urgeons can choose among several multifocal intraocular lenses (IOLs) to correct presbyopia at the time of cataract removal or refractive lens exchange. Most multifocal IOLs act as bifocal IOLs (ie, they form two primary focal points providing functional distance and near vision). The near add usually ranges between +3.00 and +4.00 diopters (D) at the IOL plane and in the average eye enables a near focal distance between 36 and 48 cm. Several studies employing a defocus curve to assess eyes with bifocal IOLs found reduced visual function at intermediate distances, especially with the highest degrees of near add. Multifocal IOLs with low near add (eg, +2.50 or +2.75 D) improve vision at intermediate distances. Different presbyopia-correcting IOL designs have been developed to minimize the typical through-focus V-pattern of multifocal IOLs with two foci: they include trifocal IOLs, which add a third focus for intermediate vision, and extended depth-of-focus (EDOF) IOLs, which aim to provide a continuous range of vision.

This study compared the visual performance of a new EDOF IOL, the Mini Well (SIFI, Catania, Italy), which has recently been shown in vitro to increase the depth of focus, to that of a multifocal IOL with low near add power, the AcrySof ReSTOR SV25T0 (Alcon Laboratories, Inc., Fort Worth, TX).

**PATIENTS AND METHODS**

**Patient Selection**

A retrospective comparative case series study was designed to investigate the visual function of the Mini Well EDOF IOL and the AcrySof ReSTOR SV25T0 multifocal IOL. The study was approved by the institutional review boards of each participating center.

**METHODS:** Patients implanted with an EDOF IOL (Mini Well; SIFI, Catania, Italy) inducing spherical aberration and with a multifocal IOL (ReSTOR SV25T; Alcon Laboratories, Inc., Fort Worth, TX) were analyzed. The following monocular parameters were investigated: corrected distance visual acuity (CDVA), distance-corrected near visual acuity (DCNVA), reading speed, defocus curve, contrast sensitivity, and halos and glare as quantified by a simulator (Halo & Glare Simulator; Eyeland-Design Network GmbH, Vreden, Germany) and questionnaire.

**RESULTS:** Twenty patients with the EDOF IOL and 37 with the multifocal IOL were enrolled. No statistically significant difference was observed for CDVA. The defocus curve of the EDOF IOL revealed no gaps for the intermediate range. Statistically significant differences were observed at -1.00 diopter (D) (EDOF IOL: 0.08 ± 0.09 logMAR; multifocal IOL: 0.21 ± 0.12 logMAR; P < .0001) and -1.50 D defocus (EDOF IOL: 0.15 ± 0.11 logMAR; multifocal IOL: 0.24 ± 0.13 logMAR; P = .0122). The reading speed at 40 cm was similar at all print sizes. The mean DCNVA was the same (EDOF IOL: 0.35 ± 0.14 logRAD, multifocal IOL: 0.35 ± 0.13 logRAD). No differences in contrast sensitivity were detected. According to the simulator, halos had a smaller mean size (P = .0439) and a lower mean intensity (P = .0222) with the EDOF IOL. No statistically significant differences were detected for glare size.

**CONCLUSIONS:** The new EDOF IOL performed similarly to a multifocal IOL at distance and near but was superior at intermediate distances.

**ABSTRACT**

**PURPOSE:** To investigate the clinical performance of a new extended depth-of-focus (EDOF) intraocular lens (IOL) and compare it to that of a distance-dominant diffractive multifocal IOL.

**METHODS:** Patients implanted with an EDOF IOL (Mini Well; SIFI, Catania, Italy) inducing spherical aberration and with a multifocal IOL (ReSTOR SV25T; Alcon Laboratories, Inc., Fort Worth, TX) were analyzed. The following monocular parameters were investigated: corrected distance visual acuity (CDVA), distance-corrected near visual acuity (DCNVA), reading speed, defocus curve, contrast sensitivity, and halos and glare as quantified by a simulator (Halo & Glare Simulator; Eyeland-Design Network GmbH, Vreden, Germany) and questionnaire.

