ARTICLE

Two-surgeon, two-center evaluation of a new combined EDOF intraocular lens approach

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Purpose: To evaluate visual performance and quality of life after bilateral implantation of 2 extended depth-of-focus intraocular lenses (EDOF IOLs).

Setting: Ophthalmology Clinic, Department of Medicine and Science of Ageing, University "G. d'Annunzio" Chieti-Pescara, Italy, and Ophthalmic Unit, Department of Neurosciences, Biomedicine and Movement Sciences, University of Verona, Italy.

Design: Prospective clinical study.

Methods: 60 eyes of 30 patients with senile cataract were enrolled in this study. Patients underwent phacoemulsification and bilateral implantation of the Mini WELL IOL in the dominant eye and the Mini WELL PROXA IOL in the nondominant eye within a month. The main outcome measures over a 3-month follow-up period were uncorrected and corrected visual acuity at different distances (33 cm, 60 cm, and 4 m), defocus curve, contrast sensitivity, and patient satisfaction (evaluated by mean of the National Eye Institute Refractive Error Quality-of-Life instrument-42 questionnaire).

Results: Binocular uncorrected visual acuity at 90 days was 0.03 ± 0.11 logMAR for long distance, 0.05 ± 0.10 logMAR for intermediate distance, 0.03 ± 0.08 logMAR at 40 cm, and 0.06 ± 0.08 logMAR at 33 cm. Statistically significant differences between the 2 EDOF IOLs in favor of Mini WELL PROXA IOL were observed for uncorrected near visual acuity at 40 and 33 cm ($P < .001$ and $P < .001$, respectively) and for distance-corrected near visual acuity at 40 cm ($P < .001$). Significant differences between the 2 IOLs in the defocus curves were reported.

Conclusions: In this small pilot study, bilateral implantation of Mini WELL IOL and Mini WELL PROXA IOL achieved good quantity and quality of vision.

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Patients undergoing cataract surgery with intraocular lens (IOL) implantation have the opportunity to reach high quality of vision and increased spectacle independence. Monofocal IOL designs supply either near or distance vision according to target refraction, leaving the patient in front of a dichotomous choice. Due to the exponential growth in the use of computers, tablets, and other small hand-held electronic devices, the request for a good near and intermediate vision is of extreme importance for a patient aiming to gain spectacle independence.[1,2] Multifocal IOLs (mIOLs) were introduced to overcome this patient choice improving patient quality of life.

However, due to the characteristics associated with mIOL technology (multifocality, light dispersion, and higher-order aberrations [HOAs]), their implantation was reported to be associated with unpleasant visual symptoms such as halos, glare, and loss of contrast sensitivity.[3,4] Thus, to increase the depth of mIOL focus, technological advances have been introduced such as diffractive IOLs with lower near addition power, trifocal IOLs, and extended depth-of-focus (EDOF) IOLs that provide an improvement in intermediate vision without impairing distance and near visual acuity.[5–7]

This pilot study evaluating the 136 eyes of 68 patients bilaterally implanted with Mini WELL (Sifi Medtech Srl) EDOF IOLs reported patients to have good visual acuity at different distances and an enhanced contrast sensitivity with low incidence of photic phenomena.[8] In the study, 75% of the patients did not experience halos and 81% did not perceive glare.[8]

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The Mini WELL EDOF IOL optical principle is based on wavefront technology featuring 2 concentric central zones with aberrations of opposite signs and a monofocal periphery.

Initial evaluations with a PMTF optical bench top device that measures optical quality for different pupil sizes showed that the Mini WELL EDOF IOLs, although similar to the AT LISA (Carl Zeiss Meditec AG) and Finevision (Physiol S.A.) IOLs for intermediate vision, were better for distance vision with large apertures.[9]

A new addition to the Mini WELL line is the Mini WELL PROXA (Sifi Medtech Srl) IOL, which is based on the same EDOF platform with the distribution of spherical aberrations of opposite signs in the central part of the optics (Table 1).

The 2 IOLs are intended to be used jointly in a binocular system called WELL Fusion, where the Mini WELL is implanted in the dominant eye and the Mini WELL PROXA in the nondominant eye to compensate for the near vision gap, thus providing the patient with high-quality vision at all distances and in all lighting conditions.

