European Ophthalmologists See Promise in Trifocal IOLs

Refractive Surgery Outlook **| February/March 2014**
By Linda Roach

Ophthalmic surgeons and a growing body of peer-reviewed clinical research papers are reporting good clinical outcomes and high patient satisfaction with the two types of trifocal intraocular lenses commercially available to international ophthalmologists.

These lenses, the FineVision trifocal (PhysIOL, Liege, Belgium) and the AT LISA tri 839MP (Carl Zeiss Meditec, Jena, Germany), incorporate a third focal point for intermediate vision (70 to 80 cm) into the intraocular lens (IOL). Surgeons experienced with these lenses say they are notable for enabling at least 90 percent of pseudophakes to see well enough at all distances to become spectacle-independent.

Patient satisfaction rates in clinical studies often approach 100 percent, even among the 5 to 10 percent who admit to having some glare or seeing haloes around lights at night.

“If we have the goal that we need to achieve really good visual acuity at all distances, then this has been achieved,” said Béatrice Cochener, MD, PhD, who chairs the department of ophthalmology at University Hospital in Brest, France. During the past five years, Dr. Cochener has led or participated in several clinical studies of both of the commercially available trifocal IOLs.

“Patients will be able to see without any glasses most of the time. And more than 95 percent of the patients will have no glasses at all,” Dr. Cochener said.

She has implanted more than 300 FineVision lenses and approximately 100 AT LISA trifocals. A trifocal lens now is her preferred choice for about two-thirds of cataract patients who ask for a multifocal IOL, she said. But neither lens is a perfect solution to presbyopia, she pointed out.

“We are not talking about the dream of restoring what is lost, the accommodation. We are just compensating for what is lost. That’s why trifocal lenses are not ideal. But so far they are the best of all the surgeries for correcting presbyopia,” she said.

Iva Dekaris, MD, PhD, professor of ophthalmology at the University of Rijeka’s medical school in Zagreb, Croatia, said she, too, is shifting most of her multifocal patients to trifocals.

“If the patient’s style of life demands good intermediate vision then I don’t think there’s any doubt that we should use trifocals,” Dr. Dekaris said.

She directs a refractive cataract surgery clinic at University Eye Hospital Svjetlost in Zagreb, where she estimates that more than 250 AT LISA tri lenses were implanted over the last year.

“It’s not that we’ve stopped doing Tecnis and Restor, but especially in younger patients, we prefer to use the trifocal lens. In my personal experience, there are only rare cases in which I would use something else,” she said.

As a co-designer of the FineVision IOL, Damien Gatinel, MD, assistant professor and head of anterior segment and refractive surgery at the Rothschild Ophthalmology Foundation in Paris, says the FineVision is the only multifocal lens he uses, with the exception of cases requiring toric correction. He retains a proprietary interest in the FineVision IOL, for which a toric version is awaiting marketing approval in Europe.

“Beyond any financial interests, though, I really truly believe that it does not have any drawbacks compared to bifocal IOLs. It’s just adding better vision in the intermediate range,” he said. “I think it’s always better to provide superior performance, so I’m only implanting trifocal diffractive IOLs.”

Why trifocal IOLs?

Today’s cataract patients want to be able to see their smartphones, portable music players and computer monitors, all of which call for good intermediate (70 to 80 cm) visual acuity. Up until now, multifocal IOLs, with focal points only for distance and near vision, produce blurry images in the intermediate range, these surgeons noted.

Intermediate acuity also is important for nonelectronic tasks like reading music, cooking and maintaining one’s balance outdoors, Dr. Dekaris said.

“An older patient who is coming for cataract surgery, this patient needs good intermediate vision for walking down the street,” she said.

The FineVision trifocal lens uses the optical principle of constructive interference to capture and redistribute incoming light that otherwise would be lost to diffractive effects. Instead of losing 18 to 20 percent of the incoming light, as other diffractive multifocals do, bench testing found that the FineVision reduces the loss to 14 to 16 percent.[1,2] Zeiss claims in its product literature that the AT LISA trifocal IOL reduces light loss to an average of 14.3 percent, although the mechanisms by which it does so are unclear.

Two approaches to trifocality

While the FineVision and AT LISA trifocal IOLs achieve similar results, they appear to use different approaches to get there.

FineVision
The FineVision IOL creates trifocality by combining two diffractive profiles (one for distance and near, and the other for distance and intermediate). Edge to edge, the optic's anterior surface is micro-lathed with diffraction zones based on these alternating optical profiles, which are called kinoforms. These give the lens 3.5 D of add power for near vision and 1.75 D for intermediate acuity.

