

Delivering Intermediate Vision: The New TECNIS Eyhance Monofocal IOL

Highlights from the Frankfurt January
2019 Advisory Board Meeting

Attendees:

Valentin Apostolov, the Netherlands
Alfonso Arias Puente, Spain
Gerd Auffarth, Germany
Oliver Findl, Austria
Gonzaga Garay Aramburu, Spain
Frank Goes Jr., Belgium
Oege Goslings, the Netherlands
Remi Mascali, France
Rita Mencucci, Italy
Scipione Rossi, Italy
Marco Tavalato, Italy
Daniele Tognetto, Italy
Bart Zijlmans, the Netherlands

*This supplement reflects the opinions and
experiences of Advisory Board meeting participants,
who met in Frankfurt, Germany, on January 11, 2019.*

Since the introduction of aspherical IOLs in 2001 (1) improvements in the optical performance of monofocals IOLs have been minor. However, this could be set to change with the introduction of the TECNIS Eyhance IOL, model ICB00, from Johnson & Johnson Vision. In January of this year, 13 leading ophthalmic surgeons from Germany, Austria, France, Italy, Spain, the Netherlands and Belgium met in Frankfurt to compare their experience with this novel IOL. These surgeons were first introduced to the TECNIS Eyhance IOL in September 2018, during the ESCRS Congress in Vienna. Subsequently, they evaluated the lens in their own practices, as part of a limited introduction.

What were the results of this real-world evaluation? In brief, the surgeons' experiences reflected the TECNIS Eyhance IOL clinical trial results (Part II). Specifically, the new TECNIS Eyhance IOL provided comparable distance vision to the TECNIS[®] monofocal IOL ZCB00 and gave the patients enhanced intermediate vision outcomes. Patients fed back that they were able to enjoy activities dependent on intermediate vision – such as handicraft or woodwork – and walk more confidently on uneven surfaces. Furthermore, photic phenomena reports after TECNIS Eyhance IOL implantation were similar to those typically associated with monofocal lenses. These results – like those of the clinical trial (Part II) – are due to the unique technology built into the TECNIS Eyhance IOL.

Part I: The technology

With the naked eye the TECNIS Eyhance refractive IOL (ICB00) is indistinguishable from the TECNIS[®] Monofocal lens ZCB00 and refers to the same base geometry as all other

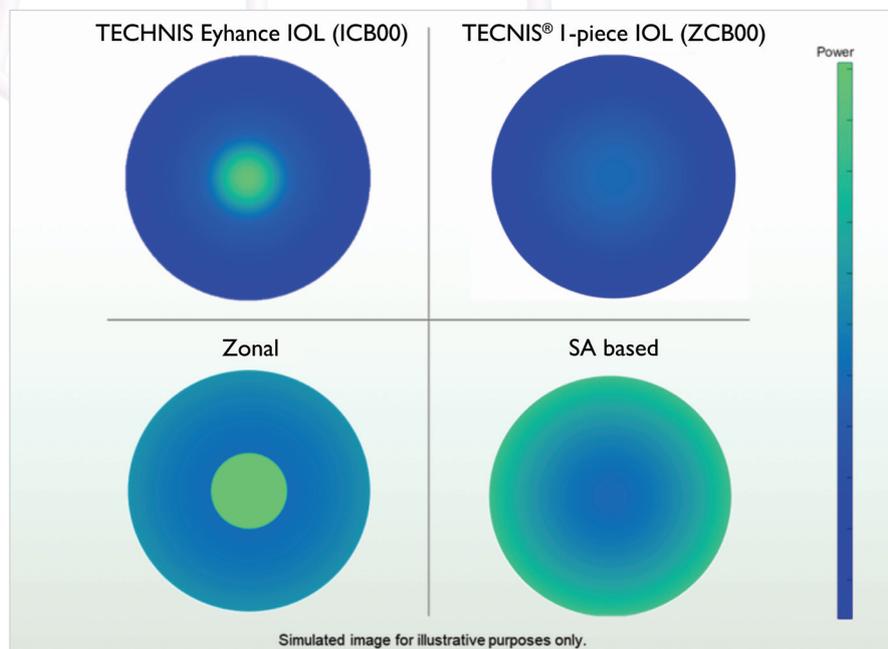


Figure 1. Power maps of the TECNIS[®] Monofocal (ZCB00) and TECNIS Eyhance (ICB00) IOLs.

