Mini WELL
The Progressive EDOF IOL: One Year Later

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Introduction

The Mini WELL IOL (SIFI Medtech), the first progressive aspheric intraocular lens (IOL), incorporates a novel optical design to provide an extended depth of focus (EDOF) from distance to near vision. Published results from in vitro studies show that the Mini WELL delivers good optical quality at distance, intermediate, and near foci and offers some performance benefits when compared with trifocal IOLs and an extended range of vision IOL.1,2

In a satellite education programme during the XXXIV Congress of the ESCRS in Copenhagen, Denmark, speakers shared new data from preclinical and clinical investigations of the Mini WELL IOL. Summarised in this supplement, their reports provide additional evidence of the unique optical characteristics of the Mini WELL IOL and demonstrate its excellent clinical performance in terms of functional and safety outcomes. Experienced surgeons also share insights on patient selection and other considerations for optimising success.

REFERENCES:

New Preclinical Optical Assessments

David P Piñero PhD

Results from optical bench testing confirm that the progressive aspheric Mini WELL IOL generates both negative primary spherical aberration and positive secondary spherical aberration, a combination that significantly increases depth of field, said David P Piñero PhD.

In addition, the laboratory measurements show that with increasing pupil size, the level of higher-order aberrations (HOAs) generated by the Mini WELL remain within a physiological range. This aberrometric profile distinguishes the Mini WELL from other presbyopia-correcting IOLs that induce increasing HOAs as the pupil size increases.

“Because the Mini WELL maintains a similar aberrometric profile with increasing pupil size, it may be expected to have reduced potential for causing photic phenomena and night vision disturbances. Data collected in clinical studies of the Mini WELL are consistent with this hypothesis derived from preclinical measurements,” said Dr Piñero, University of Alicante, Alicante, Spain.

Based on findings from ray tracing simulation of the retinal image achieved with the Mini WELL IOL, Dr Piñero also suggested that the novel implant may be an acceptable option in eyes with aberrated corneas, such as in those with a history of non-customised LASIK.

“Our testing indicates that the Mini WELL generates an optimum level of intraocular optical quality in post-LASIK eyes. Now its performance needs to be confirmed in clinical studies,” Dr Piñero said.

DESIGN AND ABERROMETRIC CHARACTERISATION

The Mini WELL IOL has an overall diameter of 10.75 mm, a 6.0 mm optic, an equivalent addition of +3.00D, and is available in powers of 0.0 to 30.0D. The wavefront-engineered optic is designed to introduce an appropriate spherical aberration at the pupil’s centre and to control HOAs at the pupil’s periphery in order to increase the depth of focus and generate a progressive multifocality. The optic consists of three zones – a central zone with positive spherical aberration, a middle zone with negative spherical aberration, and an outer aspheric monofocal zone.

To confirm that the Mini WELL provides different types of spherical aberration in its central and middle zones, Dr Piñero and colleagues measured the IOL’s wavefront aberrations using a Hartmann-Shack Sensor and a device specifically designed to maintain the IOL’s position and its temperature close to physiologic values.

Aberrometric characterisation was also carried out for the Mplus X (Oculents), a rotationally asymmetric refractive multifocal IOL, and the TECNIS Symfony Extended Range of Vision IOL (Abbott Medical Optics). For each IOL, a 20D implant was tested, and third, fourth, fifth and sixth order Zernike coefficients were analysed for 3.0, 4.5 and 6.0 mm pupil sizes.

The results showed that at the 3.0 mm aperture, the Mplus X generated vertical coma and vertical trefoil, whereas the Mini WELL and Symfony IOLs did not generate any third order aberrations. “The Mplus X IOL induces primary coma that induces a significant increase in depth of field, but its induction in significant amounts can also degrade visual quality,” Dr Piñero said.

The three diagrams show an increase of HOAs with increased pupil size in Mplus and Symfony IOLs. The level of HOAs is maintained within a physiological range with increased pupil size in the Mini WELL IOL, i.e. potential less photic phenomena and night vision disturbances.
The Mini WELL generated negative primary (fourth order) and positive secondary (sixth order) spherical aberration, whereas neither the MPlus X or Symfony IOLs generated fourth or sixth order aberrations.

