

Read John A. Hovanesian, MD, FACS's, blog, "Secrets of successful refractive cataract surgery practices, part 2" **17**

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OSN EXCLUSIVES

COMPLICATIONS CONSULT

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A man presented with complaints of painless swelling in the lower lid of the right eye, with the swelling gradually increasing in size. **41**

LINDSTROM'S PERSPECTIVE

Drops may offer another possible way to eliminate presbyopia **5**

BY THE NUMBERS

Cost containment: Getting the lead out

The concept of zero-based budgeting would benefit many practices. **22**



CLINICAL OPTICS 101

Managing excessive residual astigmatism after toric IOL implantation

Two methods of back calculation help to ensure ideal alignment of a toric IOL. **24**

OSN NEW YORK PRODUCT SHOWCASE

OSN New York 2016 Product Showcase. **26**

COVER STORY

Ophthalmologists explore new and pending optical concepts for enhancing vision in presbyopic patients

Corneal inlays, or more specifically presbyopic inlays, are gaining traction as another viable option to improve vision.

Over the past 18 months, the FDA has approved the first two of these inlays: the Kamra (AcuFocus) in April 2015 and the Raindrop (ReVision Optics) in June 2016.

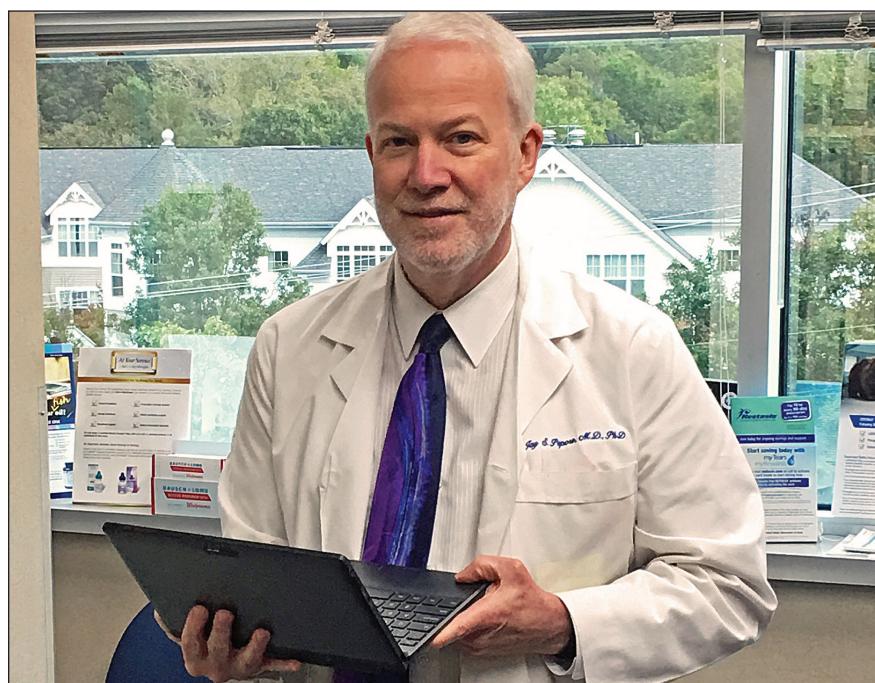
Although the optical concepts of the inlays vary markedly, the outcomes are comparable and complementary to LASIK.

Kamra

The Kamra inlay "provides a broad continuous depth of focus and is relatively immune to the effects of progressive presbyopia, given its mechanism of action — blocking unfocused peripheral rays of light," Jay S. Pepose, MD, PhD, director of the Pepose Vision Institute in St. Louis, said. "The contrast sensitivity remains excellent, and since there is minimal impact on distance vision, the loss of stereopsis associated with monovision is obviated."

The small aperture Kamra inlay has a 1.6 mm

Cover story continues on page 10



The best candidates for the Kamra inlay are presbyopic emmetropic patients between the ages of 45 and 60 years who have reasonable expectations and corneas of at least 500 µm, according to Jay S. Pepose, MD, PhD.

