POINT/COUNTERPOINT: WILL I USE THE FDA-APPROVED CORNEAL INLAY?

Yes, data demonstrate the safety and efficacy of this device, which fills an unmet need in the surgical correction of presbyopia.

BY GEORGE O. WARING IV, MD

My experience with corneal inlays began 8 years ago. I have served as a world surgical monitor for AcuFocus for a number of years, and I am a member of the company's scientific advisory board. I have therefore watched the Kamra's journey through the developmental pipeline. I have had the opportunity to implant half a dozen devices outside the United States and to observe Kamra surgeries and outcomes around the world.

I view presbyopic correction as an emerging "sub-subspecialty," one that constitutes a large part of my practice now. The number of people coming to my office in search of surgical options to reduce their dependence on reading glasses and bifocals continues to grow. Certainly, proper patient selection is essential, and every option for the surgical correction of presbyopia involves trade-offs. I believe, however, that the Kamra fills an important niche.

PATIENT SELECTION

I will consider a corneal inlay for patients with stage 1 dysfunctional lenses who are seeking a surgical solution. The crystalline lens has lost its ability to focus for near vision, and presbyopia has progressed to a point that requires these individuals to wear reading glasses. The Kamra is FDA approved for patients with near-plano presbyopia, but this group represents a relatively small segment of the market. I will therefore also use the Kamra to treat congenital ametropia by means of a staged procedure. Specifically, patients will have LASIK to correct their congenital refractive error and then, a week to a month later, undergo creation of the corneal pocket and implantation of the inlay to correct their age-related presbyopia.

I will continue to offer lens extraction to patients desiring

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No, the cost to my practice—financial and otherwise—is too great.

BY JAMES C. LODEN, MD

This past week, after much debate and research involving my practice's CEO and COO and with input from my practice's cornea specialist, we all decided not to proceed with our initial plan to offer corneal inlay refractive surgery. Before continuing this discussion, I must make three disclaimers:

1. I myself have never implanted a corneal inlay.
2. I have managed one patient with a Kamra (AcuFocus) who went to Canada for the procedure and was extremely happy with the outcome, and I have managed another whose corneal inlay was explanted in an FDA trial and who was very unhappy. That comes to a total of two cases!
3. My practice's final decision was made after collecting the confidential opinions of corneal refractive surgeons around the world and their administrators. We did not rely on peer-reviewed data, so I cannot provide a bibliography. Of note, we found that administrators can often give a more objective assessment of real-world practice issues than surgeons.

INLAYS AND LASIK

The week I wrote this piece, I spent 3 days in clinic managing patients from my nine-doctor practice who were unhappy with the outcome of their presbyopia-correcting surgery. I am continually amazed by the dissatisfaction that patients who have a binocular UCVA of 20/15 can feel after LASIK and refractive cataract surgery. Also remarkable is the number of patients who see 20/20 at distance and J1 at near after presbyopia-correcting cataract procedures with a multifocal IOL or monovision who do not feel that their vision is good enough.

At the 2015 annual meeting of the American Society of Cataract and Refractive Surgery, I listened to presentations reporting that about 80% of patients saw J3 or better with the Kamra (AcuFocus). This means that 20% of patients' near

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UCVA was less than J3![1] In other words, after paying at least $4,500 (the minimum feasible price based on my practice's calculations), at least 20% of the patients in my practice who received a corneal inlay would be very unhappy postoperatively.

I think about the young myopes with whom I would not have the time to meet about LASIK, because my chair time would be sucked away by dissatisfied inlay patients.

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> **—James C. Loden, MD**

STARTUP COSTS

According to my practice's calculations, it costs well over $80,000 to begin offering corneal inlays. This price tag includes the HD Analyzer (Visiometrics), instrumentation, and a minimal purchase of inlays at a cost of $1,300 each. This amount does not include marketing. My operations team concluded that we might have to perform 80 procedures to break even.

I think of all the costs and chair time incurred. First, the patient needs LASIK with a refractive target of -0.50 to -0.75 D. This is an excimer laser click fee and a femtosecond laser flap click. He or she must have a postoperative examination prior to receiving the inlay. Next, the patient undergoes an inlay procedure with a pocket click and a $1,300 fee for the inlay plus the time to perform a second procedure. There are postoperative examinations. Then comes the unknown. How many patients will return multiple times and demand to see me, the surgeon, because "I'm not seeing as well as I thought I would"?

PROCEDURES THAT HAVE FLOPPED

How many times in my 17 years of practice have I heard key opinion leaders swear that a procedure always works perfectly and they have never seen an unhappy patient. Let me think ... laser thermal keratoplasty, conductive keratoplasty, intracorneal ring segments, epi-LASIK, and laser cataract surgery. Need I beleaguer the point?

REVERSIBILITY OR LACK THEREOF

One of the features touted by the inlay industry is simple reversibility through removal of the device. This claim is not totally true. A patient is intentionally left with -0.50 D of refractive error, for example. Removal of the inlay will require a subsequent LASIK enhancement to establish monovision or enhance distance vision. This is not a matter of just taking it out and going home.