The computer-optimized peaks and valleys in the diffractive zones have heights and widths that are sized to cause constructive interference with light diffracted by the two adjacent zones. Step heights also are attenuated gradually from the center of the optic to the periphery, which is known as apodization and has been shown to minimize haloes at night and facilitate smooth revisions in light distribution as the pupil widens. In this way, the IOL captures light lost by other diffractive multifocals, increasing the total light energy available to the three foci.

Optical bench testing has shown that at baseline (a 3 mm "pupil"), 42 percent of the light energy transmitted through the FineVision IOL went to the distance focal point, 15 percent to intermediate and 29 percent to near. The remaining light was lost to higher-order diffractive effects.[2]

The light distribution became distance-dominant at 4.5 mm, and the proportion of light energy devoted to intermediate acuity also dropped, researchers found. With a 5 mm pupil, the distance and near focal points received about 62 and 18 percent, respectively, of the incoming light; the proportion sent to intermediate vision declined to around 5 percent. (This compares to a constant 30 percent allocated for intermediate vision by the AT LISA tri.)

AT LISA trifocal
Zeiss has released limited information in the past about how its trifocal IOL partitions incoming light. The company currently is not commenting on the matter because of a PhysIOL lawsuit alleging patent infringement.

However, according to Zeiss' physician handouts and product brochures, the central 4.34 mm of the AT LISA tri's posterior surface is micro-lathed with a series of equally spaced, concentric diffractive rings that send light to the three focal points. However, at pupil diameters between 4.34 mm and 6 mm, the lens becomes bifocal.

The diffractive rings have main and phase zones, with their edges smoothed to minimize reflections that can lead to patient complaints. The phase zones serve the same function as the stepped profiles on the surface of other diffractive multifocal IOLs, the company's literature says. At the IOL plane, the AT LISA tri has +3.33 D of add power for near acuity and +1.66 D for intermediate vision.

Bench tests have found that with a 2.0 mm pupil the lens transmits 50 percent of the usable light to the distance focus, 30 percent to intermediate and 20 percent to near, according to Zeiss. The proportion of light energy sent to the intermediate focal point is virtually the same at all pupil sizes, about 30 percent.

At larger pupil sizes, the bifocal periphery makes the IOL strongly distance-dominant; nearly 60 percent of light goes to distance vision with a 6 mm "pupil." Because the proportion sent to the intermediate focal point remains at about 30 percent, the fraction of light devoted to near vision plummets to well under 10 percent.

Patient outcomes

Dr. Cochener is one of the few clinical researchers who has extensive experience with both the FineVision and the AT LISA tri. She believes that neither trifocal IOL has a clear advantage over the other. She noted that both are hydrophilic lenses and have demonstrated posterior capsular opacification rates in the range typical for this material: 5 to 10 percent in the first post-op year.

"I would say that these lenses are really comparable and competitive on the market. I think there is a place for the two of them," she said.

"We did a small study comparing the two, and we were able to conclude that the two of them were able to meet the goal of good vision at all distances," Dr. Cochener said. "And we just found out in our series of about 30 patients that there might be a little better quality of vision with AT LISA compared to FineVision, but it was not statistically significant."

Other clinical results reported for the trifocal IOLs include:

- At the 2013 Congress of the ESCRS in Amsterdam, Dr. Cochener reported on a retrospective study of 40 patients, half of whom had FineVision IOLs implanted bilaterally and half AT LISA bifocal IOLs. Three months post-op, 100 percent of the FineVision patients reported being spectacle-independent, compared to 85 percent of the bifocal IOL patients.
- Also at the ESCRS meeting, Dr. Dekaris reported on comparative outcomes in bifocal and trifocal AT LISA recipients (104 and 84 eyes, respectively) at six months post-op. The mean monocular uncorrected intermediate visual acuity (UCIVA) in the trifocal group was 0.85, compared to 0.69 in bifocal IOL eyes, and all of the trifocal patients were spectacle-independent.
- In optical bench tests, one study measured the optical performance at different focal points and aperture sizes of the AT LISA trifocal IOL and two models of the bifocal AcrySof ReSTOR (Alcon, Fort Worth, Texas). The researchers reported that the AT LISA had the highest modulation transfer function (MTF) value at the -1.5 D focal point at all apertures. The ReSTOR SV25T0 (+2.5 D add) had the highest MTF at the 0.0 D focal point; ReSTOR SN6AD1 (+3.0 D add) was best at -2.5 D and -3.0 D focal points, if the aperture was 3.0 mm. When the aperture widened to 4.5 mm, the AT LISA had the highest MTF value at the -3.0

mm focal point.[3]
- A recently published study found that presbyopic patients who underwent bilateral refractive lens exchange and implantation with the AT LISA tri experienced improved near, intermediate and distance vision six months after surgery compared to preoperatively. Postoperative refractive status was within the range of +1.00 to -1.00 diopter in all 30 patients, and total internal aberrations decreased significantly.[4]

Other comparisons

Both commercially available trifocals are biconvex, aspheric, microincisional lenses made from a hydrophilic acrylic (25 to 26 percent water content) containing UV and blue light filters. The materials have proven track records in other IOLs the manufacturers make. They have -11µm of spherical aberration in order to neutralize the average amount of positive spherical aberration in the eyes of older adults. There also are many differences between the lenses.

