Short-Term Visual Outcomes After Bilateral Pentafocal Intraocular Lens Implantation. A Pilot Study

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Abstract

Objective: To evaluate short-term refractive and visual behavior after implantation of a new pentafocal intraocular lens to manage presbyopia in otherwise healthy patients.

Methodology: A retrospective observational study was conducted, in which the postoperative outcome was evaluated three months after surgery. Patients in whom the Hanita Intensity SL intraocular lens was implanted in immediate sequential bilateral surgery were assessed. Medical records were reviewed to collect information on corrected and uncorrected vision, subjective refraction, and defocus curves with correction.

Results: Twenty eyes belonging to 10 patients were included. There was a preference for the female sex (70%). The 100% of patients achieved vision equal to or better than 20/25 in near and far vision; 100% of the patients achieved a vision equal to or better than 20/40 in intermediate vision. The defocus curve showed excellent visual performance in the vergences from infinity to approximately 33cm, with functional vision at all distances; 100% of the patients reported being free of glasses for all distances.

Conclusion: Hanita Intensity SL intraocular lens implantation is a safe and effective technique for managing presbyopia. In well-selected patients, it can provide a high proportion of independence in spectacle wear for distances up to approximately 33cm.

Keywords: Lens implantation, refractive surgical procedures, visual acuity.

Introduction

Presbyopia is one of the most common refractive conditions in the human population. Essentially, all people over 45 years-old experience a progressive loss in their accommodative range, usually resulting in losing the ability to focus on objects near them.

The implantation of simultaneous vision intraocular lenses is one of the most common surgical procedures for managing presbyopia, [1] generally with excellent results. New designs of simultaneous vision intraocular lenses promise substantial improvement in visual quality after surgery. However, a reasonable and detailed evaluation of the results with these devices is required to determine the true nature of the results obtained.

Hanita Lenses (Hanita, Israel) has recently launched a hydrophilic intraocular lens called Intensity SL. According to Bianchi, [2] a pentafocal distribution characterizes it, with a light distribution based on five foci, symmetrically distributed around zero order. This author reported an excellent result after bilateral implantation of this type of intraocular lens in his population of Argentine patients. [2]

To date, Colombian experience with the use of Intensity SL intraocular lenses is scarce, and no local study has been published regarding their use. Given the above conditions, the publication of a pilot study to determine the early results after bilateral implantation of this type of lens in Colombian patients is pertinent.

Methods

Study Design

This is a retrospective, descriptive study designed to report refractive and visual outcomes after three months of bilateral Intensity SL intraocular lens implantation in a population of patients with presbyopia. All interventions were performed by the same Refractive Surgeon, in the same operating room, using a standardized surgical technique. In all patients, surgery was performed bilaterally, sequentially, and immediately, with both eyes being operated on the same day according to established protocols. [3]

Study Population

The present study comprises 20 eyes belonging to 10 patients older than 40 years with a history of presbyopia. All patients had a normal routine physical examination except for presbyopia, with or without lens opacity or cataract. All patients required a correct visual acuity of at least 20/50 or better in both eyes and a standard corneal tomography. Patients were excluded if they had a previous ocular surgery history or if the results were considered unreliable for any reason.

Intraocular Lens Selection and Calculation

All patients in this study underwent immediate sequential bilateral implantation of Hanita Lenses Intensity SL pentafocal lens.

All lenses were calculated by the main author (K. B.). The biometric data were taken in their entirety using Pentacam AXL Wave equipment (Oculus Optikgeräte GmbH; Wetzlar, Germany) by an experienced technical assistant. The digital calculator of the European Society of Cataract and Refractive Surgeons (https://iolcalculator.escrs.org/) was used for the calculation using the state-of-the-art formulas Barrett Universal II, Emmetropia Verifying Optical (EVO), Hill-Radial Basis Function (Hill-RBF), HofferQST, Kane and Pearl DGS.

The recommended lens and the estimated post-surgical spherical equivalent were evaluated individually by the surgeon who made the final decision on the intraocular lens to be implanted, aiming in all cases at the first residual positive

spherical equivalent. For all formulas (except HofferQST), the constant A selected for the calculation was 118.4. For HofferQST, the constant pACD used was 5.15.