Image: Pepose JS

MACRA rule may help ophthalmologists avoid penalties

CHICAGO — The recently finalized MACRA rule from the Centers for Medicare and Medicare Services may help ophthalmologists avoid penalties by shifting physician payments from a volume based payment program to a value based payment program, according to speakers here.

"MACRA has established, really, an entirely new payment policy for physicians. They're calling it a quality payment program. In a nutshell, they're paying for value rather than volume ... The final rule has



David G. Glasser

Academy of Ophthalmology Health Policy Committee, said at a press briefing at the

been pretty encouraging in terms of what we believe is the ability for most of our members to avoid the penalties and perhaps achieve some of the bonuses in the program," David G. Glasser, MD, associate secretary, American

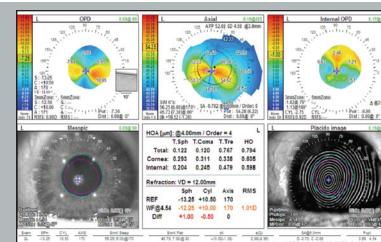
American Academy of Ophthalmology meeting.

The new system, which was finalized on Friday, Oct. 14, will evaluate physicians on resource use, quality reporting, electronic health care usage and clinical practice improvement technologies. Ophthalmologists who are registered for and use AAO's Intelligent Research in Sight (IRIS) registry may find they can avoid any penalties through the new system and could possibly be

MACRA continues on page 12

Surgical Maneuvers: Femtosecond laser, toric IOL used to treat high level of astigmatism

A surgeon explains how she handles these challenging cases at her center. **8**



COVER STORY

Corneal inlays and LASIK together expand the presbyopia market to include wider age range

continued from cover

central aperture and a 3.8 mm diameter and is 6 μm thick. It has 8,400 holes “to allow flow of oxygen and nutrients,” Pepose said. Furthermore, the inlay is carbon impregnated and made of polyvinylidene fluoride, “which is a highly biocompatible material used in IOL haptics.”

The best candidates for the inlay are emmetropic patients with reasonable expectations and corneas of 500 μm or greater who are presbyopic and between the ages of 45 and 60 years, according to Pepose.

“It is best to insert the Kamra in the non-dominant eye,” Pepose said. “The inlay is optimized if the preop refraction is close to -0.75 D in the non-dominant eye.”

A pocket of at least 40% corneal depth is created to insert the inlay. “Using line-spot laser settings of 4×4 or less optimizes the outcomes,” Pepose said.

Pepose, who was involved in the clinical trial of the Kamra, finds that his results since approval are similar: Distance vision averages 20/20, intermediate 20/25 and near 20/30, with patients gaining on average 3.5 lines of uncorrected near vision.

Pepose was a co-author of a multicenter clinical study of the Kamra that appeared earlier this year in the *Journal of Refractive Surgery*. The study assessed contrast sensitivity in 507 patients with emmetropic presbyopia before and after implantation, and it concluded that postop contrast sensitivity was stable both monocularly and binocularly. Average contrast sensitivity also remained within the normative ranges.

“Postoperative contrast sensitivity was mildly reduced monocularly but not binocularly, and the ratio of area under logCS (log₁₀ unit of contrast sensitivity) function comparing postoperative to preoperative values was above 90% for all but one condition,” the study authors wrote.

Pepose was also a co-author of a 2015 study in the *American Journal of Ophthalmology* that enlisted the same

Kamra cohort of 507 patients, plus 78 subjects randomized to an accommodating IOL or a multifocal IOL, for comparison of contrast sensitivity and through focus. The Kamra demonstrat-



“Most patients have very little healing time or difficulty adjusting to their new vision. Many patients immediately gain reading vision.”

— JOHN A. HOVANESIAN, MD, FACS

ed better contrast sensitivity in the inlay eye compared with the two multifocals and better binocular contrast sensitivity compared with all three IOLs.