**RESULTS:** Twenty patients with the EDOF IOL and 37 with the multifocal IOL were enrolled. No statistically significant difference was observed for CDVA. The defocus curve of the EDOF IOL revealed no gaps for the intermediate range. Statistically significant differences were observed at -1.00 diopter (D) (EDOF IOL: 0.08 ± 0.09 logMAR; multifocal IOL: 0.21 ± 0.12 logMAR; P < .0001) and -1.50 D defocus (EDOF IOL: 0.15 ± 0.11 logMAR; multifocal IOL: 0.24 ± 0.13 logMAR; P = .0122). The reading speed at 40 cm was similar at all print sizes. The mean DCNVA was the same (EDOF IOL: 0.35 ± 0.14 logRAD, multifocal IOL: 0.35 ± 0.13 logRAD). No differences in contrast sensitivity were detected. According to the simulator, halos had a smaller mean size (P = .0439) and a lower mean intensity (P = .0222) with the EDOF IOL. No statistically significant differences were detected for glare size.

**CONCLUSIONS:** The new EDOF IOL performed similarly to a multifocal IOL at distance and near but was superior at intermediate distances.
adhered to the tenets of the Declaration of Helsinki for the use of human participants in biomedical research and was approved by the G.B. Bietti Foundation IRCCS Ethical Committee. Written informed consent was obtained from all patients.

Surgery was performed between March 2014 and March 2016 on patients with cataract. At the time of surgery, exclusion criteria were preoperative corneal astigmatism higher than 0.75 D, any corneal disease, previous eye surgery, and reduced zonular/capsular stability. At the time of enrollment, we also excluded patients with any ocular comorbidity that could influence the postoperative evaluation or any intraoperative complication. The preoperative assessment included optical biometry (Aladdin; Topcon EU, San Giovanni Valdarno, Arezzo, Italy) and corneal and pupil evaluation by a rotating Scheimpflug camera combined with a Placido corneal topographer (Sirius; CSO, Florence, Italy).

IOLs and Surgical Technique

The Mini Well is a progressive EDOF IOL with an optical design based on wavefront engineering. The technical innovation consists of the implementation of positive and negative spherical aberrations in the central part of the optic: the introduction of different and controlled amounts of spherical aberration generates a continuum of foci to increase the depth of focus (Figure A, available in the online version of this article). As previously described by Bellucci and Curatolo, the IOL profile was optimized by estimating visual acuity using retinal images.

It is a single-piece, aspheric biconvex hydrophilic-hydrophobic copolymer IOL (Figure B, available in the online version of this article) with three different optical zones. The inner zone (diameter: 1.95 mm) induces a positive spherical aberration, the intermediate zone (diameter: 3 mm) induces a negative spherical aberration, and the outer zone has a monofocal aspheric design. The transitions between the three optical zones are smooth and present a gradual power shift to support a progressive vision. The optic diameter is 6 mm, the overall diameter is 10.75 mm, and the vault is 5°.

The AcrySof ReSTOR SV25T0 is a single-piece hydrophobic acrylic IOL with an apodized diffractive structure with near addition of 2.50 D at the IOL plane. The optic diameter is 6 mm and the overall diameter is 13 mm. The diffractive structure, located within the central 3.4-mm optic zone, comprises seven concentric steps of gradually decreasing height. The center of the lens is the distance zone and the refractive zone outside the diffractive region is also used for distance vision.

Surgery was performed by an expert surgeon through a temporal sutureless 2.2-mm incision under topical anesthesia. Both IOLs were implanted in the capsular bag and centered on the third Purkinje reflex.

Postoperative Examinations

The postoperative evaluation took place between 4 and 8 weeks after surgery. Monocular corrected (CDVA) and uncorrected (UDVA) distance visual acuity were measured using the Early Treatment of Diabetic Retinopathy Study (ETDRS) chart at 6 m. Near vision assessment was performed with the Radner Reading Chart (Italian validated version) under bright light conditions. Monocular distance-corrected near visual acuity (DCNVA) at 40 cm was expressed in log-arithm of the reading acuity determination (logRAD, the reading equivalent of logMAR). The reading speed (words per minute) was calculated for each reading acuity using the formula reading speed = number of words in the sentence/time in seconds needed to read the sentence. The reading length limit was set at 25 seconds. The critical print size (CPS) was defined as the smallest print size the patients were able to read with their optimum reading speed.

