Add-On Sulcus-Based Versus Primary In-the-Bag Multifocal Intraocular Lens: Intraindividual Study

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ABSTRACT

PURPOSE: To compare the clinical outcomes of add-on sulcus-based multifocal and standard in-the-bag multifocal intraocular lens (IOL) implantation.

METHODS: Twenty-one patients with unilateral monofocal pseudophakia underwent add-on sulcus-based Acri.LISA 536D multifocal IOL (Carl Zeiss Meditec, Jena, Germany) implantation (add-on multifocal IOL group) and contralateral phacoemulsification with in-the-bag Acri.LISA 376D multifocal IOL (Carl Zeiss Meditec) implantation (primary multifocal IOL group). Uncorrected distance visual acuity, uncorrected near visual acuity, corrected distance visual acuity, distance-corrected near visual acuity, photopic (90 cd/m²) distance, near contrast sensitivity, mesopic (5 cd/m²) distance contrast sensitivity with and without glare, wavefront aberrations, and complications were measured 6 months postoperatively.

RESULTS: Primary in-the-bag multifocal IOLs provided slightly but significantly better uncorrected distance visual acuity (0.08 ± 0.10 vs 0.17 ± 0.15 logMAR, P = .028), uncorrected near visual acuity (0.09 ± 0.17 vs 0.18 ± 0.11 logMAR, P = .005), and corrected distance visual acuity (0.01 ± 0.04 vs 0.04 ± 0.05 logMAR, P = .038). There were no significant differences in distance-corrected near visual acuity, photopic or mesopic contrast sensitivity under different conditions, and wavefront aberrations. Complications included pigment dispersion in one eye (4.8%) and pupillary capture in 2 eyes (9.5%) of the add-on multifocal IOL group.

CONCLUSIONS: The secondary add-on sulcus-based multifocal IOL provided useful pseudoaccommodation with vision quality similar to the primary in-the-bag multifocal IOL. The technique should be considered in patients diagnosed as having unilateral or bilateral monofocal pseudophakia seeking near spectacle independence.

IOL implantation in a previously monofocal pseudophakic eye and contralateral cataract surgery with primary in-the-bag multifocal IOL implantation. Inclusion criteria were age older than 18 years, and potential visual acuity of at least 0.3 logMAR in both eyes determined by dilated near-pinhole test. Exclusion criteria were ocular diseases other than cataracts (including uveitis, amblyopia, glaucoma, retinal detachment, diabetic retinopathy, macular degeneration, corneal disease, and neuro-ophthalmic disease), previous refractive surgery, anterior chamber depth narrower than 3.8 mm in the pseudophakic eye, and a pupillary diameter less than 4 mm in either eye under photopic conditions (90 cd/m²). Written informed consent was obtained from all patients before surgery according to the Declaration of Helsinki and Institutional Review Board approval was obtained from the hospital ethics committee.

**IOLS**

The piggyback system was composed of the previous monofocal IOL and the Acri.Lisa 536D IOL (Carl Zeiss Meditec, Jena, Germany), a foldable three-piece multifocal IOL with a 6.0-mm acrylic optic, monofilament haptics with 5° angulation, and an overall diameter of 12.5 mm. The primary in-the-bag multifocal IOL was the Acri.Lisa 376D (Carl Zeiss Meditec), a single-piece diffractive acrylic multifocal IOL with a 6.0-mm optic, haptics with 0° angulation, and an overall diameter of 12.5 mm. Both multifocal IOLs had a near addition of +3.75 diopters (D) at the lens plane and a light distribution of 65:35 for the distance and near foci, respectively. The power of the primary multifocal IOL was selected for a target of emmetropia with the SRK/T formula for eyes with an axial length greater than 22 mm and with the Holladay 2 formula for eyes with an axial length less than 22 mm. Axial length was measured using the IOLMaster noncontact optical biometer (Carl Zeiss Meditec). The power of the secondary piggyback multifocal IOL was calculated for a target nearest to -0.50 D after subjective refraction using the van der Heijde formula.  

