Introducing the ELENZA Sapphire AutoFocal IOL, the world's first implantable lens with artificial intelligence

Imagine offering a cataract patient an IOL powered by its own power cell and computer chip embedded inside. It’s rechargeable and fully programmable, allowing the physician to tweak its optical power as the patient’s visual needs change. It’s an IOL that won’t just mimic natural human accommodation, it’s designed to surpass it. This isn’t some lofty overpromise by a science fiction-obsessed surgeon; this is the future of IOL technology. And it’s standing on our doorstep.

Andrew Mazzocchi is chief executive officer of ELENZA (Roanoke, Va.), the developer of the IOL with the same name. His voice elevates with excitement when speaking of the IO L, calling it the type of innovation that “comes along once in a lifetime.”

“This will probably be the biggest thing I’ll ever do,” he said. “It’s big not only for the ophthalmology industry, but also represents a pioneering step in the development of active, programmable human implants.”

ELENZA combines nanotechnology, artificial intelligence (neural networks-based memory), and advanced electronics to seamlessly autofocus an optic from far to near without movement. Therefore, the lens doesn’t have to rely on precise contact with ciliary muscles to move and accommodate properly.

“You’ve seen windows where you flip a switch and it polarizes the glass and turns it dark. This is a similar concept,” said Mr. Mazzocchi. “We’re changing the molecular configuration of the liquid crystal to alter the optical power of the lens.”

The IOL builds upon an existing technology from PixelOptics (Roanoke, Va.), which created the world’s first electronically focusing prescription eyewear.

“Three or 4 years ago, I would have described this as science fiction,” said Richard L. Lindstrom, M.D., founder and attending surgeon, Minnesota Eye Consultants, as well as a member of ELENZA’s board of directors. “I am also involved with PixelOptics and thought this was science fiction even for glasses. Once that was achieved, the question became could [the technology] be made small enough to be duplicated in an IOL? It turns out that it can be duplicated and is being duplicated.”

ELENZA is an extraordinarily complicated system unlike anything ophthalmology has seen, relying on our individual pupillary response to automatically trigger accommodation between far and near.

“It’s been proven that the pupil responds to accommodation by getting smaller,” Dr. Lindstrom explained. “The IOL includes sensors that detect very small changes in pupil size. The pupillary response to accommodation is different from the pupillary response to light in regard to amplitude and how rapidly it occurs in response to accommodation.”

The microscopic rechargeable lithium-ion battery powering ELENZA didn’t even exist at the beginning of the project, said Andrew Maxwell, M.D., Ph.D., chairman of ELENZA’s medical advisory board. Similar batteries have been used in cochlear implants, but the batteries ELENZA uses are the smallest currently known to man. Although Dr. Maxwell estimates the battery itself will have a 50-year cycle-life, it requires recharging every 3–4 days.

The company is conducting demographic studies with select patient populations to create an ideal, noninvasive charging process. The most promising idea is to charge the IOL while the patient sleeps, building a system into a pillow or an eye mask.

As anyone with a computer knows, though, electronics fail. Batteries can clunk out. So what happens to the IOL and, more importantly, the patient’s vision, if something goes awry?

“The fail-safe system is the IOL falling back to having only optimal distance vision ... defaulting to a monofocal IOL,” Dr. Maxwell said. “The patient goes back to needing reading glasses.”

ELENZA also has a back-up plan for the absentminded patient who may forget the charger while on an extended vacation: a hibernation mode. If not recharged, the IOL defaults to a monofocal lens and can be rebooted up to 9 months later.

Furthermore, the lens is fully programmable and customizable, allowing the physician to remotely adjust the sensitivity and magnitude of the switching point of the add power in the IOL by up to three-quarters of a diopter, based on the particular needs of the patient.

“This is the most sophisticated computer chip and algorithm ever used in an implantable medical device,” Mr. Mazzocchi said. “Within the first 300 seconds, this IOL is going to learn the specific pupil dynamics of that patient and customize its own internal algorithm. As the patient’s needs change with time, the physician during a visit can reboot that algorithm and alter its program remotely and noninvasively. It’s a patient-specific, adaptive, programmable IOL.”

**AT A GLANCE**

- ELENZA is the world’s first IOL with artificial intelligence
- It uses advanced electronics to seamlessly autofocus an optic from far to near without movement
- The lens is fully programmable and customizable after implantation

**Source:** Eyemaginations/ELENZA
**Lingering questions**

Even with all of ELENZA’s promises, there are remaining safety and technological issues the company must overcome before the lens is ready for prime time. For example, what happens to the electronic components if the lens is hit with a YAG laser? Are any of the materials toxic? What if there’s leakage?

“These sapphire-coated batteries are sealed and encased in 24-carat gold,” Mr. Mazzocchi said. “We’ve tested and proven the integrity of this casing and sealed the battery and all the electronics in a thin glass wafer that’s herm etically sealed and then encapsulated into a conventional monofocal IOL.”

“At this point, knowing what the chemists and engineers know about the [lens] material, we don’t think [toxicity] will be a problem, but you never know until you test it,” Dr. Maxwell said.