For uncorrected intermediate vision, the accommodating IOL was superior to the Kamra but worse in near vision. Conversely, the two multifocals were superior in near vision yet worse in intermediate vision compared with the Kamra.

Raindrop

“As with the Kamra inlay, we have had an extremely high success rate with the Raindrop in our clinical trials and in use outside the U.S., with about 95% of patients very satisfied with their result,” **John A. Hovanesian, MD, FACS**, OSN Cataract Surgery Section Editor, said. “With Raindrop, patients gain a fairly consistent ability to read without glasses and retain about 20/25 uncorrected distance vision in the treated eye.”

The Raindrop inlay is made of a hy-

drogel material, similar to the material of soft contact lenses.

“The inlay is currently approved to go under a corneal flap and soon to be approved to go in a corneal pocket, which steepens the central cornea in a fashion that creates a multifocal surface, so patients can achieve near vision in an otherwise emmetropic eye,” Hovanesian said.

The best candidates for the permanent Raindrop are mostly between the ages of 50 and 65 years and have healthy eyes with refraction between plano and roughly $+0.75$ D without significant astigmatism, according to Hovanesian. “Patients also need to have an adaptable personality type that can tolerate a device to help them read, primarily with one eye,” he said.

During the 5-minute procedure, a

femtosecond laser is used to create the corneal flap, which is then lifted. Next, the inlay is placed, centered over the pupil, while the patient fixates on the device’s fixation light. “The flap is then carefully placed back in position, making sure not to hydrate the flap in a way that would displace the device,” Hovanesian said.

In most cases, the procedure takes less time than LASIK because there is no laser ablation.

“Most patients have very little healing time or difficulty adjusting to their new vision,” Hovanesian said. “Many patients immediately gain reading vision.”

However, approximately 2% to 3% of Raindrop and Kamra inlays will need to be explanted due to dry eye or corneal inflammation, according to Hovanesian.

“Clinicians who follow inlay patients need to realize that it is typically a longer-term follow-up period than LASIK,” he said. “In many cases, though, we can put patients on a mild steroid to control the

inflammation. Patients also tend to be highly motivated to retain the inlay because they desire the vision it provides.”

Hovanesian, who has personally implanted nearly 40 Raindrop inlays since 2013 through continuing FDA studies, was a co-author of a 373-eye study of the Raindrop that appeared in the March issue of *Ophthalmology*. “At 1 year, the effectiveness and safety of the inlay were very good,” he said.

Mechanisms of action

Jack T. Holladay, MD, MSEE, FACS, OSN Optics Section Editor, said the op-



“I think corneal inlays have a role in the clinical practice of ophthalmology and correcting presbyopia.”

— MICHAEL GORDON, MD

tical concepts of the Kamra and Raindrop are totally different.

“The Kamra uses the pinhole effect, also called a small aperture optic, to improve the intermediate and near vision,” Holladay said.

The Raindrop is 2 mm in diameter and shaped like a positive meniscus lens (convex-concave).

“The Raindrop works by increasing the central power of the cornea over the 2 mm zone, so that when someone looks up close to read, the pupil becomes smaller and uses the added power,” Holladay said.

Holladay, who is a fan of both corneal inlays, said it has taken more than 20 years for inlays to gain regulatory approval.

“The original ones had problems with material and location, and we did not have lasers to make flaps and pockets,” he said. “These new devices are very successful in their ability to overcome earlier obstacles, including reversibility and removal in less than 5% of cases. In those cases where the devices were implanted, patients return to their preoperative visual acuity, so they did not lose any lines of vision.”

Overall, 95% of Kamra and Raindrop patients in FDA studies achieved near vision of better than 20/30, according to Holladay. “Before surgery without the corneal inlay, this value was less than 1%,” he said.

Despite the different mechanisms of the Kamra and Raindrop, “they are certainly promising for long-term results and improving intermediate and near vision for patients that have good distance vision and are presbyopic,” Holladay said. “At this point, I do not think there is any evidence that one is better than the other. Both of them deserve consideration by both surgeons and patients.” He also feels the learning curves for the inlays are comparable and

straightforward.

