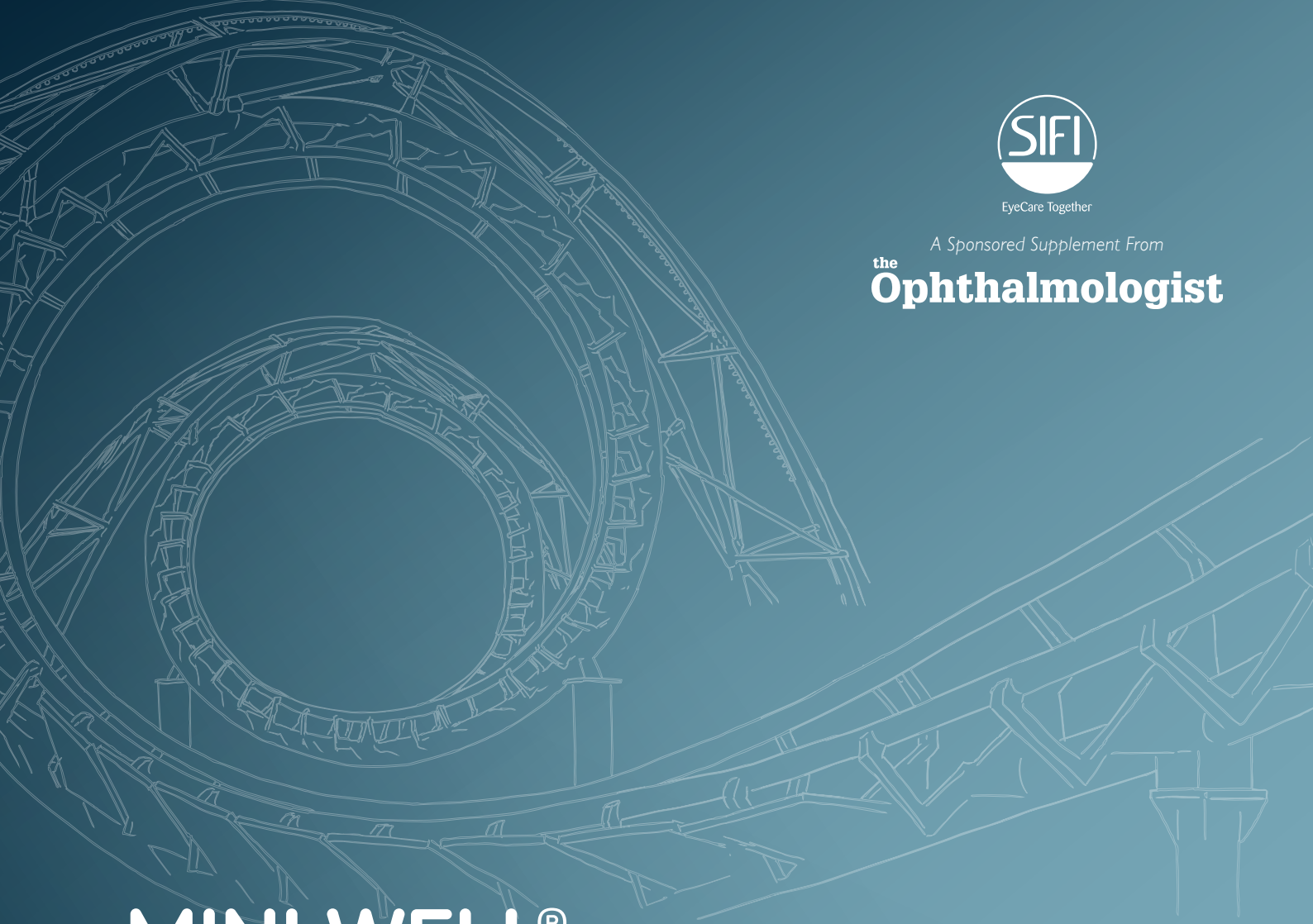

SIFI
EyeCare Together

A Sponsored Supplement From
the Ophthalmologist

MINI WELL®
A Better Vision

Highlights from the Milan 2017 SIFI User Meeting

Panel

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This supplement reflects the opinions and experiences of meeting participants in Milan on May 25, 2017. Data presented are representative of each participating surgeons' own experience, and do not arise from formal clinical studies. Trademarks are the property of their respective owners.

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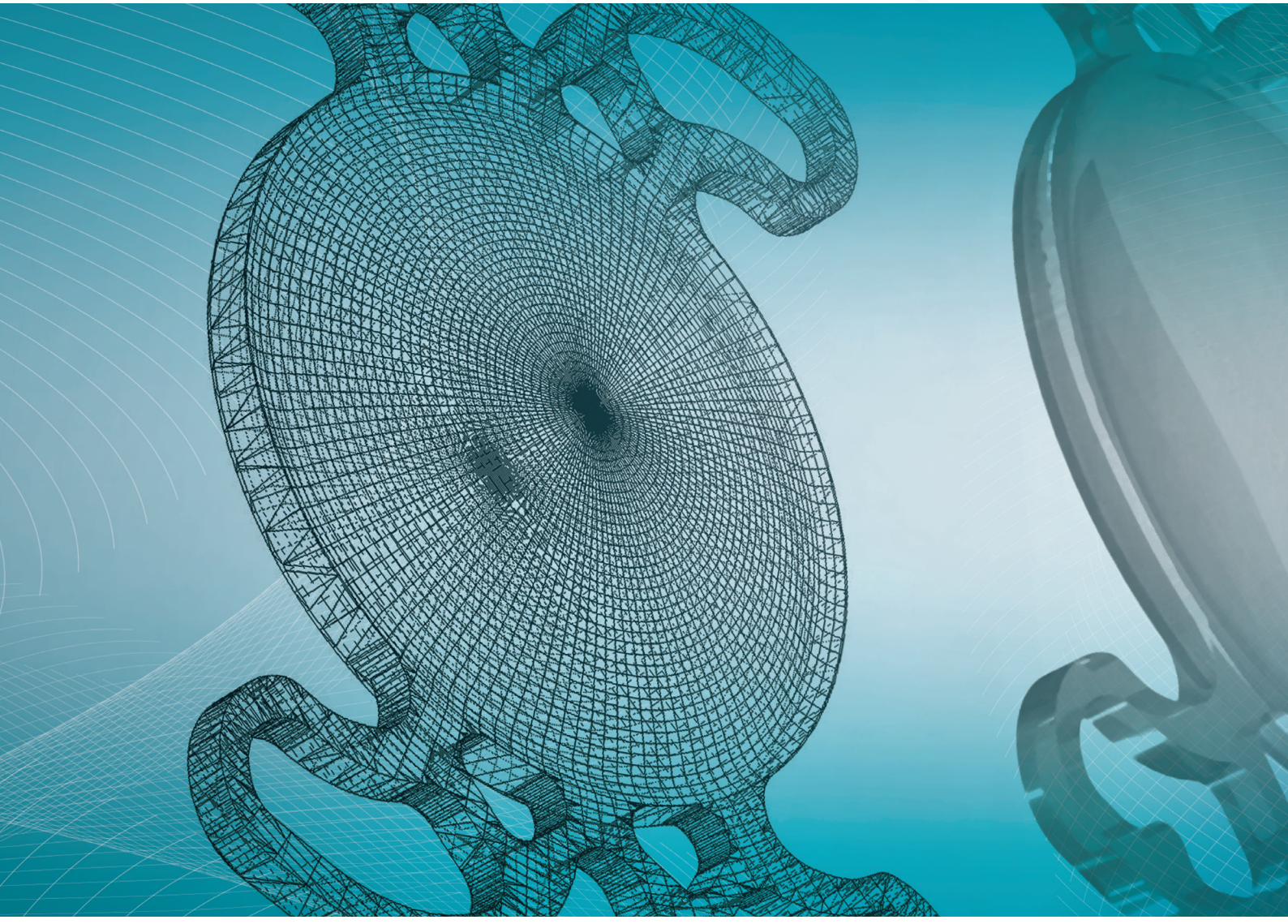
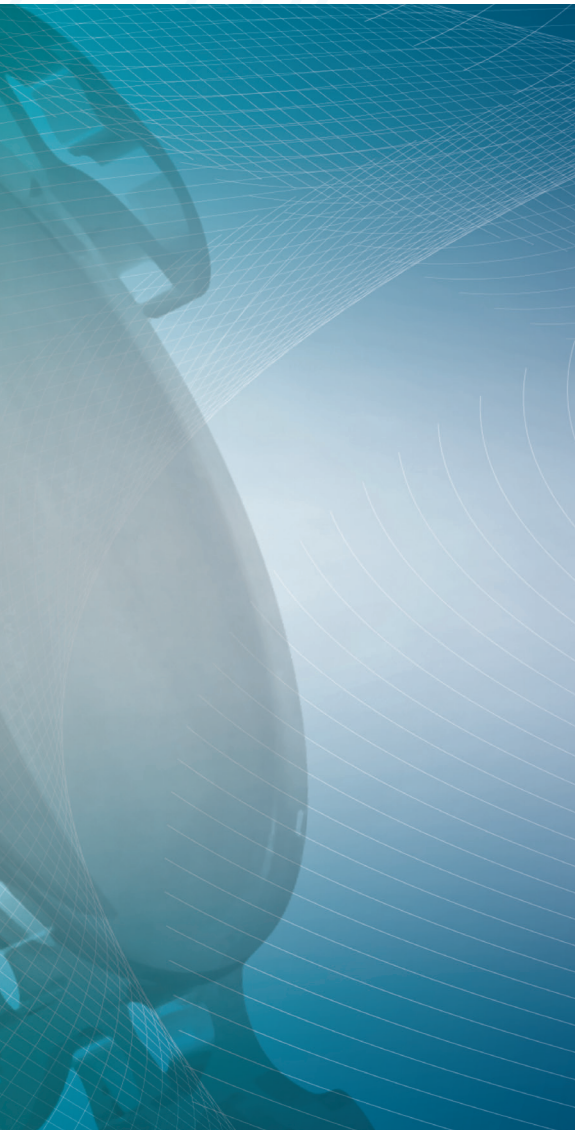


