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Cataract & Refractive Surgery TODAY

EUROPE

LONG-TERM EXPERIENCES RECOGNIZE FINEVISION AS THE GOLD STANDARD MULTIFOCAL IOL

What experts are saying about this trifocal lens.

FINEVISION

3focal optic Far Intermediate Near

Principles and Concept of a Diffractive Trifocal IOL

The FineVision IOL combines two diffractive structures to create three foci.

BY THOMAS F. NEUHANN, MD

There is one distinct difference between the optics of monofocal and multifocal IOLs. In short, monofocal IOLs are defined by optics that have one focus point for far vision whereas multifocal IOLs are defined by optics that have multiple foci. In the past, this strictly meant two foci, one for far vision and one for near vision; however, this has recently changed with the introduction of a new trifocal lens design. The optics of the FineVision IOL (PhysIOL) combines two diffractive structures to create not two but three foci for near, intermediate, and far vision.

For monofocal IOLs, almost 100% of the incident light passes through the optic, meaning that the loss of contrast sensitivity is very low and the modulation transfer function (MTF) is high. However, as I previously mentioned, these lenses only produce one focus for far vision. For diffractive multifocal IOLs that create two foci—in essence, bifocal IOLs—the light is split between the foci. Unfortunately, because a considerable amount of this light is lost during the light splitting, there is a considerable loss of contrast sensitivity and, therefore, a low MTF. However, these lenses typically provide patients with an increased range of vision.

In diffractive bifocal IOLs, far focus is defined by the curvature of the lens as well as the refractive index of the material. The steps of the diffractive gratings determine how much light goes into the far and near foci, and their construction determine how strongly the light rays are bent. The step width determines the addition power. In other words, the larger the step, the lower the addition power. The step height determines the energy distribution between near and far vision. Therefore, with high steps, more light goes into the near focus and, with low steps, more light goes into the far focus. Decreasing the step height from the center of the lens to the periphery, thus providing more light in the near focus, when the pupil is small and increasingly more light to the distance focus, as the pupil diameter increases.

Now that we understand how two foci are created, the question remains: How do you create three foci? The answer is by combining two optics—one diffractive optic that has a far focus and a grating that is narrow enough to create a near focus of 3.50 D and another optic that has the same far focus but a near focus that is precisely half of the first near focus (1.75 D).

With a bifocal lens, the second order of diffraction (about 7.00 D) is lost; however, when combining two optics, the second order of the 1.75 D diffraction grating is 3.50 D. This resultant diffraction is useful for near vision. In essence, you steal back some light for the near focus from the otherwise lost light of a bifocal optic.

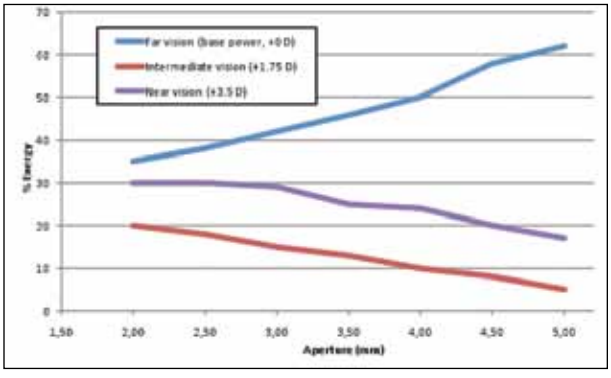

Figure 1. With this pattern, there is adequate light for near, intermediate, and far foci, with the most light being directed toward the far focus during pupil dilation and the most light being directed toward the near and intermediate foci during constriction.

By integrating two diffractive optics, this IOL has a combination of long and short steps, apodized as far as the periphery, which will decrease the amount of lost light. This pattern ensures that there is adequate light for near, intermediate, and far foci, with more light being directed toward the far focus during pupil dilation and more light being directed toward the near and intermediate foci during constriction (Figure 1).