Holladay said a corneal inlay is complementary to LASIK in patients with presbyopia. “Although you need to have good distance vision in order for these inlays to work, it expands the market to include those people that are over age 40 and up to age 60,” he said. “Previously, presbyopic patients who had LASIK needed to have a refractive error — myopia or hyperopia — and required glasses afterward for reading.”

Corneal inlays, in contrast, target the presbyopic population that would otherwise need reading glasses.

Flexivue Microlens

The Flexivue Microlens (Presbia) is a corneal inlay that received a CE mark in 2009. Patient enrollment has been completed for an FDA phase 3 clinical trial.

“Patients seem to enjoy the near vision that it gives them,” Michael Gordon, MD, the assistant medical monitor for the FDA study, said. “There is very little, if any, biocompatibility issues.”

From a clinical practice standpoint, Gordon believes the Flexivue would be an addition to options currently offered to presbyopes.

The 3.2 mm diameter refractive inlay has a 1.6 mm clear non-refractive area in the center, with a doughnut-shaped addition from 1.25 D to 3.25 D.

“The Flexivue is the only refractive inlay, unlike the Kamra or Raindrop inlay,” Gordon said. “Our inlay truly refracts light differently to achieve a near focus and a far focus.”

The best candidates are typically those older than 40 years who do not have a significant amount of refractive error and are presbyopic, according to Gordon.

“It is actually very simple to insert the Microlens,” Gordon said. “You create a

Cover story continues on page 12

POINT / COUNTER

Under what circumstances would you consider the off-label combination of corneal inlay surgery and LASIK?

POINT

Two procedures in one setting

With the Kamra inlay, we have found the “sweet spot” for our happiest patients is a refractive error around -0.75 D. However, at least half of our presbyopic patients present with a refractive error significantly different from this value. In these cases, we have used LASIK to correct the refraction to this value.

Initially, we sequentially performed LASIK followed by implantation of the Kamra inlay about 1 month later. We achieved excellent results, but patients were dissatisfied with the longer healing process and having to undergo two procedures. Therefore, over the past 6 months, we have transitioned to combining LASIK with Kamra at the same surgical setting.

When combining the procedures, it is important to ensure that there is at least a $100\text{-}\mu\text{m}$ separation between the LASIK flap and the inlay pocket. It is advisable to keep at least $250\text{ }\mu\text{m}$ between the inlay pocket and the endothelium. I typically create the LASIK flap at $110\text{ }\mu\text{m}$ and the Kamra pocket around $275\text{ }\mu\text{m}$. I first dock temporally to create the pocket and then redock nasally to create the LASIK flap. After implantation of the Kamra inlay, I lift the flap to complete the LASIK procedure.

For our ametropic presbyopic patients, we perform LASIK alone in the dominant eye and combined LASIK/Kamra in the non-dominant eye. Patients are educated to expect excellent vision in the dominant eye the next day but a slower visual recovery in the non-dominant eye lasting up to 6 to 8 weeks. With this approach, we are achieving excellent results. Our patients are happy with both their uncorrected near and distance vision as well as being able to reach these outcomes with only one procedure.

Shamik Bafna, MD, is a cataract and refractive surgeon at Cleveland Eye Clinic. Disclosure: Bafna reports he is a consultant to AcuFocus.



Shamik Bafna

COUNTER

LASIK before Kamra

The best candidates for a combined LASIK/inlay procedure are those who are presbyopic and for whom their distance correction is not in the “sweet spot” or final refractive error meant for that inlay.

What is beautiful about inlays is that you can either perform refractive correction and inlay placement at the same time or separate the two procedures — treat the refractive error now and place the inlay later. There is flexibility. Ideally, though, if I had a choice, I would do LASIK first.

