed consent for the publication of their data, protecting their identity.

### *Author contributions*

**Germán R. Bianchi:** Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Supervision; Validation; Visualization; Writing – original draft; Writing – review & editing.

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### *Competing interests*

The author declares that there is no conflict of interest.

### *Availability of data and materials*

The data are available upon request to the corresponding author.

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## Supplemental material

Supplemental material for this article is available online.

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