TECNIS[®] IOLs. Nevertheless, the new lens is distinguished by a critical difference in design – namely, a continuous change in power from the periphery to the center of the lens, creating a unique anterior surface that improves intermediate vision, maintains distance image quality comparable to aspheric monofocal IOLs, delivers a profile of photic phenomena similar to ZCB00 and keeps on reducing spherical aberration to near zero.

Note that the TECNIS Eyhance IOL, unlike other monofocal lenses, is not based on a spherical-aberration (SA) based or zonal design, but the continuous power profile is created with a higher order asphere. A comparison of power maps spotlights the unique structure of the new lens (Figure 1) and emphasizes that ~85 percent of the surface of the TECNIS Eyhance IOL and TECNIS[®] Monofocal lenses have exactly the same features; the difference between them lies only in the central area.

The consequence of this novel design is a very favorable contrast profile: data indicate an equivalent contrast to

other approved aspheric monofocal IOLs (2). Furthermore, in large pupil eyes the TECNIS Eyhance IOL provides significantly better contrast than other monofocal IOLs.

Part II. The clinical trial

The prospective, multi-center, randomized clinical study compared the clinical performance of the TECNIS Eyhance IOL with that of the TECNIS[®] Monofocal IOL ZCB00 (3). Both the evaluator and the subject were masked. The primary endpoint for the study was distance-corrected intermediate visual acuity (DCIVA); secondary endpoints were best corrected distance visual acuity (BCDVA) and uncorrected intermediate visual acuity (UCIVA). From a total of 68 subjects bilaterally implanted with the TECNIS Eyhance IOL, and 72 controls bilaterally implanted with TECNIS[®] Monofocal, 67 and 72 individuals respectively were followed up at six months.

The results were striking – a monofocal IOL has been shown in a clinical trial

Furthermore, the TECNIS Eyhance IOL has been shown to provide a similar daytime contrast performance to other IOLs, but superior night-time contrast. In large pupils, image contrast is 31 percent better than with the Clareon® IOL, and 45 percent better than HOYA Vivinex™ (2).

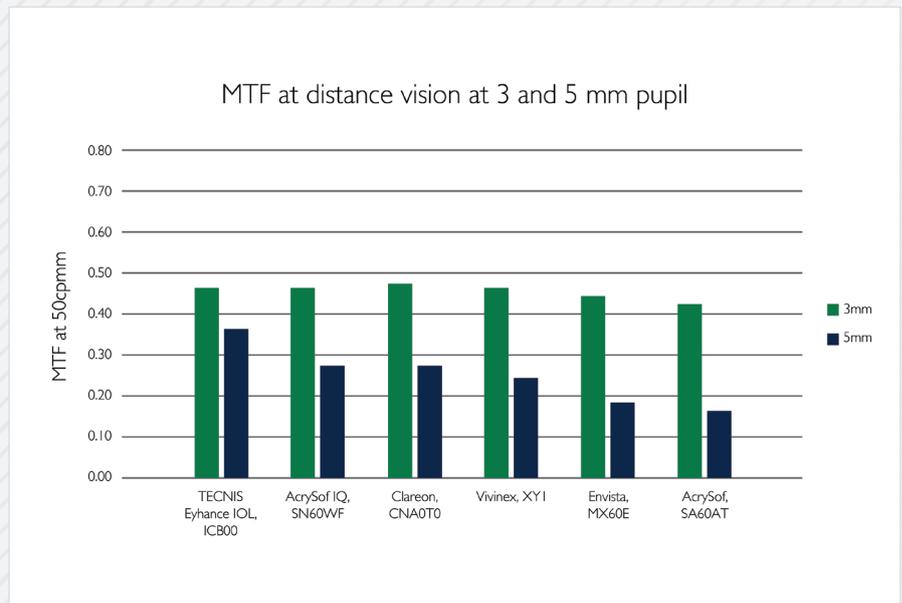


Figure 2. Modulation transfer function (distance vision): 3 and 5 mm pupils.