We hypothesized that using these IOLs in combination would have an added advantage of being produced by the same manufacturer using the same IOL technology. This study aimed at testing this hypothesis by evaluating visual performance (distance, intermediate and near visual acuity), defocus curve, contrast sensitivity, HOAs, and quality of life. The reproducibility of the visual outcomes was evaluated by comparing the results obtained by 2 surgical centers.

METHODS

This prospective multicenter clinical study adhered to the tenets of the Declaration of Helsinki. The protocol was approved by the Institutional Review Boards of both University "G. d'Annunzio" of Chieti-Pescara and the University of Verona. The trial settings were the Ophthalmology Clinics of the Department of Medicine and Science of Ageing, University "G. d'Annunzio" of Chieti-Pescara and Eye Clinic of the Department of Neurosciences, Biomedicine and Movement Sciences, University of Verona. All patients provided written informed consent before enrollment.

This study comprised 60 eyes of 30 patients with senile cataract who underwent bilateral phacoemulsification and IOL implantation and who, based on their preferences stated when planning the surgical procedures, were candidates for implantation of a Mini WELL IOL (dominant eye) and the Mini WELL PROXA IOL (nondominant eye) within a month. Other inclusion criteria were bilateral age-related cataract (LOCS III <N3), preoperative corneal astigmatism less than 1.0 diopter (D), and patients aged more than 45 years.[10]

The exclusion criteria were a history of previous ocular surgeries and presence of other ocular condition such as glaucoma, retinal diseases, or corneal diseases. Patients who presented intraoperative complications not strictly correlated with the IOL were excluded from statistical analysis.

All patients underwent complete ophthalmologic examination including manifest refraction before surgery; distance, intermediate and near visual acuity; topography; slitlamp biomicroscopy; tonometry; and fundus ophthalmoscopy after pupil dilation. IOL Master 700 (Carl Zeiss Meditec AG) was used to measure axial length and to calculate IOL spherical power using the Barrett Universal II formula with targeted refraction for emmetropia.

Surgical Technique

Standard phacoemulsification was performed in all patients by the same surgeon for each center (L.M., E.P., respectively) with a 2.2 mm tip and sleeve using the Alcon Constellation System (Alcon Laboratories, Inc.) using topical anesthesia. All IOLs were implanted in the capsular bag after the injection of Healon GV pro ophthalmic viscosurgical device (Johnson & Johnson Vision). Intracameral injection of 1 mg cefuroxime was performed at the end of surgery. Ofloxacin 0.3% and dexamethasone 0.2% eyedrops were administered 4 times per day for 3 weeks. Patients were examined over a 3-month follow-up period.

Outcome Measures

The main outcome measures were spherical equivalent manifest refraction, monocular and binocular uncorrected and corrected distance visual acuity (UCDVA–CDVA), monocular and binocular uncorrected and corrected intermediate VA at 60 cm (UCIVA–CIVA), monocular and binocular uncorrected and corrected near VA at 33 cm and at 40 cm (UCNVA–CNVA), monocular and binocular defocus curve, and contrast sensitivity. In addition, quality of life using the National Eye Institute Refractive Error Quality-of-Life instrument-42 (NEI-RQL-42 questionnaire) was assessed in all patients.

All evaluations were performed preoperatively and 90 days postoperatively by an ophthalmologist who was blinded to the patient's dominant eye.

Table 1. Differences between Mini WELL and Mini WELL PROXA

Parameter	Mini WELL	Mini WELL PROXA
Material	Acrylic, copolymer hydrophilic–hydrophobic	Acrylic, copolymer hydrophilic–hydrophobic
Aspheric	Yes	Yes
Optic diameter (mm)	6.0	6.0
Overall diameter (mm)	10.75	10.75
Shape	Biconvex—anterior aspheric EDOF surface	Biconvex—anterior aspheric EDOF surface
No. of loops	4	4
Refractive index (at 35 degrees)	1.46	1.46
Dioptric range	0 to +30 D (0 to +10 D incr. 1 D; +10 to +30 D incr. 0.5 D)	0 to +30 D (0 to +10 D incr. 1 D; +10 to +30 D incr. 0.5 D)
Equivalent addition (D)	+3.00	+3.25
Distribution of aberrations	Two concentric central zones with aberrations of opposite signs and a monofocal periphery	Distribution of spherical aberrations of opposite signs in the central part of the optics

Mini WELL PROXA has a higher equivalent additional value than Mini WELL. This is explained by a different distribution of spherical aberrations in the 2 lenses.

