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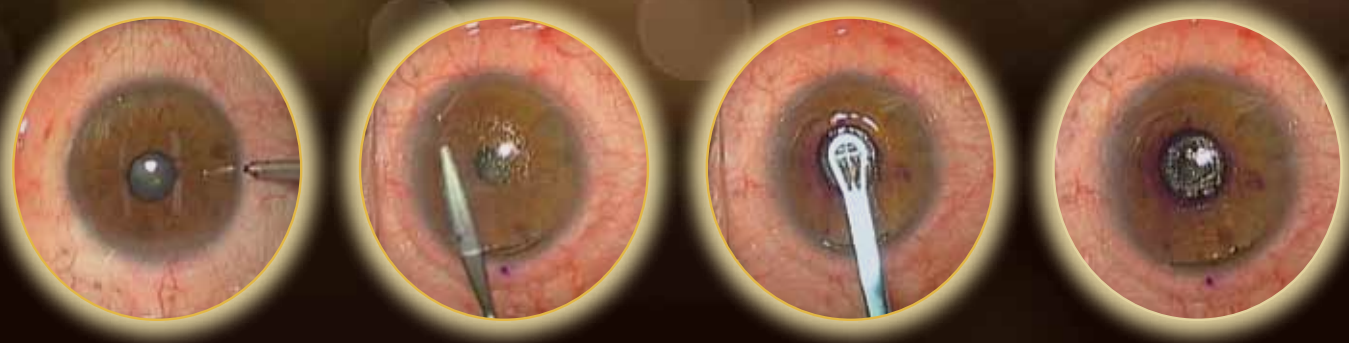
APPLYING THE POWER OF SMALL APERTURE OPTICS



Surgeons discuss their clinical experience with the KAMRA inlay

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Applying the Power of Small Aperture Optics

Presbyopia is a ubiquitous condition from which every person will suffer eventually. Fortunately, during the past several years, ophthalmic manufacturers have been developing some exciting innovations to treat presbyopia. One of the most impressive of these treatments is the KAMRA inlay (AcuFocus, Inc.). A group of esteemed ophthalmic surgeons recently assembled in Cannes, France, to discuss the latest research and clinical findings of the KAMRA inlay, and their conversation is summarized here. Watch the full video of the roundtable discussion at http://eyetube.net/series/physician-perspectives/fiwif.

PARTICIPANTS

Moderator: Robert P. Rivera, MD, is a cataract and refractive surgeon at Hoopes Vision Institute in Salt Lake City, Utah. He has a financial interest in STAAR Surgical Company, and he serves as a medical advisor to the company. Dr. Rivera may be reached at (602) 955-1000; rpriveramd@aol.com.

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Roger Zaldivar, MD, is the Scientific Director of the Instituto Zaldivar, Mendoza, Argentina. He is a member of the AcuFocus scientific advisory board. Dr. Zaldivar may be reached at +54261 441 9999; zaldivar@zaldivar.com.

PRACTICE OVERVIEW

Dr. Rivera: First, I'd like each of you to tell me about your practices individually and your experience with the KAMRA inlay.

Dr. Vukich: I work mostly in the anterior segment. Approximately 60% of my practice is cataract surgery, and the rest is refractive surgery, involving LASIK, PRK, and phakic IOLs.

Presbyopia has become an increasingly important part of our practice. When we started performing LASIK, the average age of our patients was 34 years. It is now 38, an age that is starting to get into the presbyopic range for a significant number of our patients.

My staff and I are now gathering 6-year data on our patients implanted with a KAMRA inlay. I was involved in this product's development through various iterations, and I served as a phase 2 clinical investigator for it in the United States. My staff and I have had great results with the inlay that have only improved as we have come to understand how to use it effectively: centering it properly, creating the appropriate plane in which to place it, etc.

Dr. Maus: My staff and I began implanting the inlay in November 2011. My practice also focuses mainly on the anterior segment. Approximately 70% of our business is refractive surgery, and 30% of it is cataract surgery. Our average age for refractive surgery is higher than Dr. Vukich's—I'd say it is above 40—so we have a lot of presbyopic patients.