Fixation
The FineVision has four closed-loop haptics (which in the second generation are being replaced by two pairs of open-loop haptics), whereas the AT LISA has a plate haptic design.

Size
There are small differences in the dimensions of the trifocal IOLs. The FineVision has an optic 6.15 mm in diameter and a total width of 10.75 mm, compared to AT LISA's 6.0 mm and 11.0 mm.

Manual folding vs. pre-loading
Although both IOLs are injectable, the pre-implantation steps differ. The AT LISA trifocal and its toric counterpart are sold already folded and loaded into a cartridge, which the surgeon attaches to an injector (Bluemixs 180, Zeiss).

However, the FineVision must be manually folded and then loaded into an injector before insertion through a 1.8 mm or 2.0 mm incision (Viscoject 1.8 or Accuject 2.0; Medicel AG, Wolfhalden, Switzerland).

Incision size
Unlike the AT LISA trifocal's toric version, the FineVision Toric cannot be injected through a 1.8 mm wound. It will require 2.0 mm when it becomes available commercially.

Range of toric powers
A toric version of the Zeiss trifocal IOL, the AT LISA tri toric 939M, received approval last year for European marketing, which made it the first toric trifocal available to international cataract surgeons. FineVision's trifocal toric lens does not yet have the CE mark for marketing in Europe.

When approval comes, this IOL will be able to correct greater amounts of astigmatism, from +1.0 to +6.0 D, than the AT LISA tri toric, which is currently available with cylinder powers of +1.0 to +4.0 D.

Second generation

PhysIOL in recent months announced changes to the original FineVision lens, and it introduced two new trifocal lenses, including the toric version of its trifocal IOL. The company's original trifocal IOL was renamed as the Micro FineVision (Micro F) and given a wider range of spherical powers, but it has the same shape, size and haptic configuration as the initial lens.

One of FineVision's new IOLs is a second-generation trifocal, the POD FineVision (POD F). This new lens will be fabricated from a different type of hydrophilic material than is used in the original IOL. It also has four new, open-loop haptics of a type that PhysIOL already uses in other IOLs in its product line.

The other new IOL, the FineVision Toric, for which the company hopes to win a CE mark soon, has the same optic-haptic configuration and dimensions as the POD F.

A legal cloud

While the future looks promising for trifocal IOLs, the two manufacturers of the currently available devices are ensnared in some legal wrangling. PhysIOL filed a patent infringement lawsuit in November against Zeiss asking a German district court to stop the sale and manufacture of the AT LISA tri and to recall stocks of the lenses from buyers. A German decision against Zeiss potentially could impact surgeons worldwide because the AT LISA tri is manufactured in Germany for international distribution.

The suit in a Dusseldorf court alleges that the Zeiss trifocal's design infringes on PhysIOL patents covering the combination of two diffractive designs to achieve trifocality, said Christophe Pagnoulle, PhD, manager of research and development for PhysIOL.

In a press release, PhysIOL said the challenge is based on a patent (EP 2 503 962 B1) and a utility model (DE 20 2011 110 144 U1) that the company was granted by the European Patent Office and the German Patent Office, respectively. The company has the same patent pending outside of Europe.

"At the moment, PhysIOL is not taking legal actions against commercial buyers or resellers of the products. However, the action also includes a request to the Court that all infringing products have to be recalled from commercial buyers," the press release said.

It concluded: "Contrary to some rumors in the market, Zeiss has no possibility to legally sell under a license. Zeiss has not requested a license from PhysIOL, and PhysIOL has no intention to grant a license."

While the companies await a decision, researchers continue to publish studies indicating that patients are demonstrating improved vision with trifocal IOLs compared with bifocal IOLs.

Financial Disclosures

Dr. Gatinel is a consultant for PhysIOL and holds a patent and proprietary interest in the FineVision trifocal IOL diffractive design.

Dr. Cochener is a clinical investigator for PhysIOL with no personal financial interest in the product.

Dr. Dekaris has no financial interests to disclose.

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