Surgical Technique

All patients underwent phacoemulsification of the crystalline lens together with immediate sequential bilateral Intensity SL intraocular lens implantation by the same Refractive Surgeon (K. B.) using the following surgical technique:

- All surgeries were performed in the same operating room (Oftalmólogos El Tesoro, Medellín, Colombia).
- All surgeries were performed under intracameral anesthesia, with venous sedation guided by an anesthesiology specialist.
- In all patients, the most curved meridian, according to the Total Corneal Refractive Power of the Pentacam AXL Wave, was selected as the site for positioning the main incision.
- After asepsis, antisepsis, and placement of sterile fields, two paracenteses were performed in the "knife and fork" position. Next, preservative-free lidocaine was placed, and the anterior chamber was filled with viscoelastic sodium hyaluronate 1.4% (Bio-Hyalur Plus; Biotech Healthcare; Ahmedabad, India).
- The main incision was made with a 2.75-mm blade, which was used to penetrate the anterior lens capsule.
- According to the usual techniques, manual continuous circular capsulorhexis, phacoemulsification of the crystalline lens, and mass aspiration were performed.
- Subsequently, the intraocular lens was mounted and injected into the capsular bag using the manufacturer-supplied injector.
- After viscoelastic aspiration, the anterior chamber was filled with moxifloxacin 5mg/mL (Vigamox; Alcon; Fort Worth, USA).
- After surgery, outpatient management was started with Ciprofloxacin 0.3% + Dexamethasone 0.1% (Sophixin DX; Sophia; Guadalajara, Mexico) every six hours and Chondroitin Sulfate 0.18% + Sodium Hyaluronate 0.1% without preservatives (Humylub PF; Sophia; Guadalajara, Mexico) every three hours.

Bioethics

The research protocol for this project was previously evaluated and approved by the Ethics Committee of the Universidad Pontificia Bolivariana. Given that this was a retrospective study based solely on the review of clinical histories, it was not considered necessary to obtain informed consent.

Results

A total of 20 eyes belonging to 10 patients were included. Most patients (n = 7; 70%) were female; the mean age was 57.2 ± 4.2 years. On average, the implanted intraocular lens power was 21.9 ± 1.6 D (minimum 20.0 D - maximum 25.0 D). 100% of the patients wore glasses for reading, and 30% required glasses for distance activities. One patient (10%) also wore multifocal contact lenses in both eyes.

All surgeries were performed conventionally. There were no complications during or after surgery. There was no episode of excessive swelling, macular edema, or posterior capsule opacification.

Three months after surgery, there was a marked improvement in refractive and uncorrected visual parameters over the pre-surgical data. **(Table 1)** No patient lost two or more lines of corrected vision.

Three months after surgery, 100% of the eyes had an uncorrected visual acuity of 20/25 or better in far and near vision, while the same percentage had 20/40 or better in intermediate vision. **(Figure 1)** The defocus curve showed adequate behavior. **(Figure 2)**

When asked, 100% of the subjects reported being independent of using glasses or contact lenses for all their daily activities.

Discussion

Presbyopia is one of the most common ocular conditions worldwide, and its presence is associated with a significant decrease in quality of life. [4] Although nonsurgical options for presbyopia exist, including eyeglasses, multifocal contact lenses, and medications, [5] more patients are seeking a surgical option for the condition. [6] The population undergoing lens refractive exchange is generally younger and expects more accurate and perfect results than the population with a cataract diagnosis. [7]

Intraocular lens designs have evolved. Today, advanced technology intraocular lenses, including those with extended range, and those referred to as simultaneous vision, including bifocals and trifocals, are common. Recently, Hanita Lenses launched a hydrophilic, foldable lens with a refractive

Table 1. Refractive parameters before and three months after bilateral intraocular lens implantation. Data are expressed as median followed by their Inter-Quartile Range (IQR) given their non-normal nature according to the Shapiro-Wilk test. Pre- and post-surgical data are compared using the Wilcoxon non-parametric test.

