

Future of noninvasive presbyopia treatment

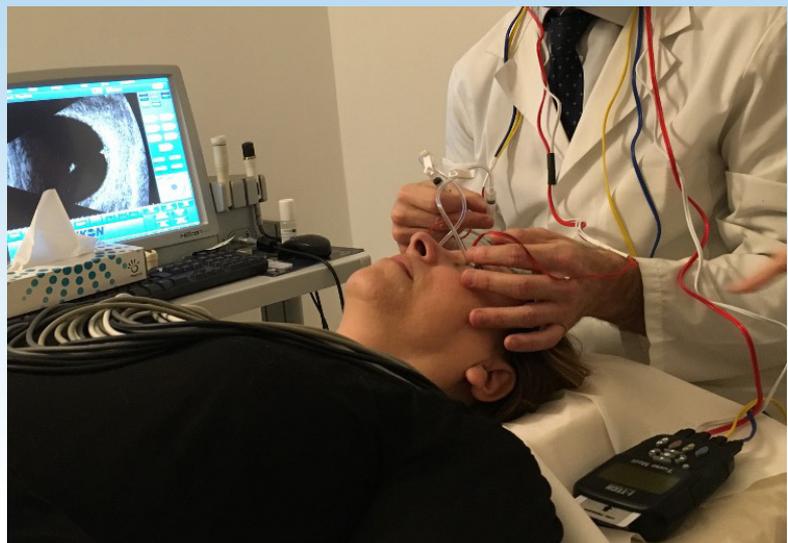
by Liz Hillman EyeWorld Staff Writer



Micro-electrostimulation is 1 nonsurgical option that could be used to correct presbyopia. A scleral contact lens with electrodes delivers low-voltage pulses to the ciliary body to “exercise” the muscle and temporarily improve its ability to accommodate.



Dr. Gualdi performs a micro-electrostimulation treatment of the ciliary body on a patient with presbyopia.



Source: Luca Gualdi, MD

New generation of nonsurgical presbyopia options show promise, but will they make it to market?

While there are many options for presbyopia management, patients eager to give up glasses might not be willing to take the plunge into surgical correction. Currently, work is being done to fill that void with many possible noninvasive solutions.

From drops to electrostimulation, there is a growing body of research on new methods to help the lens accommodate, but are they safe? Are there side effects? And do

they actually work? Although these questions—and more—in many cases have yet to be answered by peer-reviewed, scientific research, **John Berdahl, MD**, Vance Thompson Vision, Sioux Falls, South Dakota, thinks the future of noninvasive presbyopia treatments looks bright.

“Everyone gets presbyopia and no one likes it,” he said. “In general, no one wants surgery, but people do want to see, so they’re willing to undergo surgery as long as it is safe, effective, and improves their quality of life. But I think that most people would prefer a nonsurgical option if it was easy and convenient and worked. Nonsurgical options have yet to show that they’re easy, convenient, and work, but they certainly have that promise.”

Presbyopia-correcting drop

L. Felipe Vejarano, MD, Popayán, Colombia, admits that his invention—a drop formula that provides dynamic pseudoaccommodation by stimulating the ciliary muscle—might sound “unbelievable.”

The physician with a pharmacological background created the drop to use on himself more than 5 years ago. Currently called PresbV Tears, the drop contains a patent-pending mix of FDA-approved substances that he said allow the pupil to go from 2.5 mm to 4 mm (depending on light conditions). One drop, he said, lasts 4–5 hours with the effect starting 15–30 minutes after its application.

Dr. Vejarano presented at the American Academy of Ophthalmology’s Refractive Surgery

2015 Subspecialty Day on research involving the drop that included 20 patients. Each subject was given 1 PresbV Tears drop in each eye and was evaluated before the drop, 0.5, 1, 2, 3, 4, and 5 hours later, as well as 1 week and 1 month later. Dr. Vejarano reported no negative side effects from the drop. He also observed improved vision at 1 line for distance and 3 lines for near, and noted other factors that “[showed] the accommodation stimulus.”

Dr. Vejarano is working with European and Colombian pharmaceutical companies to manufacture the drop, and it is expected to be released before June 2016 in Colombia; they will soon begin a larger clinical study in Europe, which he hopes to publish in order to validate his preliminary results.

What do his colleagues have to say about this drop?

“My good friends congratulate me, but [others say it] doesn’t work, but the best thing is when I apply the drops, then they’re convinced,” he said.

Dr. Vejarano is not alone on the drop front. The search for a topical solution has been on for decades. In the past year alone there was a report out of Al-Azhar University in Cairo regarding the safety and efficacy of a carbachol-brimonidine solution,¹ another that EV06—a lipoic acid choline ester—by Encore Vision (Fort Worth, Texas) enrolled its first subject in its phase 1 and 2 clinical trials, and yet another that Presbyopia Therapies (Coronado, California) presented the phase 2 results for its Liquid Vision drop, just to name a few.

Dr. Berdahl said presbyopia-correcting drops in general have produced “very promising anecdotal reports,” but ultimately, “what’s going to drive the profession to adopt them are well-controlled trials that show good data on efficacy and safety.”