The defocus curve (visual acuity over imposed defocus) was recorded by adding negative lenses on the trial frame in half-diopter steps up to -4.00 D and positive lenses up to +1.00 D to the distance-corrected manifest refraction. Measurements were taken at 6 m under photopic conditions, with letters randomized between presentations. All recorded information was then represented in a two-dimensional graphic display using Cartesian coordinates (x-axis, spherical blur; y-axis, visual acuity). The direct comparison method of analysis, involving statistical comparison of the visual acuity at each defocus level, was adopted.

Monocular distance-corrected contrast sensitivity was measured using a computer screen (Vision Chart, CSO) enabling the presentation of sine-wave gratings at different spatial frequencies (1.5, 3, 6, 12, and 18 cycles per degree [cpd]). This computer has a background illumination calibrated at 85 cd/m² and thus provides independence from room illumination. Absolute values of log₁₀ contrast sensitivity were obtained for each spatial frequency, and means and standard deviations were calculated. The contrast sensitivity results of the two IOLs were compared to a normative database of 20 eyes of 20 age-matched patients with a monofocal IOL (AcrySof SN60WF, Alcon Laboratories, Inc.).

The presence of visual disturbances under low illumination was tested monocularly with a simulator (Halo & Glare Simulator; Eyeland-Design Network GmbH, Vreden, Germany), as recently done by Kretz et al.21 This simulator uses a scale for intensity and size of both halos and glare from 0 (none) to 100 (extremely

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disturbing). Likewise, the simulator allows the classification of the halo perceived by the patient into three types: H1 (diffuse halo ring), H2 (starburst type), and H3 (distinct halo ring). It also allows a classification of the glare into two types: G1 (diffuse glare) and G2 (irregularly shaped glare).

In addition, patients were asked if they were suffering from visual disturbances at night, including glare, halos, starbursts, hazy vision, monocular polyopia, simultaneous vision, and defocus. For this purpose, we relied on the images and the scale described by McAlinden et al.22

**Statistical Analysis**

In cases of bilateral implantation of the same IOL, only one eye was randomly selected. All statistical analyses were performed by Instat (version 3.1; Graphpad, La Jolla, CA). Normal distribution of data was assessed by the Kolmogorov–Smirnov test. The Mann–Whitney test was used to compare CDVA and CPS. An unpaired t test was used to compare the reading speed at different print sizes. A P value of less than .05 was considered statistically significant.

The calculation of the required sample size was based on the primary outcome parameter of monocular CDVA with a defocus of -1.00 D. A pilot study with the EDOF IOL used in this study found this value to be 0.09 ± 0.12 logMAR (data on file). A difference between groups of 0.1 logMAR was assumed to be clinically significant. Based on this assumption, an alpha value of 0.05, and a power of 0.8, the PS program for power and sample size calculations (version 3.0.12; http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize. Accessed October 7, 2017) calculated that 11 eyes were required in each group.

**RESULTS**

Twenty patients (mean age: 65.6 ± 9.7 years; range: 44 to 86 years) with the EDOF IOL and 37 (mean age: 64.0 ± 8.9 years; range: 51 to 84 years) with the multifocal IOL were enrolled. A bilateral implantation of the same IOL model had been performed in most patients (15 of 20) with the EDOF IOL and in a minority of cases with the multifocal IOL (3 of 37). The power of the implanted IOL was 21.10 ± 3.00 D for the EDOF IOL and 21.60 ± 4.10 D for the multifocal IOL. Table 1 shows the mean preoperative parameters of the two groups (no statistically significant differences were observed between them).

**VISUAL ACUITY AND DEFOCUS CURVE**

Regarding CDVA, no statistically significant difference (P = .3021) was observed between the EDOF IOL (-0.03 ± 0.06) and the multifocal IOL (-0.05 ± 0.06). There was also no difference (P = .4842) between the UDVA of the EDOF IOL (0.04 ± 0.06) and the UDVA of the multifocal IOL (0.03 ± 0.06) (Figure 1).

