The implantation of a multifocal intraocular lens (IOL) after the extraction of cataract has been reported as an alternative to improve the near vision performance and the quality of life of some patients. The use of multifocal IOLs offers a significant opportunity to improve distance and near vision. However, these improved IOL designs are insufficient if the lens does not suit the lifestyle of patients recovering their vision at all distances, including intermediate distance. Many IOL technologies are commercially available for implantation after cataract surgery and several studies have reported that diffractive multifocal IOLs with an aspheric profile perform better than refractive multifocal or accommodating IOLs in terms of near visual acuity. On the other hand, aspheric profiles give better optical quality in comparison to spherical profiles. Recently, a new multifocal model IOL has been introduced in clinical practice combining two diffractive apodized profiles that can provide three foci for distance, near, and intermediate vision. There are few publications describing the outcomes after the implantation of a trifocal intraocular lens and some of these have limited samples. Additionally, this new IOL offers the possibility to be implanted through a sub–2-mm incision, accomplishing the advantages of microincisional cataract surgery (MICS).

The aim of the current study was to evaluate the visual and the intraocular performance of this new trifocal IOL in eyes implanted following cataract surgery performed through MICS.

ABSTRACT
PURPOSE: To evaluate the visual outcomes of patients with a new diffractive trifocal intraocular lens (IOL).

METHODS: A trifocal diffractive Fine Vision IOL (Physiol, Liege, Belgium) was implanted after microincision cataract surgery (MICS) in 40 eyes of 20 patients with bilateral cataract. The monocular and binocular visual performance and the refractive status were assessed, as well as the defocus curve and contrast sensitivity at 1 and 6 months postoperatively.

RESULTS: The monocular visual outcomes (logMAR) at 6 months postoperatively were uncorrected distance visual acuity 0.18 ± 0.13, uncorrected near visual acuity 0.26 ± 0.15, and uncorrected intermediate visual acuity 0.20 ± 0.11. With the best distance correction, the visual outcomes were 0.05 ± 0.06 for corrected distance visual acuity, 0.16 ± 0.13 for distance corrected near visual acuity, and 0.17 ± 0.09 for distance corrected intermediate visual acuity. Binocular defocus curve at 6 months shows a wide range of useful vision with 0.19 ± 0.08 (logMAR) at -1.50 diopter defocus. The monocular contrast sensitivity under scotopic conditions (3 cd/m²) was within normal range for a population older than 60 years.

CONCLUSION: The trifocal Fine Vision IOL can restore vision at different distances after cataract surgery, specifically intermediate and near vision.

PATIENTS AND METHODS

Patients
In this prospective, consecutive, non-comparative interventional study, we included 40 eyes of 20 patients with
bilateral cataract with ages ranging from 54 to 82 years (mean age: 66.49 years). The inclusion criteria were patients with bilateral cataract, patients older than 48 years, topographical anterior corneal surface astigmatism of 1.50 diopters (D) or less, and uncomplicated surgery. The exclusion criteria were patients with previous ocular surgery, other ocular comorbidities, complications during surgery, and corneal astigmatism greater than 1.50 D. All patients were adequately informed and signed a consent form. The study adhered to the tenets of the Declaration of Helsinki and was approved by the local Ethical Board Committee.

SURGERY
All surgeries were performed by the same surgeon (JLA) using a sutureless MICS phacoemulsification technique. All patients received topical anesthesia before surgery. Adequate dilation was obtained with intracameral mydriasis. The main incision was placed at the axis of the positive corneal meridian. The Fine Vision IOL (Physiol, Liege, Belgium) was implanted in the capsular bag through a corneal incision of 1.8 mm. Postoperative topical therapy included a combination of topical antibiotic and steroid agents were prescribed.

IOL
The Fine Vision IOL is a trifocal, single-piece, foldable and aspheric IOL with two fully diffractive structures, one with +1.75 D addition for intermediate vision and the other with +3.5 D addition for near vision. It is made of 25% hydrophilic material with yellow chromophore embedded in the matrix polymer. The optic body diameter is 6.15 mm and the overall IOL diameter is 10.75 mm. The theoretical light distribution for a 20 D diffractive Fine Vision IOL is 42% for far focus, 15% for intermediate focus, and 29% for near focus with 14% lost energy at 3-mm pupil diameter. The distribution of light is variable. The larger the pupil diameter, the greater the light distribution in far focus, which favors distance vision in dim light. A smaller pupil diameter proportionally increases the amount of light on the near and intermediate focus. The power range available is from 10 to 35 D (steps of 0.50 D). The IOL has a gradual decrease in the step height from center to periphery to reduce halo symptoms at night.

