

## REFRACTIVE SURGERY

# The Kamra Corneal Inlay in the Clinic

BY LESLIE BURLING-PHILLIPS, CONTRIBUTING WRITER

INTERVIEWING WAYNE CREWE-BROWN, MB, CHB, MMED, SHELDON HERZIG, MD, FRCSC, AND  
DAVID G. KENT, MD, MBChB, FRANZCO, FRACS

Commercially available in Europe, the Asia-Pacific region, South America, and the Middle East prior to FDA approval in April this year, the Kamra corneal inlay (AcuFocus) now offers U.S. ophthalmologists an alternative treatment for presbyopia. According to the FDA, the device is indicated for phakic presbyopes between the ages of 45 and 60 who do not require glasses or contact lenses for distance vision but have a near vision correction need of +1.00 D to +2.50 D. Three ophthalmologists—from New Zealand, Canada, and England—share their experiences with the Kamra corneal inlay.

### How the Inlay Works

The Kamra is a disk, 3.8 mm in diameter, made of polyvinylidene fluoride and carbon with a small opening (1.6 mm in diameter) in the center. The design is based on the principle of small-aperture optics: The inlay is positioned over the central zone of the cornea—directly in front of the pupil—in a patient's nondominant eye. The exterior opaque ring blocks the unfocused peripheral light rays, while letting in the focused central rays through the opening, which increases depth of focus and improves near vision. This effect is well known to photographers, who gain depth of focus by decreasing the size of the aperture on the camera lens.

Theoretically, “the Kamra corneal inlay could be considered a modified form of monovision. The primary ad-

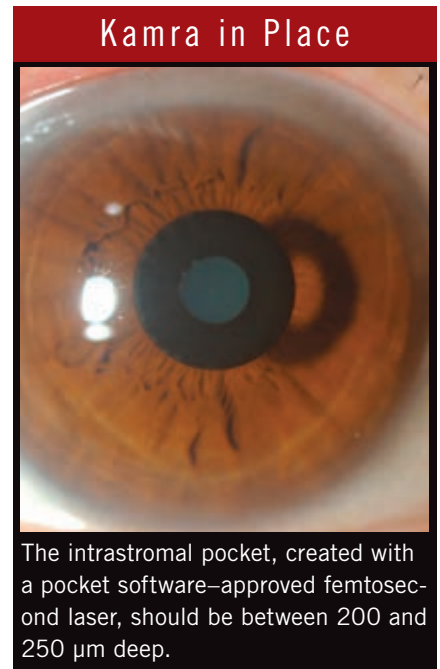
vantage of the inlay is that the distance vision compromise in the reading eye is significantly less than what is experienced with monovision, where the patient must tolerate and accommodate for the distance vision blur created in the reading eye,” said David G. Kent, MD, MBChB, FRANZCO, FRACS, at the Fendalton Eye Clinic in Christchurch, New Zealand.

**Studies.** Long-term study results indicate that the inlay is a safe, effective, and reversible treatment for presbyopia. Patients in one study gained 2 or more lines of uncorrected near visual acuity and did not show significant loss in distance vision when evaluated 4 years after inlay implantation.<sup>1</sup> Reading performance is also positively affected. Significant improvements were reported after 12 months, with improvement continuing for up to 24 months, though at a slower pace.<sup>2</sup>

### Candidates

While presbyopes typically range in age between 40 and 60, said Dr. Kent, not all are ideal candidates for the Kamra corneal inlay. For example, “there are certain circumstances when it is more applicable to perform a refractive lens exchange with multifocal intraocular lenses. This is more common among patients at the upper end of the presbyopic age range because it is likely that their lenses are aging, showing signs of cataract, and an inlay is not the optimal solution,” he said.