**SURGICAL TECHNIQUE**

All eyes were operated on by the same surgeon (GM) following the same protocol. Cataract surgery was performed first and secondary add-on implantation was performed within 1 week. Eyes undergoing cataract surgery were fully dilated with tropicamide and phenylephrine eye drops (Alcon Laboratories, Inc., Fort Worth, TX) three times within 30 minutes before surgery. Phacoemulsification using a 2.75-mm clear corneal incision on the steepest meridian, capsulorhexis, and symmetric implantation of the Acri. Lisa 376D multifocal IOL in the capsular bag were performed under topical anesthesia. Eyes undergoing piggyback implantation were initially dilated using the same protocol as in the primary procedures, but after two cases of pupillary capture, the eyes were dilated with one drop of tropicamide 30 minutes before surgery. Secondary sulcus-based IOL implantation was performed under topical anesthesia using a 2.75-mm clear corneal incision. After injecting ophthalmic viscosurgical device in the anterior chamber and under the iris, the Acri.Lisa 536D multifocal IOL was implanted in the sulcus. After washing the viscoelastic completely, acetylcholine was intracameral injected to ensure that the IOL was retained behind the iris to avoid intraoperative pupillary capture. No sutures were used in any case. Postoperative treatment included tobramycin-dexamethasone eye drops (TobraDex; Alcon Laboratories, Inc.) four times daily and diclofenac eye drops (Diclofenaco-lepori; Angelini Farmaceutica, Barcelona, Spain) three times daily for 3 weeks. Eyes with the add-on multifocal IOL also received pilocarpine 2% eye drops (pilocarpina 2%; Alcon Laboratories, Inc.) twice daily for 1 week to prevent postoperative pupillary capture.

**POSTOPERATIVE ASSESSMENT**

All patients completed a follow-up protocol with examinations at 1 day, 1 week, and 1, 3, and 6 months after surgery. Data for the study were collected at the last visit, including slit-lamp examination, tonometry, uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), corrected distance visual acuity (CDVA), distance-corrected near visual acuity (DCNVA), and monocular defocus curve. Monocular UDVA and CDVA were measured using a Snellen chart at 6 m, whereas UNVA and DCNVA were tested using a near Snellen chart at 33 cm. These values were transformed into logMAR notation for statistical analysis. Vector analysis of refractive outcomes was performed as suggested by Thibos and Horner. Photopic (90 cd/m²) distance and near contrast sensitivity and mesopic (5 cd/m²) distance contrast sensitivity with and without glare were measured using the Functional Visual Analyzer or FACT test (Stereo Optical Co., Inc., Chicago, IL). The testing procedure was performed on a double-blind basis because the examiner did not know the correct answer at the time of testing or the type of multifocal IOL system being tested. Patients adapted to mesopic conditions for 10 minutes before mesopic testing. The HD 9221 radiometer (Delta OHM S.r.L., Padova, Italy) was used to measure the conditions in the room where contrast sensitivity was measured to ensure equal lighting.
levels for all patients in all testing sessions. A Colvard pupillometer (OASIS Medical, Inc., Glendora, CA) was used for measuring pupil diameter under both illumination levels considered in the study.12

Ocular aberrations were measured using a Hartmann-Shack L80 aberrometer (Visionix Ltd., Jerusalem, Israel) for a 3.0-mm pupil. Total higher-order and spherical aberrations and coma were analyzed as Zernike coefficients.

**Statistical Analysis**

SigmaPlot v11 software (Systat Software, Inc., San Jose, CA) was used for statistical analysis and graphics. The Shapiro–Wilk test was used to verify the normality distribution of data. The unpaired t test (or the nonparametric Mann–Whitney U test if normality test failed) was used for group comparisons. The paired t test (or Wilcoxon signed-rank test if normality test failed) was used in the add-on multifocal IOL group to compare results before and after piggyback implantation. The significance level was set to alpha = 0.05.

Defocus curves were compared by means of the two-way repeated measures analysis of variance (ANOVA), with type of multifocal IOL (primary vs add-on) and defocus level as the two factors. Likewise, contrast sensitivity was compared by means of the two-way repeated measures ANOVA, but with type of multifocal IOL (primary vs add-on) and spatial frequency as the two factors. The Holm–Sidak method was used for post hoc testing when ANOVA revealed statistically significant differences.