PREOPERATIVE EXAMINATION
Preoperatively all patients had a full ophthalmological examination including the evaluation of the refractive status, distance and near visual acuities, slit-lamp examination, tonometry, and funduscopy. The visual acuity was measured with the Early Treatment Diabetic Retinopathy Study (ETDRS) charts. Besides these clinical tests, corneal topography (CSO, Florence, Italy) and biometry by optical coherence interferometer (IOL Master v.4.3, Carl Zeiss Meditec, Dublin, CA) were performed. The target in the IOL power calculation was plano in all cases included in the study.

POSTOPERATIVE EXAMINATION
Patients were evaluated during follow-up at 1 day, 1 week, 1 month, 3 months, and 6 months after surgery. The same independent experienced investigator (RM) performed all postoperative examinations using the same investigational protocol. The manifest refraction and visual acuity for distance, intermediate (80 cm), and near (40 cm) with and without corrected distance was evaluated at 1, 3, and 6 months with ETDRS charts. The visual acuity was evaluated in monocular and binocular photopic conditions. In addition, the corrected distance visual acuity (CDVA) was measured in monocular vision with OPTEC 6500 (Vision Science Research Corp., Walnut Creek, CA) in scotopic (3 cd/m²) conditions. Monocular contrast sensitivity function test was evaluated under scotopic conditions (3 cd/m²) with OPTEC 6500 at 1 and 6 months postoperatively.

In addition, defocus curves were obtained at 6 months postoperatively. To generate defocus curves, the visual acuity was measured with the ETDRS charts at 4 m. The defocus curve was obtained with monocular vision and with best distance correction by adding plus lenses in 0.50 D steps and recording the visual acuity achieved by the patient with each type of blur. Following this, the procedure was repeated but with negative lenses. The same protocol was followed to obtain the binocular defocus curve.

STATISTICAL ANALYSIS
For the statistical treatment of the data, the program used was version 17.0 of SPSS for Windows (SPSS, Inc., Chicago, IL). The Kolmogorov–Smirnov test was applied for all data samples to check normality. When parametric statistical analysis was possible, the Student’s t test for paired data was applied to assess the significance of differences between preoperative and postoperative data, whereas the Wilcoxon Rank Sum test was applied when this was not possible. All statistical tests were two-tailed, and P values less than .05 were considered statistically significant.

RESULTS
All 40 surgeries were performed successfully with no complications. All implantations were performed through a 1.8-mm incision.
Refractive Outcomes
The defocus equivalent changed significantly from 2.56 ± 2.00 (range: 0.00 to 9.63) to 0.39 ± 0.27 (range: 0.00 to 1.13) at 6 months (P < .001). The defocus equivalent at 6 months was less than 1.00 D in 95% of the cases.

The refractive cylinder had a slight but not significant improvement from -0.98 ± 0.61 (range: -2.25 to 0.00) at 1 month to -0.77 ± 0.47 (range: -2.25 to 0.00) at 6 months (P = .077). Postoperatively, 36 eyes (90%) had an astigmatism of 1 D or less, 2 eyes (5%) had 1.25 D, 1 eye had 1.75 D (2.5%), and 1 eye had 2.25 D (2.5%).

Visual Outcomes
The monocular uncorrected distance visual acuity in logMAR showed a significant change between preoperative and postoperative values at 6 months from 0.70 ± 0.34 (range: 0.24 to 1.30) to 0.18 ± 0.13 (range: 0.00 to 0.52), respectively (P < .001).

The monocular CDVA in logMAR changed significantly (P<.001) from a preoperative value of 0.24 ± 0.22 (range: 0.00 to 0.82) to 0.05 ± 0.06 (range: 0.00 to 0.24) at 6 months. Figure 1 shows binocular distance visual acuity at 6 months of follow-up.

