Prospective study of the Acri.LISA bifocal intraocular lens

José F. Alfonso, MD, PhD, Luis Fernández-Vega, MD, PhD, Ana Señaris, MD, PhD, Robert Montés-Micó, PhD

PURPOSE: To assess the visual results after bilateral implantation of the bifocal Acri.LISA 366D intraocular lens (IOL) (Acri.Tec AG).

SETTING: Fernández-Vega Ophthalmological Institute, Oviedo, Spain.

METHODS: Eighty-one patients had bilateral implantation of the distance-dominant bifocal Acri.LISA 366D IOL in a prospective study. Monocular and binocular best corrected distance visual acuity and best distance-corrected near visual acuity, binocular best distance-corrected intermediate visual acuity, and distance contrast sensitivity under phopic (85 cd/m^2) and mesopic (5 cd/m^2) conditions were determined.

RESULTS: At the 3-month postoperative visit, the mean binocular best corrected distance acuity was 0.048 ± 0.111 logMAR and the mean binocular best distance-corrected near acuity, 0.012 ± 0.0084 logMAR (both approximately 20/20). The mean binocular best distance-corrected intermediate acuity changed significantly as a function of the distance of the test, from 0.012 ± 0.084 logMAR (approximately 20/20) at 33 cm to 0.265 ± 0.099 logMAR (approximately 20/40) at 70 cm (P<.01). Contrast sensitivity was within normal limits under photopic and mesopic conditions. Binocular contrast sensitivity was statistically significantly better than monocular contrast sensitivity at all spatial frequencies under both illumination levels (P<.01).

CONCLUSION: The Acri.LISA 366D IOL provided a satisfactory full range of vision; a high level of uncorrected and corrected distance, intermediate, and near acuity; and improved contrast sensitivity under photopic and mesopic conditions.


Multifocal intraocular lens (IOL) implantation can provide good distance and near vision after cataract surgery. Differences in visual outcomes achieved with these IOLs result from the optical principle used and the shape design of the IOL surfaces. Refraction and diffraction principles have traditionally been used to create multifocality from near to distance. In refractive optics, the different zones of equal refractive power have a mutual focus. Phases of incoming light are incoherent, creating some destructive interference. This interference affects the intensity of the focus light and thus leads to a reduction in brightness and visual acuity.\(^1\) The retinal image with multifocal refractive IOLs depends on pupil diameter because of the IOLs' power profile.\(^1\) Diffractive IOLs are less pupil dependent and have advantages over refractive IOLs in near vision\(^2\); however, they can induce slight night-vision disturbances and a reduction in contrast sensitivity.\(^3,5\) A new optical concept, refractive–diffractive optics, was recently applied to IOL design. The Acri.LISA 366D IOL (Acri.Tec AG) uses this hybrid concept to reduce the disadvantages of conventional refractive and diffractive multifocal IOLs.\(^6\)

The bifocal Acri.LISA 366D IOL was designed to provide simultaneous good distance and near vision...
and to improve intermediate vision over that achieved with previous designs. Different near addition (add) and light distribution between distance and near foci may play a significant role in the visual performance with this IOL. However, to our knowledge, no studies of this IOL have been published in the peer-reviewed literature.

The goal of the current study was to assess the visual function in patients with bilateral implantation of the Acri.LISA 366D IOL by evaluating distance, near, and intermediate visual acuity and distance contrast sensitivity under photopic and mesopic conditions.

PATIENTS AND METHODS

A prospective study assessed 162 eyes of 81 consecutive patients who had bilateral implantation of the Acri.LISA 366D IOL at the Fernández-Vega Ophthalmological Institute between January 2006 and October 2006. Exclusion criteria included ocular disease other than cataract and a history of ocular surgery or inflammation. The tenets of the Declaration of Helsinki were followed. Informed consent was obtained from all patients after the nature and possible consequences of the study were explained.