**RESULTS**

The study included 42 eyes of 21 patients (Table 1). The power of the monofocal IOL was available in 9 patients (42.9%). Five pseudophakic eyes (23.8%) had a previous posterior Nd:YAG capsulotomy and 6 eyes (28.6%) showed significant posterior capsular opacification that required laser treatment during the first month of follow-up.

**Refractive and Visual Outcomes**

Monofocal pseudophakic eyes showed a mean spherical equivalent of 0.75 ± 1.14 D that changed to -0.69 ± 0.35 D after add-on multifocal IOL implantation (paired t test, P < .001). Primary in-the-bag eyes showed a mean postoperative spherical equivalent of -0.05 ± 0.40 D (Table A, available in the online version of this article). There was a statistically significant difference between the mean postoperative spherical equivalents of both groups (t test, P < .001). Vector analysis showed no differences in astigmatism (Mann–Whitney rank-sum test J0, P = .36; Mann–Whitney rank-sum test J45, P = .09).

Table 2 displays visual acuity results. Primary in-the-bag multifocal IOL implantation provided slightly but statistically significant better UDVA, UNVA, and CDVA, with no significant differences in DCNVA. Table B (available in the online version of this article) shows the comparison of visual results before and after the add-on multifocal IOL implantation. Both UNVA and DCNVA improved significantly, with no changes in UDVA or CDVA. In other words, the add-on multifocal IOL significantly improved uncorrected near vision with no significant effects on uncorrected or corrected distance visual acuity. Only one eye (4.8%) in the add-on group lost one line of CDVA after surgery.

The mean defocus curves for the two groups are shown in Figure A (available in the online version of this article). The two-way repeated measures ANOVA revealed differences between the groups and post hoc multiple comparisons with the Holm–Sidak method revealed differences of 0.00 and -3.00 D for the defocus levels. Figure 1 shows the mean defocus curve of both groups in decimal notation for easier visualization.

**Contrast Sensitivity**

There were no statistically significant differences in distance or near photopic contrast sensitivity or mesopic distance contrast sensitivity with or without glare at any of the tested frequencies (two-way repeated measures ANOVA, P > .30) (Figures B-D, available in the online version of this article). The two groups were comparable in terms of distance contrast sensitivity under photopic and mesopic conditions (with and without glare) and near contrast sensitivity under photopic conditions.

**Optical Aberrations and Complications**

Table 3 shows the wavefront aberrations of both groups for a 3.0-mm pupil. There were no statistically significant

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (F/M)</td>
<td>12/9</td>
</tr>
<tr>
<td>Age (y)</td>
<td>67.0 ± 7.8; range: 53 to 80</td>
</tr>
<tr>
<td>AXL (mm)</td>
<td>22.38 ± 1.24; range: 20.80 to 24.14</td>
</tr>
<tr>
<td>ACD (mm)</td>
<td>3.54 ± 0.90; range: 2.28 to 4.98</td>
</tr>
<tr>
<td>Add-on multifocal IOL power (D)</td>
<td>1.4 ± 1.3; range: 0 to 4</td>
</tr>
<tr>
<td>In-the-bag multifocal IOL power (D)</td>
<td>23.38 ± 3.01; range: 19.50 to 30.00</td>
</tr>
</tbody>
</table>

SD = standard deviation; AXL = axial length; ACD = anterior chamber depth; IOL = intraocular lens; D = diopters
differences in total higher-order and spherical aberrations or coma (two-way repeated measures ANOVA, \( P > .05 \)).

No complications were reported in the primary multifocal IOL group. In the add-on group, there were no cases of interlenticular opacification or IOL decentration, but one eye (4.8%) showed pigment dispersion and 2 eyes of 2 patients (9.5%) presented pupillary capture of the sulcus-based multifocal IOL. In both cases, the pupillary capture presented in the first postoperative visit 1 day after surgery and was solved at the slit lamp under topical anesthesia using a 30-gauge needle to press the multifocal IOL behind the iris through the side-port incision (Figure D). There was no recurrence of the pupillary capture in any case. The 3 patients with complications were included in the analysis of refractive and visual outcomes, contrast sensitivity, and optical aberrations.