Stimulating the ciliary muscle

Another nonsurgical option could be electrostimulation of the ciliary muscle.

Luca Gualdi, MD, Rome, recently presented the results of a small, preliminary study involving Ocuft (SOOFT, Montegiorgio, Italy). The device—patented in 2009 by Massimo Filippello, MD, for treatment of glaucoma and presbyopia—

consists of a 20-mm polycarbonate scleral contact lens that is placed, for presbyopia-correcting purposes, on the bulbar conjunctiva 3.5 mm from the corneal limbus. This lens has 4 electrodes connected to a power source, which will emit electricity at a low voltage to passively contract the ciliary muscle for about 8 minutes.

Dr. Gualdi’s study, which involved 20 eyes and emmetropic presbyopia patients ranging from 40–50 years old, measured pre- and postoperative uncorrected visual acuity using both objective and subjective tests, ultrasound biomicroscopy, aberrometry, and the AR-1A accommodation module.

Dr. Gualdi found patients improved in uncorrected near (40 cm) and intermediate (70 cm) distance and reading speed time, maintained their distance vision, and had no negative side effects.

The negatives of this treatment for the patient, he said, are that it requires maintenance and it is not as effective on older presbyopic patients. He recommends 4 treatments within the first 2 months, followed by 1 treatment every 3 months to sustain it.

Dr. Berdahl said he “loves outside-of-the-box ideas,” such as electrostimulation of the ciliary body to address presbyopia.

“I love that companies are willing to take risks on ideas that are unconventional as long as they are studied well,” he said. “The question, of course, is ‘Is the lens

flexible enough to change its shape in someone who is presbyopic by increasing the ability of the ciliary muscle to pull on the lens?’ I think that has yet to be shown, but I like the thought process behind it.”

Other options

Drops and electrostimulation are not all that’s going on in the field of noninvasive presbyopia research. Noninvasive laser thermal keratoplasty (LTK) called optimal keratoplasty (Opti-K) with the Opti-K System (NTK Enterprises, Austin, Texas) is another option. This procedure, according to a 2011 study published by Rogers et al. in the *Proceedings of SPIE Ophthalmic Technologies*, involves “laser heating of the cornea to change its shape.”² While the paper acknowledged that the history of LTK has been “unsatisfactory” in the past, Opti-K, which is currently in clinical trials as a hyperopia treatment, was found to be “simple, rapid, comfortable, and repeatable.”

Conductive keratoplasty (CK) is a non-laser thermal treatment that could be used to correct presbyopia. As Rogers et al. said, “CK remains the most widely used technology for presbyopia treatment with over 200,000 procedures completed.”

Dr. Berdahl said advances in accommodating contact lenses could provide another avenue as well.

With all the work and research being done to create newer presbyopia treatments, Dr. Berdahl said it is a condition that will be solved.

“With the amount of effort that people are putting in, it’s going to be a solvable problem and we’re making more progress toward it now than we ever have,” he said.

“I’m all for safe and effective surgical options. I’m all for safe and effective pharmaceutical options. I love having new tools in my toolkit because some patients might be able to take drops, for example, others may be averse to surgery or not good candidates for surgery, so the more tools we have in our bag, the better,” Dr. Berdahl said. “I’m mostly concerned about solving the problem for our patients, and the more tools we have, the more likely we’re going to solve it for more people.” **EW**

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2. Rogers JK, et al. Improved method of laser thermal keratoplasty to overcome presbyopia. *Proc. SPIE 7885, Ophthalmic Technologies XXI, 78850N*, 12 February 2011.

Editors’ note: Dr. Vejarano has financial interests with PresbV Tears. Dr. Berdahl has financial interests with Abbott Medical Optics (Abbott Park, Illinois), Bausch + Lomb (Bridgewater, New Jersey), and Alcon (Fort Worth, Texas). Dr. Gualdi has no financial interests related to his comments.

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LASIK continued from page 99

efficacy record when properly and appropriately delivered.”

Dr. Kanellopoulos sees the primary difference between people who wish they had LASIK done and those who had it done as fear rather than finances. “Creating public awareness that this is an extremely safe procedure—perhaps safer than wearing contact lenses—will increase the number of LASIK cases performed,” he said.

“It still amazes me that patients wear everyday contact lenses, and they are very casual about it in regard to how old their lenses are and the hygiene that they use,”

he said. They may sleep with their lenses in but then balk at the idea of having surgery on their eyes.

“I think that we as an ophthalmic community need to propagate the data and the truth,” he said. “I have personally taken the road of being very honest with my patients, speaking openly about complications, and not trying to ‘sell’ the procedure, and I think this has helped me to have a tremendous turnaround in my patients in regard to how many of them decide to have surgery.”

Dr. Kanellopoulos thinks that people are far more educated today

than 20 years ago. “I think we are past the era of testimonials and more into the era of real science, educating our patients, and having them decide what the best solution is,” Dr. Kanellopoulos said.

Dr. Chang thinks that good patient education and understanding of the misconceptions as well as good marketing techniques will help increase LASIK in areas where it may have declined. “Ultimately, good patient experience, low complication rates, and excellent results [are] the recipe for patients referring their friends and relatives,” he said. **EW**

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