A statistically significant improvement in distance corrected near visual acuity (DCNVA) was detected after 6 months. The preoperative value in logMAR was 0.24 ± 0.22 (range: 0.00 to 0.82) and 6 months later it was 0.16 ± 0.13 (range: 0.00 to 0.52) (P = .020, Student’s t test). Figure 2 shows binocular near visual acuity at 6 months of follow-up.

The mean value of monocular distance corrected intermediate visual acuity (DCIVA) in logMAR at 6 months was 0.17 ± 0.09 (range: 0.00 to 0.40) measured at 80 cm. Figure 3 shows binocular intermediate visual acuity at 6 months of follow-up.

There were no significant changes between 1 and 6 months after the surgery for any of these variables (P > .05).

Table 1 shows the mean values for distance, intermediate, and near monocular visual acuities.

Defocus Curve
The mean monocular and binocular visual acuities (logMAR) and their standard deviations for different values of the defocus curve are shown in Figure 4. As can be seen in Figure 4, for high values of the defocus curve (positive or negative) the visual acuity decreases as expected if the patients are properly refracted. The most remarkable finding is that the vision of the patients does not change abruptly between the different foci. It was found that this multifocal IOL provides two peaks corresponding to distance focus of approximately 0.00 D and near focus of approximately +2.50 D. Between these two peaks, approximately +1.50 D defocus, useful intermediate vision was obtained with a binocular condition result (0.19 ± 0.08) better than that of the monocular condition (P < .01 Wilcoxon test).
FIGURE 5. Mean monocular contrast sensitivity function (CSF) under scotopic (3 cd/m²) conditions (cpd = cycles per degree). Dotted lines mark the normal range for age 60 years or older under scotopic conditions without glare with the OPTEC 6500 device (Vision Science Research Corp., Walnut Creek, CA). (Data from Hohberger et al.17)
0.18 ± 0.13 at 6 months and 83% of the eyes achieved 0.10 in binocular UDVA. In a previous study about the same IOL, Sheppard et al.\textsuperscript{15} reported a similar distance result (UCDVA 0.19 ± 0.08) at 2 months. However, Cochener et al.\textsuperscript{19} reported slightly higher values (UDVA 0.08 ± 0.12) at 6 months. This discrepancy can be attributed to differences in the size of the samples because Cochener’s sample was twice the size of the sample in the current study.

The current multifocal IOLs on the market provide adequate visual acuity for working distance but these lenses have a bifocal optical performance.\textsuperscript{6-13,20} The vision of eyes implanted with multifocal IOLs had fewer limitations in visual functions and less spectacle dependence than those with traditional monofocal IOLs.\textsuperscript{3,5} Similarly, the Fine Vision IOL reported 0.16 ± 0.13 monocular DCNVA at 6 months and 89% of the patients reached binocular DCNVA of 0.20 logMAR or more. These near distance results are comparable with previous studies of our research group that assessed visual outcomes of two diffractive multifocal IOLs.\textsuperscript{5} That study reported a postoperative DCNVA (logMAR) of 0.08 ± 0.11, 0.15 ± 0.10, and 0.51 ± 0.23 for a multifocal IOL Acrysof ReSTOR (4 D addition in the lens plane), a multifocal IOL Acri.Lisa 366D, and a monofocal control lens Acri.Smart 48S, respectively.

It is clear from the current study that postoperative near vision is better with multifocal than with monofocal IOLs and, following this trend, near vision with the new trifocal IOL is satisfactory. Comparing the value of DCNVA achieved with the trifocal model (0.16 ± 0.13), we did not find statistically significant differences. Therefore, no great dissimilarities were found for near vision between the trifocal lens and other multifocal diffractive lenses such as the Acri.Lisa 366 D. In the same study,\textsuperscript{5} a value of 0.10 ± 0.11 for UDVA and 0.01 ± 0.03 for CDVA was reported with the Acri.Lisa lens. In the current study, UDVA was 0.18 ± 0.13, and CDVA was 0.05 ± 0.06. There were no significant differences regarding UDVA; CDVA was compared with a value of 0.03 and there were no significant differences. Although the values achieved for distance and near visual acuity were slightly better for the Acri.Lisa lens, these differences seem to be related to the patient’s age. The mean age of the patients was 66.50 ± 7.07 years in the current study and 59.09 ± 8.79 years in the Acri.Lisa study ($P < .05$).