**DISCUSSION**

The main finding of the current study was that the visual performance of the primary in-the-bag and add-on multifocal IOLs was similar, with no differences in contrast sensitivity under photopic or mesopic conditions for both distance and near. The differences in UDVA and UNVA in favor of the in-the-bag system may be attributed to the different refractive outcomes of both groups, with the add-on group having a residual mean spherical equivalent of approximately -0.75 D that was significantly different from the residual mean spherical equivalent of emmetropia for the primary in-the-bag group. Measurement of higher-order and spherical aberrations and coma revealed similar results between both systems for a 3.0-mm pupil. Currently, we are not aware of any intraindividual study comparing secondary add-on and primary in-the-bag multifocal IOL implantation.

Several studies reported the clinical outcomes of combining a monofocal and multifocal IOL in the same eye to avoid the optical aberrations of extremely high-powered single multifocal IOLs needed in cases of high hyperopic eyes.\(^{13-17}\) The add-on multifocal IOL as a secondary implant in the sulcus of previously monofocal pseudophakic eyes was first reported by Alfonso et al.\(^{6}\) using the Acri.Twin diffractive multifocal IOL (Acri.Tec; Carl Zeiss Meditec). Excellent near visual acuity was obtained with no significant complications or deleterious effect on distant vision. More recently, Schrecker et al.\(^{18}\) used a piggyback system composed of a monofocal IOL and an add-on multifocal IOL designed for sulcus placement that were implanted simultaneously, aiming for a better reversibility of the procedure. When they compared the results to a different group of patients with standard in-the-bag multifocal IOLs, they found good performance in both groups with even better results for monocular UDVA, intermediate visual acuity (both corrected and uncorrected), and contrast sensitivity in the add-on group. They also reported similar defocus curves (except for -2.50 D), with better results for the add-on multifocal group.\(^{18}\)
Previous studies in vitro showed that the optical quality provided by the piggyback system is similar to that provided by a unique IOL, for both monofocal and multifocal IOLs. Schrecker et al.\textsuperscript{19} compared the surface reflections in a pseudophakic model eye with and without a monofocal add-on IOL and concluded that monofocal add-on IOL implantation did not induce relevant additional disturbing glare compared to conventional pseudophakia. Artigas et al.\textsuperscript{20} used an artificial eye simulating in vivo conditions of the anterior chamber to measure the modulation transfer function of a piggyback system integrated by a monofocal IOL plus a bifocal IOL of zero power and +3.75 D of addition. They then compared it to the optics quality of a simple multifocal IOL of the same power and addition for near and distance vision and pupil diameters of 3 and 5 mm. They concluded that the modulation transfer functions for distant and near foci of the bifocal piggyback were similar to those of the simple multifocal IOLs for both pupil diameters. Our clinical results and those of previous studies suggest that the quality of vision provided by the add-on piggyback multifocal IOL system is satisfactory and may be a good alternative for providing pseudoaccommodation in patients diagnosed as having monofocal pseudophakia.

One weakness of the current study is that the add-on multifocal IOL used is not specifically designed for sulcus placement. However, there are commercially available multifocal IOL model designs for sulcus implantation that may improve the results presented herein.\textsuperscript{5,7} Because of the risk of pupillary capture and iris shaving, the selection of the multifocal IOL model for sulcus implantation is of utmost importance. In countries where specifically designed add-on multifocal IOLs for sulcus are available, this is the best option for judicial matters.

Centration and tilt of the sulcus-based multifocal IOL need to be considered. One theoretical disadvantage of the add-on multifocal IOL is its dependence on centration over both the monofocal IOL and eye optical axes. Decentration would increase higher-order aberrations and coma, and may affect the distribution of light intensity to the two foci, reducing near visual acuity. In the current study, wavefront aberrations were similar between the add-on and primary in-the-bag multifocal IOL systems, suggesting no significant effect of tilting or decentration.

