INLAY TO TREAT PRESBYOPIA GETS US APPROVAL

It is the first implantable device for the correction of near vision in presbyopic patients who have not had cataract surgery.

BY CONNI BERGMANN KOURY, EXECUTIVE EDITOR

The FDA has approved the Kamra inlay (AcuFocus), a device that is implanted in a presbyopic patient's cornea to improve near vision by extending the depth of focus. The inlay is indicated for those who have emmetropic refractions (+0.50 to -0.75 D), the company stated. It is the first implantable device for the correction of near vision in patients who have not had cataract surgery, according to an FDA news release.

"The Kamra inlay is the number one implanted corneal inlay globally," said Jim Mazzo, chairman and CEO of AcuFocus. "After a decade of research, development and clinical investigation, we are delighted to bring this innovative technology to surgeons and patients in the United States.

THE INLAY

The Kamra inlay is an ultrathin, opaque, ring-shaped device intended for use in phakic patients 45 to 60 years old who are unable to focus clearly on near objects or small print and who need reading glasses with +1.00 to +2.50 D of power but do not need glasses or contact lenses for clear distance vision. The total diameter of the inlay measures 3.8 mm, and it has a 1.6-mm central aperture. As a result of the novel design, central focused light reaches the retina uninterrupted, resulting in functional vision from near to far without reading glasses, according to the company.

"Presbyopia is a natural part of aging and can make reading and performing close-up work difficult," said William Maisel, MD, deputy center director for science in the FDA's Center for Devices and Radiological Health in a news release. "The Kamra inlay provides a new option for correcting near vision in certain patients."

The device is implanted intrastromally in a femtosecond laser-created pocket. The opaque annulus of the inlay reduces the aperture of the pupil, which improves near vision by increasing depth of focus in the implanted eye. The inlay is made of polyvinylidine difluoride, pigmented with carbon nanoparticles, according to AcuFocus.

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The technology is based on the well-established concept of small-aperture optics. In cameras, depth of focus is increased by reducing the size of the aperture through which light enters: the smaller the aperture, the greater the depth of focus to a point at which the image quality becomes diffraction limited. The Kamra inlay's aperture size has been

PATIENT SELECTION

Ideal patient profile for the Kamra inlay

- aged 45 to 60 years with a cycloplegic spherical equivalent refraction between +0.50 and -0.75 D
- less than 0.75 D of cylinder
- less than 1.00 D of difference between the cycloplegic and manifest spherical equivalent refraction
- less than or equal to a 0.50 D change in manifest refractive spherical equivalent in the past 12 months
- requirement for a near add of +1.00 to +2.50 D
- 20/20 BCVA
- good general health

Source: AcuFocus

PEARLS FOR IMPLANTATION

- The targeted depth for the intrastromal pocket is 200 to 250 µm.
- To properly create the pocket's side-cut incision, place the incision as close as possible to the temporal limbus to avoid inducing astigmatism and coma.
- Set a target within 0.5 mm of the limbus to avoid the limbal arcade. Mark this area once, and wash away excess ink.
- Use the laser centration software to adjust the side-cut incision to the optimal location.
- Mark the cornea to aid inlay centration.
- Create the pocket with a femtosecond laser using a spot/line separation of 6 x 6 µm or less.
- Dissect the pocket.

DO NOT proceed with inlay insertion if there is bleeding, use balanced salt solution within the pocket, or leave any of the pocket undissected.

Next steps:

- Load, center, and insert the inlay.
- Use a long-tipped Sinskey hook or similar instrument to open the pocket side cut.
- When entering the pocket opening, align the forceps with the angle of the entry incision.
- Make manipulations small to keep the inlay moving smoothly.
- Go past the centration mark if the inlay folds, and then pull it back into position.
- Open the forceps slightly, and remove them slowly to avoid displacing the inlay.
- Visually confirm that the inlay is in the desired location.