The two IOLs produced different defocus curves (Figure 2). The multifocal IOL revealed a typical V-shaped curve, with highest visual acuity at zero defocus and a second peak between -2.00 and -2.50 D. The EDOF IOL revealed gradually decreasing visual acuity for increasing negative defocus levels, with a continuous performance and no visual acuity gaps for the intermediate range. The mean visual acuity was clearly higher with the EDOF IOL between -0.50 and -2.00 D, whereas the multifocal IOL had a slight, but clinically negligible, advantage at 0.00 and -2.50 D. Specifically, the difference in mean visual acuity was statistically significant at -1.00 D defocus (EDOF IOL: 0.08 ± 0.09 logMAR; multifocal IOL: 0.21 ± 0.12 logMAR; P < .0001) and -1.50 D defocus (EDOF IOL: 0.15 ± 0.11 logMAR; multifocal IOL: 0.24 ± 0.13 logMAR; P = .0122). No statistically significant differences were detected at the remaining defocuses. With a defocus of -2.50 D, the visual acuity was 0.33 ± 0.15 and 0.31 ± 0.16 logMAR with the EDOF and the multifocal IOLs, respectively.

**TABLE 1**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EDOF IOL Group</th>
<th>Multifocal IOL Group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keratometry (D)</td>
<td>42.64 ± 1.28</td>
<td>43.27 ± 1.77</td>
<td>&gt; .05</td>
</tr>
<tr>
<td>Anterior chamber depth (mm)</td>
<td>3.26 ± 0.36</td>
<td>3.25 ± 0.41</td>
<td>&gt; .05</td>
</tr>
<tr>
<td>Axial length (mm)</td>
<td>23.76 ± 0.97</td>
<td>23.46 ± 2.12</td>
<td>&gt; .05</td>
</tr>
<tr>
<td>Photopic pupil diameter (mm)</td>
<td>3.15 ± 0.53</td>
<td>3.27 ± 0.52</td>
<td>&gt; .05</td>
</tr>
<tr>
<td>Scotopic pupil diameter (mm)</td>
<td>4.66 ± 0.92</td>
<td>4.89 ± 0.94</td>
<td>&gt; .05</td>
</tr>
<tr>
<td>Pupil decentration (mm)</td>
<td>0.26 ± 0.10</td>
<td>0.28 ± 0.13</td>
<td>&gt; .05</td>
</tr>
</tbody>
</table>

EDOF = extended depth-of-focus; IOL = intraocular lens; D = diopters

**TABLE 1**

**Mean Preoperative Parameters**

**Reading Speed**

Overall, the two IOLs evaluated in this study provided the same results for monocular near vision. The
Figure 1. Visual outcomes reported in Standard Graphs for Lens-Based Surgery format for the (top) extended depth-of-focus intraocular lens (EDOF-IOL) and (bottom) multifocal IOL (MF-IOL). UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; D = diopters
reading speed at 40 cm was similar at all print sizes, with no statistically significant differences, as shown by Table 2. The monocular mean DCNVA, measured as mean reading acuity (ie, the smallest print size that could be read) was the same (0.35 ± 0.14 logRAD for the EDOF IOL and 0.35 ± 0.13 logRAD for the multifocal IOL). The monocular mean CPS of the EDOF IOL (0.54 ± 0.15 logRAD) was close to that of the multifocal IOL (0.55 ± 0.15 logRAD, \( P = .5035 \)). With a print size of 0.5 logRAD (corresponding to a common book print size), a fluent reading speed (≥80 words per minute) was achieved in 65% of eyes with the EDOF IOL and 67.5% of eyes with the multifocal IOL (Fisher’s exact test, \( P = 1.000 \)).

**CONTRAST SENSITIVITY**

At all frequencies, the mean values of log10 contrast sensitivity were similar for the EDOF IOL and the multifocal IOL (Table 3). The former had slightly higher values at low frequencies (1.5 cpd) and the latter at medium-high frequencies (6 and 12 cpd). With both IOLs, the mean values were slightly lower than those recorded for the monofocal IOL, but the Kruskal–Wallis test failed to detect any statistically significant difference among the three groups.

