

Novel intrastromal device

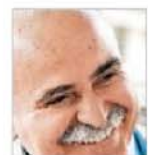
Implant improves near vision

Patient satisfaction with outcomes, spectacle independence rates are high at 1 year

By Cheryl Guttman Krader

Reviewed by Ioannis G. Pallikaris, MD, PhD

Crete, Greece—Results from 1 year of follow-up in patients receiving a novel intrastromal implant (Flexivue Microlens, Presbia Coöperatief U.A.) show that it safely and effectively improves near vision in patients with emmetropic presbyopia without compromising binocular distance acuity, said Ioannis G. Pallikaris, MD, PhD.



Dr. Pallikaris

The implant is a doughnut-shaped, bifocal lens with a peripheral refractive zone (+1.25 to +3 D) and a central neutral zone that is implanted in the nondominant eye. Dr. Pallikaris, professor of ophthalmology, University of Crete, and director, Institute of Vision and Optics, Heraklion, Greece, presented outcomes from 12 months of follow-up for a series of 15 patients (mean age 51 years) who had the lens placed inside a corneal tunnel created using a femtosecond laser.

Rapid improvement

The data showed all patients achieved rapid improvement in near vision with no change in binocular distance uncorrected visual

Take-Home Message

Intrastromal implantation of a doughnut-shaped, bifocal lens in the nondominant eye of patients with emmetropic presbyopia improves near vision without loss of binocular distance uncorrected visual acuity.

acuity (UCVA). Near UCVA increased from 20/50 preoperatively to 20/32 at 1 week, reached 20/30 at 1 month, and was stable at 20/25 from 3 months onward. Distance UCVA in the operated eye decreased from 20/20 preoperatively to 20/40 at 1 week, but returned to ~20/30 at 3 months where it remained unchanged. Distance best spectacle-corrected visual acuity did not change and binocular distance UCVA was 20/20 preoperatively and unchanged after surgery.

Consistent with the UCVA data, patient responses demonstrated excellent visual function. One hundred percent of patients gave ratings of excellent or good to questions about perceptions of their uncorrected near vision, distance vision in the operated eye, and binocular uncorrected distance vision. With a single exception, no patient used spectacles for reading, and the remaining patient reported wearing glasses for near activities less than 50% of the time.

“In addition to these very positive results, implantation of this novel lens has many advantages as a treatment for presbyopia,” Dr. Pallikaris said. “The procedure is simple, minimally invasive, and takes only minutes to complete. Unlike LASIK, there are no flap-related concerns, and the device can be replaced or easily removed without adverse effects.

‘The doughnut shape allows use of some central vision for distance, and distance vision is influenced less than expected for the amount of near correction because of the bifocality of the lens and its pupil dependence.’

Ioannis G. Pallikaris, MD, PhD

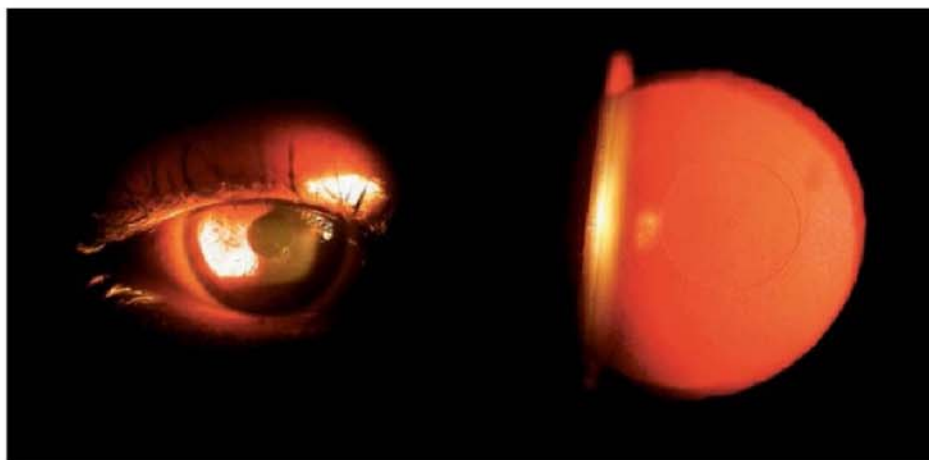


Figure 1 The implant is made of a hydrophilic polymer, measures 20 μm in thickness with a diameter of 3 mm, and is implanted at a depth of 280 to 300 μm . The lens itself is invisible, Ioannis G. Pallikaris, MD, PhD, noted, and so there are no cosmetic issues or interference with a fundus or slit-lamp exam.