At the 4.5 mm aperture, the MPlus X was again the only IOL that generated third order aberrations, which included vertical coma, vertical trefoil, and vertical pentafoil. Again, the Mini WELL generated negative primary and positive secondary spherical aberration, while the Tecnis Symfony also generated negative primary spherical aberration at this larger aperture.

“The Symfony IOL design incorporates some negative spherical aberration to compensate for the positive spherical aberration of the cornea. This negative spherical aberration was not seen, however, at the smaller, 3 mm pupil size,” Dr Piñero said.

Analyses of data collected at a 6.0 mm aperture showed that the Mini WELL still induced negative primary spherical aberration and positive secondary spherical aberration without generating other aberrations. The MPlus X was associated with induction of vertical and horizontal coma and trefoil along with some other fourth and fifth order aberrations. Negative primary spherical aberration was generated by the Symfony IOL along with some horizontal trefoil and some fifth and sixth order aberrations.

Analyses of total RMS by Zernike order showed that for the Mini WELL levels of fourth and sixth order aberrations (which relate to primary and secondary spherical aberration, respectively) decreased slightly as pupil size increased.

“The Mini WELL is the first IOL in which spherical aberration decreases with pupil size, and this is the opposite of what we would expect,” Dr Piñero said.

Multifocality: Which Place for the Depth of Focus IOLs?

Pascal Rozot MD

Cataract surgery patients who are interested in presbyopia correction are benefitting from the availability of multifocal IOLs (MIOLs) with refined optic designs and new depth of focus IOLs (DOF IOLs), said Pascal Rozot MD.

It is important, however, for surgeons to understand the optical performance of the different lens types because the information serves as a basis for individualizing implant selection.

In his presentation, Dr Rozot gave an overview of MIOLs and DOF IOLs and discussed his current strategy for choosing between these types of presbyopia-correcting IOLs according to different patient characteristics.

“Refractive cataract and clear lens surgery aims to both correct distance vision and compensate for presbyopia, and with careful case selection, about 90% of patients implanted with a current-generation MIOL will achieve spectacle independence. However, certain features of MIOLs, including gaps in intermediate vision for bifocal MIOLs, reduced contrast sensitivity, and the potential for photic phenomenon, may pose limitations to the use of MIOLs,” said Dr Rozot, Clinique Juge, Marseille, France.

“The DOF IOLs may overcome some of the drawbacks of MIOLs and therefore may have extended indications for implantation. The DOF IOLs may also provide better quality vision. However, these lenses are still relatively new, and more studies are needed to understand their role,” he added.

MIOL EVOLUTION

Dr Rozot noted that quality of far and near vision with traditional diffractive MIOLs has been improved with techniques that include apodization, diffraction smoothing, spherical aberration correction, and compensation for chromatic aberration. In addition, the gap in intermediate vision associated with bifocal diffractive IOLs has been addressed by lowering the add power and with the introduction of trifocal diffractive IOLs.

Developments have also occurred in the design of refractive multifocal IOLs, and currently available models with a sectorial optic provide a good binocular defocus curve, Dr Rozot said.

DOF IOLs

DOF IOLs are represented by implants from several manufacturers that use different optical principles. The category includes the Info Instant Focus (SAV-IOL), which works on the same principle of a diffractive
INDICATIONS FOR MIOLs AND DOF IOLs

In general, the DOF IOLs may provide better contrast and less risk of photic effects compared with the MIOLs. In addition, they are associated with very good quality far and intermediate vision. As a possible drawback, near vision may be weaker with the DOF IOLs than with MIOLs.

“Patients choosing a DOF IOL should be willing to accept the possibility of wearing glasses for sustained near vision tasks,” Dr Rozot said.

“Near vision with the DOF IOLs, however, depends on the effective addition of the lens and may be improved with a micro-monovision strategy targeting slight myopia (-0.5D to -0.75D) in the nondominant eye,” he added.