to deliver significant improvements to intermediate vision. Eyes implanted with the TECNIS Eyhance IOL had significantly better monocular intermediate vision at 66 cm than the controls (mean TECNIS Eyhance IOL DCIVA value was 1.1 lines logMAR better than the mean DCIVA for TECNIS® Monofocal: $p < 0.0001$), and better results were obtained for UCIVA outcomes, too. Similar results were observed for binocular intermediate vision: eyes implanted with the TECNIS Eyhance IOL had mean DCIVA and UCIVA values superior to those of eyes implanted with the TECNIS® Monofocal (differences of 1.1 line logMAR and 1 line logMAR, respectively; $p < 0.0001$ in both cases) (Figure 3 (3)).

The TECNIS Eyhance IOL also provides excellent (20/20) distance vision: monocular and binocular distance vision is comparable to that provided by the TECNIS® Monofocal IOL, i.e. a BCDVA difference of 0.4 lines (Snellen equivalent) binocular (3). Thus, the TECNIS Eyhance IOL is very similar, and

not inferior, to the TECNIS® Monofocal IOL in terms of binocular distance vision.

In addition, reported rates of photic phenomena (halo, glare, starbursts) were similar for both lenses. Regarding defocus, measurements indicate that the TECNIS Eyhance IOL has a larger 'landing zone' than the TECNIS® Monofocal IOL (Figure 4 (3)).

Clinical trial: patient outcomes

How did the patients themselves feel about the new IOL? The results were highly encouraging: significantly more TECNIS Eyhance IOL recipients reported no difficulty in walking on uneven surfaces, as compared with the TECNIS® Monofocal (3). Furthermore, the great majority of TECNIS Eyhance IOL patients could continue to engage in activities requiring intermediate vision: more than 93 percent were able to perform handicraft or woodwork with no difficulty (55 percent) or just some difficulty (39 percent). Similarly, 100 percent of those implanted with the

“Eyes implanted with the TECNIS Eyhance IOL had significantly better monocular intermediate vision at 66 cm than the controls.”

TECNIS Eyhance IOL had no difficulty (79 percent) or some difficulty (21 percent) with seeing to engage in an activity/hobby that they are interested in.

Daily activities enjoyed without glasses

Patients implanted with the new TECNIS Eyhance monofocal IOL as part of a limited launch reported being able to enjoy the following activities (without glasses):

- Driving, including night-driving
- Reading price tags when shopping
- Watching TV, including reading subtitles
- Cooking and eating
- Playing cards
- Reading at a computer/tablet/smartphone distance
- Playing piano and other instruments
- Feeling more confident while walking, particularly when going downstairs or walking on uneven surfaces

Part III. The real world: results from a limited launch of the TECNIS Eyhance IOL

The clinical trial outcomes were immensely encouraging – but trials take place under precisely controlled conditions. How would the TECNIS Eyhance IOL perform in the real world? Johnson & Johnson Vision collaborated with ophthalmic surgeons, with the aim of collecting accounts of real-world patient experiences and to learn whether the TECNIS Eyhance IOL may become a candidate to change the standard of care in monofocal IOL implantation.

Accordingly, eighteen surgeons – all of whom routinely implant large numbers of TECNIS® Monofocal IOLs – were asked to evaluate the TECNIS Eyhance IOL and, in total, performed 381 TECNIS Eyhance IOL implantations from October 2018 to early January 2019, including 149 bilateral procedures.

And the results were highly encouraging. All surgeons reported bilateral distance vision to be good or very good, the A-constant working well, and it seemed numerous patients getting 20/20 distance vision due to the broader landing zone of the IOL. In addition, surgeons reported on a broad variety of daily activities their patients told them they could execute comfortably without glasses (see sidebar).