We know that the Kamra inlay works best with a small amount of myopia (-0.5 D to -0.75 D) and that the inlay is more effective in a pocket than under a flap. Consequently, when we combine the Kamra with LASIK, we are dialing in a refractive correction that provides that small amount of myopia. We are also creating a pocket depth of $250\text{ }\mu\text{m}$, or for a $110\text{-}\mu\text{m}$ flap, $130\text{ }\mu\text{m}$ under the flap.

I know surgeons have had good luck doing this all at the same time. However, I have had more experience with first dialing in the -0.75 D with LASIK, and then 1 to 3 months later coming back and doing the inlay in a pocket; or first doing the inlay in a pocket, and then returning to perform PRK over the inlay. However, you do not want to do LASIK over an inlay because femtosecond energy can negatively affect the material. But the excimer laser fine-tuned over the inlay works just great, like with PRK.

I encourage surgeons to perform combined LASIK/inlay procedures, in part because if you restrict your patients to those with corrective error that has already been optimized with an inlay, you are not going to do nearly the volume that you could. Still, sometimes after an inlay, refractive error changes slightly. So you need to be comfortable with handling refractive error both before and after an inlay to optimize the optics. I believe that the combined procedure will become increasingly popular.

Vance M. Thompson, MD, is an OSN Refractive Surgery Board Member. Disclosure: Thompson reports he is a researcher and consultant to AcuFocus.



Vance M. Thompson

Cover story continued from page 11

femtosecond pocket at about a depth of 300 μm . Centration is very easy with an epithelial mark, either under the laser or a slit lamp. No specific instrumentation is needed for centration. The procedure normally takes me 5 minutes or less.”

The permanent inlay has been implanted by Gordon in about 70 patients over the past 2 years. “The efficacy has been great,” he said. “For the most part, our patients are not wearing reading glass-



“Possibly the largest group that will profit from the technique will be monocularly pseudophakic patients that request additional benefit in the second eye without side effects.”

— GÜNTHER GRABNER, MD

es and they are very happy with the inlay.”

Gordon likes the fact that the power of the Flexivue can be changed. “You can put one power in when a patient is 40, then take it out, and put another power in when the patient is 48 or 50, at a time in the patient’s life when lens surgery makes more sense,” he said.

Four of Gordon’s inlays have been removed due to patient unhappiness with night glare or reading distance. This is consistent with the explantation rate of other inlays.

“I think corneal inlays have a role in the clinical practice of ophthalmology and correcting presbyopia,” Gordon said. “It is an evolving area of extreme interest.”

IC-8 IOL

The IC-8 IOL (AcuFocus) is a standard one-piece hydrophobic acrylic lens that combines the benefits of IOL technology with the pinhole camera effect of the Kamra inlay.

The IOL received a CE mark in 2014, but the company has yet to begin the clinical trial for U.S. registration.

“The black pinhole disc is incorporated into the optic, with a central opening of 1.36 mm,” **Günther Grabner, MD**, an OSN Europe Edition Board Member, said.

Grabner has implanted about three dozen lenses since 2012 and has seen excellent results. “Patients are very satisfied,” he said. “There are basically no side effects and a large depth of focus is achieved.”

However, good centration with an intact anterior rhexis during routine cataract surgery “is a requirement for optimal function,” Grabner said.

The best candidates for the IC-8 IOL are cataract patients who desire an increased depth of focus for personal computer and/or reading, while maintaining excellent distance vision acuity, according to Grabner. “Possibly the largest group that will profit from the technique will be monocularly pseudophakic patients that request additional benefit in the second eye without side effects,” he said. “This IOL is always only implanted monocularly.”

Grabner was the lead author of a 12-patient study of the IC-8 IOL that

appeared in 2015 in the *American Journal of Ophthalmology*. Mean uncorrected distance, intermediate and near visual acuities improved significantly, from 0.42, 0.52 and 0.66 preoperatively, respectively, to 0.06, 0.07 and 0.11 at 1 month. Vision remained stable at 1 year.