Outlining his current strategy for choosing IOLs for presbyopia correction, Dr Rozot said that because reduced contrast sensitivity with MIOLs can compound the loss from age-related macular senescence, he considers age older than 80 years a relative contraindication for implantation of MIOLs.

“DOF IOLs, particularly when implanted with a micro-monovision strategy, may have a role in these older patients,” Dr Rozot said.

At present, MIOLs remain his choice for presbyopia correction in most patients who are younger than 80. Because of their potential to cause photic effects, however, he considers MIOLs relatively contraindicated in patients who do a lot of driving at night.

Dr Rozot said that DOF IOLs should be explored as an option in the group of cataract surgery patients <80 years, and he suggested they may be a reasonable choice for patients in this age group where there are concerns about photic effects with a MIOL.

“With DOF IOL implantation for the latter patients, both eyes should be targeted for emmetropia so as not to impair far vision when driving at night,” he said.

Dr Rozot also suggested the DOF IOLs may be considered in other groups of patients for whom MIOLs would be contraindicated because of concerns about reduced contrast sensitivity. These candidates would include patients with ocular hypertension who have no evidence of glaucoma or family history of glaucoma and anyone who has undergone successful retinal surgery for epimacular membranes.

Dr Rozot was cautious about proposing these indications, however, as he noted the need for more DOF IOL outcomes data.

RESULTS: Reading Speed (Radner chart)

The Mini WELL allows up to 90% of implanted patients to read book size fluently without correction

“Furthermore, it remains unknown whether there are any clinical parameters able to predict outcomes after multifocal IOL implantation. Therefore, we are analysing our data for possible correlations between preoperative ocular characteristics and postoperative outcomes.”

Keratometry, axial length, anterior chamber depth, lens thickness, anterior and posterior corneal aberrometry, corneal asphericity, pupil size under different lighting conditions, and angle kappa (pupil decentration) were examined as possible predictors of visual performance.

The study included 164 eyes of 97 patients. The patients had a mean age of 68.6 years, and 67 patients were operated on bilaterally. Mean keratometry was 43.6±1.6D, mean axial length was 23.5±1.1 mm, and mean IOL power was 21.1±2.8D (range 10.0 to 29.0D).
Clinical outcomes were assessed at one to two months after surgery and included logMAR corrected distance visual acuity (CDVA), logRAD distance corrected near visual acuity (CNVA), reading speed at 40 cm using the Radner chart, monocular defocus curve, monocular contrast sensitivity, and an objective assessment of halo using proprietary software, Halo v.1.0 (University of Granada). Postoperatively in monocular testing, mean CDVA was 0.02±0.07 logMAR (~20/20 Snellen) and mean CNVA was 0.38±0.15 logRAD. Data from binocular testing in patients who were bilaterally implanted showed the CDVA and CNVA achieved by patients who received the Mini WELL IOL in both eyes was significantly better than the values recorded in monocular testing. Mean binocular CDVA was 0.00±0.05 logMAR (P=.02 vs monocular), and mean binocular CNVA was 0.27±0.13 (P=.0002 vs monocular).

Results from the reading test provided further confirmation of the good near vision performance achieved with the Mini WELL and again showed improved outcomes with bilateral implantation. “As we expected, the patients implanted with the Mini WELL IOL also achieved a higher reading speed at all print sizes compared with a control group of patients who were implanted with an aspheric monofocal IOL (AcrySof IQ SN60WF, Alcon),” Dr Savini said.

Book print size (0.5 logRAD) could be read fluently (≥80 words per minute) by 90% of patients, while fluent reading performance was possible at print size as small as 0.27 logRAD.

“From a practical point of view, we might want to know how many patients were able to read a book without glasses. Not only did we find that almost all patients could read book size print fluently, but their average reading speed was 140 words per minute, which is quite high,” Dr Savini said.