Until we started using the KAMRA inlay, our only treatments for presbyopia were monovision or multifocal IOLs. I do not perform multifocal refractive

Cover images courtesy of Minoru Tomita, MD, of Shinagawal LASIK Centre.

"The KAMRA's optical principle was easy to understand, and the technology does not induce any spherical aberrations or coma. These features enabled me to start implanting the KAMRA device with enthusiasm, and the claims about its effectiveness proved to be true."
– Matthias J. Maus, MD

surgery, because I am not a fan of multifocal corneas. The KAMRA's optical principle was easy to understand, and the technology does not induce any spherical aberrations or coma. These features enabled me to start implanting the KAMRA device with enthusiasm, and the claims about its effectiveness proved to be true. My staff and I have implanted the device in approximately 200 eyes, and I am still very enthusiastic about it.

Dr. Rivera: I agree that the KAMRA's clinical performance has been wonderful. The practice with which I am affiliated, Hoopes Vision in Salt Lake City, was one of the clinical trial investigational sites, and my colleagues and I were amazed at the KAMRA's effect in patients.

Dr. Zaldivar: Our main goal with this new option to correct presbyopia is to use it as a solution for early sufferers of presbyopia, those who range from 40 to 60 years old. I think this is a great solution for this demographic, and for the surgeon, it is something that does not require touch-ups. Its simplicity and effectiveness are very important points for convincing our patients to have the KAMRA implanted.

TALKING TO PATIENTS

Dr. Rivera: Dr. Zaldivar, tell us about your experience with offering this procedure as a first-line choice for treating presbyopia. How do you approach the patient?

Dr. Zaldivar: I always spend some chair time with my patients discussing their options for presbyopic treatments. It is very important to set the patient's expectations for any surgery. I implanted the KAMRA inlay in my aunt's eyes, and I have invited her to give me constant feedback on her vision since the surgery. She keeps giving me the same responses: she has not experienced any problems after the surgery, and she has not had to use glasses since. Two days after the surgery, she had to drive 3 hours to another province near Mendoza, and she did so without any problems. That is the type of feedback that makes a surgeon confident in a chosen device.

Dr. Maus: Like Dr. Zaldivar said, you need some chair time with a patient, although patient selection for the KAMRA inlay is easier than with other modalities. Unlike other presbyopic treatments that are designed for individuals with only moderate symptoms, patient selection for the KAMRA inlay pertains mainly to preexisting medical conditions, such as severe dry eye disease prior to surgery, or overwhelming dominance in one eye. Those types of issues are contraindications for the implant.

In my experience, patients respond very well when my staff and I demonstrate the KAMRA's effect: we put the patient in a trial frame with 0.25 D of myopia in the nondominant eye, and then give him or her a pinhole demonstration card through which to look with the dominant eye. Candidates immediately understand the principle. It does not decrease patients' optical quality; it simply extends their depth of focus. On top of this demonstration, once they learn that the inlay is removable if they are unhappy, it is usually an easy decision for them to make.

PREOPERATIVE TESTING

Dr. Rivera: How do you evaluate patients preoperatively for a KAMRA inlay?

Dr. Maus: In my practice, patients undergo an extensive examination, including a discussion of surgical options, by an optometrist before they see me. If a patient expresses interest in the KAMRA inlay, we give him or her a pair of trial frames with a pinhole to look through and ask them to try reading. And then the patient makes the decision to undergo the procedure or not. It's easy.

Dr. Rivera: Dr. Zaldivar, do you alter your preoperative evaluation at all for a KAMRA candidate? How does that impact your practice?

Dr. Zaldivar: Preoperatively, my staff and I conduct all the standard tests: evaluating the cornea for dry eye disease, including staining, testing with the AcuTarget HD (AcuFocus, Inc.), questionnaires, etc. We find most patients are pleasantly surprised when you tell them you can treat their presbyopia with a corneal procedure. They prefer not to go inside the eye (*see Next-Generation Diagnostic and Surgical Planning Technology: AcuTarget HD on pg. 7*).