Instead of losing up to 20% of light through a diffractive bifocal lens, we now only lose 14% with the FineVision IOL. This not only enhances near vision but also provides intermediate vision, the latter of which has always been the weak point of bifocal lenses. In short, the FineVision is the first diffractive IOL to improve intermediate vision while maintaining good near and far vision. ■

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Early Experience With the FineVision IOL

This surgeon found good agreement between theoretical and clinical outcomes with this trifocal lens.

BY JORGE L. ALIÓ, MD, PHD

For the past several years, I have been intrigued by the idea of what multifocal IOLs can potentially provide patients, which is a reduction of spectacle dependence after cataract surgery. I have worked with numerous companies as a clinical investigator studying these lenses, and I must say that, in many cases, patients do achieve some level of spectacle dependence. However, intermediate vision is frequently undesirable, with many patients requiring spectacles to see in this range.

We have all seen, heard about, or implanted at least one of the various diffractive and refractive multifocal IOLs on the market today. These lenses have become commonplace, and patients are also aware of their potential benefits after cataract surgery. They do come with tradeoffs, however, including glare, halos, and less-than-optimal vision at the intermediate range.

Recently, PhysIOL introduced a new category of multifocal IOL: the *trifocal* lens. This IOL works similarly to other multifocal IOLs, which are in essence bifocal lenses, but features an additional step for intermediate vision. Although surgeons and patients alike may not be as familiar with this lens design, its benefits over bifocal IOLs is real.

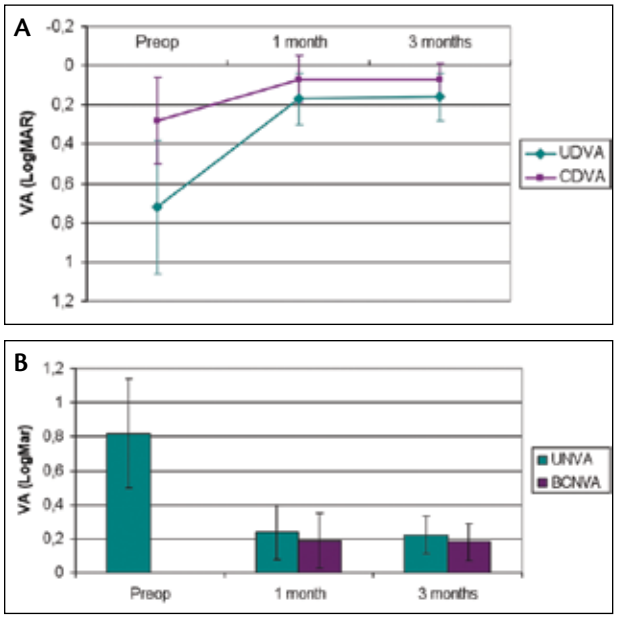

Figure 1. After FineVision IOL implantation, (A) distance UCVA and BCVA as well as (B) near UCVA improved significantly.

ONE- AND THREE-MONTH RESULTS

I recently conducted a study of 38 patients presenting for cataract surgery in whom I implanted the FineVision trifocal IOL. Follow-up at 1 and 3 months clearly showed that, compared with my previous results with other diffractive bifocal IOLs, the FineVision lens provided better intermediate visual acuity and was able to restore visual function in all eyes after surgery. Additionally, scotopic contrast sensitivity with the FineVision was similar to that of bifocal nonapodized and apodized IOLs. A summary of this study is described below.

One-month results. At the first follow-up, the mean distance UCVA was 0.17 (0.13 logMAR; range, 0.00–0.52), with a mean sphere and cylinder of 0.30 D (0.44 logMAR; range, -0.50 to 1.25) and -0.78 D (0.41 logMAR; range, -1.75 to 0.00), respectively.

Additionally, the mean distance BCVA was 0.07 (0.12 logMAR; range, 0.00–0.52), the mean near UCVA was 0.24 (0.16 logMAR; range, 0.00–0.62), the mean intermediate UCVA at 80 cm was 0.23 (0.16 logMAR; range, -0.08 to 0.59), and the distance-corrected near BCVA was 0.19 (0.16 logMAR; range, 0.00–0.70).