Above all, patient selection and counseling are important.<sup>3</sup> When pa-



**Kamra in Place**  
The intrastromal pocket, created with a pocket software–approved femtosecond laser, should be between 200 and 250  $\mu$ m deep.

tients are chosen carefully and they participate in a full informed consent discussion, most of them will be satisfied with their postoperative vision, said Sheldon Herzig, MD, FRCSC, of The Herzig Eye Institute in Toronto, Canada. He noted that he has achieved the best results in: 1) patients with a spherical refraction between  $-0.50$  and  $-0.75$  D, 2) patients who do not have significant dry eye, and 3) patients who are free of ocular surface disease.

**Look for clues.** “Pay close attention to tear film quality, the condition of the cornea, and a patient’s eyelids during your assessment,” said Dr. Kent, explaining that patients with meibomian gland dysfunction and blepha-

ritis do not do as well with the Kamra corneal inlay because of poor-quality tear film. These patients are much more likely to develop postoperative dry eye, he said. “Treat and resolve these conditions to a satisfactory level prior to embarking on inlay use.”

**Does pupil size matter?** Pupil size could be a factor in patient selection for the Kamra corneal inlay, albeit an uncommon factor, said Wayne Crewe-Brown, MB, ChB, MMed. He noted that current protocol suggests a maximum pupil size of 6 mm because large pupils could affect the inlay’s performance due to its fixed diameter of 3.8 mm. As the pupil increases to sizes of 4 mm or larger, light rays are able to pass around the inlay, decreasing reading performance. “Although this is something to take into account, we see very few middle-aged patients with large pupils, and this has not been a hindrance.” Dr. Crewe-Brown is head of Crewe-Brown Vision in London.

### Set reasonable expectations.

“Patients with very high near-vision demands—a watchmaker or contract attorney who reads copious amounts of documents, for example—may not be the ideal patient for this procedure. Unless these patients recognize that they may still need reading glasses on certain occasions, they may not be happy with the outcome,” said Dr. Crewe-Brown, who also described another challenging group of patients: “We are dealing with a population, particularly females, who inherently have dry eyes. This condition can be exacerbated postoperatively. It generally resolves with treatment and time but should be carefully managed.”

### The Procedure

The Kamra corneal inlay is a good option when treating the right subpopulation of presbyopic patients, and it offers a number of surgical benefits, said Dr. Crewe-Brown. He noted that the inlay portion of the procedure takes 15 minutes, is minimally invasive, and can be performed in the surgical suite with a femtosecond laser; it requires the acquisition of a few devices and pocket-creating software.

## Surgical Tips

Dr. Kent of New Zealand offered his tips for successful inlay placement. (Note that in the United States, the physician labeling specifically warns that safety and effectiveness of Kamra implantation in conjunction with or after LASIK or other refractive procedures is “unknown.”)

- If LASIK is needed, aim for a target refraction of  $-0.75$  D. Wait 4 weeks after LASIK before placing the inlay. “Some surgeons try to do it all in one day—that’s a very advanced procedure—it’s highly technically difficult,” he said. (Dr. Crewe-Brown waits from a few days to a few weeks between procedures.)
- Measure the thickness of the flap with an anterior segment OCT to ensure that the flap is sufficiently thin—and that there is enough distance between the LASIK flap bed interface and the pocket, where the inlay is placed. “That’s important because you don’t want to find that, when you create the pocket with the femtosecond laser, gasses are escaping into the flap bed interface. You need roughly 100  $\mu\text{m}$  between the flap bed interface and where the inlay is going,” he said.
- When creating the pocket, it is essential that you use a femtosecond laser with the proper pocket creation software. Target depth for the pocket is between 200 and 250  $\mu\text{m}$ .
- It is important to achieve a smooth interface in the pocket. Any roughness will increase the likelihood of haze around the inlay and hyperopic shifts.
- Centration of the inlay is important. Center the inlay in the pocket with one smooth motion, using minimal manipulation. Optimal placement is approximately halfway between the center of the pupil and the first Purkinje light reflexes.
- Use the lowest energy setting that will create a pocket that allows for easy opening. Too much energy will create an irregular pocket, which can negatively affect a patient’s response to the inlay.