	Pre Surgical Median (IQR)	Three Months Median (IQR)	Wilcoxon W *(p)*
Sphere	1.36 (1.53)	–0.18 (0.02)	44.0 (0.013)
Cylinder	-0.43 (0.21)	–0.18 (0.21)	9.0 (0.120)
Uncorrected Distant Visual Acuity (LogMAR)	0.47 (0.24)	0.03 (0.08)	54.0 (0.004)
Uncorrected Intermediate Visual Acuity (LogMAR)	0.80 (0.30)	0.23 (0.20)	55.0 (0.002)
Uncorrected Near Visual Acuity (LogMAR)	1.00 (0.27)	0.00 (0.08)	55.0 (0.006)
Corrected Distant Visual Acuity (LogMAR)	0.00 (0.00)	0.00 (0.03)	6.00 (0.855)
Corrected Intermediate Visual Acuity (LogMAR)	0.00 (0.00)	0.00 (0.04)	6.00 (0.866)
Corrected Near Visual Acuity (LogMAR)	0.00 (0.00)	0.00 (0.00)	92.00 (0.789)

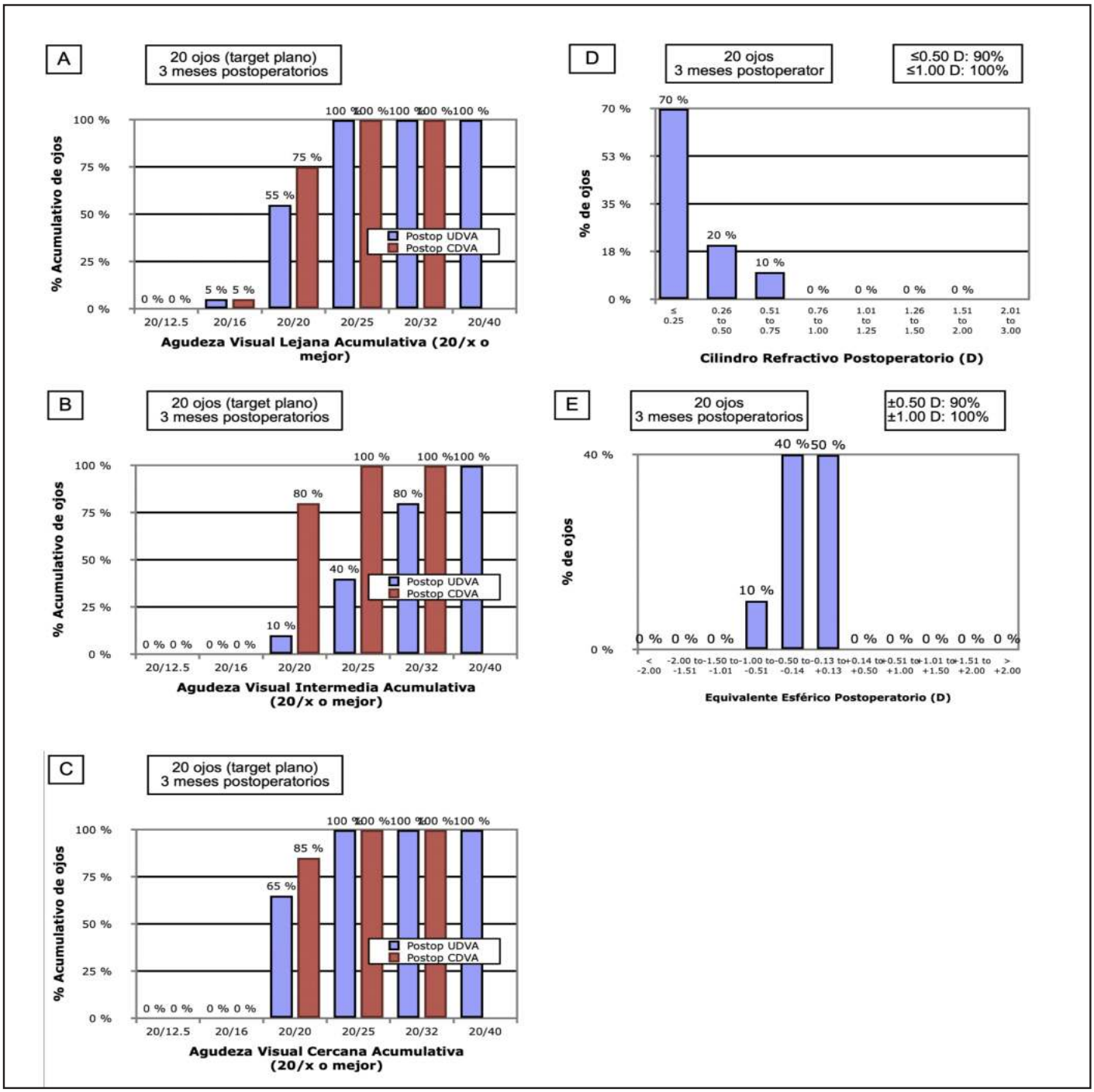