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Visual Performance

Monocular and binocular uncorrected and corrected distance visual acuity was measured at 4 meters using ETDRS charts. Monocular and binocular uncorrected and distance-corrected near visual acuity was examined at 33 cm and 40 cm using a hand-held ETDRS near the reading chart. Monocular and binocular uncorrected and distance-corrected intermediate visual acuity was evaluated at 60 cm using the same chart used for near assessment.

Defocus Curve

Monocularly and binocularly defocus curves for each patient were obtained by measuring CDVA at 4 m and adding 0.50 D steps from +2.0 to −4.0 D.

Contrast Sensitivity

Contrast sensitivity was evaluated monocularly and binocularly with distance correction at 1.5 cycles per degree (cpd), 3 cpd, 6 cpd, 12 cpd, and 18 cpd under photopic (80 cd/m^2), mesopic (6 cd/m^2), and scotopic (3 cd/m^2) conditions by means of Vistech contrast sensitivity charts displayed by the Yang vision tester (Sifi Diagnostic SPA).

Refractive Error QoL Assessment

To evaluate patient satisfaction and degree of independence, all patients completed the Italian version of the NEI RQL-42 questionnaire during the 3-month follow-up examination. The NEI-RQL-42 is a questionnaire used to measure refractive error-related quality of life. The scored questionnaire consists of 42 items (questions) across 13 subscales.

Statistical Analysis

The sample size calculation for the study was based on the primary outcome measure of uncorrected visual acuity at the 3-month follow-up. For an $\alpha = 0.05$ and a $\beta = 0.20$, a sample size of 24 eyes per group was sufficient to detect mean differences of 1 SD or greater with the *t* test. Considering a drop-out rate of 25%, 30 eyes for each type of EDOF IOLs (15 for each center) were enrolled. Preoperative parameters included sex, age, corrected distance visual acuity, keratometry (K1 and K2), and pupil size (in scotopic, mesopic, and photopic). The presence of statistically significant differences in nonparameters was evaluated using the Fisher exact test, and parameters were evaluated with a Mann-Whitney *U* test. A repeated measures analysis of variance (ANOVA) was used to evaluate the effect of IOL and distance on visual acuity for the entire patient population. All statistical tests were evaluated at a 2-sided α level of 0.05. Statistical analysis was performed using SPSS 26.0 (IBM Corp.). A false discovery rate correction for multiplicity was independently applied to the primary and secondary outcome measures to reduce the risk for a type 2 error (ie, accept a null hypothesis that is actually false or exclude the presence of a statistically significant result when actually present).

RESULTS

Patient characteristics for each center are reported in Table 2. Preoperatively, statistically significant differences between the 2 centers were not observed (Table 2). All surgical procedures were uneventful, all IOLs were successfully implanted in the capsular bag, and all patients successfully completed the 3-month follow-up. The mean intervals between first and second eyes for the 2 centers were 22.3 ± 3.6 and 23.9 ± 3.4 days ($P = .718$, independent samples *t* test).

A repeated measures ANOVA with a Huynh-Feldt correction for the uncorrected and corrected visual acuities showed a statistically significant effect of distance ($P < .001$ and $P < .001$, respectively) and the interaction for distance and IOL ($P = .009$ and $P = .001$, respectively) but not for center or the interaction of center and IOL (Table 3). In detail, the 2 IOLs showed statistically significant differences for UNVA at 40 and 33 cm ($P < .001$ and $P < .001$, respectively) and for DCNVA at 40 cm ($P < .001$) with better visual acuities for the Mini WELL Proxa compared with the Mini WELL.

Table 2. Comparison of preoperative patient characteristics

Parameter	Center C (N = 15 patients)	Center V (N = 15 patients)	*P* value	Multicenter (N = 30 patients)
Age (y)	68.9 ± 8.7	70.0 ± 8.8	.722	69.3 ± 8.6
Sex			.651	
M	4	2		6
F	11	13		24
Dominant eye			.272	
Right	5	9		14
Left	10	6		16
IOP (mm Hg)	15.0 ± 1.9	14.3 ± 1.9	.322	14.7 ± 1.9
Pupil size (mm)				
Photopic	2.80 ± 0.18	2.82 ± 0.18	.763	2.81 ± 0.18
Mesopic	6.57 ± 0.50	6.33 ± 0.50	.199	6.45 ± 0.52
Refraction				
Sph (D)	0.13 ± 1.69	0.73 ± 1.69	.339	0.43 ± 1.69
Cyl (D)	0.48 ± 0.93	0.28 ± 0.93	.561	0.38 ± 0.81
SE (D)	0.36 ± 1.56	0.86 ± 1.56	.388	0.61 ± 1.61
CDVA	0.19 ± 0.12	0.23 ± 0.10	.173	0.21 ± .11
K1 (D)	43.5 ± 1.1	43.4 ± 1.3	.749	43.5 ± 1.2
K2 (D)	44.2 ± 1.0	44.0 ± 1.4	.527	44.1 ± 1.2