**HALOS**

Based on the images in the article by McAlinden et al., halos were reported by 1 patient (5%) with the EDOF IOL and 10 patients (27%) with the multifocal IOL. The severity of halos was considered mild (grade 1) in the only patient with the EDOF IOL and mild to moderate (grade 2) in patients with the multifocal IOL. Mild glare (grade 1) was reported by 2 patients (10%) with the EDOF IOL and by 2 patients (5.4%) with the multifocal IOL. Mild to moderate starbursts were reported by 10 patients (27%) with the multifocal IOL and none with the EDOF IOL.

According to the Halo & Glare Simulator, halos had a mean size of 34.8 ± 22.08 and a mean intensity of 38.50 ± 16.47 with the EDOF IOL. With the multifocal IOL, the mean halo size (53.57 ± 23.67) and intensity were higher than those recorded for the EDOF IOL.
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(54.76 ± 20.53) were significantly larger (P = .0439 and .0222, respectively). No statistically significant differences were detected for glare size (EDOF IOL = 4.40 ± 8.69; multifocal IOL = 8.52 ± 14.54) and intensity (EDOF IOL = 15.70 ± 26.33; multifocal IOL = 13.81 ± 23.70).

With both IOLs, 100% of halos were classified as H2 (starburst type) and 100% of glare as G1 (diffuse type).

DISCUSSION

The results of the current study reveal interesting differences between the EDOF IOL and the multifocal IOL. First, the EDOF IOL provides a better visual acuity at intermediate distances, as shown by the progressive profile of the defocus curve. Second, the EDOF IOL induces fewer night halos according to the Halo & Glare Simulator. These advantages are not counterbalanced by a loss of CDVA, near vision, and contrast sensitivity.

Defocus curve evaluation is one of the most useful methods to compare different presbyopia-correcting IOLs and has overcome many of the issues of selected distance visual acuity measures. With traditional multifocal IOLs, which produce two foci, the curve has a typical V-shaped profile, with two peaks of optimum acuity: one at the distance focal point (zero defocus) and the other at the near focal distance. The lowest part of the curve between the two peaks typically corresponds to the lower visual acuity at intermediate distances. On the contrary, the EDOF IOL produces a curve that progressively declines as the reading distance gets closer, with no gaps at -1.00 or -1.50 D defocus. Such a profile shows that the EDOF IOL produces a continuous range of foci, thus improving vision at intermediate distances compared to multifocal IOLs. Statistically, this is demonstrated by the difference in visual acuity between the two IOLs with a defocus of -1.00 and -1.50 D. The extension of the depth of focus depends on the systematic induction of targeted amounts of spherical aberration by the EDOF IOL; such induction has been previously shown to improve the depth of focus in young healthy volunteers. On the other hand, the mean CDVAs at 0.00 and -2.50 D were similar to those of the multifocal IOL, thus showing that the improvement at intermediate distances does not impair far and near vision (compared to the multifocal IOL) and that the EDOF IOL actually provides an extended focus from far vision to a distance of 40 cm. These findings are in good agreement with previous in vitro studies that analyzed the modulation transfer factor through-focus curve of the same EDOF IOL. Bellucci and Curatolo reported a uniform performance for up to near distance, with better modulation transfer factor values at an intermediate distance compared to multifocal and bifocal refractive IOLs at a 3-mm aperture. Domínguez-Vicent et al. observed that, at the same aperture, the EDOF IOL has a smoother and wider transition between the intermediate and near vision foci than another EDOF IOL (Tecnis Symphony ZXR00; Abbott Laboratories, Abbott Park, IL) and two trifocal IOLs (AT LISA; Carl Zeiss Meditec, Germany, and Finevision; PhysIOL S.A., Liège, Belgium).