Figure 1. Refractive and visual outcomes after bilateral intraocular lens implantation. Uncorrected visual acuity (**purple**) and corrected visual acuity (**brown**) for far vision (**Panel A**), for intermediate vision (**Panel B**) and near vision (**Panel C**). Postoperative refractive cylinder (Panel D). Postoperative spherical equivalent (Panel E). UDVA = Uncorrected Distance Visual Acuity. CDVA = Corrected Distance Visual Acuity. D = Diopter.

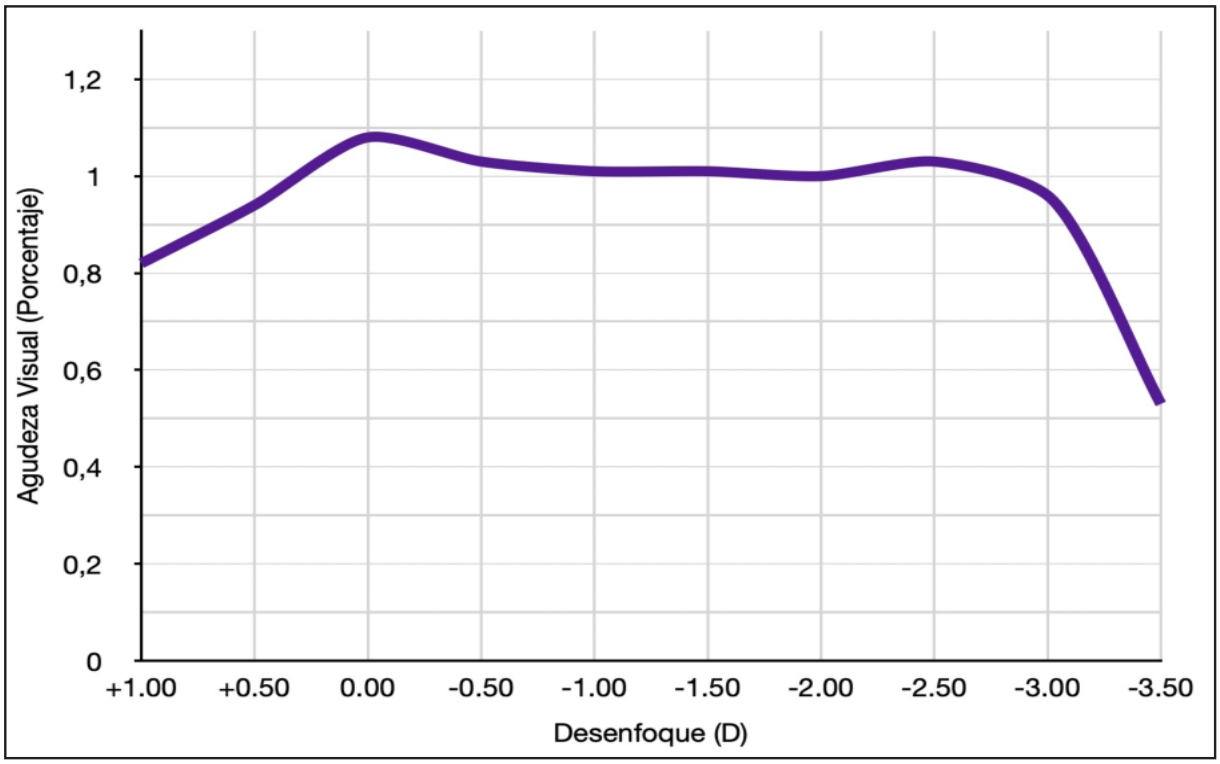

Figure 2. The average defocus curve with correction in monocular vision for the Hanita Intensity SL intraocular lens was evaluated in the sample. Visual acuity is represented in a percentage scale (1 represents 20/20, LogMAR 0).