Cyl = cylinder; K = keratometry; SE = spherical equivalent; Sph = sphere
Values are expressed as mean ± SD or frequency
P values obtained using the Fisher exact test or independent sample *t* test

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Table 3. Postoperative uncorrected and corrected visual acuity at different distances

Parameter	Mini WELL	Mini WELL PROXA	*P* value	Binocular
UDVA (4 m)	0.09 ± 0.13	0.11 ± 0.11	.523	0.03 ± 0.11
UIVA (60 cm)	0.11 ± 0.09	0.12 ± 0.09	.669	0.05 ± 0.10
UNVA (40 cm)	0.13 ± 0.11	0.02 ± 0.11	<.001	−0.03 ± 0.08
UNVA (33 cm)	0.16 ± 0.08	0.08 ± 0.09	<.001	0.06 ± 0.08
CDVA (4 m)	0.01 ± 0.07	0.03 ± 0.06	.240	−0.02 ± 0.08
DCIVA (60 cm)	0.09 ± 0.07	0.11 ± 0.11	.404	0.06 ± 0.09
DCNVA (40 cm)	0.10 ± 0.08	0.00 ± 0.08	<.001	−0.05 ± 0.05
DCNVA (33 cm)	0.18 ± 0.13	0.09 ± 0.12	.007	0.05 ± 0.06

A repeated measures ANOVA for the uncorrected and corrected visual acuities showed a statistically significant effect of distance ($P < .001$ and $P < .001$, Huynh-Feldt correction) and the interaction for distance and IOL ($P = .009$ and $P = .001$, Huynh-Feldt correction), but not for center (data not shown). The *P* values for the post hoc comparisons between the 2 IOLs using a Mann-Whitney *U* test are shown.

Post hoc analysis using the Kruskal-Wallis test indicated statistically significant differences between the 2 IOLs at +2.0 D ($P = .001$), +1.5 D ($P = .008$), +1.0 D ($P = .019$), −0.5 D ($P = .003$), −3.0 D ($P = .021$), −3.5 D ($P < .001$), and −4.0 D ($P < .001$) (Figure 1). The defocus curve showed statistically significant differences between the 2 IOLs with higher visual acuity values from +2.0 D to −0.5 D for the Mini Well IOL (at +2.0 D, $P = .001$; +1.5 D, $P = .008$; +1.0 D, $P = .019$; −0.5 D, $P = .003$) and higher values of visual acuity for the Mini Well Proxa from −3.0 D to −4.0 D (−3.0 D, $P = .021$; −3.5 D, $P < .001$; and −4.0 D, $P < .001$) (Figure 1). In detail, an inversion for the 2 individual EDOF-IOLS was compared with the binocular curve between −2.0 D and −2.5 D, thus indicating a complementary coverage over the evaluated range. Specifically, the Mini WELL PROXA IOL did not differ from the binocular results from −3.0 to −4.0 D, while the Mini WELL IOL difference from binocular vision was statistically significant ($P = .026$, $P < .001$, and $P < .001$, respectively).

The differences in photopic, mesopic, and scotopic distance-corrected contrast curves between the 2 centers and between the 2 IOLs were not statistically significant (Figure 2). The differences between monocular and binocular photopic, mesopic, and scotopic distance-corrected contrast curves were also not statistically significant.

Patient satisfaction measured with the NEI RQL-42 questionnaire yielded the mean results ranging from 60% for Expectations to 100% for Activity limitations (Figure 3). The between-center differences in the 13 subscales for the patient responses to the NEI RQL-42 were not significant (Figure 3). The mean and SD for Near Vision, Glare, and Symptoms were the only NEI RQL-42 subscales that do not include 100%.