To share the details of the limited launch, thirteen of the eighteen participating surgeons gathered at the Advisory Board Meeting in Frankfurt. This was an excellent opportunity to present and discuss their real-world experiences with the TECNIS Eyhance IOL, and to share their insights into this new IOL. Key points to emerge from this meeting mainly focused on confirming the excellent distance vision and confirming two additional benefits this lens delivered over traditional monofocal IOLs – improved intermediate vision and a broader landing zone.

There was a series of comments on the benefits of improved intermediate vision with Alfonso Arias Puente who had expected intermediate vision to improve considerably in younger adult patients but in fact found the greatest benefit in a 70-year-old patient. Thus, he commented the quality of intermediate vision may not be related that much to the age of the patient. This finding was shared by Marco Tavalato who thinks “the age of 75-80 years is the age of intermediate vision: playing cards, using the computer. For this reason, I believe this lens will work very well.” Actually, he added that if he was choosing an IOL for his mother – who is 75 – he would

“The age of 75-80 years old is the age of intermediate vision: playing cards, using the computer. For this reason, I believe this lens will work very well.” – Marco Tavalato

choose the new TECNIS Eyhance IOL. Gonzaga Garay Aramburu asserted that his TECNIS Eyhance IOL recipients reported an improvement in their quality of life; in fact, a patient who had - for reasons of limited diopter availability during this phase of early launch – received the TECNIS Eyhance IOL in one eye and a monofocal TECNIS® ZCB00 in the other could clearly see the difference in intermediate vision with the TECNIS Eyhance IOL. This patient exclaimed that she had “won the lottery” with the new IOL.

An anecdotal comment from another surgeon was referring to a couple where both of them had received cataract surgery quite recently: while the male had received a standard monofocal IOL, his wife experienced better intermediate vision for daily activities after having received the TECNIS Eyhance IOL.

Bart Zijlmans confirmed the impressions of previous speakers regarding reports of improved visual acuity outcomes with the TECNIS Eyhance IOL and gave the example of patients who were able to use in-car navigation or music systems without glasses.