Generation Xchange

Presbyopia correction should be one of the biggest markets in eyecare. Presbyopia is the most common refractive disorder in people aged 40 years and over, and it's a very noticeable sign of aging: reaching for the reading glasses when you never had to before. Many people undergoing cataract surgery – the most commonly performed elective surgical procedure in the developed world – also want to be spectacle-free after the procedure. In both cases, exchanging the natural crystalline lens with a multifocal intraocular lens (IOL) can give these patients what they desire – and it's clear that there's a growing market for multifocal IOLs for both refractive lens exchange (RLE) and in "premium" cataract surgery for "Generation Xchange." Advances in IOL optic designs and improvements in biometry, aberrometry and the introduction of femtosecond laser-assisted cataract surgery (FLACS) has helped increase the adoption of these lenses, as well as patients' refractive outcomes. However, the market isn't nearly as large as it could be – and part of the reason for this could be due to some of the drawbacks associated with what might be termed "traditional" IOL designs with diffractive optics or that include apodization – principally photic phenomena. What this means is you have to be very careful with patient



selection – in terms of both physical and mental inclusion and exclusion criteria – to ensure you have a happy patient after the surgery. This definitely limits the market. Could a more advanced IOL design minimize these drawbacks and expand the market? The first SIFI MINI WELL® Users' Conference was convened against this background. Thirteen leading cataract surgeons, led by Vittorio Picardo, came together in Milan in May 2017 to discuss these issues and more.

The ideal psychological profile

It's long been clear that ophthalmic surgeons who offer premium refractive/cataract surgery need to be not only skillful at the surgery, but also at understanding the psychology of the patients that present to them. Nicola Passarelli was clear: "Our job is to interpret the real needs of the patient, and match those to the available IOL options" – and this means 'chair time.' If cost isn't a consideration, the first question to address is this: how motivated is the patient with regard to achieving independence from spectacles? If the answer to that question is 'not very', consider implanting a monofocal IOL, as this patient type will be content to use spectacles.

It is very challenging to understand a patient's psychology; reaching a true understanding of their character and of what they expect from the procedure. It all requires a lot of chair time.

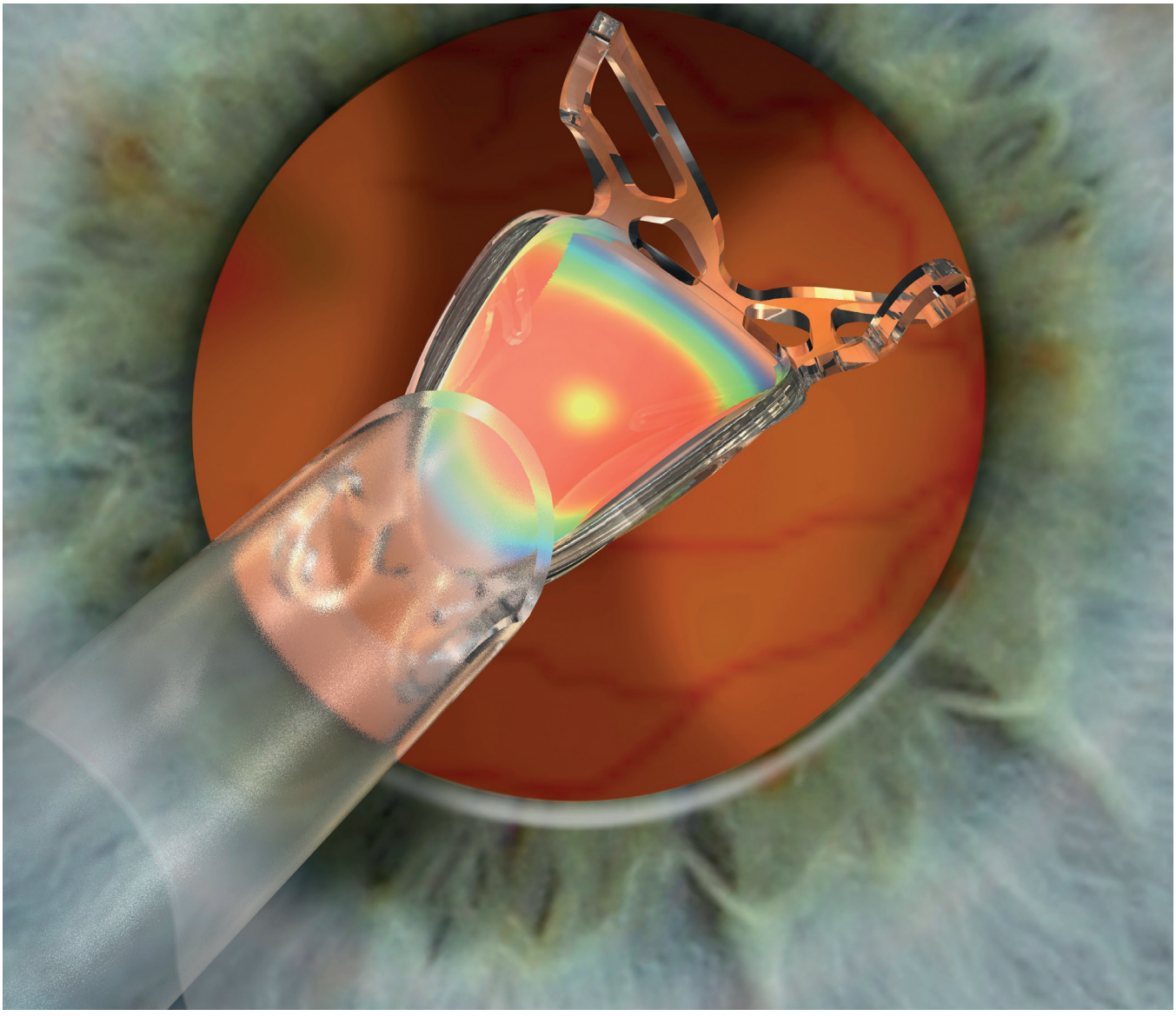
Even if your patient has the right personality (easy-going patients are ideal candidates), there are other factors that can trip you up. You need a comprehensive understanding of your patient's lifestyle – and again, this takes chair time. Passarelli detailed the most pertinent questions to ask: "At what distance do they read, under what illumination, and by what medium? Smartphones and newspapers are typically read at different distances – and today, more newspaper articles are read on phones than in print. Do they drive – in particular, do they drive often at night? What are their activities and hobbies?" You have to understand these aspects of a patient's life before you can select – with due regard to the compromises and drawbacks associated with most currently available products – the most appropriate IOL for them. Surgeons who skimp on chair time risk ending up with a patient who has paid a premium price for a premium procedure but is profoundly dissatisfied.

That said, the state of the art in IOL optics moves on, and it may be possible to offer a solution that will satisfy the majority of patients. The MINI WELL® IOL from SIFI is a true extended depth-of-focus (EDOF) IOL that sidesteps many of the compromises of traditional multifocal IOL designs: it offers a good range of vision from far to near.

So what would an ideal MINI WELL® patient look like, in terms of their psychological profile? Passarelli's description was: "They are quite likely to enjoy an active social life, drive, have hobbies, and play sports. Most will use a personal computer at work, and most probably they will use a smartphone for media consumption. Such personality types are highly likely to be satisfied by the MINI WELL® lens."

The ideal clinical profile

But what of these patients' clinical profiles? Giovanni Alessio detailed some of his inclusion and exclusion criteria for MINI WELL® implantation. He started with the eyelids: blepharitis, ectropion, entropion, blepharospasm and ptosis are all contraindications, as they can have effects not only on corneal topography, but also on the tear film. This raised, in Alessio's opinion, perhaps the most important clinical consideration in IOL implantation: dry eye. "The primary cause of dissatisfaction after the implantation of a presbyopia-correcting (PC) IOL is uncorrected blurry vision – and the main identifiable cause of that is residual refractive error and dry eye syndrome (1)," Alessio explained, before recommending tear film analysis (for example, Schirmer's test and tear film break-up time tests) when assessing patient suitability for MINI WELL®, noting that "Aggressive identification, prevention and the treatment of ocular surface disease can help improve patient satisfaction with PC-IOLs" (2).



Next: the cornea. "You should perform specular microscopy and corneal topography to identify irregular corneas and corneal disease or disorders. The ideal patient should have a cornea free of opacities, dystrophies, and higher order aberrations (HOAs), and should have no history of refractive surgery (although you may wish to consider this on a case-by-case basis). There should be no asymmetry between the corneas (difference K<1 D) (3)", he explained.