Three-month results. At the second follow-up, the mean distance UCVA was 0.16 (0.12 logMAR; range, 0.00–0.44), with a mean sphere and cylinder of 0.36 D (0.41 logMAR; range, 0.00–1.00) and -0.69 D (0.45 logMAR; range, -2.00 to 0.00), respectively.

Additionally, the mean distance BCVA was 0.07 (0.08 logMAR; range, 0.00–0.30), the mean near UCVA was 0.22 (0.11 logMAR; range, 0.00–0.52), the mean intermediate UCVA at 80 cm was 0.17 (0.07 logMAR; range, 0.00–0.28), and the distance-corrected near BCVA was 0.18 (0.11 logMAR; range, 0.00–0.40).

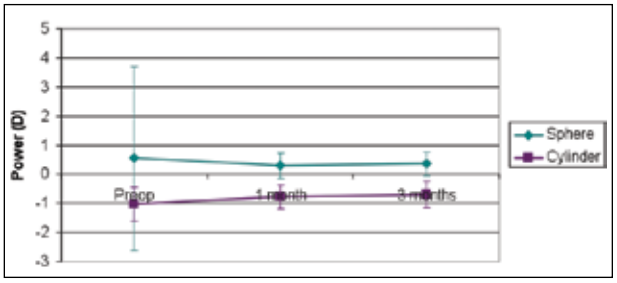

Figure 2. Total stability was found in both manifest sphere and cylinder.

THE RESULTS SPEAK FOR ITSELF

From these results, I concluded that the distance UCVA and BCVA improved significantly (Figure 1), as well as the near UCVA, and that total stability was found in both manifest sphere and cylinder (Figure 2) with implantation of the FineVision IOL. Additionally, the efficacy and safety indexes were 1.58 and 1.93, respectively, indicating to me that this lens is safe and effective to implant in patients. Compared with nonapodized and apodized bifocal IOLs, the FineVision trifocal IOL has a higher level of contrast sensitivity.

CONCLUSION

My early experience with the FineVision trifocal IOL indicates that patients achieved good quality of vision for far, intermediate, and near vision, without the presence of visual disturbances like halos, glare, and ghost images.

As the first trifocal diffractive IOL on the market, I believe that this represents a new trend in visual quality after cataract surgery. I expect these results to improve over time. ■

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Comparison of Diffractive Trifocal and Refractive Bifocal IOLs

Near and intermediate vision with the FineVision is far superior to a refractive bifocal IOL, and patients have superior image quality and a lower enhancement rate.

BY ERIK L. MERTENS, MD, FEBOPHTH

Early theoretical evaluations of the FineVision trifocal IOL (PhysIOL) showed that combining two diffractive optic profiles would create good vision in the intermediate range without sacrificing the quality of vision at near and far. We now have evidence that clinical results reinforce these theoretical findings.

Previously I was a heavy Lentis M-plus (Oculentis GmbH) user, because distance vision was outstanding and reading vision was acceptable. After having such good results, I did not want to ever go back to a diffractive multifocal design. However, I learned of the FineVision trifocal lens and decided to give it a try. Since then, I have been more impressed with the FineVision IOL.

COMPARISON

The FineVision is a hydrophilic acrylic lens with blue light and ultraviolet blockers and an aspheric, biconvex design. In comparison, the Lentis M-plus is a one-piece acrylic bifocal lens with an asymmetrical design. Similar to the FineVision, it is an aspheric, biconvex design. I recently compared these lenses, and a summary of my results is below.

Injection into the anterior chamber. Two videos comparing injection with these lenses are available at eyetube.net/?v=vaneh and eyetube.net/?v=didah. The Lentis M-plus is a bit stiffer to inject, mostly because its C-loop plate haptics are much stiffer than the haptics on the FineVision. This translates into slower injection of the Lentis M-plus into the anterior chamber.