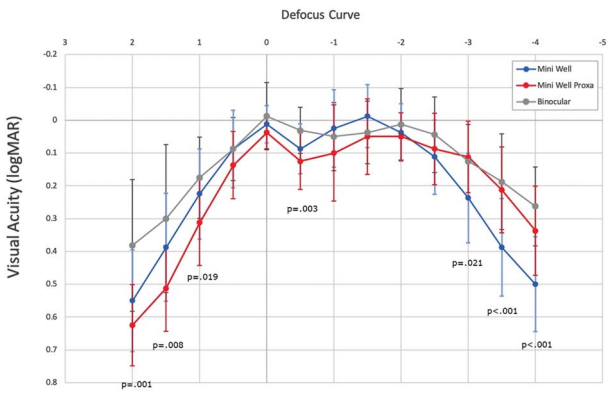

Figure 1. Monocular defocus curves of Mini WELL IOL and Mini WELL PROXA IOL and binocular defocus curve of the combined implant Mini WELL IOL and Mini WELL PROXA IOL. The *P* values indicate statistical differences between the 2 EDOF-IOLs using the Kruskal-Wallis test.

DISCUSSION

This study aimed at comparing results obtained with bilateral implantation of Mini WELL IOL in the dominant eye and the Mini WELL PROXA IOL in the nondominant eye in a 2-center 2-surgeon study. The between-center differences in spherical equivalent manifest refraction, uncorrected and corrected UCDVA–CDVA at 4 m, UCIVA–CIVA at 60 cm, UCNVA–CNVA at 40 and 33 cm, and NEI-RQL-42 questionnaire were not statistically significant. Similarly, the repeated measures ANOVA results did not show statistically significant differences between centers and thus confirmed the differences in depth of focus of the 2 IOLs with the Mini WELL PROXA increasing the quantity and quality of near vision.

The most commonly implanted type of IOL after cataract surgery is monofocal IOL. To meet the expectation of independence in the context of a modern lifestyle, refractive and diffractive multifocal IOLs were introduced. Traditional diffractive mIOLs provide good near and distance vision, whereas traditional refractive mIOLs allowed good distance and intermediate vision with worse visual performance for near when compared with diffractive mIOLS.[11,12] These lenses altered the quality of vision by reducing contrast and increasing photic phenomena compared with monofocal IOLs.[3,4]

The main causes of patient dissatisfaction were incomplete independence associated with blurred vision with photic phenomena and reduced contrast sensitivity. Different technical innovations have been proposed to overcome these shortcomings, in particular advancements to improve the depth of focus or improvements of the optics

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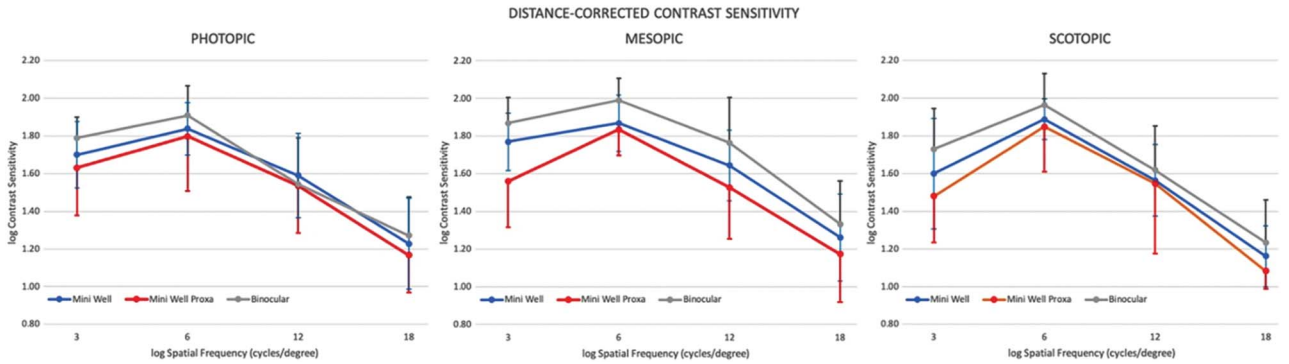

Figure 2. Monocular distance-corrected photopic, mesopic, and scotopic contrast sensitivity of Mini WELL IOL and Mini WELL PROXA IOL and photopic, mesopic, and scotopic contrast sensitivity of the combined implant Mini WELL IOL and Mini WELL PROXA IOL.

to increase the quality of vision and increase patient satisfaction and quality of life.