Moving on, we reach the lens. "Even though we'll be exchanging it, note that the presence of pseudoexfoliation, subluxation or any zonular weakness contraindicates the use of MINI WELL® as well as multifocal IOLs. Similarly, the presence of vitreous pathologies such as asteroid hyalosis, synchysis scintillans, vitreous amyloidosis or vitreous hemorrhage are also exclusion criteria."

Pupil abnormalities can also cause problems, "and so any pupil abnormality or displacement are contraindications," noted Alessio, before adding, "It's important to bear in mind that, in diffractive lenses at least, an increasing angle kappa (the distance between the center of the pupil and the center of the visual axis) can result in photic phenomena if incident light passes through the ring's edge area (4). In this regards the angle kappa is not a

crucial variable for MINI WELL® due to its innovative (and not diffractive) optic design. Similarly, any strabismus contraindicates a patient too. Another important factor is total corneal astigmatism – anything above ~0.75–1 D tends to negate the multifocal or EDOF effect of these IOLs."

Patients with glaucoma or diabetes tend to make poor candidates for this kind of IOL; it's best to exclude such patients. Alessio reminded the group of the necessity to perform a retinal OCT since the presence of any retinal disease risks poor outcomes and, again, unhappy patients (Box 1).

Pre-operative parameters

Claudio Carbonara summarized the parameters he uses to guide the choice of IOL (Box 2), and emphasized the advantages of modern optical biometers (particularly those that include a swept-source OCT, which can image through posterior and dense cataract and corneal opacities) and aberrometers.

Briefly, critical measurements that should be taken prior to MINI WELL® implantation include total astigmatism, HOA, spherical aberration and corneal asphericity, pupil size, pupil position and angle kappa (although angle kappa may be less critical for the MINI WELL®). It's also important to use modern IOL calculation formulae to analyze your readings, and to run an OCT scan and perform an endothelial cell count. Carbonara gave more detailed advice regarding some of these parameters, as follows.

Corneal asphericity: If Q-values deviate from expected ranges (-1 to 0 for a prolate cornea, and >0 for an oblate cornea), expect refractive surprises! Thus, where Q is <-1, a myopic refractive surprise can be present; and a hyperopic refractive surprise could be present if Q>0. Remember that the IOL power may be underestimated when the corneal asphericity changes from prolate to ablate; if we rely on SRK/T with an abnormal Q value in virgin cornea, the risk of a hyperopic refractive surprise is very high.

Higher Order Aberration: Beware of patients in whom aberrometry identifies coma and trefoil in the cornea to avoid an enormous coma, because the procedure will exacerbate the pre-existing situation. Carbonara avoids implantation of MINI WELL® in such patients.

Formulae: While the old formulae are still valid, consider using the newer Barrett, Olsen and Haigis ones – and that the Barrett Universal 2 formula will be probably the gold standard of the future. A recent paper (5) indicated that while all formulae resulted in some inaccuracies, only the Barrett was good for eyes with axial lengths of >22 mm. That said, the Hoffer Q formula appears to be superior to Barrett in short eyes with axial lengths ≤22 mm. For evaluating axial length in cases of high myopia, however, Carbonara recommended the Koch-Wang formula. "This is very useful, because it converts biometer measurements of axial length into a more correct value." It was developed to obtain a new axial length value – one that can be different if IOL power depending on whether it is calculated with the SRK/T or the Haigis Formula. It goes without saying that relying on uncorrected axial length measurements provided by biometers can result in post-operative surprises like unexpected hyperopia.

Pupil: Don't implant MINI WELL® in pupils that are very small or which have restricted movement, as these pupil types are not good for reading.

In Carbonara's view, the most important measurement is the tear film. "If the tear film is poor, I prefer not to

Box 1. Satisfying Your Patient – Making Things Go Right

- Chair time is crucial! However, the chair time burden tends to be lower for MINI WELL® than for diffractive multifocal IOLs, due to its lower incidence of photic phenomena.
- Re-evaluate pre-operative indications: commonest causes of patient dissatisfaction include biometric error, irregular cornea/ corneal disease, dry eye, strabismus, vitreous pathology, total corneal astigmatism, macular disease, glaucoma and diabetes.
- Secrets of success: respect the indications, perfect surgery, – and in some cases a lot of patience!

Box 2. Pre-operative exams for MINI WELL® implantation

- Topography and aberrometry for corneal asphericity, spherical aberration, HOA, and angle kappa
- Biometry with the correct formula (emmetropia is the refractive target)
- Pupillometry: avoid small or motionless pupils
- OCT and Endothelial cell count
- Do not implant in eyes with pathology, poor tear films, dense/cloudy vitreous body, >0.75 D astigmatism or irregular astigmatism

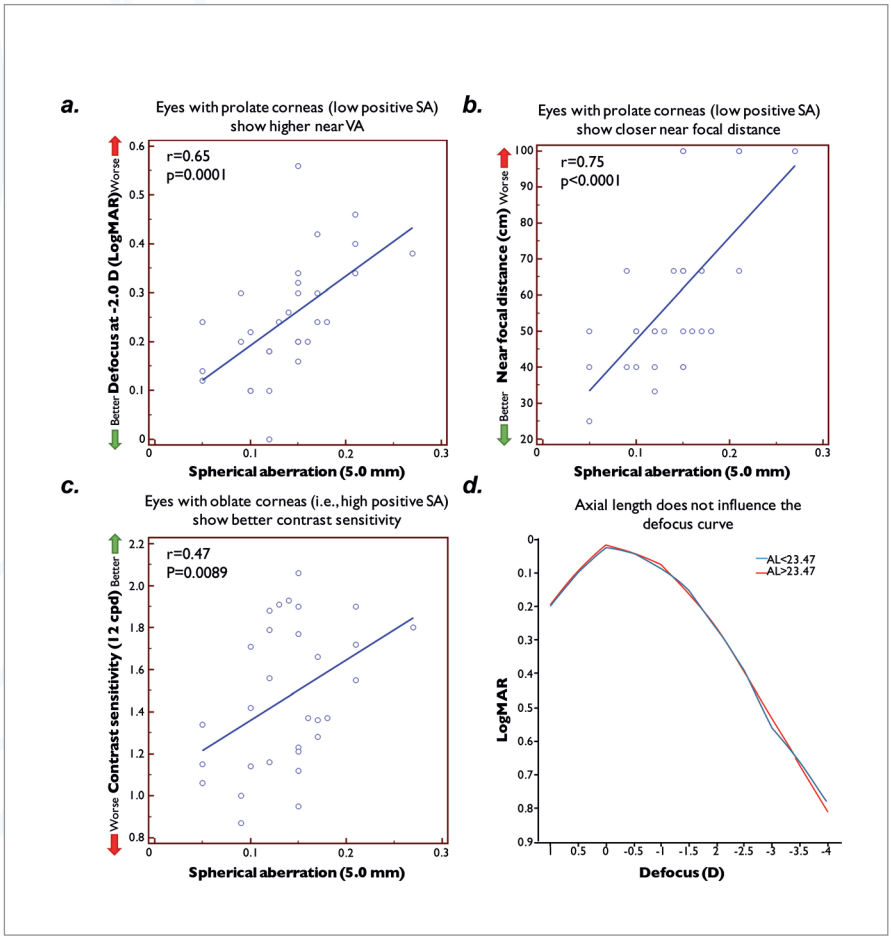


Figure 1. Correlation between preoperative corneal spherical aberration and (a) near visual acuity, (b) near focal distance, and (c) contrast sensitivity. Panel (d) displays the correlation between preoperative axial length and postoperative defocus curve. *Figure courtesy of Giacomo Savini.*

implant MINI WELL® because – within a month of surgery – the patient will complain about discomfort."

Correlation between pre-operative parameters and post-operative results

Giacomo Savini acknowledged that ocular biometry is normally performed in order to optimize the IOL constant and help the surgeon avoid refractive surprises. But here, his presentation featured analysis of biometric data that was used to examine the correlation between preoperative variables and postoperative clinical outcomes. To do this, he analyzed a selection of pre- and post-operative parameters from 30 of his MINI WELL® patients. These parameters (Table 1) represent the routine measurements taken in Savini's clinic when assessing EDOF IOL candidate patients.

Were there any statistically significant relationships between these variables? Yes; one of the most apposite was the correlation between near visual acuity and corneal spherical aberration – better near visual acuity is strongly correlated with lower spherical aberration (Figure 1a; r=0.65; P<0.0001). In other words, eyes with prolate corneas will have better post-operative Near Visual Acuity after MINI WELL® implantation than eyes with oblate corneas. Savini found almost the same result for near focal distance (Figure 1b; r=0.75, p<0.0001) – the closer to zero the corneal spherical aberration, the closer the focal distance for reading, or in other words, eyes with prolate corneas have a closer postoperative near focal distance. However, it's a different story when it comes to contrast sensitivity – the best results are obtained in eyes with higher corneal spherical aberration (i.e., oblate corneas). So in terms of contrast sensitivity at least, eyes with prolate corneas have a better near performance, whereas eyes with oblate corneas have a better distance performance (Figure 1c; r=0.47 p=0.0089).

