

Advantages of Corneal Inlays for Presbyopia

Flexivue's *smart monovision* technique is reversible and minimally invasive.

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Presbyopia is a multifactorial physiologic aging mechanism that leads to the progressive loss of functional near vision. Scleral expansion surgery,¹ corneal laser surgery with multifocal patterns or monovision approaches,² conductive keratoplasty (CK),³ and clear lens extraction or cataract surgery using multifocal, accommodating, or monovision monofocal IOLs^{4,5} are among the techniques that have been used for the treatment of presbyopia. Corneal laser surgery and CK are minimally invasive methods, but they provoke irreversible changes in corneal anatomy, whereas scleral surgery and

clear lens extraction are more invasive techniques.

The desire to develop a minimally invasive, reversible, stable, and safe surgical technique with an easy learning curve for patients between the ages of 45 and 60 years—patients who could be considered too old for presbyopia corneal surgery and too young for lens extraction—led to the development of a new approach based on the use of refractive corneal inlays. These devices are placed inside a tunnel created in the corneal stroma.

The Flexivue Micro-Lens corneal inlay (Presbia Coöperatief UA, Amsterdam, Netherlands) is a refractive hydrophilic polymer lens intended for insertion inside a corneal stromal tunnel in the nondominant eye. The lens' central zone is free of refractive power, and the peripheral zone has a standard positive refractive power. The diameter of the Flexivue is 3 mm, and the thickness is less than 20 μm .



Figure 1. Implantation of the inlay into the corneal tunnel.

FOCAL POINTS

The Flexivue inlay provides the operated (nondominant) eye with two focal points, one for far vision and one for near.

Far vision. The rays passing through the central zone of the implant (ie, neutral zone without refractive power) and the free peripheral corneal tissue are focused sharply on the retina. Alternatively, the rays passing through the refractive peripheral zone are focused in front of the retina.

Near vision. The rays passing through the peripheral refractive zone are focused on the retina, and the rays passing through the central zone of the inlay are out of focus (ie,

TABLE 1. AVAILABLE CORNEAL INLAYS

AcuFocus Kamra Corneal Inlay*AcuFocus, Inc., Irvine, California*

The AcuFocus Kamra corneal inlay (formerly the AcuFocus ACI corneal inlay) is an implant designed to improve near vision in presbyopic patients. The Kamra inlay

received the Conformité Européene (CE) Mark approval 5 years ago. AcuFocus markets the corneal inlay in Europe and Asia. In the United States, enrollment for clinical trials for US Food and Drug Administration (FDA) approval has been completed. More than 1,000 inlays have been safely implanted in three FDA clinical trials.

The Kamra inlay is placed intrastromally under a corneal flap or in a corneal pocket. The inlay is an opaque circular micro-disc with a 1.6-mm opening in the center and thousands of high precision laser openings in a proprietary pattern around the ring of the inlay. It is 3.8 mm in diameter, which is smaller than a contact lens. When placed in the cornea, the small aperture of the Kamra inlay provides increased depth of focus and improved near visual acuity. Unlike with a monovision inlay, both eyes are binocular at distance. The Kamra inlay's small-aperture technology also provides intermediate vision superior to alternatives that use a multifocal approach, according to the manufacturer. The Kamra inlay does not require irreversible tissue removal to treat presbyopia.

Flexivue Micro-Lens*Presbia Coöperatief UA, Amsterdam, Netherlands*

Presbia's Flexivue Micro-Lens solution uses an implantable lens to specifically treat presbyopia, correcting the loss of near vision. The procedure is a safe, effective, permanent yet reversible solution for presbyopia. Of several hundred patients in the European Economic Area who have had the lens implanted for more than 3 years, more than 90% have report-

ed satisfaction with the procedure, according to the company. Presbia received the CE Mark for the Flexivue Micro-Lens. The lens, made of a hydrophilic polymer, is 3 mm in diameter and has an edge thickness of less than 20 μm . The approximately 10-minute implantation procedure for the device is conducted without general anesthesia and typically in the nondominant eye. Using a femtosecond laser, the surgeon creates a pocket in the cornea and inserts the Flexivue Micro-Lens with Presbia's proprietary insertion tool. The pocket then seals itself, allowing the lens to stay in place permanently or, if needed, easily and safely removed or replaced with a stronger prescription.

The Flexivue Micro-Lens and related medical procedures are not available in the United States and have not been evaluated or approved by the FDA.