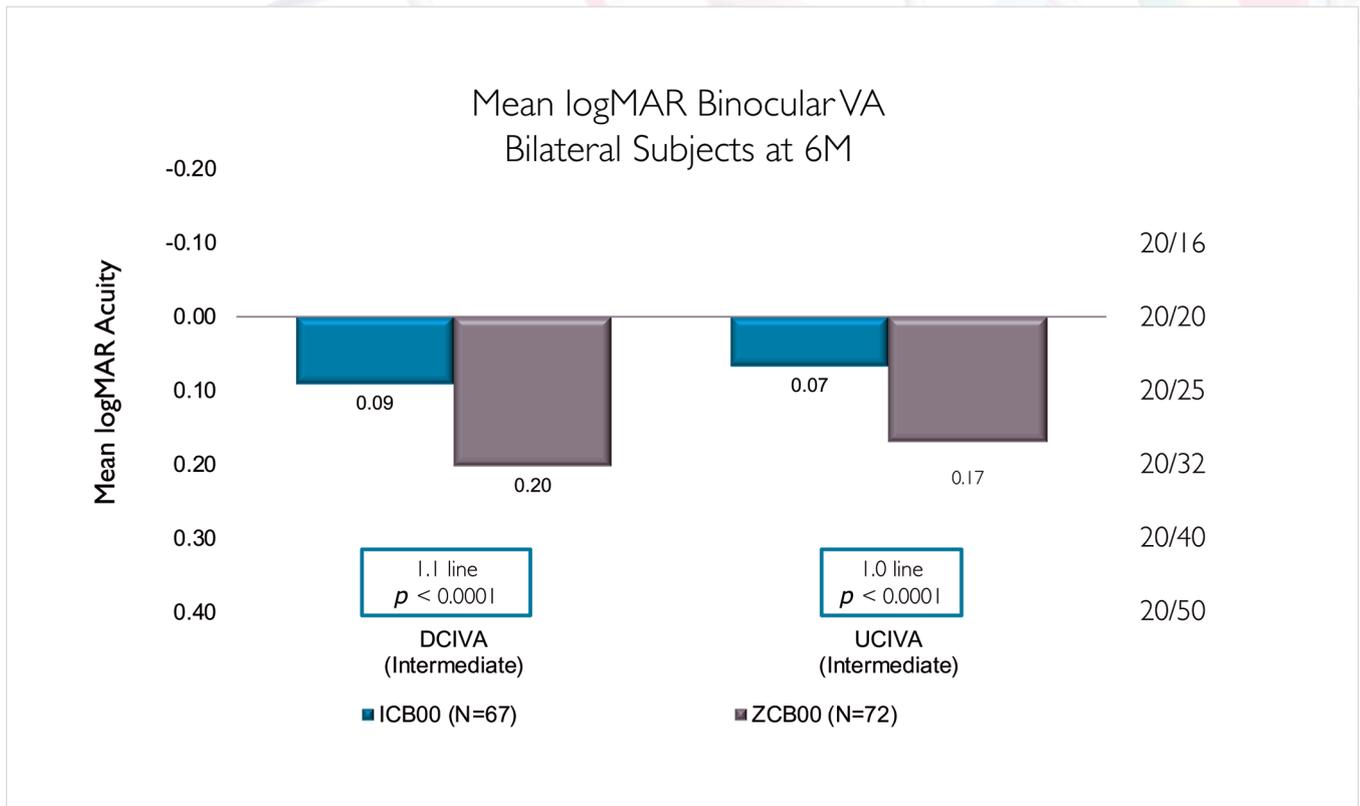


Figure 3. TECNIS Eyhance IOL provides statistically significant improvement in binocular intermediate vision at 66 cm (3).

He commented on patients “gaining” intermediate visual acuity, and asserted that, for that reason, he would like to see his current Monofocal IOL replaced with the new TECNIS Eyhance IOL.

In general, there was consent among many attendees on this view including Gerd Auffarth who reported little observable difference between TECNIS[®] Monofocal and the TECNIS Eyhance IOL: patients were positive about the performance of the TECNIS Eyhance IOL in terms of distance vision, intermediate vision, and the tasks they were able to perform following implantation. As he saw no advantage to using his current Monofocal rather than the TECNIS Eyhance IOL, he suggests replacing the former with the latter.

Rita Mencucci also agreed on very good UCIVA results with the TECNIS Eyhance

IOL, and good UCIVA. She agreed with Valentin Apostolov’s suggestion that the TECNIS Eyhance IOL could replace her current Monofocal. Like Marco Tavalato, she suggested that surgeons in busy hospital settings, with large volumes of patients, might find it more convenient to have a single IOL option rather than being obliged to choose between the multiple Monofocal IOLs.

Valentin Apostolov reported that he was happy to see that TECNIS Eyhance IOL recipients have not complained about photic phenomena or impaired night-driving ability, and he was confident that he would offer the new lens to his patients, most likely as a replacement for the monofocal lens he currently uses. Other clinicians present agreed that TECNIS Eyhance IOL recipients have not complained about photic phenomena or

impaired night-driving ability, incl. Remi Mascali, who found his patients being highly satisfied with the procedure and outcomes, and none of his patients reporting on photic phenomena. He is very keen to use the TECNIS Eyhance IOL in adult patients under 70 years old, in whom he expects the lens to achieve better outcomes.