Although the procedure is relatively simple, these patients will require considerably more postoperative follow-up than PRK or LASIK patients, said Dr. Crewe-Brown. Follow-up is typically scheduled at week 1 and months 1, 3, 6, and 12; but patients with complications should be monitored even more closely, he said.

Most patients begin to have improved near vision within days or weeks of inlay placement, said Dr. Kent. Corneal haze associated with inlay implantation generally subsides spontaneously with time, but other complications such as dry eye and hyperopic shift require additional patient management, he noted.

### Removal Scenarios

Despite comprehensive preoperative screening, the inlay is just not a good “fit” for 5% to 10% of patients, said Dr. Herzig. Although AcuFocus states that quality of distance vision is not affected significantly by the Kamra inlay, Dr. Herzig, who had an inlay removal

rate of approximately 5%, found that was not always the case. “Some patients had blurred distance vision with occasional night vision issues, and their best-corrected vision was reduced in the treated eye.”

Although hyperopic shift was a more frequent problem among patients who underwent earlier forms of the procedure (which used a thick flap as opposed to an intrastromal pocket) and now occurs only occasionally, it remains a complication associated with inlay use, said Dr. Crewe-Brown. In the more than 800 inlays that he has implanted, 3 or 4 required removal due to hyperopic shifts. “Sometimes a patient does well for several months. Suddenly their vision drops off, and re-refraction reveals the change. In general, this is resolved with a short course of steroid drops,” he said. However, he noted that if a steroid regimen is not successful after 3 attempts, removal should be considered.

**Cataract surgery.** When it comes time for Kamra patients to have rou-

tine cataract surgery and monofocal IOL implantation, Dr. Crewe-Brown said that the inlay can be left in situ, retaining the small aperture effect. Conversely, the inlay can be removed to allow for multifocal IOL surgery, if that is the preferred solution for the patient. U.S. physician labeling, however, warns that safety and effectiveness of cataract extraction with IOL implantation after Kamra implantation is not known.

**Remove the inlay.** Inlay removal typically takes a matter of seconds, said Dr. Herzig. He instructed: “Simply open the pocket—which is no different than grasping the edge of a LASIK flap—slide in the inlay forceps or a Sinsky hook, and pull out the inlay.” He said that it’s been his experience that the patient’s vision typically returns to preoperative levels. However, the U.S. physician labeling advises surgeons to monitor these patients, as they may not recover their pre-inlay best-corrected visual acuity.<sup>4</sup> ■

1 Yilmaz OF et al. *J Cataract Refract Surg.* 2011;37(7):1275-1281.

2 Dexl AK et al. *J Cataract Refract Surg.* 2012; 38(10):1808-1816.

3 Arlt EM et al. *Clin Ophthalmol.* 2015;9:129-137.

4 Kamra Physician Labeling. [www.acufocus.com/int/sites/default/files/Physician%20Labeling.pdf](http://www.acufocus.com/int/sites/default/files/Physician%20Labeling.pdf). Accessed July 5, 2015.

*Dr. Crewe-Brown is head of Crewe-Brown Vision, a private ophthalmic center and consultant-led practice in London, England. Relevant financial disclosures: AcuFocus: C,L; Presbia: C,L.*

*Dr. Herzig is cofounder and medical director of The Herzig Eye Institute in Toronto, Canada. Relevant financial disclosures: None.*

*Dr. Kent is the Director of Refractive and Cataract Surgery at the Fendalton Eye Clinic in Christchurch, New Zealand. Relevant financial disclosures: None.*

*See the disclosure key, page 8.*

**IN LAS VEGAS.** This year Refractive Surgery Subspecialty Day will take place on Friday only. **When:** Friday, Nov. 13, 8:00 a.m.-5:15 p.m. **Where:** Venetian Ballroom EF. **Access:** Subspecialty Day badge (for Friday).



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\* Bloomenstein, Marc. "Punctal Occlusion May Improve Visual Acuity for Contact Lens Patients." *Optometry Times*, July 2014.