As I stated earlier, I have provided a corneal consultation for one patient who had a corneal inlay explanted after enrolling in an FDA trial. In addition to midstromal scarring and haze 1 year after explanation, this person's BCVA has dropped from 20/20 to a poor-quality 20/25. Ask this patient if the procedure was reversible.

LONG-TERM EFFECTS

In my brief career, I have seen that the cornea often balks at foreign bodies. I think of the five sets of intrastromal corneal rings that I have explanted after corneal thinning or extrusion. I recently discussed this point with a cornea specialist 20 years my senior. He related experiences with epikeratophakia and how patients would do well with perfectly clear corneas for 10 to 15 years only to walk in one day with corneal opacification. There are multiple case reports of haze with various inlays and the need for prolonged steroid use to control it. Do I really want some of my patients using steroids long term, and if haze is an issue 3 months postoperatively, what will the situation be in 10 or 15 years? Will the patient walk into my office 5 years after surgery with corneal opacification or a total melt?

CONCLUSION

In my opinion, the holy grail of an effective treatment for presbyopia is not here yet. Because all the doctors in my practice are at 80% to 90% capacity with cataract surgery, laser cataract surgery, and LASIK, we are not going to allow ourselves to be distracted by a procedure that may generate unfavorable online reviews written by unhappy patients. Instead, we have decided to focus on procedures that have a satisfaction rate of 95% or higher and to wait for unbiased, prospective, postmarket clinical trials to report the true success rate with corneal inlays.

1. FDA approves first-of-its-kind corneal implant to improve near vision in certain patients. US Food and Drug Administration. April 17, 2015. Accessed May 28, 2015.

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spectacle independence who have stage 2 dysfunctional lens syndrome or who are moderately to highly hyperopic.

A SUPERIOR ALTERNATIVE TO CURRENT OPTIONS

Prior to the Kamra's FDA approval, all that US surgeons really had to offer in terms of a cornea-based procedure to patients with stage 1 dysfunctional lens syndrome was monovision or blended vision with an excimer laser. Although I use this strategy routinely, it has its drawbacks, including loss of stereopsis, and can affect activities like driving at night. The effect of conductive keratoplasty can regress over time, and presby-LASIK is still in evolution.

The Kamra uses the principle of small-aperture optics, which increases depth of focus. Traditionally, the inlay is placed in the nondominant eye, improving both near and intermediate

distance vision and maintaining distance vision. In other words, this small-aperture device does not sacrifice stereopsis. With blended vision, patients give up distance vision in their non-dominant eye, and with it goes stereopsis.

TRADE-OFFS

As I stated, all of the surgical options for presbyopic correction involve a trade-off. Visual recovery after implantation may be slightly slower compared with LASIK. Based on my experience with the Kamra outside the United States, however, this difference is really a matter of setting realistic expectations for patients.

A large body of data in the peer-reviewed literature as well as the FDA trials supports the safety and efficacy of the Kamra placed in a corneal pocket. This is "additive" corneal refractive surgery, as opposed to "subtractive" or ablative surgery with an excimer laser. As a result, the procedure should be treated differently than LASIK in terms of specific femtosecond laser settings and the perioperative regimen, including a longer steroid taper.

Furthermore, the small-aperture principle works by blocking out-of-focus light. If, in a rare instance, a patient has difficulty with the device (eg, problems reading in low light), the implant is removable, which is a major benefit of an opaque inlay, because it is simple to find in the cornea.[1]

THE BENEFITS OF HISTORY

The biggest factor in my decision to offer the Kamra was its safety. Would the cornea tolerate a foreign body? José Barraquer, MD, described "synthetic keratophakia" in 1949.[2] More than half a century of research and development have since been invested in this space. Some of the key lessons can be summed up as follows: corneal inlays must be sufficiently thin and permeable, and they must be implanted at an appropriate depth.[3-7]

The second factor in my decision to offer the Kamra is its efficacy. In the FDA trials and other published studies, the device improved patients' uncorrected distance, intermediate, and near visual acuity.[8]

Of benefit to US surgeons is not only the rich history of corneal inlays in general but also our international colleagues'

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> **—George O. Waring IV, MD**

extensive experience with the Kamra inlay in particular. One key lesson, for example, is implantation of the device in a femtosecond laser-created corneal pocket with a tight spot and line setting.

A CONSERVATIVE BEGINNING

When I adopt a new technology, I begin conservatively by enrolling perfect candidates or "low-hanging fruit." My strategy for commercial implantation will be to pick the ideal candidates and to monitor my outcomes. This is the same way I began with multifocal IOLs, which have become an integral part of my practice over the years.

CONCLUSION

There is no single solution to presbyopia for all patients, and the surgical options are expanding. It is for this reason that my partners and I are thinking about offering a fellowship in this area. The challenges of a corneal approach are preserving distance vision in both eyes, maintaining stereopsis, and offering a broad range of vision with increased depth of focus. The Kamra meets these goals well. ■

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AT A GLANCE

- All of the current surgical options for correcting presbyopia involve trade-offs.
- Safety was the biggest factor in Dr. Waring's decision to offer the Kamra inlay, followed by efficacy.
- Dr. Loden takes issue with the assertion that the procedure is easily reversible.

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