index of 1.45 and a spherical aberration of -0.13 called the Intensity SL. [2] This lens has a modified sinusoidal pattern profile with 12 steps of different heights. It is based on a modified Gerchberg-Saxton algorithm called "Dynamic Light Utilization," designed to provide light distribution in focal ranges for far, intermediate, and near, with minimal light loss. [8] Additionally, it has two extra foci (called "intensifiers"), one between the far and intermediate foci and one between the intermediate and near foci, allowing a smoother distribution and thus configuring a pentafocal distribution.

The present study aimed to retrospectively evaluate the refractive, visual, and visual satisfaction behavior at three months in a group of 10 patients implanted with Intensity SL lenses bilaterally.

The results obtained were excellent. 100% of the surgically operated eyes achieved an uncorrected visual acuity of 20/25 or better in both near (33cm) and far vision. Similarly, 100% of the operated eyes achieved "functional" vision (at least 20/40) in the intermediate vision range. Similar results with this intraocular lens had been reported previously by Nov *et al.*, [8] who found that 100% of their patients who underwent surgery had a vision of 20/40 or better in intermediate vision and 20/20 or better in near vision.

These results are similar to those previously reported by Van Der Linden and colleagues, using lenses of a similar platform and from the same manufacturer [SeeLens MF (FullRange); Hanita Lenses], where excellent near, intermediate, and far vision quality had also been found. [9] However, according to Bianchi, [2] vision performance at intermediate and far distances would appear to be better with the Intensity SL lens than with the SeeLens MF (FullRange).

The safety of the surgical procedure was excellent. None of the patients lost two or more lines of best-corrected vision at any distance evaluated.

These results are compatible and identical to previous studies, where the procedure did not negatively alter the patients' maximum visual capacity.

The lens's defocus curve demonstrates excellent visual quality without correction up to vergences equivalent to approximately 33cm. The profile of the curve was relatively flat, with no prominent appearance of distinct peaks in visual quality at different distances. This morphology confirms the findings previously reported in the literature. [2, 8]

The 100% of patients reported complete independence of spectacle wear for activities at all distances. This statistic is identical to that of Nov *et al.*, [8] in a similar study using the same intraocular lens, where all patients answered "never" when asked about their use of glasses for any of the distances after surgery. According to these authors, "no patient had any difficulty with reading books or newspapers, reading the telephone." [8] Using the same intraocular lens, Bianchi [2] also found a high proportion of patients who reported being independent of spectacle wear (94.6%). In the latter study, 100% of patients reported that "the postoperative outcome was on par with their preoperative expectations." [2]

This high rate of spectacle independence at all distances is striking and speaks to the excellent performance of this intraocular lens in well-selected patients. This perception of independence is critical to patient satisfaction after surgery. [10] The rate of total spectacle independence at all distances achieved with the Intensity SL lens in the present study and previous studies is higher than that reported after implantation of the SeeLens MF (Full-Range) lens from the same manufacturer. [11]

The present study has some weaknesses that should be recognized:

- First, since this is a retrospective study, we do not have all the information and studies a prospective process could provide. We only have the data that is routinely collected in clinical practice. For this reason, there are no results from standardized scales or surveys or any measurements of contrast sensitivity or dysphotopsia. The rate of total spectacle independence is taken from a standard question that the first author always asks in the office, but it is not derived from a standardized survey. A new study, this time of prospective design, could significantly help to provide more varied evidence regarding the postsurgical behavior of this type of lens.

- Second, it is clear that 20 eyes is a small sample size. However, the results have been clear and consistent with the previously published literature. A prospective study with a more significant number of patients is currently being considered to provide more information.

In summary, the present pilot study confirms the excellent refractive, optical, and spectacle independence rate results obtained with Intensity SL intraocular lens implantation in a population of presbyopic patients undergoing immediate sequential bilateral surgery.

Conclusion

Intensity SL pentafocal intraocular lens implantation is a simple, safe, and effective surgical procedure for treating presbyopia in patients with dysfunctional lens syndrome. It is associated with excellent uncorrected vision at various distances and a very high rate of total spectacle independence.

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