The reduced incidence, size, and intensity of halos with the EDOF IOL in comparison to the multifocal IOL likely depends on the different design of the optics because the EDOF IOL does not have the typical diffractive rings of the multifocal IOL; moreover, the central area inducing the spherical aberration in the EDOF IOL has a smaller diameter (3 mm) than the central diffractive area of the multifocal IOL (3.4 mm). Interestingly, our results for the multifocal IOL (mean halo size: 53.57 ± 23.67, mean halo intensity: 54.76 ± 20.53) are close to those previously reported by Kretz et al., who tested the same software on patients implanted with a trifocal diffractive IOL (mean halo size: 50.67 ± 15.69, mean halo intensity: 54.89 ± 17.86). Thus, it seems that different diffractive designs lead to similar outcomes in terms of night disturbance.

The monocular mean CDVA of both the EDOF IOL (-0.03 ± 0.06) and the multifocal IOL (-0.05 ± 0.06) is similar to the corresponding value reported 6 months after surgery for a trifocal (0.01 ± 0.11) and a bifocal (0.02 ± 0.08) multifocal IOL, and slightly better than the value reported 3 months after surgery for a rotational asymmetric multifocal IOL (0.10 ± 0.16) and an accommodating IOL (0.04 ± 0.08). These data show that the extension of the depth of focus does not impair the distance vision compared to other multifocal IOLs. The similar outcomes for contrast sensitivity provided by the two IOLs likewise demonstrate the good optical quality of the EDOF IOL because the multifocal IOL tested in this study has been previously shown to be one of the multifocal IOLs offering the best contrast sensitivity, both in vitro and in vivo.

Near visual acuity measurements with standardized charts cannot fully represent actual performance at near distance. Thus, the reading performance during real reading tasks was measured in this study. Our results did not show any relevant difference between the two IOL models and are similar to those previously reported by Alió et al. for a multifocal IOL, which provided a postoperative CPS of 0.49 ± 0.17 logRAD. Of course, a significant improvement in reading acuity is expected with bilaterally implanted EDOF IOLs. Preliminary data, in fact, showed that the percentage of eyes reaching a binocular reading speed of greater
than 80 words per minute at a 0.5 logRAD print size increase up to 92% and that CPS decreases to 0.48 ± 0.15 logRAD.28

This study is the first in vivo investigation of this EDOF IOL. However, in addition to its retrospective nature, it has some limitations. First, in this series we had only a few patients bilaterally implanted with either the EDOF IOL or the multifocal IOL, so we were unable to investigate their bilateral performance. Second, we compared the results of the IOL models to those obtained with a monofocal IOL only for contrast sensitivity, but could not compare them for the other parameters. Third, we did not formally assess the satisfaction of our patients with a specific questionnaire. Fourth, the results of the simulator we used to assess haloes and glare must be interpreted with caution because this tool needs further validation. Finally, we did not correlate the preoperative measurements to the postoperative outcomes. All of these issues will be the subjects of future studies.

The EDOF IOL seems to be a good option for patients looking for spectacle independence because it provides a better visual acuity at intermediate distances and induces fewer night halos with respect to the distance-dominant diffractive multifocal IOL, without impairing distance vision and near vision.

AUTHOR CONTRIBUTIONS

Study concept and design (GS, DS-L, NB, PB); data collection (GS); analysis and interpretation of data (GS, DS-L, NB); writing the manuscript (GS); critical revision of the manuscript (DS-L, NB, PB); administrative, technical, or material support (DS-L); supervision (PB)

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22. McAlinden C, Pesudovs K, Moore JE. The development on an
instrument to measure quality of vision: the Quality of Vision (QoV) questionnaire. *Invest Ophthalmol Vis Sci.* 2010;51:5537-5545.


Figure A. Design and optical principles of the Mini Well (SIFI, Catania, Italy) extended depth-of-focus intraocular lens. (Left) Front image of the lens. (Right) The inner green zone induces a positive spherical aberration with marginal foci ($F_M$) anterior to the paraxial foci ($F_P$); the intermediate red zone induces a negative spherical aberration with $F_M$ posterior to $F_P$. The distance between the $F_P$ of negative and positive aberration corresponds to continuum foci.

Figure B. Slit-lamp image of the Mini Well extended depth-of-focus intraocular lens (SIFI, Catania, Italy).