**PresbyLens***ReVision Optics, Inc., Lake Forest, California*

The PresbyLens is a corneal inlay designed to improve near and intermediate vision in presbyopes by microscopically changing the shape of the corneal surface. This miniature lens is 2 mm in diameter and made of a medical-grade material that is mostly water, making it similar in appearance and refractive index to the cornea. The PresbyLens has received the CE Mark and has received an Investigational Device Exemption from the FDA to begin a clinical study.

** Compiled with information from industry resources and reviews.*

focused behind the retina). The pupil blocks the rays passing through the peripheral clear cornea.

SURGICAL PROCEDURE

Using a femtosecond laser (IntraLase; Abbott Medical Optics Inc., Santa Ana, California) and a special mask, a tunnel is created inside the corneal stroma, from the temporal periphery to the mid-nasal periphery, passing through the center of the cornea. Using the centration device of the

Allegretto excimer laser (WaveLight Laser Technologie, AG, Erlangen, Germany), the center of the visual axis is marked on the cornea. The stroma is then separated with a spatula, and the lens is implanted using a special inserter (Figure 1). With the spatula, the lens is positioned at the marked center of the visual axis (Figure 2).

Presbyopic patients with emmetropia who are between the ages of 45 and 60 years are a particular target group for corneal inlays because they have healthy eyes, usually with

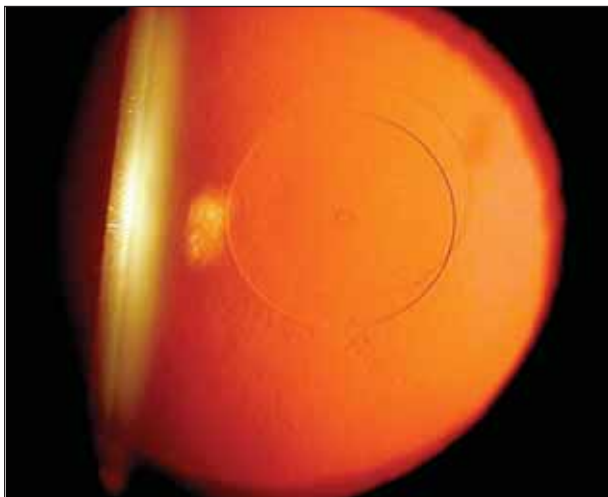


Figure 2. Slit-lamp examination shows the corneal inlay in place.

excellent distance visual acuity. Many surgeons consider these individuals too old for corneal laser surgery and too young for cataract surgery. Furthermore, these patients are dissatisfied with procedures that leave even minimal damage to their far binocular visual acuity and quality of vision.

In our clinic, we started performing corneal inlay implantation in 2007 with the InVue system (BioVision AG, Bruggs, Switzerland), which used a mechanical microkeratome for tunnel creation.⁶ Mean near UCVA improved to 20/25 the first week after surgery and remained stable at 1-year follow-up. Binocular far vision remained 20/20; however, in the operated eye far vision decreased to 20/32.

ADVANTAGES

Implantation of corneal inlays is differentiated from simple monovision procedures with laser correction or cataract surgery not just in the procedure's reversibility but also in its dependence on pupil size.

Measuring wavefront refraction, there was a noticeable effect of the Flexivue inlay only when we analyzed the central 3-mm zone (corresponding to the diameter of the inlay). When we analyzed the central 6-mm zone, the effect decreased. Therefore, the maximal inlay effect occurs during near vision when the pupil becomes smaller, and it decreases during far vision when the pupil is larger. We called this phenomenon *smart monovision*.

TAKE-HOME MESSAGE

- Corneal inlays provide the eye with near and far focal points.
- Patients with emmetropia and presbyopia are good candidates if they are between the ages of 45 and 60 years.

The Flexivue Micro-Lens is just one available corneal inlay on the market. Its unique mechanism of action is the smart monovision that we just described; other inlays have different mechanisms of action, including increasing depth of focus (AcuFocus; AcuFocus, Inc., Irvine, California), and reshaping of corneal curvature (PresbyLens; ReVision Optics, Inc., Lake Forest, California). See *Available Corneal Inlays* for further description of these inlay technologies.

We are studying the visual outcomes and safety of the Flexivue corneal inlay in the treatment of presbyopia using a femtosecond laser for tunnel creation. Our initial reaction is that this combination maximizes precision and customization. Ease of implantation and reversibility are the main advantages of the procedure. Additionally, the transparent lens is aesthetically acceptable and does not interfere with ophthalmologic examinations. We believe that surgeons should consider corneal inlays as a treatment option for emmetropic presbyopes 45 to 60 years old. Further follow-up and a larger series of surgeries are needed to demonstrate the safety and efficacy of this promising surgical method. ■

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