PATIENT SELECTION

Dr. Rivera: Dr. Vukich, how do you approach patient selection for the KAMRA inlay? What types of eyes do you think are good candidates for the implant, and which are not?

Dr. Vukich: In the past, when I've heard that patient selection is a critical component of success with a particular device, I would cringe, because to me that meant that it didn't work all that well. With the KAMRA inlay, this is not an issue.

I think the real key to successful implantation is determining whether physiologically there is a suitable place for it. We as surgeons must determine whether the cornea is stable, will the cornea need a pocket, is the cornea free of keratoconus or any other irregularities? These are the same sort of things we are used to screening in other refractive procedures.

The quality of the tear film is important when implanting inlays. With a small aperture, a rapid tear break-up time or inadequate tear quality can affect the quality of vision. So, even someone who does not complain of dry eyes or necessarily demonstrate symptoms of it needs to be tested for a healthy tear film.

Finally, we must make sure we do not implant this device in patients who are amblyopic. If these individuals underutilize their nondominant eye, they simply will not get the benefit of the inlay, because they ignore that image anyway. Beyond those considerations, this is a very good technology that provides a stable, consistent outcome, as long as we choose physiologically appropriate candidates.

Dr. Zaldivar: I consider it critical to assess the health of the entire eye before proceeding with KAMRA surgery. With candidates older than 55, we have to know if any capsular opacity is affecting their optical quality. Therefore, I feel it is very important to use an objective technique such as the AcuTarget HD from AcuFocus to assess the eye's optical quality, including the tear break-up time.

PATIENT OUTCOMES

Dr. Rivera: What is the typical patient outcome you have experienced with the KAMRA inlay?

"KAMRA patients achieve an excellent quality of vision within the first few days of implantation that is remaining consistent up to now, 5 years out."

– John A. Vukich, MD

Dr. Vukich: In the clinical trial, investigators were required to perform a rigid and prescribed follow-up on the KAMRA inlay's outcomes, including ETDRS quality of vision in both eyes implanted as well as not. We are continuing to collect data on these recipients' near visual acuities, biometric measurements, as well as subjective assessments. Remarkably, the line is basically flat. KAMRA patients achieve an excellent quality of vision within the first few days of implantation that is remaining consistent up to now, 5 years out (Figure 1).

We are also keeping data on these patients' fellow eyes (they were implanted unilaterally), and now those eyes are 3, 4, 5 years more presbyopic and are continuing to lose near vision, as you might expect in any presbyope. So, we are seeing the clear divergence of the near-vision capability, where the KAMRA inlay maintains and sustains that capability for its recipients. Interestingly, these patients tell us subjectively that their reading vision is very comfortable, and they have almost begun to take it for granted that they can still read.

Dr. Zaldivar: I am completely obsessed with optical quality, and what has really caught my attention about my personal outcomes with the KAMRA inlay is the perfection in the retinal image quality achieved by these patients. It is something that I have not experienced in other procedures, and I am really dazzled by it.

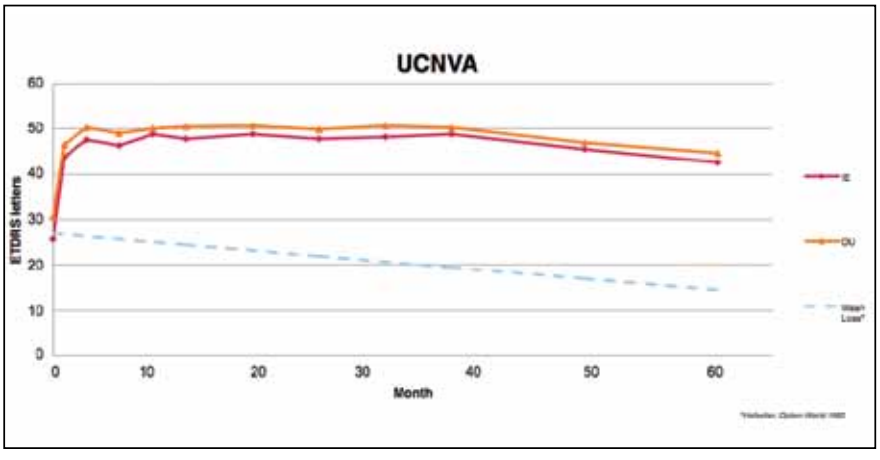

Figure 1. The visual gains provided by the inlay are maintained over the long term.