Oliver Findl was very positive about the unaided distance acuity associated with the TECNIS Eyhance IOL, thanks to the broader landing zone, and he was encouraged by patient-reported intermediate vision acuity in the four weeks after surgery. Likewise, Frank Goes believes that he achieved uncorrected 20/20 vision more easily and more rapidly with the TECNIS Eyhance IOL than with TECNIS[®] Monofocal. He added that he would willingly replace his current

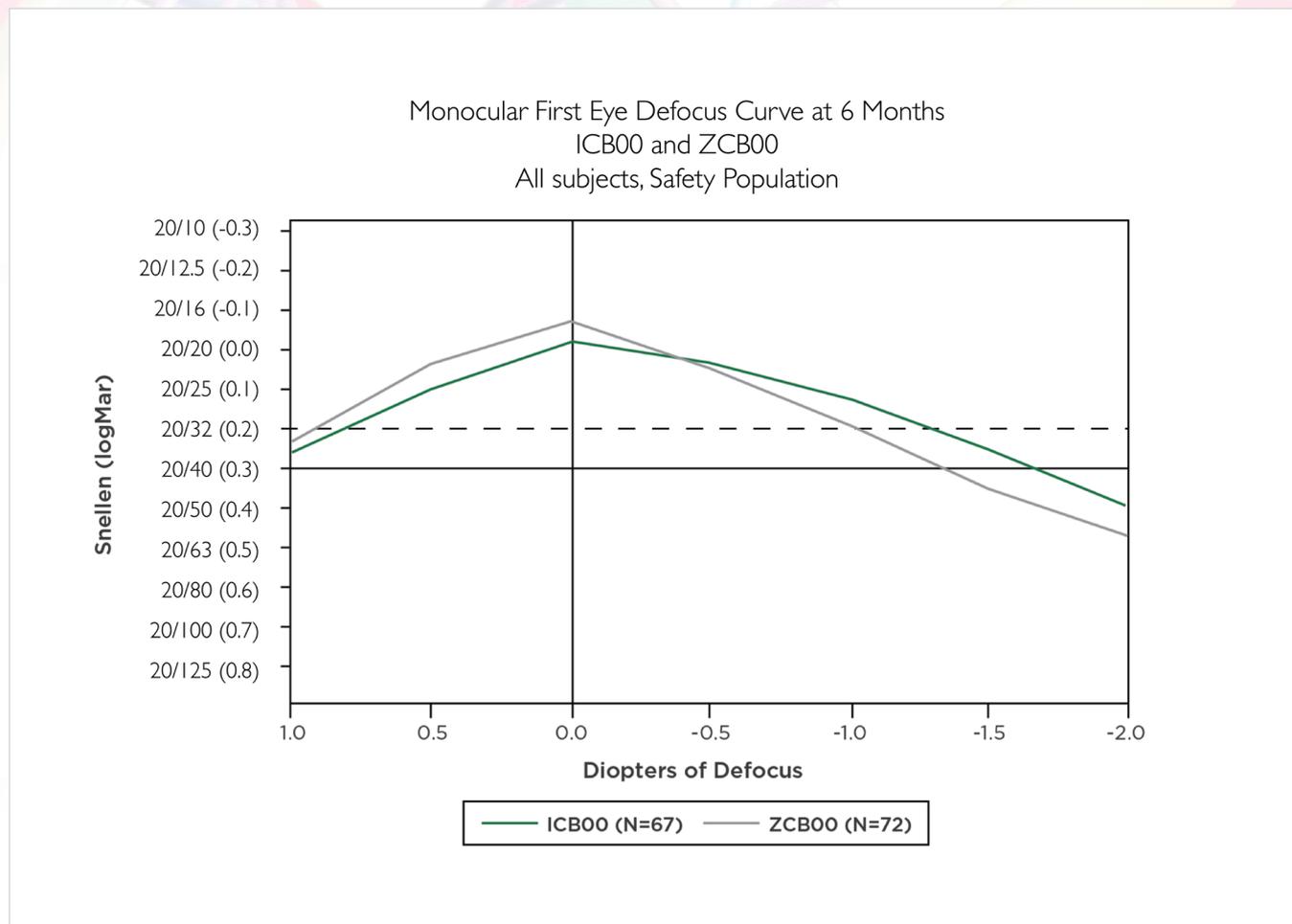


Figure 4. TECNIS Eyhance IOL delivers a bigger landing zone than the TECNIS® 1-piece IOL (3).

