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PROFESSIONAL UPDATE: OPHTHALMOLOGY

The KAMRA corneal inlay

Maintaining a natural range of vision

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Presbyopia is a common visual complaint for many individuals as they near the age of 40 and beyond. When people develop presbyopia, they find themselves holding books, magazines, newspapers, menus, and other reading materials at arm's length in order to focus properly. When they perform near work for any length of time, such as embroidery or handwriting, they may develop headaches, eyestrain, or feel fatigued.

Presbyopia is an age-related condition and is generally believed to stem from a gradual thickening and loss of flexibility of the natural lens inside the eye. This differs from astigmatism, nearsightedness, and farsightedness, which are related to the shape of the eyeball and are caused by genetic and environmental factors. Age-related change occurs within the proteins in the lens, making the lens harder and less elastic over time. Changes may also take place in the muscle fibers surrounding the lens, which prevents the eye from being able to focus up close.

Presbyopia continues to progress 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 55 may depend more and more on reading glasses or contact lenses to see while focusing on near vision tasks throughout the day. The need for reading glasses is part of growing older, but for many people it can be downright uncomfortable and frustrating. Now an advanced device, approved by the FDA, may offer certain individuals with presbyopia a new way of addressing this condition.

A new device

Developed by AcuFocus, the KAMRA corneal inlay received FDA approval for use in the United States in April 2015. The device received a CE mark in 2005 for the European Economic Area, allowing it to be marketed in over 50 countries across Europe, Asia, South America, and the Middle East.

The inlay is designed to reduce the need for reading glasses among people age 45 and over who have good distance vision without glasses, but have problems seeing up close due to presbyopia. The goal of the inlay is to restore everyday near vision, so the patient can once again see text messages, read a computer screen, and see the time on their wristwatch, without always needing reading glasses.

The KAMRA inlay is smaller than a contact lens—just 3.8 millimeters (about 0.15 inch) in diameter and 6 microns thick (about half the thickness of plastic wrap used to store food). It consists of an opaque outer ring and a tiny (1.6 mm) central opening that is placed directly in front of the center of the pupil. It works on the same principle as a small camera aperture by increasing the depth of focus. The central opening of the inlay allows only focused light into the eye, enabling an individual to see near, far, and everything in-between.

The entire procedure typically takes less than 20 minutes.

KAMRA inlay vs. other refractive procedures

The KAMRA inlay is not to be confused with LASIK, or other refractive procedures. In LASIK and similar procedures, laser energy reshapes the curvature of the eye's cornea to alter the way light rays focus on the retina. Artificial lenses surgically inserted into the eye can also refocus light to sharpen vision.

Monovision LASIK leaves one eye in focus for far vision, and the other eye corrected for near vision tasks. Patients will get improved near vision, but will have some diminished capacity to see at a distance and loss of depth perception. While monovison works well for most patients, some people who have monovision LASIK have difficulty adapting and experience a sense of feeling off balance, and loss of depth perception. Further, the improved near vision that the procedure produces can decrease as the patient ages and the presbyopia progresses.

The KAMRA inlay is typically implanted in the non-dominant eye, so the distance vision of the patient's dominant eye is completely unaffected and the patient retains distance vision in both eyes.

Corneal inlay surgery may be combined with refractive corneal laser (LASIK and PRK) surgery to correct presbyopia, as well as nearsightedness, farsightedness, and/or astigmatism. This was not a part of the IDE (investigational device exemption) study and is considered an "off-label" use of the procedure in the United States. However, it is routinely performed with great success.

Who is not an ideal candidate?

The KAMRA inlay does not reduce nearsightedness or farsightedness. A common situation is someone who has both nearsightedness and presbyopia or farsightedness and presbyopia. In these patients, the nearsightedness or farsightedness can often be improved with LASIK, PRK, or Natural Lens replacement (where the natural lens is replaced with a lens implant). In patients over age 60, mild lens opacities often exist where Natural Lens replacement (even using a multifocal or accommodating intraocular lens implant) may be a better option. Many options exist and during the eye examination, the surgeon can determine the best option to achieve the patient's goals.

Who is the ideal candidate?

The KAMRA inlay is ideal for people who want to reduce their dependency on reading glasses. The device is indicated for people 45 to 60 years old, who have normal distance vision but require reading glasses between +1.0 and +2.5 diopters of power.

The device is not intended for patients who have 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.

The inlay is designed to reduce the need for reading glasses.

Procedure details

The KAMRA inlay is the number one prescribed corneal inlay in the world and provides an excellent, long-term range of vision from near to far. The entire procedure typically takes less than 20 minutes. Numbing drops are used to ensure the patient's comfort throughout the procedure.

Using a femtosecond laser, the surgeon creates a small pocket in the cornea and 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 pocket, but should experience no pain and little discomfort. There are no stiches or bandages needed. However, post-operatively the patient will need to use eye drops for a period of time to ensure proper healing.

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.

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

FDA approval and outcomes

To evaluate the safety and efficacy of the KAMRA inlay, the FDA reviewed the results of three clinical studies. The results of the main study showed that 83.5 percent of the evaluable 507 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. An average three line gain was achieved at 12 months and remained stable over the remainder of the study.

Before considering the KAMRA inlay procedure, individuals should have a complete eye examination. Eye surgeons should discuss the potential benefits, complications, risks, and time required for healing with patients. If the visual effects are not ideal, the inlay can be surgically removed at a later point.

Conclusion

In 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, the KAMRA inlay offers treatment for near, or reading vision. With the KAMRA inlay, patients receive a:

- FDA approved sustainable near vision solution
- Complete uninterrupted range of vision
- Minimally invasive surgical procedure
- Treatment that leaves the natural lens in place
- Lasting uncorrected vision improvement at near

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