Source: AcuFocus

REMOVAL

The Kamra can be removed. In the clinical trial, through 60 months, 45 of 508 subjects (8.9%) elected to have the inlay removed. The reasons for removal were

- appearance of the inlay in situ (4.4%; 2/45)
- medical indication (8.9%; 4/45)
  - folds in the inlay at the time of implantation (2.2%; 1/45)
  - stromal thinning due to foreign body, trauma (2.2%; 1/45)
  - posterior vitreous detachment (large floater in eye; 2.2%; 1/45)
  - sustained loss of vision due to a scar in the visual axis (2.2%; 1/45)
- visual complaints (86.7%; 39/45)
  - hyperopic shift (55.6%; 25/45)
  - myopic shift (4.4%; 2/45)
  - induced astigmatism (2.2%; 1/45)
  - inadequate benefit/inability to adapt (15.6%; 7/45)
  - inlay not centered (4.4%; 2/45)
  - inlay placed in the dominant eye (2.2%; 1/45)

All but one patient in the study had a distance BCVA of 20/20 or better after inlay removal; the one patient who had a distance BCVA of 20/25 after removal had a small scar in the cornea.

Source: AcuFocus

optimized to provide the human eye with the best depth of focus and image quality, the company stated.

In a presbyopic eye that does not require distance correction, the crystalline lens cannot accommodate sufficiently to focus the light rays from a near object onto a single point on the retina. Thus, a point object is imaged as a blurry circle on the retina.

CLINICAL STUDY

The inlay's approval was based on the results of 508 patients treated at 24 investigational sites worldwide, according to AcuFocus. To evaluate the safety and efficacy of the inlay, the FDA reviewed the results of three clinical studies. In the main study, 83.5% of the evaluable 478 participants had a near UCVA of 20/40 or better at 12 months. This represented an average improvement of 3 lines between the preoperative examination and follow-up and is the level of vision needed to read most text in magazines and newspapers, the FDA said.

The mean preoperative distance UCVA in the inlay-implanted eye was maintained across all follow-up examinations, unlike after other presbyopia-correcting procedures, which compromise distance vision to improve near vision, the company stated.

The device is not intended for patients who have had cataract surgery or who have severe dry eye disease, an active eye infection or inflammation, corneal abnormalities related to thinning and an irregularly shaped ocular surface, insufficient corneal thickness to withstand the procedure, a recent or recurring herpetic eye infection or problems resulting from past infection, uncontrolled glaucoma or diabetes, or active autoimmune or connective tissue disease.

> **"The central aperture is surrounded by 8,400 perforations that reportedly allow oxygen and nutrients to flow freely and naturally through the eye."**

The labeling warns that the device's safety and effectiveness in patients who have had LASIK or other refractive procedures is unknown.

The FDA disclosed that the Kamra inlay may cause or worsen dry eye disease and problems such as glare, halos, difficulty with night vision, and blurry vision. It also can cause corneal complications such as swelling, clouding, thinning, and potentially perforation, and the device may pose challenges for evaluating and managing eye problems. For patients experiencing vision problems after surgery, removal of the device may improve vision in some cases. In others, decreased vision could become permanent. There is also a potential risk for the focusing power of the eye to change, causing blurry vision and requiring glasses.

LACK OF OPTIONS

"Surgical options for patients frustrated with near vision loss have previously been limited and often required patients to accept compromises like loss of effect over time," said John Vukich, MD, associate clinical professor at University of Wisconsin, in the company news release. "With the Kamra inlay, now available in the United States, we have a safe, effective and long-term solution for presbyopes that is designed especially for their needs.

"Near vision loss from presbyopia can be a significant challenge in the everyday lives of patients, especially those who are emmetropic," said Daniel S. Durrie, MD, founder of Durrie Vision, Overland Park, Kansas, in a company news release. "With the approval of the Kamra inlay, we now have a reliable solution for presbyopes who want to enjoy many daily activities without reading glasses.

AcuFocus stated that the Kamra corneal inlay provides a long-term solution to presbyopia, which will have an impact on virtually everyone older than 50 years—about 2.1 billion people worldwide by 2020.[1] The central aperture is surrounded by 8,400 perforations that reportedly allow oxygen and nutrients to flow freely and naturally through the eye. According to the company, the implant remains effective over time, even as presbyopia progresses. ■

Drs. Durrie and Vukich are consultants to AcuFocus.

1. Market Scope. The Comprehensive Report on The Global Market for Presbyopia-Correcting Surgery. 2014.