Dr Savini also compared the monocular defocus curve for the patients implanted with the Mini WELL IOL and the monofocal IOL-implemented controls. It showed the progressive IOL was associated with the same or better visual acuity than the monofocal IOL at all levels of defocus, and the curve for the Mini WELL was progressive with no gaps at intermediate distances.

“We know that multifocal IOLs with a traditional bifocal optic design are associated with low visual acuity for intermediate vision. In contrast, the monocular defocus curve for the Mini WELL shows an extended depth of focus with visual acuity of better than 20/40 maintained between 0 and -2.0D of defocus,” Dr Savini said.

Monocular contrast sensitivity testing showed that results for eyes implanted with the Mini WELL were within normal limits at all spatial frequencies. The results from the objective assessment of halos showed patients experienced minimal disturbance from night vision phenomena, and there was only a single patient who complained of halo.

**PROGNOSIS VARIABLES**

The analyses to identify possible predictors of outcomes included data from 30 eyes operated on by Dr Savini. The results identified a statistically significant correlation between corneal spherical aberration measured at 5.0 mm and near visual acuity (r=.65; P=.0001), such that the lower the positive spherical aberration, the better the defocus at -2.0D. “In other words, eyes with a prolate cornea that have low positive spherical aberration achieved higher near visual acuity,” Dr Savini said.

A statistically significant correlation was also found between near focal distance and corneal spherical aberration (r=0.75; P<.0001) in which eyes with prolate corneas showed a closer near focal distance.

“A possible explanation for these findings is that cornea-induced spherical aberration adds to the IOL-induced spherical aberration,” Dr Savini proposed.

“Further studies are needed, however, to elucidate the role of corneal spherical aberration in visual performance of the Mini WELL.” Other analyses showed that the defocus curve was not influenced by axial length as the curves for eyes with axial length <23.47 mm and longer eyes overlapped each other.

“What this means is that the Mini WELL may be the first progressive IOL that can provide the same near vision performance in long and short eyes,” Dr Savini said.

Near vision was not influenced by pupil size, and no correlations were found between pupil decentration and either CDVA or contrast sensitivity.
Results from a prospective study show that the Mini WELL progressive aspheric IOL provides excellent distance and good near vision without sacrificing intermediate vision, said Eugene Ng MD.

Analyses of the collected data also indicate that the Mini WELL performs particularly well in patients with a steeper (regular) cornea. In addition, they support a micro-monovision strategy for optimising near vision outcomes.

Dr Ng, Institute of Eye Surgery, Waterford, Ireland, noted that he became interested in investigating the clinical performance of the Mini WELL IOL because the implant’s unique optical characteristics set it apart from other presbyopia-correcting IOLs. Together with Dominique Pietrini MD, Paris, France, Dr Ng planned a study enrolling patients who were suitable candidates for and consented to non-femtosecond laser cataract surgery with implantation of a multifocal IOL. Because the study did not aim to correct all existing astigmatism, patients were excluded from participation if they had >1.0D of astigmatism. Patients with any cornea disease, macular disease, or history of ocular surgery were also excluded.

Patients underwent a comprehensive ocular examination at baseline and returned at one week, one month, and three months after surgery. Data collection at the earliest follow-up visit included measurement of unaided visual acuity, manifest refraction, and adverse events. At one and three months, wavefront aberrometry, contrast sensitivity, and defocus curves were also assessed.

The study included 34 bilaterally implanted patients who had a mean age of 71 years, mean axial length of 23.0 mm, and mean keratometry of 43.9D. Mean IOL power was 23.1±2.0D and mean target refraction was -0.09±0.17D.

“The demographic and clinical characteristics of the patients in the study were fairly typical of a cataract surgery cohort. Considering our previous experience with multifocal IOLs, we tended to recruit patients who were a little hyperopic. The outcomes of our study showed, however, that the shorter eyes did not have any particular advantage over longer eyes,” Dr Ng said.

Data from the three-month visit showed mean ±SD decimal (Snellen) uncorrected distance visual acuity was 0.77 (20/26) in monocular testing and 0.86±0.15 (20/23) binocularly.