Why might this be? The answer may lie in MINI WELL®'s optics. We all know that MINI WELL® provides a positive aberration in the center, and a negative one in the mid-periphery (see back cover). "Indeed, we performed some aberrometry, and saw that, on average, the lens provides a negative spherical aberration, so it's possible that a positive corneal spherical aberration compensates for the negative spherical aberration of the IOL, while the opposite occurs with prolate corneas with a less positive, and more negative spherical aberration," explained Savini, noting that "We need to pay more attention to the relationship between corneal spherical aberration (measured through the anterior and posterior surface) and the spherical aberration of the IOL." Further investigations are ongoing to assess such as correlation. He emphasized that this relationship holds only for the MINI WELL®, not for any other multifocal IOL.

That said, Savini reminds the group that "Competing multifocal IOLs have other problems: axial length, for example," adding, "We know that refractive multifocal IOL designs don't work as well in long eyes with a

Pre-operative parameters	*Post-operative parameters (2–3 months after surgery)*
Axial length, keratometry, anterior chamber depth, lens thickness	Corrected distance visual acuity (CDVA) = LogMAR
Corneal aberrometry (anterior + posterior)	Distance corrected near visual acuity (CNVA) = LogRAD
Corneal asphericity (Q-value)	Reading speed (words/min) at 40 cm with Radner's charts
Pupil size (photopic, mesopic, scotopic)	Defocus curve
Pupil decentration (angle kappa)	Contrast sensitivity

Table 1. The pre- and post-operative parameters assessed in Giacomo Savini's study.

deep postoperative anterior chamber (ACD)." In other words, eyes with longer distances between the IOL and the cornea exhibit worse performance for near, because a lower amount of near add power is transferred from the IOL to the corneal plane. The opposite is true for hyperopic eyes, where the lens is closer to the cornea. This was why Savini said he "avoids implanting diffractive multifocal IOLs in long eyes with expected deep postoperative ACD." Interestingly, Savini's data shows that MINI WELL® appears immune to this issue (Figure 1d) – the defocus curve is completely unaffected by axial length, and is exactly the same in long and short eyes. "I think this is a great advantage of MINI WELL® – no today marketed multifocal IOL can achieve this," he said (Box 3).

MINI WELL® "provides a good depth of field, and an incredibly good aberration profile." – Roberto Bellucci

What other issues are known to affect the performance of competing multifocal IOL designs? Can these also compromise the performance of the MINI WELL®? Savini examined the correlation between post-operative measurements and pupil size and decentration, and found no correlation whatsoever between Corrected Visual Distance Acuity (CDVA) and angle kappa (pupil decentration) or near vision and pupil size. "MINI WELL®'s performance is not influenced by pupil size, nor by pupil decentration or axial length." Eugene Ng presented data from another study that aimed at examining the link between pre-operative variables and clinical outcomes. This study took place in two centers, located in France and Ireland respectively.

Ng reported that his findings mirrored those of Savini to the extent that MINI WELL® provides a defocus curve that is favorable even in myopic patients (with longer eyes). "It seems to us that even the longer eyes do as well as the short eyes." This clearly differentiates MINI WELL® from many other multifocal IOLs. However, a closer look at the data suggests that patients with steeper keratometry readings do a little better than the others; this effect is statistically significant at the 1 and 1.5 D defocus values, even with the small number of patients (n=34) in his study: "Patients with steeper K values get an even better defocus curve with the MINI WELL®", he concludes.

The take-home message from this study, said Ng, is that "MINI WELL® lens provides excellent distance and good near vision without sacrificing intermediate vision. Furthermore, the MINI WELL® seems well-suited for improving near vision via a micro-monovision strategy" (Box 4).

Finally, Andrea Bedei presented results from a study of 30 patients (56 eyes) without visual or ocular abnormalities who underwent cataract surgery without any intraoperative complications. Preoperative assessments included corneal spherical aberration (SA), corneal axial length (CAL) and ACD. The visual outcomes of each analyzed parameter were divided into three groups; and the following parameters were analyzed for each group 1–2 months after cataract surgery:

Box 3. Predictable outcomes

Eyes with prolate cornea (low positive SA):

- Show higher Near Visual Acuity
- Show closer Near Focal Distance
- Eyes with oblate cornea (high positive SA):
- Show better contrast sensitivity Axial Length does not influence defocus curve (the progressive vision is maintained even if the AL changes)

Box 4. Eugene Ng's micro-monovision experience

- Start with the dominant eye (be very careful with the IOL power formula that you use); target zero (unless highly hyperopic, in which case, target -0.5 D in the non-dominant eye first)
- Patients will otherwise invariably notice that the dominant eye has "stronger" vision (hence dominant) when compared to the operated eye and attribute the difference to the lens instead of ocular dominance
- Fine-tune the non-dominant eye, based on the first eye's refractive outcome and distance/reading performance, to improve on the first eye's near or distance vision
- This can result in vision improvements far greater than would be expected from binocular summation alone; four-point improvements in the Jaeger reading is common.
- Conclusion: "MINI WELL® lenses are particularly suited for micro-monovision strategy in the non-dominant eye"

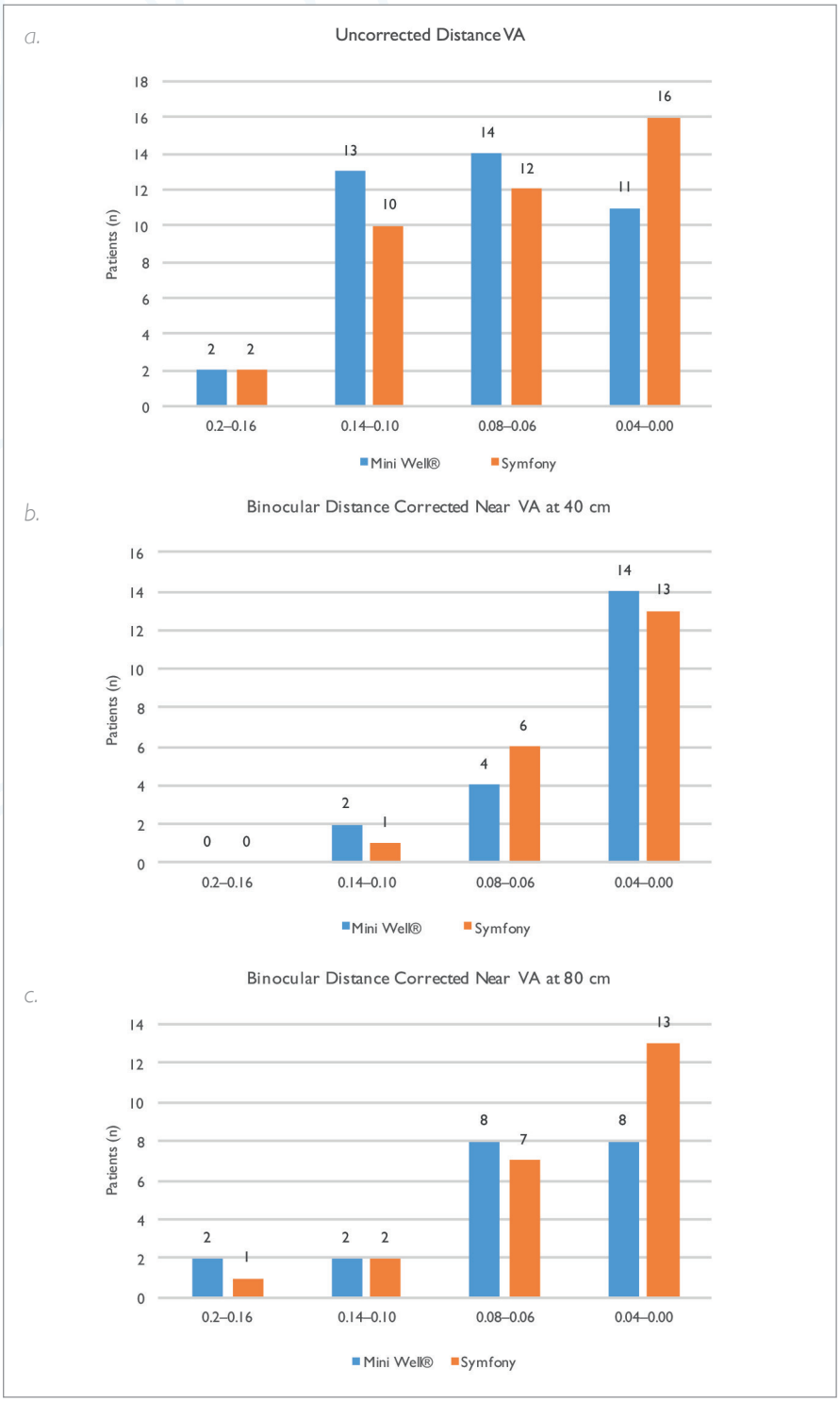


Figure 2. Comparison of MINI WELL® and Symfony: a. Uncorrected Distance Visual Acuity; b. Binocular Distance Corrected Near Visual Acuity at 40 cm, and c. Binocular Distance Corrected Intermediate Visual Acuity at 80 cm. *Figure courtesy of Roberto Bellucci.*