The Acri.LISA 366D is a bifocal biconvex refractive–diffractive single-piece IOL with a 6.0 mm foldable acrylate aspherical optic, an overall diameter of 11.0 mm, and 0-degree haptic angulation (Figure 1). The surface is divided into main zones and phase zones; the phase zones assume the function of the steps of diffractive IOLs. The phase zones have a mean refractive power corresponding to the zero diffractive power of the main zones. The IOL power responsible for distance vision is refractive and diffractive at the same time. The first diffractive power used for near vision is formed by in-phase interference of waves from the main zones. The 2 focal points are created by phase zones on the anterior surface of the IOL. The incident light is distributed with 65% to distance focus and 35% to near focus. The diffractive structure has a soft transition of the phase zones between the main zones. The adjusted phase zones were designed to reduce disturbing light phenomena (eg, scattered light, halos) to improve retinal imaging quality and visual performance. The IOL has an aspherical profile to correct positive spherical aberration of the cornea. The optic is made of acrylate (refractive index 1.46) with 25% water content and ultraviolet wavelength–absorbing properties (Acri.Lyc material). The hydrophobic surface of the Acri.LISA 366D IOL has sharp edges to reduce posterior capsule opacification. The IOL power varies from 0.00 to +32.00 diopters (D) and incorporates a +3.75 D near add power, corresponding to approximately +3.00 D in the spectacle plane.

All patients were operated on under topical anesthesia by 1 of 2 experienced surgeons (J.F.A., L.F.V.) using phacoemulsification and a 2.8 to 3.2 mm clear corneal incision. Phacoemulsification was followed by irrigation/aspiration of the cortex and IOL implantation in the capsular bag. Patients were scheduled for clinical evaluation preoperatively and 1 day, 1 week, and 1 and 3 months postoperatively. A standard ophthalmologic examination, including manifest refraction, slitlamp biomicroscopy, Goldmann applanation tonometry, and binocular indirect ophthalmoscopy, was performed at all visits. Tilt and centration of the IOLs in relation to the visual axis was assessed using a Scheimpflug videophotography system (EAS-1000, Nidek).

Visual acuity measurements were done using logMAR acuity charts under photopic conditions (85 cd/m²). Monocular and binocular best corrected distance visual acuity and best distance-corrected near visual acuity were recorded at 6 m and 33 cm in all patients. Intermediate visual acuity was measured under binocular conditions. Binocular best distance-corrected intermediate visual acuity was measured at 40 cm, 50 cm, 60 cm, and 70 cm.

Monocular and binocular photopic and mesopic contrast sensitivity was measured with best distance correction and the Functional Acuity Contrast Test (FACT) (Stereo Optical). Absolute values of log10CS were obtained for each combination of patient, spatial frequency, and luminance; means and standard deviations were calculated. The contrast sensitivity threshold measurements were taken under 2 illumination conditions: photopic at 85 cd/m² (luminance recommended in manufacturer’s guidelines) and mesopic at 5 cd/m² (room illumination at similar levels). Contrast sensitivity was measured first at the photopic level and then at the mesopic level. Patients were given 5 minutes to adapt to each level before...
testing. All examinations were performed 3 months after IOL implantation by the same ophthalmic technician who was unaware of the study’s objective.

Data analysis was performed using SPSS for Windows (version 12.0, SPSS, Inc.). Normality was checked by the Shapiro-Wilk test, and the differences in visual acuity and contrast sensitivity were compared with the t test. A 1-way analysis of variance (ANOVA) was used to explore correlations between the distance of the test and intermediate visual acuity. Differences were considered statistically significant when the P value was less than 0.01 (ie, at the 1% level).

RESULTS

The mean age of the 28 men and 53 women was 57.7 years ± 7.9 (SD) (range 45 to 77 years). The mean IOL power was 16.80 ± 8.69 D. Table 1 shows the patients’ demographics. There were no complications in any case. After the surgery, all pupils were round with no iris trauma and showed good responsiveness to light. In all cases, the IOLs were well centered and were not tilted.