Although refractive multifocal IOLs were associated with more photic phenomena than diffractive multifocal IOLs, EDOF IOLs yielded better quality with less phenomena.[13] This was probably due to the design of EDOF IOLs compared with traditional multifocal IOLs, in that the former provide a continuous range of focus without distinct asymmetric zones of power distribution to avoid secondary out-of-focus images (Supplemental Figure 1, available at http://links.lww.com/JRS/A808).[14,15]

Although binocular near visual acuity with EDOF IOLs was reported to be better than that obtained with either low-add diffractive bifocal or diffractive trifocal IOLs, contrasting results were reported where a diffractive trifocal IOL yielded better near vision.[16–19] However, equal or less photopic phenomena were reported with EDOF IOLs.[20] Gunenc and Celik suggested using 2 different kinds of multifocal IOLs using refractive and diffractive multifocal IOLs speculated because using a single multifocal IOL could not cover the entire span of vision.[21] Implanting an EDOF IOL in the dominant eye and a moderate-add bifocal IOL yielded at least 20/25 visual acuity from distance to near.[22] A mix-and-match approach using an EDOF IOL in the dominant eye and a trifocal IOL in the fellow eye did restore better near visual acuity than bilateral EDOF IOLs.[23] In both studies, patients reported a good degree of satisfaction, spectacle independence, and low incidence of visual distortions.[22,23]

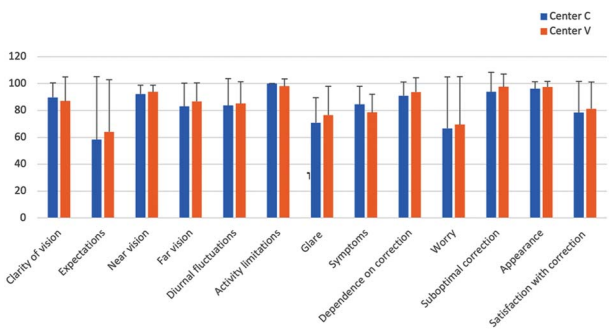

Figure 3. Responses at 90 days postoperatively to the National Eye Institute Refractive Error Quality-of-Life instrument-42 grouped for the 13 subscales.

Binocular implantation of Mini WELL EDOF IOLs yielded very good intermediate visual acuity but only good near visual acuity with a lower perception, in number of patients and intensity, of dysphotopsia.[12,24] The bilateral implantation of EDOF IOLs with similar characteristics except for the IOL in the nondominant eye favoring near vision is the next logical step.

In the case of the Mini WELL IOL and the Mini WELL PROXA IOLs, the continuous multifocality is achieved with a new technique that uses zones with spherical aberrations of opposite signs while minimizing the reduction in the quality of vision.

Using a binocular system combining 2 very similar EDOF IOLs based on spherical aberrations of opposite signs introduces the possibility of giving patients an increased depth of focus to a near vision of 30 cm while minimizing abnormal photopsia.

The main limit of this study was the lack of a control group, which was partially justified by the exploratory nature of the study design. Other limitations included small sample size and a short follow-up with a duration limited to only 90 days. In addition, the nonrandomization of the first eye that underwent surgery gave the nondominant eye a longer period (on average 22 days) for adaptation. Although this could have represented a bias, a method for isolating the effect of the dominant eye from the type of EDOF IOL would not have been possible given the suggestion by the manufacturer of using Mini WELL in the dominant eye and Mini WELL PROXA in the nondominant eye.

In conclusion, the quantity and quality of vision that can be obtained using the combined approach of Mini WELL in the dominant eye and Mini WELL PROXA in the nondominant eye are not surgeon–center dependent. Further studies will be required to preoperatively identify the patients who will benefit most from these paired IOLs.

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WHAT WAS KNOWN

- Different solutions are available for patients undergoing cataract surgery and IOL implantation to achieve a better quality of life.
- The introduction of EDOF IOLs has provided improvement in intermediate vision without impairing distance and near visual acuity.

WHAT THIS PAPER ADDS

- WELL Fusion system, entailing Mini WELL implanted in the dominant eye and Mini WELL PROXA in the recessive eye, provides high-quality vision at all distances and in all lighting conditions giving the patient good quantity and quality of vision.
- Combining 2 very similar EDOF IOLs gives the patients an increased depth of focus to a near vision of 30 cm minimizing photopsia.
- Uncorrected and corrected visual acuity at different distances, defocus curve, contrast sensitivity, and patient's satisfaction after bilateral EDOF IOL implantation are reproducible outcomes.

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