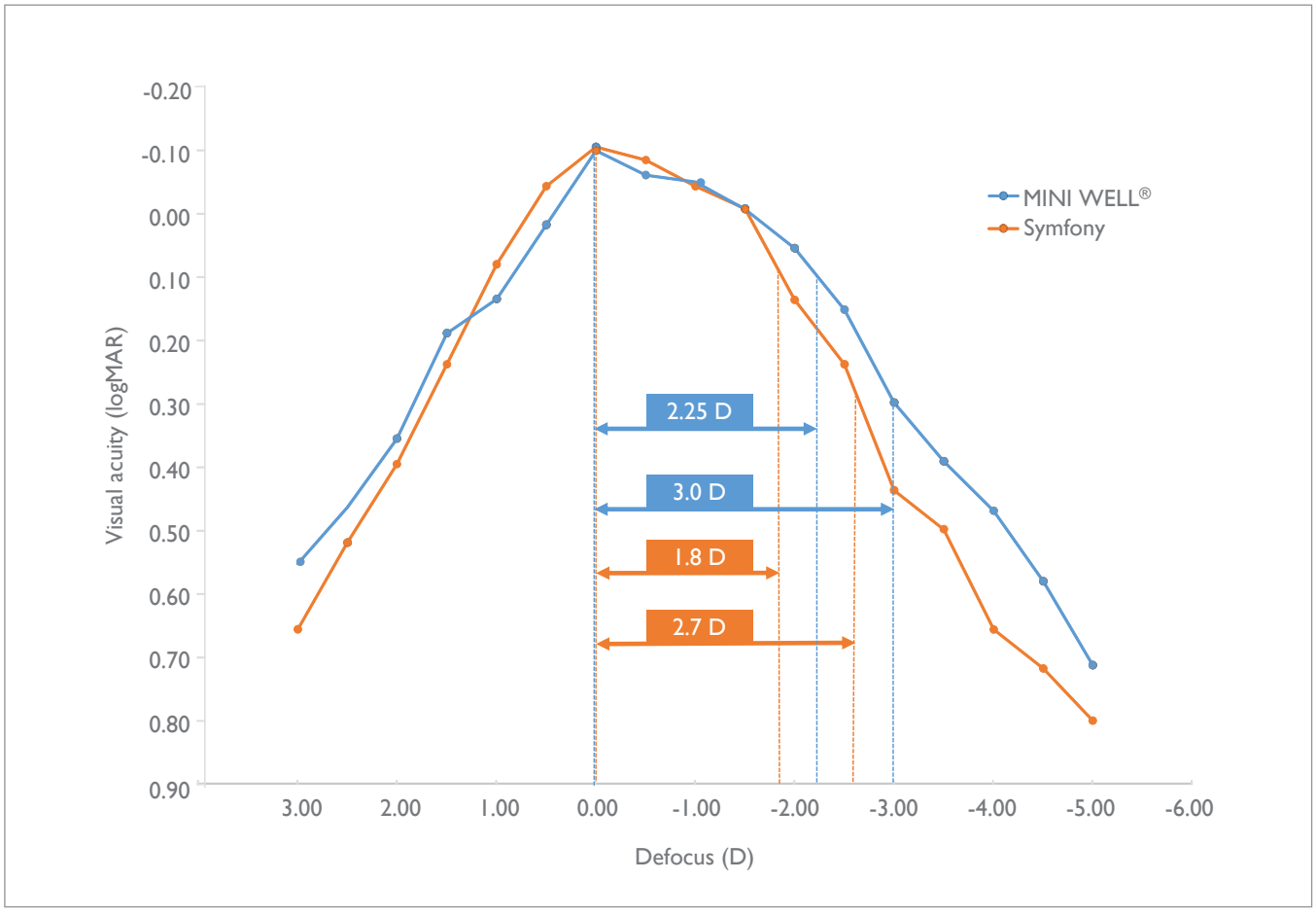


Figure 3. Comparison of MINI WELL® and Symfony defocus curves. *Figure courtesy of Gerd Auffarth.*

- CDVA and Uncorrected Distance Visual acuity (UDVA; both Snellen chart decimal scale)
- Uncorrected Near Visual acuity (UNVA) (at 33 cm, Jaeger chart)
- Contrast sensitivity (Pelli-Robson chart)
- Presence of halos and glares (on a scale of 0–10; with a score of 0 as highest discomfort, and 10, no discomfort).

Bedei's study assessed the mean, median, standard deviation (SD) and interquartile range (IQR) of each parameter, to understand if SA, CAL or anterior chamber depth influenced visual outcomes after MINI WELL® implantation. However, the study is still underway and further analysis will be performed. Nevertheless, data collected to date indicate the following:

- *Pre-operative spherical corneal aberration:* SA has no apparent effect on UDVA, UNVA and contrast sensitivity; however, higher SA is associated with more glares and halos.
- *Ocular axial length:* Has no apparent effect on outcomes.
- *Anterior chamber depth:* Does not seem to affect UNVA and contrast sensitivity, whereas UDVA, glares and halos seem to increase when the ACD is deeper.

To date, outcomes are as follows:

- UDVA: 8.6/10±1.78
- UNVA: 5.7±2, 87 (Jaeger character for single eye at 33 cm)
- Contrast sensitivity: 3.7%±3.57
- Glares and halos: 8.8/10±1.51

Bedei concluded by saying, "MINI WELL® IOLs have shown excellent visual outcomes with minimal disturbances."

Common implantation procedures

Scipione Rossi reviewed his steps for success when implanting MINI WELL®.

Use a femtosecond laser

Rossi firmly believes in the advantages of FLACS: precise, centered capsulotomies that result in a more predictable effective lens position, less IOL decentration and tilting, less PCO and less capsular bag contraction – resulting in better refraction stability and ensuring that the patient receives the best-possible quality of vision. Further, "Performing corneal clear incisions with the femtosecond laser gives you a highly predictable incision size, with low thermal and mechanical trauma, and self-healing wounds. It reduces the risk of endophthalmitis and surgically-induced astigmatism, which is dependent on corneal incision size, location and healing," explained Rossi, noting that, "In general, FLACS causes less zonular stress than standard cataract surgery and is very suitable for the MINI WELL®."

Use a good injection system

Rossi uses the disposable injector, included in the MINI WELL® box, for incision sizes under 2.4 mm, which enables him to modulate the speed of lens insertion by the pressure he places on the injector piston, and has the added advantage of also helping to avoid surgically-induced astigmatism.

He has implanted about 100 MINI WELL® with 2 years of follow up and over 90 percent of patients remain spectacle-free, with high levels of patient satisfaction.

Symfony	Near (40 cm)	Preferred near	Intermediate (80 cm)	Preferred intermediate
Median uncorrected binocular (n=15)				
Visual acuity (logMAR)	0.17	0.10	0.09	0.08
Distance (cm)	40.60	41.00	80.30	65.30
Letter size (log-scaled)	0.63	0.63	0.80	1.25
Median distance-corrected binocular (n=15)				
Visual acuity (logMAR)	0.29	0.16	0.00	0.08
Distance (cm)	40.60	41.70	80.10	65.00
Letter size (log-scaled)	0.50	0.63	1.00	1.00
MINI WELL®				
Median uncorrected binocular (n=13)				
Visual acuity (logMAR)	0.10	0.13	0.11	0.11
Distance (cm)	40.30	39.50	79.20	62.80
Letter size (log-scaled)	1.25	1.25	1.25	1.00
Median distance-corrected binocular (n=13)				
Visual acuity (logMAR)	0.21	0.19	0.10	0.12
Distance (cm)	40.30	38.90	79.40	60.00
Letter size (log-scaled)	1.50	1.50	1.25	1.00

Table 2. Comparison of uncorrected and distance-corrected binocular reading performance of MINI WELL® and Symfony. *Data on file, courtesy of Gerd Auffarth.*

MINI WELL® vs. Tecnis Symfony

So how do EDOF IOLs perform in the real world? The literature offers some insight into the relative performance of MINI WELL® and the Johnson & Johnson Tecnis Symfony IOL. Marko Hawlina asserted: "Symfony's claims of being an EDOF lens were seriously challenged by a recent study (6) which showed that Symfony's modulation transfer function (MTF) featured bifocal (rather than an EDOF) curve with near focus at approximately 50 cm, compared to extended EDOF effect and near focus around 40 cm, shown by MINI WELL®. But what has been the actual experience of the user group?

Roberto Bellucci compared postoperative visual performance of the MINI WELL® and Symfony IOLs in a trial that involved two groups of 20 bilaterally implanted patients (40 eyes per group) with preoperative corneal astigmatism lower than 0.75 D. The headline results? Both patients group presented a monocular UDVA in the range of 0.14–0.00 logMAR. Only few patients (n=2 for each IOL) had an UDVA between 0.20 logMAR and 0.16 logMAR (Figure 2a). Most of the patients had a binocular DCNVA (40 cm) and a binocular DCIVA (80 cm) that ranged from 0.04–0.00 logMAR and from 0.08–0.00 logMAR, respectively (Figure 2b and 2c).

Bellucci's final assessment of MINI WELL® was that it "provides a good depth of field, and an incredibly good aberration profile," adding, "Patient satisfaction is high; they don't see starbursts, they only see a little bit of halo – and even then, only when they're asked about it!"