Dr. Maus: Compared to monovision, the most surprising thing about the KAMRA inlay is the level of visual acuity and the stereopsis it maintains. This is what thrills patients. They come in with the idea that that one eye will be treated for near and one eye for distance, but what they get is an all-purpose eye, and this all-purpose eye has no sweet spot like multifocal IOLs have. Their computer distance is fantastic, and it definitely supports the dominant eye in the

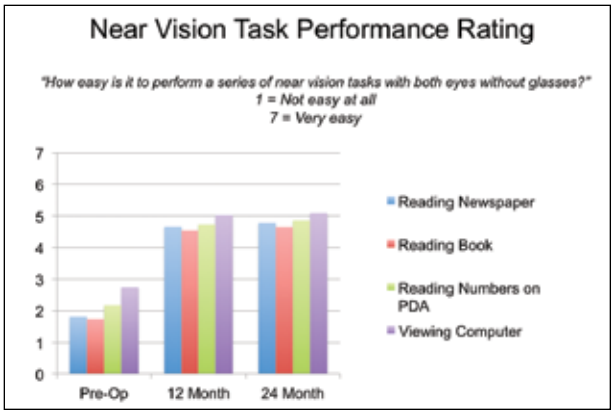

Figure 2. Subjective patient ratings of their ability to perform near-vision tasks with both eyes, without glasses, improves after implantation with the KAMRA inlay.

distance. My patients are more than happy with their outcomes.

SMALL APERTURE VS MONOVISION

Dr. Rivera: Compared to monovision LASIK, how does a KAMRA patient's postoperative neuroadaptation process differ?

Dr. Maus: I do see a difference in the postoperative response of certain KAMRA patients. Some recipients of the KAMRA inlay can experience a neuroadaptive process. Whereas some patients adjust to the new vision instantly, for others, it takes a few weeks or even a couple months to get used to using the treated eye. That is the only difference I see.

Dr. Vukich: The KAMRA procedure is not monovision. With monovision, patients are only clear at one distance in each eye. With the KAMRA implant, they are binocular. The distance vision is equal in both eyes, so patients are not fighting to suppress one image while driving or when using distance vision. At near, they are essentially using the KAMRA-treated eye for reading. Thus, I think its binocular functioning speeds patients' adaptive process. Monovision has a certain failure rate; approximately 30% of individuals cannot tolerate it. We do not see this with the KAMRA inlay, because I think its adoption is easier.

Dr. Rivera: That is a great point. In fact, my staff and I studied postoperative stereopsis in our practice, and our patients did not show any statistically significant loss of stereo acuity with implantation of the KAMRA inlay. As we all know, monovision recipients completely lose stereopsis.

POSTOPERATIVE MANAGEMENT

Dr. Rivera: We may occasionally find a patient who has some issues after implantation of the KAMRA. What are these potential issues, and should they be addressed?

"To achieve the best simultaneous near and distance acuity results, these patients' base refraction needs to be a little bit on the minus side, such as -0.50 or -0.75 D."
– John A. Vukich, MD

Dr. Maus: The typical thing is the symptoms of dry eye, which is why I prefer the pocket technique, which cuts fewer nerves versus the thick-flap procedure. I do a two-step procedure if any refractive change is required. I'll make a corneal flap and let it heal for approximately 3 months, and then I will perform the pocket technique underneath.

Dr. Zaldivar: Another issue may be a misaligned optic. The best strategy is to follow the patient for a couple of months and then perform a realignment. I have had to perform two or three realignments in my patients, and they did fantastic afterward.