“At 12 months, 100%, 100% and 92% of patients achieved 20/32 or better binocularly for these three distances,” Grabner said. In addition, 100% of eyes maintained 20/40 or better visual acuity over a range of +0.5 D to -1.5 D of defocus.

“The safety profile of the lens is also very good,” Grabner said. “I personally have not explanted one single IOL of this type, and I am not aware of any other case of explantation.”

Grabner was also a co-author of a 32-eye study implanted with the Kamra inlay that was published in 2015 in the *Journal of Cataract and Refractive Surgery*. “We showed good long-term stability,” he said. “Targeting refraction of between -0.5 D to -0.75 D yields the best results.”

The study, which was started in September 2006 with an early technique and earlier-generation Kamra implant, found that at 5 years, 74.2% of patients had uncorrected near visual acuity of 20/32 or better, 87.1% were 20/32 at intermediate range or better, and 93.5% were 20/20 or better at distance. Ten-year results will be reported in the near future.

“Overall, corneal inlays — after several important surgical improvements and design changes — are an excellent option for corneal correction of presbyopia,” Grabner said. “Still, precise surgery is required. You also need to stick to the rules of implantation depth, laser settings, pocket technique, sequential surgery with other refractive procedures like LASIK, and adherence to postoperative prescriptions like steroids and lubricants.”

Thorough preop patient counseling to set realistic expectations is also important, Grabner said.

“There are a large number of patients between the age of 45 and 60 who are looking for a solution to presbyopia,” Pepose said. “Many do not want to consider intraocular surgery, so corneal inlays are a good bridge until lens dysfunction progresses to where cataract surgery is indicated.”

Pepose said that the Raindrop may be more suited to patients who are slightly hyperopic, “whereas the Kamra has a sweet spot at -0.75 D, whether naturally occurring or post-LASIK.”

Between 1995 and 2000, “there was a fairly rapid uptake of LASIK,” Hovanesian said. “Corneal inlays need to go through the same process of public education and ophthalmic support of the technology to become popular like LASIK.”

Hovanesian believes that to some extent corneal inlays will replace monovision for reading with LASIK because

“inlays are better than monovision.” — by **Bob Kronemyer**



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For more information:

Michael Gordon, MD, can be reached at 8910 University Center Lane, San Diego, CA 92122; email: mgordon786@gmail.com.

Günther Grabner, MD, can be reached at Dr. Franz Rehr-Platz 2, 5020 Salzburg, Austria; email: g.grabner@grabner-auge.at.

Jack T. Holladay, MD, MSEE, FACS, can be reached at email: holladay@docholladay.com.

John A. Hovanesian, MD, FACS, can be reached at Harvard Eye Associates, 24401 Calle De La Louisa, Suite 300, Laguna Hills, CA 92653; email: drhovanesian@harvardeye.com.

Jay S. Pepose, MD, PhD, can be reached at Pepose Vision Institute, 1815 Baxter Road, Suite 205, Chesterfield, MO 63017; email: jpepose@peposevision.com.

Disclosures: Gordon reports he is a consultant for Presbia. Grabner reports no relevant financial disclosures. Holladay reports he has consulted for AcuFocus and ReVision Optics. Hovanesian reports he is a consultant for ReVision Optics. Pepose reports he is a consultant for AcuFocus.

MACRA

continued from page 1

qualified to receive bonuses, **David W. Parke II, MD**, CEO of the American Academy of Ophthalmology, said at the briefing.

Ophthalmologists who use the IRIS registry can feed into the Merit-based Incentive Payment System’s (MIPS) quality reporting portion, clinical practice im-



David W. Parke II

provement portion and earn bonus points for the EHR (electronic health records) advancing care information portion through their participation in the registry, Parke said.

“The IRIS Registry, and the benefits received from participation in this, should make a lot of ophthalmologist potentially be in the pool for a bonus, maybe a small bonus, but a bonus nonetheless,” Parke said. — by **Robert Linnehan**



Disclosure: Parke reports he is the CEO of AAO and Glasser reports he is the associate secretary of AAO’s Health Policy Committee.