Gerd U. Auffarth also compared MINI WELL® with Symfony in a prospective, non-randomized study run at the University Eye Clinic in Heidelberg that assessed visual function via defocus curves and reading performance assessments using the Salzburg Reading

	General satisfaction (1–10)	Significance of light for reading (1–10)	Quality of reading (1–10)	Computer (1–10)	Glasses for reading – sometimes (%)	Glasses for far – sometimes (%)	Driving: day (1-10)	Driving: night (1-10)	Halo: day (%)	Halo: night (%)
SIFI MINI WELL®	9	5	8.9	9.6	16	10	9.2	8.2	10	15
J&J Symfony	8.9	5.3	8.0*	9.9	26	6	8.3	7.3	16	25
VSY Reviol Tri-Ed	9.1	5.2	9.1	9.4	8	5	9.1	6	18	38
Physiol FineVision	9.5	6.3	9.7	9.8	10	10	9.3	7	11	35

Table 3. Subjective postoperative patient satisfaction scores across four IOLs. *Data courtesy of Marko Hawlina.*

"MINI WELL® clinical results show excellent post-operative visual acuity – both for distance and intermediate vision – as well as good near visual acuity."
– Gerd U. Auffarth

Desk (SRD). Auffarth extolled the virtues of the SRD: "The patient sits in front of a computer screen, and the SRD system measures the distance of the head and the eyes, and the movement of the eyes, so you get values for a number of parameters such as reading ability and eye speed."

Twenty-four patients (40 eyes) received MINI WELL® (preoperative spherical equivalent [median] 0.50 D, range 7.75–4.88 D), whereas the comparison group included seven patients who received the Symfony lens. So what did the Heidelberg group find?

Let's examine "preferred" distance – the point at which the patient feels most comfortable reading, not necessarily the point at which visual acuity is highest. MINI WELL's values for preferred near vision were about 2 cm less than Symfony (~39 cm vs. ~ 41 cm; Table 2), and values for preferred intermediate vision are about 3–5 cm less than Symfony (e.g., median distance-corrected binocular is 60 cm for MINI WELL® and 65 cm for Symfony). With respect to defocus curves (Figure 3), at a logMAR visual acuity of 0.3, Symfony gave a range of 2.7 D and the MINI WELL® a range of 3 D; while at logMAR 0.1 the corresponding values are 2.25 and 1.8 D.

MINI WELL® vs. Tecnis Symfony, Acriva Reviol Tri-ED and FineVision

Marko Hawlina and Petra Schollmayer reported data from a study performed at their center in Portorož, that aimed to compare the visual function and quality of vision in patients receiving SIFI MINI WELL® (44 eyes), Johnson & Johnson Symfony (42 eyes), VSY Acriva Reviol Tri-ED (42 eyes) and Physiol FineVision (42 eyes). A key point from his findings was that, while all studied IOLs gave good

Box 5. A comparison of vision quality with MINI WELL, Symfony, Acriva Reviol Tri-ED and FineVision IOLs.

IOLs:

- SIFI MINI WELL® (44 eyes)
- J&J Symfony/Symfony Toric (42 eyes)
- VSY Acriva Reviol Tri-ED (42 eyes)
- PhysIOL Fine Vision (42 eyes)

Assessments:

- Snellen charts for distance
- Jaeger charts for near
- Contrast sensitivity for near: ETDRS Adult Near Contrast Test at 100, 25, 10, 5, and 2.5%
- High and low luminance levels: 100 cd/m^2, 20 cd/m^2
- Satisfaction level 1–10
- Proportion of patients needing spectacles (%)

IOL calculations were done using Barrett II and Hill-RBF formulae.

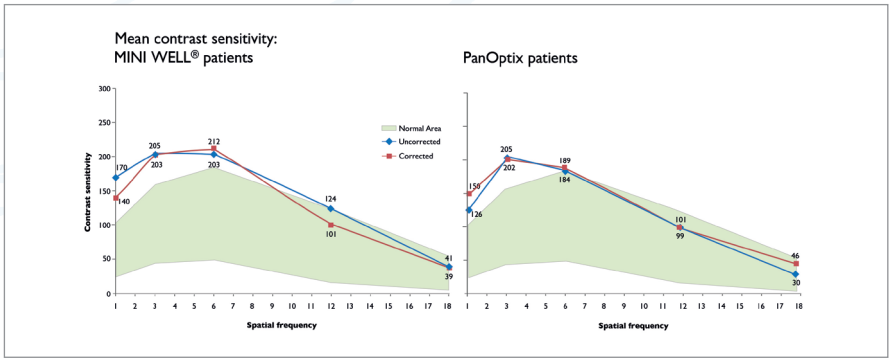


Figure 4. Contrast sensitivity –MINI WELL® vs. PanOptix. Figure courtesy of Ozana Moraru.

overall refractive outcomes and patient satisfaction, the MINI WELL® provided the lowest incidence of haloes and the highest level of patient satisfaction for night-time driving (Table 3).

Hawlina stated that, according to the study (6), at an aperture size of 4.5 mm, the MINI WELL® excels in terms of contrast sensitivity, suggesting that it might be a better lens for patients that spend extended periods of time under poor light conditions. He presented data showing good near contrast sensitivity under light and dim conditions – which was more than twice as good as the contrast sensitivity of his earlier patients with bifocal diffractive lenses. Hawlina and Schollmayer showed the videos and the results of their patients reading under light and dim conditions, using the International Reading Speed Test (IReST). "We timed how long they take reading the text under bright and dim light conditions. The differences were really small and their performances in dim light were comparable to monofocal population with near add of +2.50. Our patients did well, in particular in the MINI WELL® group, a good number of them performed exceptionally well!" (Box 5). With Symfony, mini-monovision strategy with -0.50 D target on non-dominant eye had to be used to ensure acceptable near vision.

MINI WELL® vs. PanOptix

Did this trend of excellent contrast sensitivity with MINI WELL® hold with the other faculty members? Ozana Moraru shared what she found in a 20 patients study comparing outcomes of patients who received MINI WELL® (n=10) with those who received PanOptix (n=10) – and found that MINI WELL® provided better contrast sensitivity than PanOptix in both photopic and mesopic conditions (Figure 4).

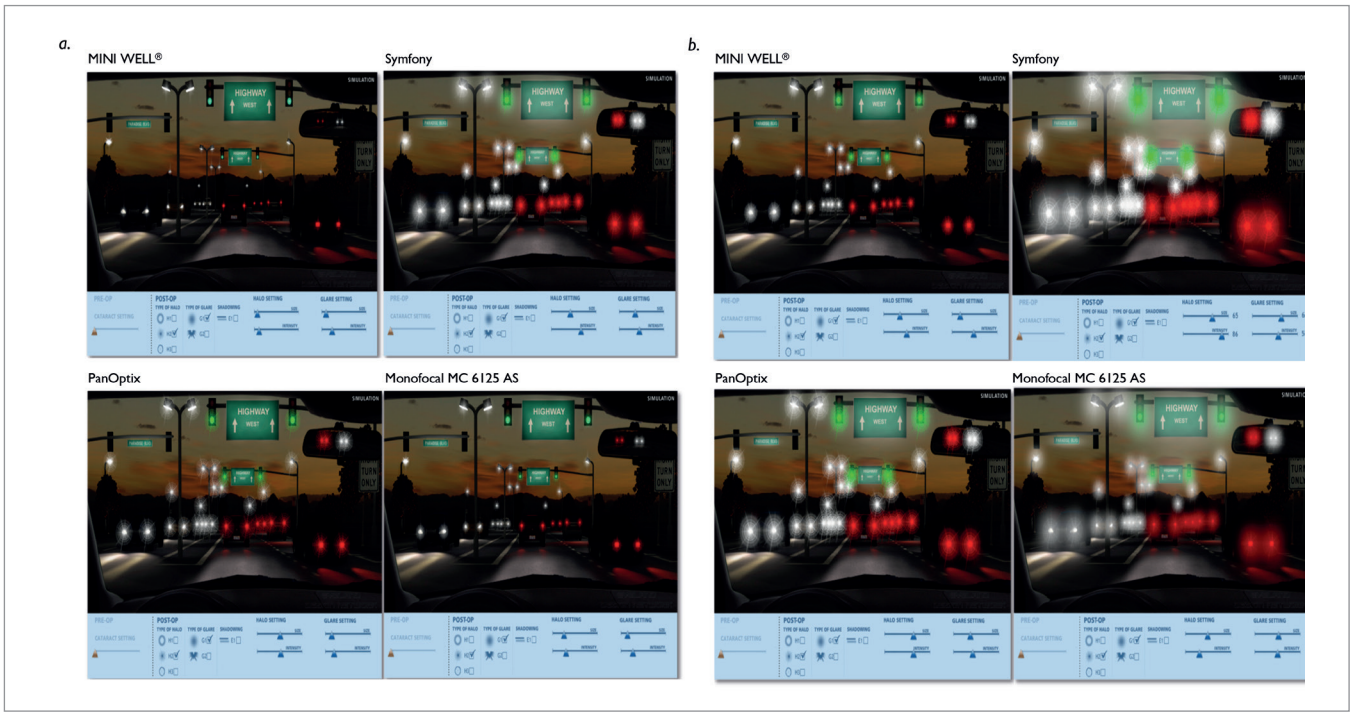


Figure 5. Mean (a) and maximum (b) halo and glare values for a variety of IOLs. *Figure courtesy of Gerd Auffarth.*

