



REFRACTIVE SURGERY

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Intracorneal micro-lens a minimally invasive option for presbyopia

The Flexivue intracorneal micro-lens is an easy, safe and reversible option for presbyopia, providing a good level of spectacle independence, according to one surgeon.

Ioannis G. Pallikaris, MD, PhD, director of the clinical trials on the Flexivue system (Presbia) in Europe, said, "It is a minimally invasive, reversible and safe approach with an easy learning curve for patients between the age of 45 and 60 who are too old for corneal refractive surgery and too young for lens extraction."

This micro-lens, made of a highly biocompatible hydrophilic polymer, is only 3 mm in diameter and 20 μ m in edge thickness. It is intended for insertion within the corneal stroma, in a pocket created by a laser in the nondominant eye. The central zone is free of refractive power, while the periphery has a positive add for near vision.

"Implantation is easy and only takes about 10 minutes," Dr. Pallikaris said.

Using the IntraLase femtosecond laser (Abbott Medical Optics) and a special mask, a tunnel is created in the corneal stroma from the temporal to the mid-nasal periphery, passing through the center of the cornea. The stroma is then separated using a spatula. Finally, the lens is loaded in a special delivery device, injected through the tunnel and positioned in the center of the cornea with the spatula.

"To make sure the lens is centered on the visual axis, I use the centration device of the Allegretto excimer laser (Alcon). I ask the patient to fix the flashing green light of the laser, and then I mark the visual axis on the cornea. Alternatively, since there is a small hole at the center of the lens, which you can very easily identify with a microscope, you can just make sure that the flashing light is in the middle of the hole. Then the lens is centered," Dr. Pallikaris explained.

Due to its small size and transparency, once in the eye, the lens is hardly visible and does not interfere with ophthalmologic examinations.

Further potentials

The Flexivue lens is designed to correct between 2.5 D and 3.5 D of presbyopia. So far in the study, it has been used for only presbyopia with no additional refractive problem. Potentially, however, a laser treatment can be used to address ametropia before implantation.

"You can do your refractive treatment, and once you have achieved a stable refraction, you can open the tunnel and implant the lens in the nondominant eye," Dr. Pallikaris said.

As far as astigmatism is concerned, the system currently allows for up to 1 D of astigmatism. In the near future, the femtosecond laser cut could be used as a relaxing incision.

“With the femtolasers company, we have developed a software that allows us to perform the tunnel incision in every position in the eye. With the help of a special nomogram, we will be able to implant the lens and at the same time correct astigmatism,” Dr. Pallikaris said.

Potentially, the Flexivue system can also be used in a large population of patients previously operated for cataract with monofocal IOL implantation.

An option with many advantages

Dr. Pallikaris has implanted the Flexivue lens in about 70 eyes. Fifty were included in the first study and now have more than 3 years of follow-up.

“We have used a mechanical keratome in the study, while the IntraLase was used in our last 20 patients,” Dr. Pallikaris said.

Results have been satisfactory. Ninety percent of patients said they are fully satisfied, and 70% are not using spectacles for near vision.

Compared with other procedures for presbyopia, the Flexivue has the advantage of being easily reversible. With photoablation techniques such as presbyLASIK, if the treatment is slightly decentered or if the patient is unable to adapt to multifocality, there is no way to go back. Multifocal IOLs require the removal of the natural lens, which can create adaptation problems and visual effects that are not always well tolerated by the patient.

“Replacing a multifocal lens can be quite complicated and is certainly not risk-free. Removing a Flexivue intracorneal lens is easy. You reopen the tunnel, flush water inside and the lens comes out. You can replace it immediately, and the entire procedure takes no more than a few minutes,” Dr. Pallikaris said.

As visual acuity changes with age, patients may need an additional power lens, and this easy way of replacing the implant is an asset.

The Flexivue micro-lens has received the CE mark in Europe, allowing the lens to be commercially available in 40 countries across Europe and Latin America. Further studies will be carried out to demonstrate the long-term safety and efficacy of this method. – *by Michela Cimberle*

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