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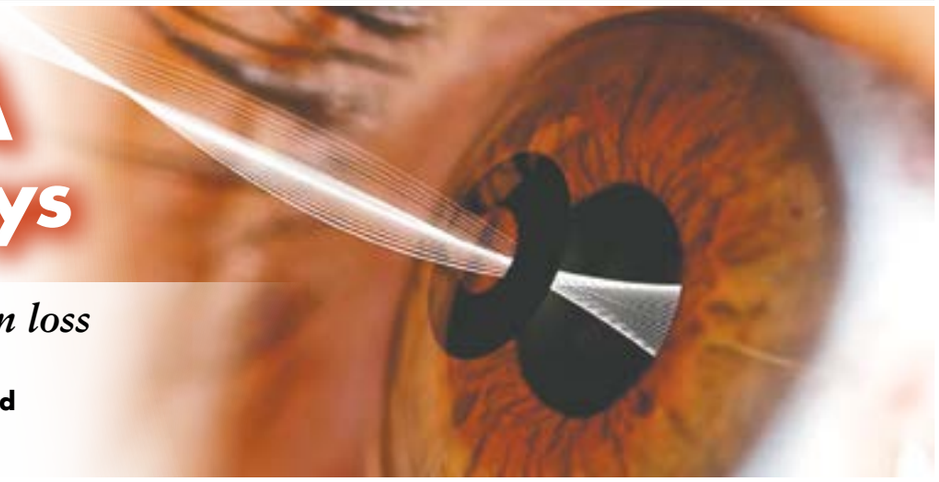
OPHTHALMOLOGY

KAMRA corneal inlays



Correcting age-related vision loss

By Richard L. Lindstrom, MD, and David R. Hardten, MD, FACS

"Why is my near vision changing?" This is a common question for many individuals as they near the age of 40 and beyond. They may begin to notice their reading, or "up close," vision beginning to get blurry. Perhaps they squint, turn on a brighter light, or extend their arm to bring an object into focus. The technical term for this condition is presbyopia (prez-bee-OH-peeah). It is a frustratingly natural condition that eventually happens to everyone.

Focusing on age

In our 20s and 30s, our eye's natural lens is elastic and flexible. Like a camera lens, it automatically adjusts and focuses our vision, allowing us to switch our gaze from something near to something far away. Over time, the natural lens in your eye begins to stiffen. It can't bend into the right shapes to bring close objects into focus.

Presbyopia progresses over time. For example, someone who is 45 may only notice it when trying to read tiny print in low light. However, someone who is 50 may depend more and more on reading glasses or contact lenses throughout the day for near vision tasks.

Presbyopia is different from another common refractive error: myopia, or nearsightedness. Nearsighted individuals typically have problems seeing well at a distance and are forced to wear glasses or contact lenses. The nearsighted eye is usually longer than a normal eye, and its front portion, or cornea, may also be steeper. Therefore, when light passes through the cornea and lens, it is focused in front of the retina. This will make distant images appear blurred.

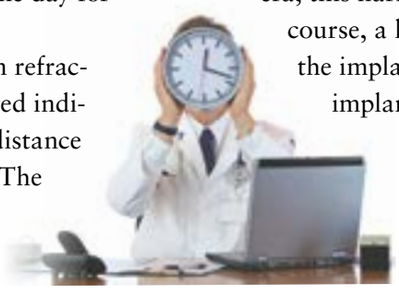
Reading glasses are a part of growing older, but many people who start wearing them in their later years find them downright awkward and uncomfortable. A new corneal inlay device, approved by the Food and Drug Administration (FDA) in April 2015, may provide a solution.

A "pinhole" inlay

The KAMRA inlay (developed by AcuFocus) is implanted into the cornea of the patient's non-dominant eye, leaving the second eye untouched. Smaller and thinner than a contact lens, the inlay is a mini-ring with a tiny opening in its center. Implanted in the first few layers of the cornea, the inlay uses the pinhole effect to focus light coming into the eye, restoring near vision while maintaining distance vision—much like squinting. It also offers long-term performance to help you continue to enjoy clear vision over time.

The device is essentially a 3.8 millimeter ring with a 1.6 millimeter aperture in the center. Just like a diaphragm in a camera, this narrow opening for light increases image focus. Of course, a lot of the peripheral unfocused light is blocked by the implant, but because only one of the eyes receives the implant, patients will maintain distance vision without losing depth perception. Unlike other refractive surgeries, distance vision remains binocular.