Box 6. Experience of MINI WELL® and PanOptix

Evaluated parameters

- UDVA and CDVA (each eye, both eyes) using the Yang Smart device
- UNVA and CNVA (each eye, both eyes) – Snellen chart at 40 cm
- Binocular contrast sensitivity (with/without distance correction) using Yang Smart
- Halo and Glare Simulator (Eyeland Design Network)
- Quality of vision (satisfaction questionnaire)

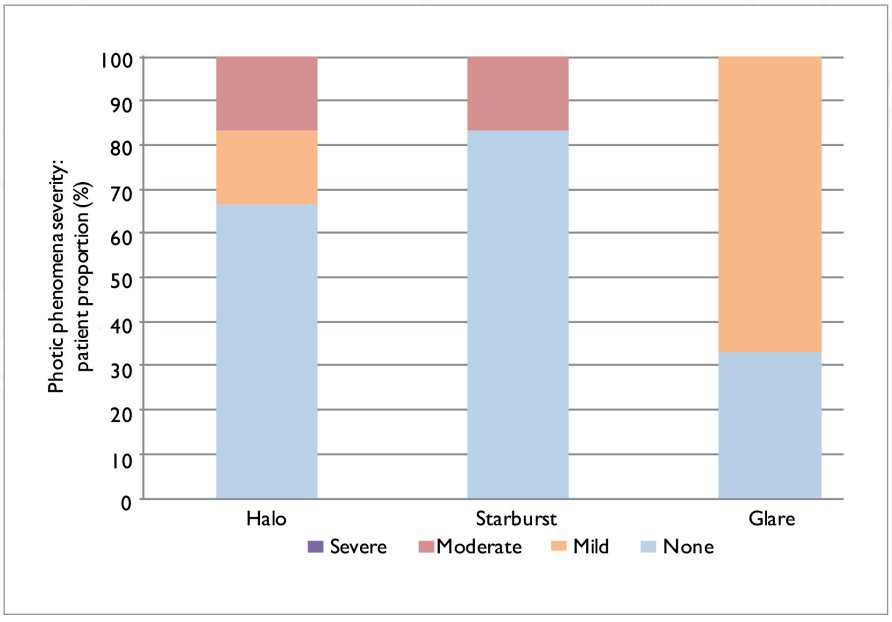


Figure 6. Photic phenomena reported after MINI WELL® implantation. *Figure courtesy of Gerd Auffarth.*

IOL	*UDVA* (logMar)*	*UNVA* (decimal)*
SIFI MINI WELL®	-0.16	0.843
Alcon PanOptix	-0.11	0.98

Table 4. Comparison of visual acuity – MINI WELL® vs. PanOptix. *Data courtesy of Ozana Moraru. *Mean values*

Ozana Moraru found MINI WELL® and PanOptix resulted in similar postoperative visual acuity, although the MINI WELL® performed a little better for UCDVA and PanOptix slightly better for UCNVA. The mean MINI WELL® UDVA was -0.16, compared with -0.11 for PanOptix; and the mean MINI WELL® UNVA was 0.843, compared with 0.98 for PanOptix (Table 4). Overall, she found that MINI WELL-receiving patients experienced a significantly better quality of vision – especially in terms of haloes, double/multiple images, clarity of vision and focus difficulties – than those who received PanOptix (Box 6).

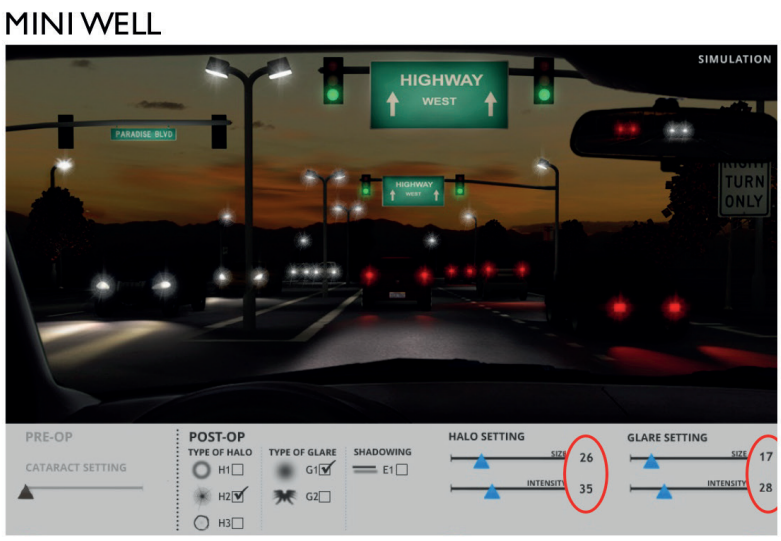
Photic phenomena

Let's focus on halo and glare. Many of the meeting's faculty use the computer-based Halo and Glare simulator (Eyeland Design Network), in which patients are exposed to an image and allowed to choose between different types of photic phenomena and to adjust the image accordingly to depict their experience of halo and glare. This allows the patient to, for example, illustrate to us what he or she sees at night. As Auffarth put it: "There is a lot of subjectivity in it, but it works!"

This system can be used to model the photic phenomena experienced by recipients of different IOLs, and strongly suggests that the MINI WELL® gives a superior patient experience (Figure 5).

Auffarth showed that a significant proportion of patients who receive MINI WELL® have no experience of photic phenomena (around 70, 80, and 30 percent experience no halo, starburst, or glare, respectively; Figure 6) – and not a single MINI WELL® patient complained of severe photic phenomena. To place this in context, Auffarth referred to a study on healthy volunteers in his lab: "Even these 20-year-olds see halos like that sometimes – if you drive a car and it's raining, you will see halo glare everywhere, even if you have the best eyes in the world!"

Similarly, Hawlina's data (Table 3) indicate that MINI WELL® is associated with fewer photic phenomena than other lenses. Only 10 percent of MINI WELL® patients sometimes see daytime haloes, and 15 percent see haloes at night. The corresponding figures for other IOLs are: Symfony 16 and 25 percent; VSY TriEd 18 and 38 percent, and Physiol Fine Vision 11 and 35 percent. Further, the MINI WELL® returned the highest score for subjective satisfaction for driving at night (8.2/10, compared with 7.3/10 for Symfony). "They do see some halos, but these are not like permanent circular rings,"



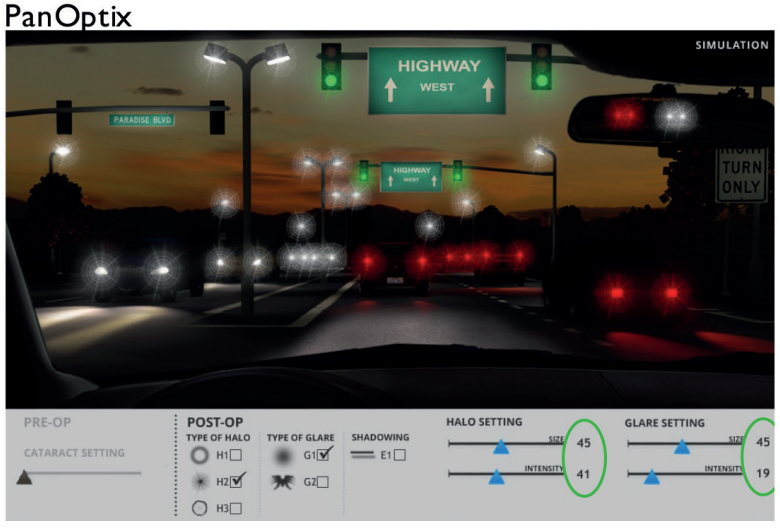


Figure 7. Mean values of most frequent halo and glare phenomena (H2 and G1) – MINI WELL® vs. PanOptix. *Figure courtesy of Ozana Moraru.*

but explained that these are "more like temporary halos depending on the angle of the incident light and are less disturbing comparable to other lenses."

Moraru used the same simulator to compare MINI WELL® with PanOptix, and Figure 7 shows the findings: MINI WELL® is associated with less frequent, and lower intensity halo and glare. Moraru's study categorized halo and glare phenomena as thick circles (H1), starbursts (H2) and thin circles (H3); glares were categorized as diffuse (G1) or zonal/sectoral (G2). The Halo and Glare simulator assessments revealed that PanOptix placement is associated with a greater range of haloes – H1, H2 and H3 all were present – than MINI WELL® (where patients experienced only H1 and H2). MINI WELL® haloes were of lower mean intensity and size (Figure 8). Similarly, with regard to glare, the MINI WELL® G1 and G2 values are much lower than those of PanOptix. Postoperative photic phenomena were assessed further using a validated quality of vision questionnaire (7). MINI WELL® is also superior to PanOptix in terms of vision under dim lighting conditions, flash/blitz sensation, and image distortion, and had fewer focus difficulties than the PanOptix. In summary, Moraru was definitive: "MINI WELL® patients are far happier with respect to haloes and transient vision loss experiences than PanOptix patients."

Summary

Firstly, remember the critical importance of carefully selecting and matching your patients to the most appropriate IOL. Don't skimp on chair time, and when considering a MINI WELL®, make sure you choose patients with appropriate psychological and clinical profiles. Ideally, you're looking for easy-going Generation X-ers, with relatively active lifestyles and realistic expectations for the surgical procedure. In addition, and critically, they should have healthy eyes – in particular a healthy tear film and no dry eye syndrome (which is one of the main contributing factors to IOL failure). So make sure you do a full and thorough evaluation of relevant pre-operative parameters; use up-to-date instruments and modern formulae, and exclude patients as necessary. In other words: when in doubt, play safe – don't relax patient selection criteria just because you have a superior IOL!