“In addition, the lens itself is invisible, and so there are no cosmetic issues or interference with fundus or slit-lamp exam,” he said.

The implant is made of a hydrophilic polymer, measures 20 μm in thickness with a diameter of 3 mm, and is implanted at a depth of 280 to 300 μm .

“Due to the depth of the implantation, the procedure has a minimal effect on topography,” Dr. Pallikaris said.

For the study Dr. Pallikaris presented, tunnel creation for lens implantation was performed using the proprietary femtosecond laser and software (iFS femtosecond

See **Implant** on page 12

Implant

Continued from page 10

laser with the iFlap or iPockets software, Abbott Medical Optics) and a special mask, although other femtosecond lasers can be used.

Once the tunnel is made, the tissue is easily separated, and the lens is implanted using a special injector. Microadjustment of lens position is achieved using an irrigating cannula.

'This diagnostic technology is also very useful for understanding how the position of the lens can affect the final vision outcome.'

Ioannis G. Pallikaris, MD, PhD

"The small hole in the center of the lens facilitates centration," Dr. Pallikaris said.

"By asking patients to fixate on the blinking light of the excimer laser, the lens can be precisely centered on the line of sight, which is very important for the performance of this type of technology," he added.

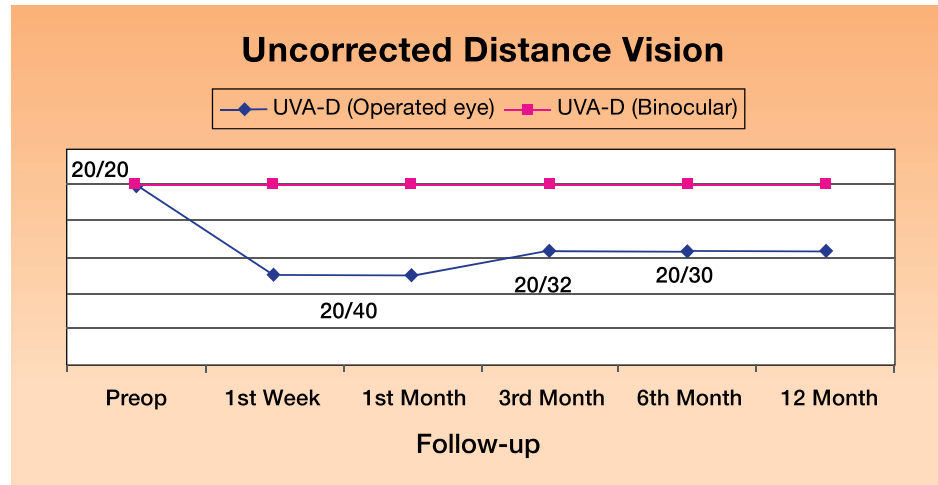


Figure 2 Distance uncorrected visual acuity (UCVA) in the operated eye decreased from 20/20 preoperatively to 20/40 at 1 week, but returned to ~20/30 at 3 months where it remained unchanged. Distance best spectacle-corrected visual acuity did not change and binocular distance UCVA was 20/20 preoperatively and unchanged after surgery. (Images courtesy of Ioannis G. Pallikaris, MD, PhD)

The mechanism of action of the implant is described using the concept of "smart monovision." In the nondominant eye, the bifocal lens offers different focal points for far and near vision, respectively. The maximum effect occurs when the pupil constricts for near vision whereas there is minimal effect on distance vision when the pupil diameter is increased.

"The doughnut shape allows use of some central vision for distance, and distance vision is influenced less than expected for the amount of near correction because of the bifocality of the lens and its pupil dependence," Dr. Pallikaris said.

Analyses of wavefront refractive maps obtained using ray-tracing technology (iTrace, Tracey Technologies) demonstrate the concept of smart monovision, showing there is a central myopic effect only when ana-

lyzing the central 3.5-mm zone, but only minimal difference between the preoperative and postoperative refraction when the analysis is based on a 5-mm zone, such as when the pupil is dilated for distance vision.

"This diagnostic technology is also very useful for understanding how the position of the lens can affect the final vision outcome," Dr. Pallikaris concluded. **OT**

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