To help the device stay in place without causing unnecessary irritation to corneal tissue, it has thousands of holes within its body that allow oxygen and nutrients to pass through.



The entire inlay procedure typically takes less than 20 minutes.

Inlay vs. onlay

Corneal inlays, developed to surgically correct presbyopia, are typically implanted within one-third to one-half the depth of the cornea, using a laser to create a "pocket" for the device.

Corneal onlays, on the other hand, were intended to be a less invasive means to correct corneal refracting power. Onlays are implanted closer to the front of the cornea, just under the outer layer or epithelium, which comprises about 10 percent of the overall thickness of the cornea. The epithelium acts as a protective barrier to keep bacteria, dust, and other foreign substances from penetrating the eye. The epithelium also absorbs oxygen and nutrients from the tear film so they can nourish the rest of the cornea.

Many ophthalmologists now consider corneal inlays to be the preferred method for corneal implants designed for vision correction.

Inlay vs. other refractive procedures

The KAMRA inlay is not to be confused with LASIK or other refractive procedures that use lasers to reshape the curvature of the cornea, altering the way light rays enter the eye. Artificial lenses surgically inserted into the eye can also refocus light rays to sharpen vision.

"Monovision" LASIK corrects one eye for near vision and one eye for distance. Near vision improves, but distance vision diminishes over time. Also, people who have LASIK with monovision report increased night glare, a sense of feeling off balance, and loss of depth perception. Further, the improved near vision decreases in the long term.

In the KAMRA inlay procedure, a device is implanted in the cornea, but the cornea is not reshaped, as it is in LASIK.

Procedure and recovery

The inlay is ideal for people hoping to reduce their dependency on reading glasses. The device is indicated for people 45 to 60 years old that have not had previous eye surgery, who have normal distance vision but require reading glasses between +1 and +2.5 diopters of power. Ideal candidates do not suffer from dry eye.

The entire inlay procedure typically takes less than 20 minutes, with numbing drops used to ensure the patient's comfort.

Using a laser, the surgeon creates a small pocket in the first few layers of the cornea. The surgeon then places the inlay into the pocket and centers it over the pupil. Patients will feel a slight pressure from the laser during the creation of the flap, but should experience no pain and little discomfort. There are no stiches or bandages, but patients will need to use eye drops for a period of time to ensure proper healing.

The goal of the inlay is to restore everyday near vision, so the patient can once again see text messages, computer screens, and wristwatches, without the frustration of reading glasses or contact lenses.

Recovery time…will depend on personal healing patterns.

As with any eye surgery, healing is a process. The recovery time (when patients will notice an improvement in near vision) will depend on their personal healing patterns. While some patients see an improvement within the first week to a month, others may require additional time.

FDA approval and outcomes

To evaluate the safety and efficacy of the inlay, the FDA reviewed the results of three clinical studies. The main study showed that 83.5 percent of the evaluable 478 participants achieved uncorrected near visual acuity of 20/40 or better at 12 months. This is the level of vision needed to read most text in magazines and newspapers.

The device is not intended for patients who have had cataract surgery or patients with severe dry eye; an active eye infection or inflammation; corneal abnormalities related to thinning and irregular shape of the surface of their eyes; insufficient corneal thickness to withstand the procedure; a recent or recurring herpes eye infection or problems resulting from past infection; uncontrolled glaucoma; uncontrolled diabetes; or active autoimmune or connective tissue disease.

It is important to understand that there may be times when additional magnification is needed to read small print in dim light or to perform a near task for an extended period of time.

Before considering the procedure, you should have a complete eye examination. Talk to your eye surgeon about the potential benefits, complications, risks, and healing time. It is important to know that some KAMRA inlay patients may still require reading glasses for activities such as reading tiny print or reading in low light and that if the inlay is not centered properly or the effects are not ideal, it can be surgically removed.

Summary

The KAMRA corneal inlay is a very favorable option for individuals interested in maintaining a natural range of vision—from near to far. As the only presbyopia procedure utilizing small aperture optics, it offers treatment for near, or reading, vision. With the inlay, patients receive:

- Safe, proven, sustainable near vision solution
- Complete uninterrupted range of vision
- Minimally invasive procedure
- Treatment that leaves the natural lens in place
- Lasting vision treatment

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