Performance. I also compared performance of these lenses in cataract and refractive lens patients. After 6 months, 80% of FineVision eyes (n=37) and 100% of Lentis M-plus eyes (n=32) had a distance UCVA of 20/25 or better. However, when we look at the loss of lines of visual acuity at 1, 3, and 6 months, we can appreciate that only 6% to 11% of eyes lose 1 line with the FineVision, whereas 25% to 29% of patients lose 1 line with the Lentis M-plus. The number of gained lines is approximately the same for both lenses. For intermediate vision (80 cm), 100% eyes are J1 or better and 71% are J1+ at 6 months with the FineVision IOL and 86% of eyes are J1 or better with the Lentis M-plus.

Figure 1. There were no visual complaints with the FineVision IOL, compared with several with the Lentis M-plus.

Figure 2. Retinal spot diagrams of the (top, right) FineVision IOL versus the (bottom, left) Lentis M-plus.

The biggest difference between these lenses in terms of performance is in near vision. After 6 months, 100% of patients are J1+ with the FineVision IOL; however, no patient achieved J1+ or better with the Lentis M-plus.

In the latter group, only 42% of patients achieved a near UCVA of J1 and 86% of J2 or better. This is clearly in favor of the FineVision IOL.

Image quality. Surveying what patients perceive with these lenses was the most interesting part of our study. We used the iTrace (Tracey Technologies, Inc.) to produce a representation of the image quality and the visual complaints with each lens. With the Lentis M-plus, patients were likely to experience night myopia, double vision, glare, and halos. However, with the FineVision, there were no traces of these visual complaints (Figure 1).

We also used the iTrace to produce retinal spot diagrams of the FineVision and Lentis M-plus IOLs, thus determining the amount of light entering the pupil (Figure 2). We concluded that, because the spot spacing was tighter with the FineVision, that there was less light scatter. We also found a greater presence of higher-order aberrations (HOAs) with the Lentis M-plus. The mean spherical aberration and coma in an eye implanted with the FineVision were 0.0192 and 0.05, respectively, for a total mean HOA of 0.104 ($P<.01$). In the Lentis M-plus group, these levels were 0.064 and 0.186, respectively, for a total mean HOA of 0.352 ($P<.05$). This was statistically significant. We performed the same measurements with the KR1W (Topcon), with the same statistically significant findings.

CONCLUSION

Although the distance UCVA of the Lentis M-plus is slightly better than that of the FineVision, both near and intermediate vision with the FineVision is far superior. Additionally, patients have superior image quality and a lower enhancement rate with the FineVision. Through this research, I have concluded that the postoperative results with the FineVision IOL warrant more frequent use in my practice. ■

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Tolerance and Patient Satisfaction With the FineVision

General guidelines for patient selection.

REVIEWED BY BÉATRICE COCHENER, MD, PHD

A good visual result after cataract surgery is only one aspect of patient care. The other aspect—the more important aspect—is patient satisfaction, Béatrice Cochener, MD, PhD, said during a recent symposium sponsored by PhysIOL. Making sure patients are satisfied after surgery has always been a goal of refractive surgery, most likely because the procedure is elective, Professor Cochener continued; however, the pursuit of patient satisfaction is a newer concept in cataract surgery, perhaps introduced because of the excellent postoperative results seen after LASIK and PRK.

Regardless of the reasoning for the increase of patient expectations, it is the surgeon's job to ensure patients are satisfied after cataract surgery. According to Professor Cochener, one way of enhancing patient satisfaction is with a trifocal lens.

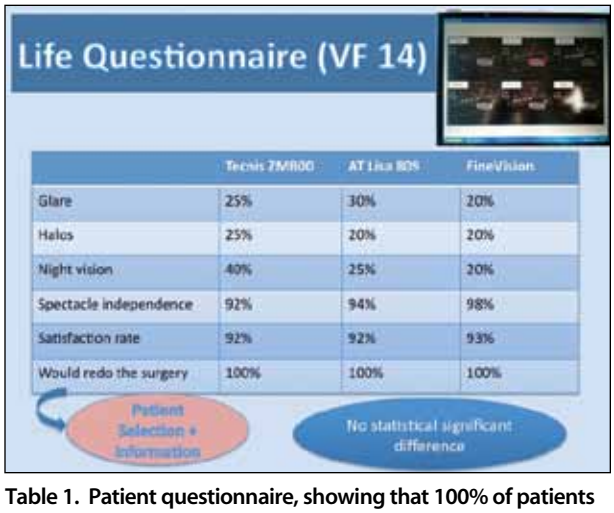

Table 1. Patient questionnaire, showing that 100% of patients would select the same IOL if they had to undergo surgery again.