“I would be happy to replace the currently used Monofocal with the TECNIS Eyhance IOL.”
– Oege Goslings

Monofocal with the TECNIS Eyhance IOL in his clinic. Intermediate vision activities reported by his patients since implantation included golf and cooking.

Daniele Tognetto observed that 40 percent of his patients implanted with the TECNIS Eyhance IOL had better visual acuity (both intermediate and distance monocular VA) than those who had received the TECNIS® Monofocal; as he saw no disadvantages for the TECNIS Eyhance IOL he would be happy to see it replace the TECNIS® Monofocal.

Finally, Oege Goslings reported that the experiences of his patients had been exclusively positive: for example,

individuals gained the ability to read from computer screens or tablets unaided. He added that he would be happy to replace his current Monofocal with the TECNIS Eyhance IOL. He also stated that insurance companies in the Netherlands require information on the percentage of patients reaching one diopter of the target and noted that he could be certain of achieving his target with the TECNIS Eyhance IOL – a point that Zijlmans agreed with.

Discussion

Findl asserted that intermediate vision has become increasingly important in

“The advantage of this lens over other lenses available on the market is that a higher number of patients will achieve uncorrected 20/20 vision.”
– Frank Goes

the last two decades, mostly due to the use of smartphones, tablets, and patients being able to devote more time to activities and hobbies requiring intermediate vision. In this context, he suggested that the TECNIS Eyhance IOL could be described as a truly “modern” monofocal lens, or according to Auffarth a “super-monofocal IOL” that is an update to a very established lens.

Surgeons agreed that the quality of IOLs is constantly improving, and the new TECNIS Eyhance IOL provides a higher standard for the field of monofocal lenses, reflecting constant evolution of design and production technology.

Apostolov stressed that ophthalmic surgeons should always under-promise and over-deliver, and therefore should make it clear that the TECNIS Eyhance IOL is an improved monofocal lens rather than promising intermediate vision to patients. Surgeons agreed that patients

are becoming increasingly well-educated regarding IOL categories and have certain expectations regarding premium lenses – which is why it is so important to correctly categorize a given IOL. Accordingly, surgeons did not see a need to change their patient education for the TECNIS Eyhance IOL from their routine for monofocal lenses and by doing so, there would be a reasonable chance to overdeliver with this new lens – an occurrence that is always appreciated by both surgeons and patients.

In addition to improved intermediate vision many surgeons appreciated that the TECNIS Eyhance IOL would be more forgiving. Due to the broader plateau in the defocus curve there would be a higher chance to provide 20/20 distance visual acuity to patients even in cases where the target of emmetropia was not achieved. Taking into account that according to large recent trials (4) more than 25 percent of all cataract patients were affected by a prediction error of more than ± 0.5 D, and 7 percent of patients by at least ± 1.0 D, the broader landing zone of the TECNIS Eyhance IOL may be helpful to expand the number of patients who receive better distance visual acuity. However, this would be at the expense of improved intermediate vision that they otherwise may benefit from when emmetropia has been reached.

Finally, Scipione Rossi initiated a debate on the idea of low-diopter monovision (within 0.5-0.75D), thanks to the larger landing zone, in order to gain additional visual acuity in intermediate or even near. However, while there is some debate among surgeons on the concept of monovision in general, the approach will not likely seem favorable with the TECNIS Eyhance IOL as patients may see significant compromise on their distance visual acuity which is known to be the most important outcome parameter. Moreover, monovision may cause photic phenomena, is not tolerated by every

patient and may demand for additional chair-time.

In summary

The new TECNIS Eyhance monofocal IOL (ICB00) redefines the concept of the monofocal lens. Data from clinical trials and real-world patient experience suggest that it will become the monofocal IOL of choice for many ophthalmic surgeons. This view is supported by views expressed at the January 2019 Advisory Board Meeting in Frankfurt; surgeons who participated in this event suggest that the TECNIS Eyhance IOL represents the next chapter in IOL innovation, comparable in importance to the evolution from spherical to aspherical lenses.

References

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