Dr. Vukich: I have learned that the base refraction is important. If patients have a slight amount of hyperopia in their KAMRA inlay eye, their distance vision will remain excellent, but their near acuity will suffer. There are optical reasons for this effect. So, to achieve the best simultaneous near and distance acuity results, these patients' base refraction needs to be a little bit on the minus side, such as -0.50 or -0.75 D. As a result of the small aperture principle, the -0.75 D does not interfere with the patient's distance vision. So I would say that paying attention to the base refraction is, in my opinion, the primary driver for optical acceptance.

Dr. Rivera: I think it is safe to say that there are minimal problems with the KAMRA inlay, but those that do occur are easily managed with simple solutions, such as artificial tears, a topical steroid treatment, or simply more time for the patient to neuroadapt. Even realignments can be completed very easily.

"The KAMRA inlay provides a very nice defocus curve that no other procedure can match."
– Roger Zaldivar, MD

PATIENT EXPERIENCE AND FUNCTIONALITY

Dr. Rivera: Panelists, what has been your greatest KAMRA success story?

Dr. Vukich: I do not have a single "greatest" story, but a consistent story, that virtually all of my KAMRA patients comment that they can read their smart phones and iPads and all other electronic devices easily. It is freeing for them to be able to read and to see what time it is. Our lives have become so dominated by small print on a portable device that patients really appreciate having that near functionality back (Figure 2).

Dr. Zaldivar: I think that functionality is this technology's strongest selling point. Functionality means being able to see clearly across a broad depth of focus. The KAMRA inlay provides a very nice defocus curve (Figure 3) that no other procedure can match. This is a huge advantage for daily activities.

Dr. Maus: The difference is, the KAMRA does not provide reading ability only. If you see KAMRA recipients sitting in the waiting room, they are all reading or looking at their iPad or their phone or whatever. They are doing these activities in a very natural way.

Dr. Vukich: There is a fundamental difference between the KAMRA inlay and the multifocal technologies that many of us have had experience with. When we implant a multifocal or an accommodative IOL, then give the patient something to read, they often struggle through it. Their reading vision may be better than it was preoperatively, but yet it feels labored rather than natural. When we test KAMRA recipients' reading ability, they read material like they are looking at the morning paper. There is a naturalness with the KAMRA inlay that is subtle but real, and you can tell the difference.

"Dry eye disease is an issue nowadays, so we should prepare these patients eyes prior to the surgery and continue treating them after the surgery to ensure an optimal outcome."
– Roger Zaldivar, MD

PEARLS OF WISDOM

Dr. Rivera: We have all seen the KAMRA technology improve over time. I believe the technology is now refined to the point where I anticipate that it will be the best treatment for presbyopia for many, many years to come. At the same time, we all are looking for newer and better technologies and better ways of serving our patients. Panelists, what pearls might you have for a surgeon who is new to treating presbyopia with a KAMRA inlay?

Dr. Zaldivar: For me, it is patient selection, which amounts to chair time before the surgery. I think the most important part of the discussion is to explain to the patient what he or she is going to experience after the surgery. Also, we must treat ocular dryness. Dry eye disease is an issue nowadays, so we should prepare these patients eyes prior to the surgery and continue treating them after the surgery to ensure an optimal outcome.

Another important point is to closely follow the implantation protocol that the company provides. An impressive team of medical advisors conducted the research, and it is best to follow their recommendations. Even if you are someone who thinks you can always do things better, it is best to follow their guidance when implanting this device.