The main advantage of the Fine Vision IOL design is its third focus for intermediate vision. In a recent report by Gatine and Houbrechts,\textsuperscript{22} several multifocal IOLs were optical bench tested. There were generally no great differences in the modulation transfer function analysis between near and far defocus. However, the Fine Vision IOL showed higher values of the modulation transfer function for a defocus value of 1.50 D, corresponding to intermediate vision. The outcomes found at intermediate vision were similar with and without distance correction. Monocular DCIVA was 0.17 ± 0.09 and 83% of the patients obtained 0.2 logMAR or better DCIVA. The Cochener et al.\textsuperscript{19} study with the same trifocal IOL implanted after cataract surgery reported 0.05 ± 0.09 logMAR DCIVA. This difference between mean outcomes for the mean intermediate visual acuity can be related to the clinical methodology at the moment of testing near vision because the intermediate vision was assessed at 65 cm in Cochener et al.’s\textsuperscript{19} study and 80 cm in the current study. In Steinert’s\textsuperscript{22} study, the satisfaction rating of patients with multifocal IOLs implanted was consistently high, with 80% of patients reaching a near visual acuity of 20/40 (J3 Jaeger) or better without correction.

Our intermediate outcomes for DCIVA have been higher than satisfactory UNVA reported in the Steiner study. In addition, on observing the defocus curve, this trifocal IOL provides two excellent peaks. This maximum vision corresponded to the distance focus and the near focus, but the profile of this curve is different than the defocus curve obtained with other bifocal IOLs. Between the two peaks, there was a clear improvement in the vision corresponding to the intermediate focus. This wide range of clear vision with this multifocal IOL design is higher in binocular conditions in both -1.50 D intermediate defocus and -2.5 D near defocus. This finding is coherent with the defocus curve reported by Sheppard et al.\textsuperscript{15} for the same trifocal IOL under photopic conditions in binocular vision. This beneficial binocular effect in the near and intermediate vision should be considered at the moment of programming a cataract surgical procedure.

Multifocal IOLs provide a reduction of contrast sensitivity function related to the distribution of light energy on the surface of the optic.\textsuperscript{23,24} In general, these contrast sensitivity function changes with multifocal IOLs are more frequent under dim light conditions.\textsuperscript{20,23} Regarding the contrast sensitivity function results obtained in the current study, it was observed that 6 months after the surgery, the Fine Vision IOL provides results under scotopic conditions that are within the physiological levels for the normal population of the same age group.\textsuperscript{17} In previous studies, this similar trend was reported for the monocular contrast sensitivity function under photopic conditions with the same trifocal IOL.\textsuperscript{15}

One reason for these satisfactory contrast sensitivity function results can be the adequate light distribution at different pupil apertures. Specifically for a 4.5-mm
pupil aperture, only 9% of light energy reaches the intermediate focus, 25% reaches the near focus, and the other 67% of the light reaches the distance focus. This light distribution with two-thirds of light for distance vision is adequate to achieve sufficient contrast sensitivity. In patients with other multifocal lenses, slow recovery of contrast sensitivity was observed during the follow-up related to the neuroadaptation process. In the current study, we observed no significant changes in the contrast sensitivity function between 1 and 6 months of follow-up, which could be due to the fact that the neuroadaptation process develops fast during the first month and the trifocality does not interfere in this process.

The new trifocal Fine Vision IOL with MICS can restore vision at different distances after cataract surgery. Specifically, intermediate vision has shown good results. The intraoptical quality performance was adequate with this kind of multifocal IOL despite having one more focus than other conventional bifocal diffractive IOLs. In the future, more studies are necessary to confirm the good outcomes with the trifocal concept and whether these are sufficient to recover the quality of life and achieve spectacle independence in patients after cataract surgery.

Author Contributions
Study concept and design (JLA, PP-G, RM, AV-E); analysis and interpretation of data (JLA, PP-G, RM, FAS, AV-E); drafting of the manuscript (JLA, PP-G, RM, FAS, AV-E); critical revision of the manuscript (JLA, PP-G, RM, FAS, AV-E); statistical expertise (RM, PP-G); supervision (JLA, PP-G, AV-E)

References