PERSONAL EXPERIENCE

Professor Cochener's personal experience implanting multifocal (bifocal and trifocal) IOLs includes the AcrySof Restor Toric multifocal (Alcon Laboratories, Inc.), the Tecnis Multifocal (Abbott Medical Optics Inc.), the AT LISA toric multifocal and trifocal IOLs (both by Carl Zeiss Meditec), and the FineVision IOL (PhysIOL). For the purpose of a recent comparative study, Professor Cochener focused on two bifocal lenses, the Tecnis Multifocal and the AT LISA, and the new FineVision trifocal lens. In this study, overall patient satisfaction was relatively high, with 100% of Professor Cochener's patients reporting that they would redo surgery with the same lens again (Table 1).

With that said, more patients have been satisfied with the FineVision IOL and have achieved spectacle independence than with the other two lenses, Professor Cochener said. Perhaps this is because the FineVision provides patients with quality of vision at all distances, instead of at two distances (near and far) like other multifocal IOLs.

BASIC CRITERIA FOR PATIENT SELECTION

Professor Cochener also believes that part of her success with multifocal IOLs is careful patient selection. Among the selection criteria that can guarantee success with multifocal IOLs, regardless of the multifocal lens design (bifocal or trifocal), are the following four considerations.

Consideration No. 1: Talk to the patient. A happy patient is an informed patient. Explain the various IOL options available to the patient. Focus on the difference between a monofocal, bifocal, and trifocal lens design and the possible range of vision with each. Remember, do not over-promise.

Consideration No. 2: Establish that the patient will tolerate a multifocal lens. Getting to know a patient before surgery will reveal if he or she can tolerate a multifocal IOL. First and foremost, make sure you understand his or her expectations after surgery and any visual requirements he or she may have. It is also advisable to learn about the patient's lifestyle, including profession, driving habits, and hobbies. This will determine how successful a multifocal lens will be to this patient.

Consideration No. 3: Explain the special considerations of a multifocal lens design. The multifocal IOL profile produces a binocular outcome, which must be discussed with the patient in detail. Additionally, the patient must understand that a neural adapdation process will occur after surgery, and this can last several months. Lastly, he or she must be aware that the IOL will perform differently in varying light conditions. For instance, reading vision at the computer may be affected, as well as night vision when driving.

Consideration No. 4: Know the contraindications for multifocal IOLs. These include patients with unrealistic expectations or those who are very happy wearing glasses, patients with no more than 1.00 D of astigmatism or a preexisting ocular pathology, and those with intraoperative complications including capsular rupture or lens decentration.

OVERVIEW

Generally speaking, good patient selection is crucial for success with both bifocal and trifocal IOLs. When selecting the FineVision, implantation should be bilateral, with the second eye implanted within 1 week of the first, Professor Cochener said. Additionally, patients should be motivated to reduce their spectacle dependence at all distances; however, they must be forewarned that it is impossible to achieve the vision they enjoyed in youth. With that said, in the experience of Professor Cochener, the FineVision IOL likely produces the closest representation of that vision. This lens may be the last refinement needed to perfect the multifocal IOL. ■

Béatrice Cochener, MD, PhD, is a Professor and the Chairman of the Ophthalmology Department at Brest University Hospital, France, and President of the French Academy of Ophthalmology. Professor Cochener states that she is a clinical investigator for PhysIOL. She may be reached at tel: +33 2 98 22 34 40; e-mail: beatrice.cochener@ophtalmologie-chu29.fr.