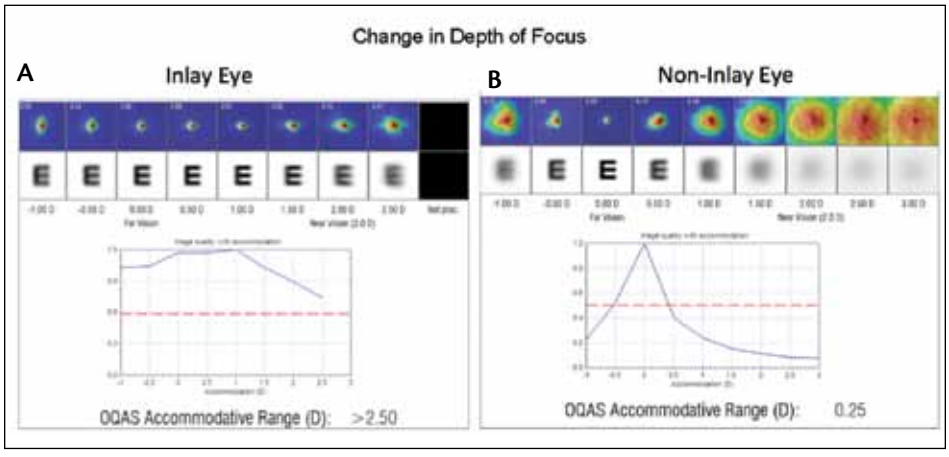

Figure 3. In a contralateral eye comparison, the AcuTarget HD showed that the eye implanted with the inlay had >2.50 D of depth of focus (A) compared to 0.25 D in the nonimplanted eye (B).

Dr. Maus: My pearl would be to take your time in identifying the dominant eye, especially in those patients who have a very low dominance. My staff and I have switched from the keyhole test, where you cover the keyhole with your thumb completely, to fogging. Fogging involves adding +1.00 D onto either eye, and then

asking the patient which one has more visual disturbances. That will be the dominant eye.

And if that test does not produce a trustworthy result, then we go to trial frames. We hand the patient two trial frames and ask him or her which vision he or she prefers.

Dr. Vukich: Implanting the KAMRA inlay is a very straightforward procedure. It is not technically difficult for anyone who has the fundamental skills of intraocular surgery. Surgeons can learn the technique very quickly, which I think is one beauty of the procedure. When I first heard the discussion of tear film quality, I was skeptical. Now, I have learned from experience that the tear film actually does make a difference in patients' postop outcomes.

CLOSING COMMENTS

Dr. Rivera: Thank you all. I appreciate the time you have been able to spend with us discussing this absolutely fascinating technology. Treatments for presbyopia have a very bright future ahead, and I encourage our colleagues to look further at the KAMRA inlay technology.

Dr. Vukich: I think the enduring appeal of this procedure is that it is fundamentally simple. As clinicians, we all understand how a pinhole works. So optically, this is a solution we can be confident in. We can apply it in a way that makes us comfortable, and we know it will provide a benefit to our patients. In my opinion, a simple and effective solution is better than a solution that is complicated. So, rather than trying to make the cornea multifocal or trying to add some aberrations to the optical system that may be beneficial, why not put an aberration-free depth-of-field solution into play in a way that physiologically makes sense? I am convinced that this is the elegant solution. ■

NEXT-GENERATION DIAGNOSTIC AND SURGICAL PLANNING TECHNOLOGY: ACUTARGET HD

The AcuTarget HD is the next-generation diagnostic and surgical planning instrument designed, in collaboration with Visiometrics, to further optimize clinical outcomes and streamline the patient care process. The AcuTarget HD capitalizes on the unmatched technological offerings of both the original AcuTarget Diagnostic device and Visiometrics' HD Analyzer.

The AcuTarget HD offers a broader range of functionality than its predecessor by combining five diagnostic tools into one state-of-the-art instrument to provide practices with new objective data to support patient selection, inlay centration, and postop patient management. This next-generation device provides the following:

- Objective assessment of visual quality
- Tear film quality over time and resulting visual impact
- Pseudoaccommodation measurement with visual demonstration of pre- and postop range of vision
- Inlay position guidance
- Assessment of targeted versus achieved inlay placement
- Enhanced patient understanding and commitment to postop care

The AcuTarget HD will be on display for the first time in the AcuFocus booth (#E01) at the ESCRS in Amsterdam over October 5–9, 2013.

The KAMRA Inlay is an investigational device, limited by federal (U.S.) law to investigational use and not available for sale in the United States.

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