Table 2 shows the mean monocular and binocular distance and near visual acuities as well as the efficacy. The mean monocular best corrected distance acuity was 0.102 ± 0.191 logMAR (approximately 20/25) with a mean correction of −0.04 ± 0.41 D sphere and −0.39 ± 0.749 D cylinder. The mean monocular best distance-corrected near acuity was 0.031 ± 0.125 logMAR (approximately 20/20). Binocularly, the mean best corrected distance acuity was 0.048 ± 0.111 logMAR (approximately 20/20) and the mean best distance-corrected near acuity, 0.012 ± 0.084 logMAR (approximately 20/20). Figure 2 shows the change in binocular best distance-corrected intermediate visual acuity. The mean changed from 0.012 ± 0.084 logMAR (approximately 20/20) at 33 cm to 0.265 ± 0.099 logMAR (approximately 20/40) at 70 cm. The binocular visual acuity values were fitted with a 3rd-order polynomial equation using the least-squares fitting method (version 8.0, SigmaPlot). Binocular visual acuity worsened as a function of the distance of the test (Figure 2 legend shows trend equation). There was a statistically significant correlation between the distance of the test and the change in the intermediate visual acuity (P < .01, 1-way ANOVA).

Figure 3 shows the monocular and binocular distance log10CS under photopic and mesopic conditions. There were statistically significant differences between monocular and binocular contrast sensitivity at all spatial frequencies (P < .01). Binocular contrast sensitivity was better than monocular contrast sensitivity under photopic and mesopic conditions.

DISCUSSION

Multifocal IOLs provide some functional near vision through increased depth of field of the eye. Depending on the diffractive or refractive technology used for current IOLs, different depths of field and different distance, near, and intermediate visual performance can be achieved. Diffractive IOLs have optical properties comparable to those of multifocal IOLs for distance vision and superior refractive properties for near vision. However, the optical properties of a specific IOL depend on its design and cannot be classified between refractive and diffractive optical properties among commercial IOLs. The Acri.LISA 366D IOL combines diffractive and refractive optics; to our knowledge, no studies of its in vitro or in vivo optical performance have been published in the peer-reviewed literature. Thus, we assessed its performance by evaluating visual indexes such as visual acuity and contrast sensitivity measured at different distances and under different light conditions.

Our study showed good monocular best corrected distance visual acuity and best distance-corrected near visual acuity (mean 0.102 ± 0.191 logMAR and 0.031 ± 0.125 logMAR, respectively). Both values were slightly better with binocular measurement (mean 0.048 ± 0.111 logMAR and 0.012 ± 0.084 logMAR, respectively). This agrees with classic data showing binocular visual acuity increases in relation to monocular visual acuity. The results differ from those in studies of diffractive bifocal IOLs with a different add and light distribution between foci. Alfonso et al. and Fernández-Vega et al. report similar monocular outcomes between eyes with Acri.Twin 737D IOLs and eyes with Acri.Twin 447D IOLs (Acri.Tec AG) (mean 0.036 ± 0.061 logMAR and 0.03 ± 0.07 logMAR, respectively, for distance, and 0.059 ± 0.091 logMAR and 0.05 ± 0.04 logMAR, respectively, for near). This is not surprising because both IOL

---

**Table 1. Patient demographics.**

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Acri.LISA 366D IOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of eyes</td>
<td>162</td>
</tr>
<tr>
<td>Mean age (y)</td>
<td>57.7 ± 7.9</td>
</tr>
<tr>
<td>Sex (male/female)</td>
<td>56/106</td>
</tr>
<tr>
<td>Mean IOL power (D)</td>
<td>16.80 ± 8.69</td>
</tr>
<tr>
<td>Mean axial length (mm)</td>
<td>25.01 ± 3.05</td>
</tr>
<tr>
<td>Mean postop sphere (D)</td>
<td>−0.04 ± 0.41</td>
</tr>
<tr>
<td>Mean postop cylinder (D)</td>
<td>−0.39 ± 0.49</td>
</tr>
<tr>
<td>Mean pupil diameter (mm)</td>
<td>3.8 ± 0.8</td>
</tr>
<tr>
<td>Photopic (85 cd/m²)</td>
<td>5.3 ± 0.8</td>
</tr>
</tbody>
</table>