FineVision IOL Combined With Laser Cataract Surgery

An exploration of two complimentary technologies.

BY PAVEL STODULKA, MD, PHD

My two favorite recent advances in cataract surgery are the femtosecond laser and the FineVision trifocal IOL (PhysIOL). Both technologies are not only pushing the boundaries of cataract surgery, but they are extremely complimentary. In my experience, postoperative results are better when laser cataract surgery is combined with trifocal lens implantation. Below is my reasoning.

I recently began implanting the FineVision trifocal IOL in conjunction with laser cataract surgery with the Victus femtosecond laser (Bausch + Lomb and Technolas Perfect Vision GmbH). Not only does this combined procedure have great marketing benefits, but I believe it also has the potential for better long-term IOL centration and on-axis positioning, resulting in precise effective lens position with greater chance for long-term postoperative emmetropia.

THE PROCEDURE

In short, two surgeons collaborate to complete the procedure. The first surgeon uses the Victus to create a capsulotomy that is 4.75 mm in diameter as well as for lens fragmentation and corneal incisions. The second surgeon performs the manual part of the surgery. He or she opens the incisions, injects a limited amount of ophthalmic viscosurgical device (OVD), and then aspirates the central anterior capsule with a phaco probe. The next step is to aspirate the anterior cortex overlaying the nucleus. The surgeon dips the phaco tip into the central nucleus, lifting it and phacoaspirating it with high aspiration (up to 600 mm Hg) using as few ultrasound pulses as possible. This creates a space to pull all four quadrants successively toward the center of the lens to be emulsified. After posterior capsular cleaning, the IOL is implanted. The FineVision IOL should be carefully placed into the injector. Wound-assisted implantation of the IOL can be achieved through a 1.8-mm incision.

In approximately 40 cases, I have not experienced a single broken haptic. I recommend implanting the FineVision with no OVD in the anterior chamber and to pressurize the eye with an irrigating cannula introduced through a sideport incision. In my experience, this lens centers well. Using the technique described above, there is no need to aspirate the OVD after implantation. But even after aspiration from underneath the optic, IOL centration is instant and excellent.

In these combined cases, 80% of patients achieved a mean distance UCVA of 20/20 and 90% achieved a mean distance BCVA of 20/25 or better at 3 months. The mean refraction was -0.12 ±0.06 D (range, -0.50 to 0.75), meaning that 90% of patients were within 0.50 D of intended refraction. In the intermediate range, 80% of patients had a mean UCVA of J2 or better at 3 months, and 90% had a mean BCVA of J2 or better. Again, 90% of patients were within 0.50 D of intended refraction, which was a mean of 0.50 ±0.25 D (range, 0.00–1.00). For near vision at 3 months, 80% of patients had a mean UCVA of J1 or better and 90% of patients had a mean BCVA of J1 or better. The refraction for this range was 0.75 ±0.20 D (range, 0.00–1.00), and 90% of patients achieved intended correction.

These results indicate a high quality of vision for all three distances and confirm that the refractive target can be precisely achieved with the FineVision IOL implanted into the bag with a capsulotomy created by a laser. No patient required LASIK fine-tuning. According to our experience, patients adapt to their new vision faster than with previous multifocal IOL models.

OTHER CONSIDERATIONS

I have also combined the use of laser cataract surgery with FineVision IOL implantation in patients with more than -5.00 D of myopia with good results; however, I would only use this strategy in a patient with -1.00 to -5.00 D of myopia if he or she could accept a slight drop in near vision quality.

Another group that may benefit from this combined treatment are emmetropic presbyopic patients. I have currently completed two bilateral cases. Although trifocal lens implantation after a refractive lens exchange in an emmetropic presbyope is controversial, these patients seem to be doing well. Further data is needed, however.

Perhaps the FineVision IOL will take the place of laser vision correction or refractive corneal inlays for the treatment of presbyopia. In the meantime, I am satisfied using this IOL in my cataract patients, because it provides them with a full range of vision across all three distances. ■

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