Another concern is how to implant the lens through a conventional small incision without inducing astigmatism.

“We have a lens design that will fold and still maintain the integrity of all the internal electronic components,” Dr. Maxwell said. “We also have designed an injecting system that the IOL will fit into so it will go into the small incision without any trauma.”

**Look for it in 2018**

ELENZA is taking all of 2012 to knock out these concerns and others one-by-one and is not far from developing a finished, clinical-grade product. The hope is for in-man studies beginning in Europe early in 2013.

“ELENZA expects to obtain a CE mark in early 2014,” Dr. Lindstrom said. “FDA approval could take 4-5 years after the first implant in man,” he said, “bringing the lens to U.S. soil around 2018.”

“ELENZA is a very exciting project for me right now,” Dr. Lindstrom said. “While there are always surprises along the way, we are pretty confident we can make this work.”

Although the IOL is years from U.S. commercialization, Mr. Mazzocchi and Dr. Maxwell don’t believe physicians and patients will be skittish about implanting a computer chip and battery in the eye.

“My philosophy is pretty simple,” said Mr. Mazzocchi. “As long as this lens feels and looks like a conventional IOL and you can use the same insertion procedure, we anticipate no major adoption issue.”

“There will be a group that will want the new technology immediately and a group that will be more conservative,” Dr. Maxwell said.

“Ophthalmology, in general, has been a specialty that’s embraced new and advanced technology, especially with achieving our Holy Grail with...”

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Determining your surgically induced astigmatism

by Michelle Dalton EyeWorld Contributing Editor

Experts weigh in on how to define, calculate, and minimize SIA

Inducing some astigmatism is to be expected during cataract surgery, but with typical cataract incisions becoming smaller and smaller, there may be a time when the discussion is moot. Until then, how surgically induced astigmatism (SIA) is caused and how to minimize it remains relevant. The increased use of toric IOLs has thrust the entire issue of SIA back into the limelight, experts say.

"The moment a keratome passes through the cornea, "the astigmatic characteristics of that cornea are different," said Warren Hill, M.D., East Valley Ophthalmology, Mesa, Ariz. "We're treating the post-op astigmatism." Douglas D. Koch, M.D., said usingkerometry "can't be done because the refraction instead of post-op keratometry will induce more astigmatism than smaller ones.

SIA is not consistent. Eyes will always heal differently from each other," and that also affects SIA, said Guy Kezirian, M.D., founder, SurgiVision Consultants Inc., Scottsdale, Ariz., an ophthalmic consulting firm.

Corneal astigmatism differs from refractive astigmatism, and the "only way" to determine the SIA is "by running cross cylinder solution—what you have pre-op and what you have post-op and the vector difference between the two tells you what your SIA is," Dr. Holladay said. Adding the incisional length and incision location will be the two key determinants of SIA.

"You'll have more of an effect at 90 degrees than at 180," he said.

Operating on the steep axis "will always cause flattening, which will always reduce the amount of astigmatism a person has," Dr. Holladay said. "You get a bigger effect vertically than horizontally, but you'd still be reducing the astigmatism if on the steep axis."

Dr. Kezirian urges surgeons to adapt incision location to be on axis "because when you have to do a vector addition, you need to know both the amount and the placement of the astigmatism to add it to the patient's corneal astigmatism to develop a solution."

Calculating your own SIA

In the post-LASIK patient, "we can't figure out the true corneal power so it's next to impossible to determine the exact IOL power to place," said Robert Brass, M.D., founder, Brass Eye Center, Latham, N.Y. Using a toric IOL can help address some of

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About 37% of cataract incisions had a small Descemet’s detachment like this one post-op.

Source: Douglas D. Koch, M.D., and Li Wang, M.D.

According to Dr. Kezirian: “Distribution of the Standard Deviations (SD) of the change in keratometric absolute cylinder amounts, by surgeon. Data are from the SurgiVision DataLink IOL Edition software. The graph is based on data from 2,264 eyes from 55 surgeons who had entered 20 eyes or more having both pre-operative and 3-month post-operative keratometry values. The data set excludes eyes that had LRIs or prior surgery. The distribution plots the SD of the absolute change in keratometry cylinder amounts for each surgeon. One SD includes approximately 67% of eyes.

“Only 6% of surgeons have SIA values with a standard deviation of 0.1 D or less, and only 37% of surgeons have induced SIA values with standard deviations of 0.30 D or less. The large variation in the induced astigmatism amounts may undermine the value of toric calculators, and speak toward the need for making surgical incisions on-axis or 90 degrees away from the pre-operative cylinder axis location.”

Source: Guy Kezirian, M.D.

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out any particular complications. We've learned to be more accepting of advanced technology.” EW

Editors' note: Drs. Lindstrom and Maxwell are medical consultants for ELENZA. Mr. Mazzocchi has financial interests with ELENZA.

Contact information

Lindstrom: rlindstrom@mneye.com
Maxwell: amaxwellmd@gmail.com
Mazzocchi: rudy@elenza.com