Means ± SD

IOL = intraocular lens
models have the same bifocal diffractive design and thus the same add (+4.00 D) and light distribution between foci. The incident light is distributed with 70% to the distance focus and 30% to the near focus. The differences between their results and ours may come from the different add and light distribution between foci. The Acri.LISA 366D creates a 65 distance and 35 near light distribution with a +3.75 D add. The reduction in the percentage for the distance focus is reflected by a reduction in monocular best distance-corrected acuity and an increase in the near focus that is achieved by improving the monocular best distance-corrected near acuity.

In Alfonso et al.’s study,5 bilateral implantation of the Acri.Twin 447D IOL resulted in a mean binocular best corrected distance acuity of 0.02 ± 0.04 logMAR and mean best distance-corrected near acuity of 0.04 ± 0.03 logMAR. Our results were slightly worse for distance vision and better for near vision, findings that correlate with the light distribution between the distance and near foci. The 0.25 D reduction in the near add in the Acri.LISA 366D IOL does not seem to reduce near visual acuity. Our near visual acuity results show that the higher percentage of light to the near focus overcomes the reduction in the near add. However, these differences are minimal and bilateral implantation of the Acri.LISA 366D IOL provides good simultaneous distance and near vision.

In terms of efficacy, all patients achieved a binocular best corrected distance acuity of 20/25 or better and a binocular best distance-corrected near acuity of 20/25 or better. These results are also comparable to those of Alfonso et al.4 and Fernández-Vega et al.5 with the Acri.Twin system and with the Acri.Twin 447D IOL, respectively. Other types of hybrid multifocal IOLs, such as the AcrySof ReSTOR (Alcon), give similar visual acuity outcomes at distance and near,9–12 improving visual performance over that provided by the previous generation of diffractive IOLs such as the 811 LE (3M13,14) or the 811E15 (Pharmacia) and refractive IOLs such as the Array (AMO).1,16,17 Ours was not a randomized comparative study of different IOL models, and comparison of mean visual acuity outcomes between studies should be performed with caution.

We found statistically significant worsening of binocular best distance-corrected intermediate visual acuity as a function of the distance (cm) of the test. The line represents the best polynomial trend equation (cubic) for the Acri.LISA 366D IOL as follows: 

\[ y = -0.007 \times x^3 + 0.067 \times x^2 - 0.124x + 0.076. \]

The y-axis shows the Snellen feet equivalent of the logMAR acuity. Error bars represent the standard deviation.
et al. with the Acri.Twin 447D IOL. Slightly better results were found at 30 cm, 40 cm, and 50 cm with the Acri.LISA 366D IOL than with the Acri.Twin 447D IOL. The lower amount of near add in the Acri.LISA 366D IOL may explain the difference. In addition, the asphericity of the IOL does not provide an additional distinct focus but aims to increase the range of focus and thus improve functional intermediate vision. This explanation does not seem plausible at distances of 60 cm and 70 cm, at which better values were found with the Acri.Twin 737D IOL, Fernández-Vega et al. with the Acri.Twin 447D IOL, and Alfonso et al. with the ReSTOR IOL.

In conclusion, we assessed the visual function in patients with bilateral implantation of the refractive–diffractive bifocal Acri.LISA 366D IOL. Based on our results, we conclude this IOL is an effective alternative that provides simultaneous distance and near vision with improved distance contrast sensitivity under photopic and mesopic conditions. Future studies of the IOL should include a longer follow-up, spectacle dependency, and a comparison with hybrid IOLs based on the same diffractive–refractive concept.

REFERENCES
13. Lindstrom RL. Food and Drug Administration study update; one-year results from 671 patients with the 3M multifocal intraocular lens. Ophthalmology 1993; 100:91–97

First author:
José F. Alfonso, MD, PhD
Fernández-Vega Ophthalmological and the Surgery Department, School of Medicine, University of Oviedo, Oviedo, Spain