With eyes divided into two groups based on axial length, there were no statistically significant differences in best corrected distance visual acuity outcomes at any level of defocus comparing eyes shorter than 23.5 mm versus longer eyes.

“Our data showed the Mini WELL is very forgiving to a low level of refractive error. Patients maintained excellent visual acuity at +0.5D and -0.5D of defocus, suggesting it may be particularly advantageous to use a micro-monovision strategy for implanting the Mini WELL IOL,” Dr Ng said.

Defocus curves plotted with eyes categorised by keratometry showed eyes with K values >43.5D performed even better than those with less steep corneas. The between-group differences in visual acuity were statistically significant at -1.0D and -1.5D defocus and trended toward significance for shorter distances (between -2.0 and -3.0D of defocus).

“We employed this favourable tolerance and forgiving nature of the IOL to enhance binocular distance and near vision outcomes by fine-tuning the refractive target in the second eye based on the result in the first eye,” Dr Ng said.

“Therefore, a patient with a slight refractive surprise of >0.5D after the first eye surgery could achieve 0.8 (20/25) distance visual acuity with excellent near reading vision when the second eye is implanted with a micro-monovision strategy targeting slight myopia. In two other cases where there was a myopic refractive surprise in the first eye, we aimed for a slightly hyperopic target in the second eye rather than considering an enhancement for refractive error correction. Both patients wound up with excellent distance and near vision,” he reported.

Results from unaided monocular and binocular testing of reading vision showed the improvement achieved with both eyes was far better than the one-line gain that would be expected from binocular summation.

“The near vision outcomes reflect not only the benefit of binocular summation but also how forgiving this IOL is and how employing a micro-monovision strategy for the non-dominant eye can result in far better binocular near vision,” Dr Ng said.

PATIENT SELECTION

In planning surgery with the Mini WELL IOL, Dr Ng said it is important to choose patients carefully based on visual potential. Therefore, he excludes patients whose cornea is not clear and unless they have a pristine macula. In addition, he cautions surgeons to beware of emmetropes or low myopes who have only a mild cataract in one eye, because such patients might be dissatisfied when they compare their vision in their implanted eye and their fellow unoperated eye.

When performing bilateral surgery and unless the eye is highly hyperopic, Dr Ng usually operates on the dominant eye first and aims for 0.0D. In high hyperopes, he operates on the non-dominant eye first and targets -0.5D. He also plans to correct as much astigmatism as possible, especially when operating on the dominant eye.

When it is time to operate on the second eye, Dr Ng chooses his refractive target based on the refractive outcome of the first eye and taking into account its distance vision and reading performance.
Clinical results from an initial series of patients implanted with the Mini WEL IOL show that this progressive aspheric IOL provides excellent far and near visual acuity along with good intermediate distance vision. In addition, the data show the Mini WEL IOL is associated with a very low incidence of unwanted optical phenomena and a high degree of patient satisfaction, said Gerd U Auffarth MD, PhD.

“The clinical performance of this presbyopia-correcting lens is really very good and the low incidence of optical side effects is astonishing,” said Dr Auffarth, International Vision Correction Research Centre, University of Heidelberg, Heidelberg, Germany.

“Of course, further assessment is needed with longer follow-up in a larger group of patients. Prospective randomised trials comparing the Mini WEL IOL with other IOLs are ongoing, and we are looking forward to seeing the results.”

The data presented by Dr Auffarth were collected from a series of 27 eyes of 14 patients operated on at the University Eye Clinic Heidelberg. The patients had a median age of 66 years (range 52 to 82 years) and a median preoperative spherical equivalent of 0.50D (range -7.75 to 4.88D).

Visual acuity testing was performed with ETDRS charts, and Dr Auffarth reported mean ± standard deviation logMAR values from evaluations performed at two to four months postoperatively. The results for uncorrected distance visual acuity and corrected distance visual acuity were 0.13±0.13D (~20/25 Snellen) and 0.00±0.12D (20/20), respectively.