In our series, the add-on multifocal IOL implantation did not significantly reduce CDVA in comparison to the previously monofocal pseudophakic situation, proving the safety of the procedure. Only one eye (4.8%) lost one line of CDVA, most likely due to the different light energy distribution provided by the new multifocal situation. After piggyback multifocal IOL implantation, UNVA and DCNVA improved significantly, balancing the possible detrimental effect on distance vision. However, preoperative discussion should include the possibility of losing some degree of distance vision when an add-on procedure with a multifocal IOL is proposed in a patient diagnosed as having monofocal pseudophakia. With regard to the primary in-the-bag multifocal IOL eyes, our results were comparable to those of previous studies using the Acri.Lisa multifocal IOL.\textsuperscript{21,22} Alfonso et al.\textsuperscript{23} and Kaymak and Mester\textsuperscript{23} assessed binocular distance and near visual acuity in more than 100 patients and reported excellent results for distance and near vision.

Specific complications of sulcus-based implantation should be considered.\textsuperscript{4,8,9} Previous studies have reported interlenticular opacification when both IOLs are implanted in the capsular bag.\textsuperscript{8} Migration of epithelial cells from the equatorial bow to the posterior capsule of the piggyback lens seems to be the likely cause. In the current study, there were no cases of interlenticular opacification because the secondary multifocal IOL was placed in the sulcus and far from the in-the-bag multifocal IOL. Postoperative pupillary capture is another concern after this type of surgery.\textsuperscript{6,9} The capture is more frequent because the zonula-lens complex of the pseudophakic eye fibres, resulting in the add-on multifocal IOL residing more anteriorly. Thus, when the pupil is dilated, the iris can capture the IOL optic. Alfonso et al.\textsuperscript{6} reported two cases of pupillary capture in 2 patients diagnosed as having hyperopia who had shallow anterior chambers and high-power monofocal IOLs. They suggested an anterior chamber depth greater than 3.8 mm to avoid this complication; to solve it, the patient was taken to the operating room and the captured IOL optic was pressed back to the posterior

### Table 3

Wavefront Aberrations After Add-On Sulcus-Based Multifocal IOL Versus Primary In-the-Bag Multifocal IOL for a 3.0-mm Pupil

<table>
<thead>
<tr>
<th>Variable</th>
<th>HOA RMS (Range)</th>
<th>Spherical Aberration (Range)</th>
<th>Coma (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add-on multifocal IOL</td>
<td>0.12 ± 0.05; (0.06 to 0.22)</td>
<td>0.01 ± 0.06; (-0.01 to 0.10)</td>
<td>0.12 ± 0.07; (0.03 to 0.19)</td>
</tr>
<tr>
<td>Primary in-the-bag IOL</td>
<td>0.11 ± 0.03; (0.07 to 0.15)</td>
<td>0.00 ± 0.05; (-0.08 to 0.08)</td>
<td>0.10 ± 0.04; (0.03 to 0.16)</td>
</tr>
</tbody>
</table>

IOL = intraocular lens; HOA RMS = higher-order aberration root mean square.
chamber with the IOL rotated 90° from the original position. Gayton et al. solved a pupillary capture at the slit lamp using a 30-gauge needle to press back the IOL.

In the current study, 2 eyes presenting with this complication were successfully treated with IOL repositioning at the slit lamp. However, this maneuver is not allowed in countries where all intraocular surgery must be performed in the operating room for legal reasons. Pupillary capture was then avoided after changing the preoperative pupillary dilating protocol because it was not necessary to obtain a fully dilated pupil for sulcus-based implantation. Only one drop of tropicamide was used so that pupillary constriction at the end of surgery could be easily obtained and the sulcus-based multifocal IOL could be retained behind the iris. The postoperative use of pilocarpine during the first week postoperatively may have also contributed to avoiding pupillary capture in the postoperative course in the current series. Obviously, prevention is the best treatment of any complication.