That said, remember too that the MINI WELL® inclusion criteria are relatively wide – this is a lens for the majority. For example, longer eyes may do just as well as shorter eyes with this lens. In particular, MINI WELL® addresses Generation X's need to be free of glasses all the time, not just for two-to-three focal points, and for spectacle-free vision at 40 cm – the "new near vision" dictated by changed habits like smartphone use. (Bear in mind that most newspapers are read on smartphones today). A new lens for a new lifestyle! Note too that this IOL may be also suited to a micro-monovision strategy for fine-tuning near vision.

Secondly, consider the lightened 'surgeon burden' provided by MINI WELL®. You no longer need to be so worried about multifocal IOL procedures on account of the possibility of post-operative photic phenomena such as haloes and glares – and the consequent dissatisfied patients. The design and physical presentation of the MINI WELL® allow for excellent centration and capsular bag stability; and it is compatible with modern FLACS approaches. In terms of outcomes, several users have shared their experience of the reduced halo/glare incidence and severity provided by MINI WELL® as compared with competitors (such as Symfony and PanOptix); and the high levels of patient satisfaction reported by MINI WELL® recipients, both in general terms and in terms of specific circumstances, such as night-time driving. Negligible side-effects, faster neural adaptation, and true EDOF, result in more satisfied patients – and hence post-operative chair time is concomitantly reduced. Everyone should be happy – not just the patient, but the surgeon too.

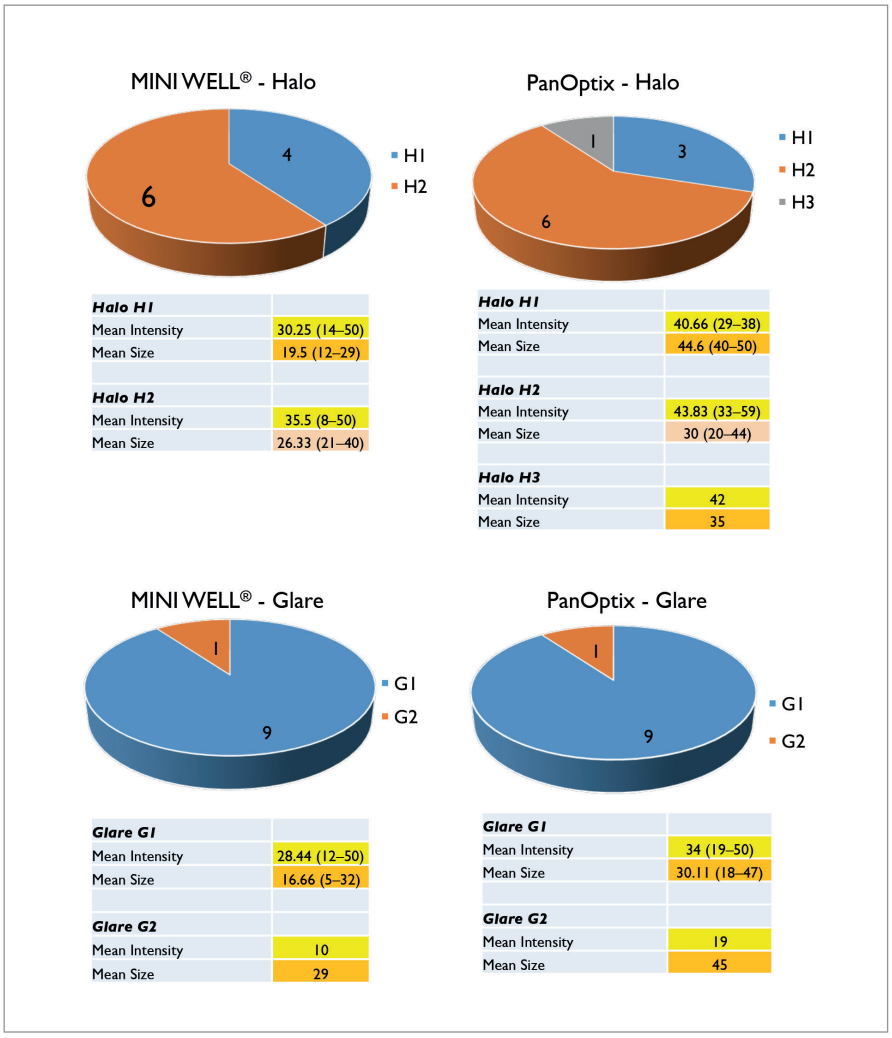


Figure 8. Halo and glare: MINI WELL® vs. PanOptix. *Figure courtesy of Ozana Moraru.*

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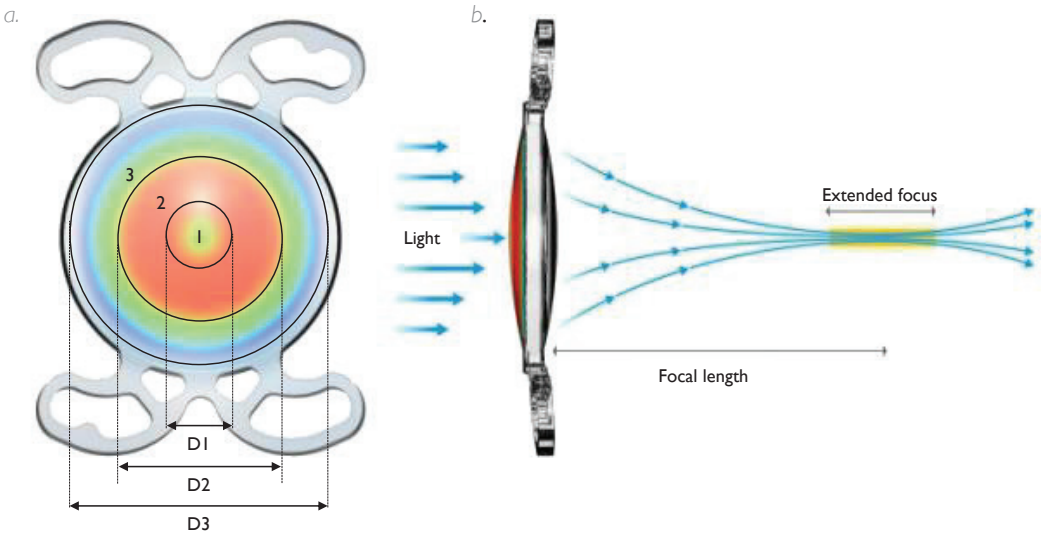

Figure 1. The Mini WELL has a progressive optic (a) with a central distance zone (D1), a surrounding distance zone (D2) with spherical aberration of the opposite sign, and a peripheral distance zone (D3) with monofocal characteristics, which leads to a progressive, extended depth of focus (b).

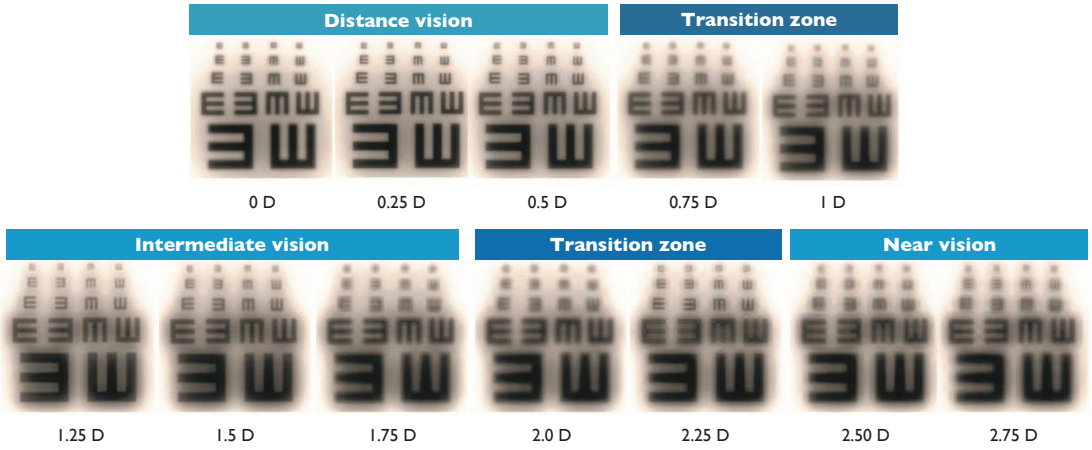

Figure 2. Retinal image simulations. The Mini WELL offers a continuum of foci across all distances (source: SIFI, data on file).

MINI WELL®: The First Progressive EDOF IOL based on spherical aberrations.

MINI WELL® is a patented design IOL providing an effective correction of presbyopia at all distances. It achieves an extended depth of focus introducing different and controlled amounts of spherical aberrations (SAs), within 3-mm diameter, in the central part of the IOL optics. The SAs provide EDOF for all focus distances under photopic and mesopic lighting conditions. The peripheral section between 3- and 6-mm diameters, without inducing any further SA, is designed to achieve optimal distance vision at night-time (8).

All this translates to a good quality of vision across all distances – and far fewer halos and glare.