Intermediate visual acuity measured at 80 cm averaged 0.01±0.17D (~20/25 Snellen) without correction and 0.04±0.19 with correction.

Mean uncorrected near visual acuity was 0.17±0.21D (~20/25 to 20/30) and mean distance-corrected near visual acuity was 0.22±0.21D. Corrected near visual acuity averaged -0.02±0.14D with a mean minimum add of 1.50D. The binocular defocus curve showed that logMAR visual acuity 0.20 or better was maintained from 0.0D to almost -3.0D, Dr Auffarth reported.

The outcomes evaluations also included an objective assessment of reading performance using an electronic reading desk (Salzburg Reading Desk). The testing evaluates reading acuity at near and intermediate at both fixed and the patient’s preferred distance.

Results from binocular testing without correction showed median reading acuity (logMAR) was 0.10 at the fixed distance of 40 cm and 0.13 at the patients’ preferred near reading distance of 39.5 cm. For intermediate testing, median reading acuity was 0.11 at both the fixed distance of 80 cm and at the patients’ preferred reading distance, which was 62.8 cm. “These data show us that 80 cm is not a realistic distance to target when designing lenses to provide good intermediate vision,” Dr Auffarth said.

**Results: Representation of Mean Values**

<table>
<thead>
<tr>
<th>Mini WEL EDOF IOL</th>
<th>Near Distance (cm)</th>
<th>Preferred Near</th>
<th>Intermediate (80 cm)</th>
<th>Preferred Intermediate</th>
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<td>Distance (cm)</td>
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<td>1.90</td>
<td>1.90</td>
<td>1.29</td>
<td>1.06</td>
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</tbody>
</table>

Excellent values of visual acuity at each of the analyzed distances.

**Halo and Glare Assessment with the Mini WELL EDOF IOL**

Halo and glare assessment was conducted using a proprietary Halo & Glare Simulator (Eyeland-Design Network). With this platform, patients can reproduce the type, size, and intensity of any halos, starburst, and glare they are experiencing.

“The settings selected by the patients for size and intensity of the photic phenomena essentially gives us visual analogue scale-like data that we can use to quantify these side effects,” Dr Auffarth said.

The median value for both size and intensity of halos was 10.5 and 34.0, respectively.

“Halo were essentially absent in these patients and glare occurred at a very low level. Corresponding with these data, only one patient expressed complaints when responding to a question about problems with photic effects during daily activities,” Dr Auffarth said.

Dr Auffarth also presented data showing that reports of halo and starburst were less common among patients implanted with the Mini WEL IOL compared with groups implanted with other IOLs that are designed to provide a continuous range of vision (AcrySof IQ Panoptix trifocal IOL, Alcon; Tecnis Symfony Extended Range of Vision IOL, Abbott Medical Optics) and even compared to a monofocal IOL (Aspira, HumanOptics AG).

Among 14 patients implanted with the Mini WEL IOL, 50% reported no halo or starburst, 30% reported halo, and 22% reported starburst. Data from ten patients implanted with the Panoptix and from seven recipients of the Symfony showed that with either lens, about 40% of patients perceived halos and the rest perceived starburst.

Among 12 patients implanted with the Aspira monofocal lens, only 2 patients (17%) reported no problems with halo or starburst, while 4 patients (33%) reported halo, and 6 (50%) perceived starburst.

“Although it is often said that photic effects are not a problem with monofocal IOLs, these data and our clinical experience tell us that is not true,” Dr Auffarth said.

Images from the Halo & Glare simulator depicting mean values associated with each IOL provided further demonstration of the differences between the Mini WEL and the other presbyopia-correcting IOLs. Even more striking was a side-by-side comparison of the perceptions of patients who for each of the lenses were experiencing the worst photic phenomena.

“Understanding the maximum values is important because it is these patients who are going to be complaining and dissatisfied,” Dr Auffarth said. “Looking at the representation of the maximum values reported by patients implanted with the Mini WEL and comparing it with the other lenses, we see the Mini WEL performs very well,” he added.