The results reported here imply that add-on and primary multifocal IOLs are comparable in terms of clinical results and vision quality. Sulcus placement of a multifocal IOL not specifically designed for sulcus implantation is only a reasonable alternative in countries where specifically designed add-on multifocal IOLs are not available. Contrast sensitivity at distance and near and under different conditions are similar. Complications after sulcus-based add-on multifocal IOL implantation, including pupillary capture and pigment dispersion, should be considered. Although a single multifocal IOL is the first option to provide pseudoaccommodation, a secondary add-on piggyback multifocal IOL may be an alternative in patients diagnosed as having monofocal pseudophakia seeking spectacle independence.

AUTHOR CONTRIBUTIONS
Conception and design (GM); data collection (CA-D, LB); analysis and interpretation of data (CA-D, GM, LB, SR); writing the manuscript (CA-D, GM, LB); critical revision of the manuscript (CA-D, GM, LB, SR); statistical expertise (CA-D); administrative, technical, or material support (LB); supervision (GM)

REFERENCES
### Table A

**Refractive Outcomes Before and After Add-On Multifocal IOL Implantation and After Cataract Surgery With Primary In-the-Bag Multifocal IOL in Contralateral Eyes**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± SD</th>
<th>J₀</th>
<th>J₄₅</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monofocal before add-on multifocal IOL</td>
<td>0.75 ± 1.14</td>
<td>0.08 ± 0.30</td>
<td>0.05 ± 0.27</td>
</tr>
<tr>
<td>After add-on multifocal IOL</td>
<td>-0.69 ± 0.35</td>
<td>0.03 ± 0.26</td>
<td>0.08 ± 0.23</td>
</tr>
<tr>
<td>After primary in-the-bag multifocal IOL</td>
<td>-0.05 ± 0.40</td>
<td>0.05 ± 0.20</td>
<td>-0.03 ± 0.19</td>
</tr>
</tbody>
</table>

SD = standard deviation; IOL = intraocular lens

*Manifest refractions in conventional script notation (S [sphere], C [cylinder] × φ [axis]) were converted to power vectors coordinates (M, J₀, J₄₅) by the following formulas: M = S + C/2; J₀ = (-C/2) cos (2φ); J₄₅ = (-C/2) sin (2φ).*

### Table B

**Visual Acuity Results Before (Monofocal) and After Secondary Piggyback Multifocal IOL in the Sulcus**

<table>
<thead>
<tr>
<th>Visual Acuity</th>
<th>UDVA</th>
<th>CDVA</th>
<th>UNVA</th>
<th>DCNVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>logMAR (mean ± SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monofocal IOL</td>
<td>0.18 ± 0.16</td>
<td>0.03 ± 0.03</td>
<td>0.69 ± 0.28</td>
<td>0.57 ± 0.11</td>
</tr>
<tr>
<td>Add-on multifocal IOL</td>
<td>0.17 ± 0.15</td>
<td>0.04 ± 0.05</td>
<td>0.18 ± 0.11</td>
<td>0.09 ± 0.06</td>
</tr>
<tr>
<td>P</td>
<td>.836</td>
<td>.438</td>
<td>&lt; .001</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Decimal (mean ± lines)</td>
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<tr>
<td>Monofocal IOL</td>
<td>0.66 ± 1.36</td>
<td>0.93 ± 0.34</td>
<td>0.20 ± 2.77</td>
<td>0.27 ± 1.08</td>
</tr>
<tr>
<td>Add-on multifocal IOL</td>
<td>0.68 ± 1.45</td>
<td>0.91 ± 0.49</td>
<td>0.67 ± 1.14</td>
<td>0.81 ± 0.58</td>
</tr>
</tbody>
</table>

IOL = intraocular lens; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; UNVA = uncorrected near visual acuity; DCNVA = distance-corrected near visual acuity; SD = standard deviation.
**Figure A.** Mean monocular defocus curves in logMAR notation. IOL = intraocular lens

**Figure B.** Contrast sensitivity function at photopic luminance level (90 cd/m²) for far and near vision. IOL = intraocular lens

**Figure C.** Contrast sensitivity function for far vision at mesopic luminance level (5 cd/m²) with and without glare. IOL = intraocular lens
Figure D. Postoperative pupillary capture of the add-on multifocal intraocular lens solved at the slit lamp using a 30-gauge needle to press it back.