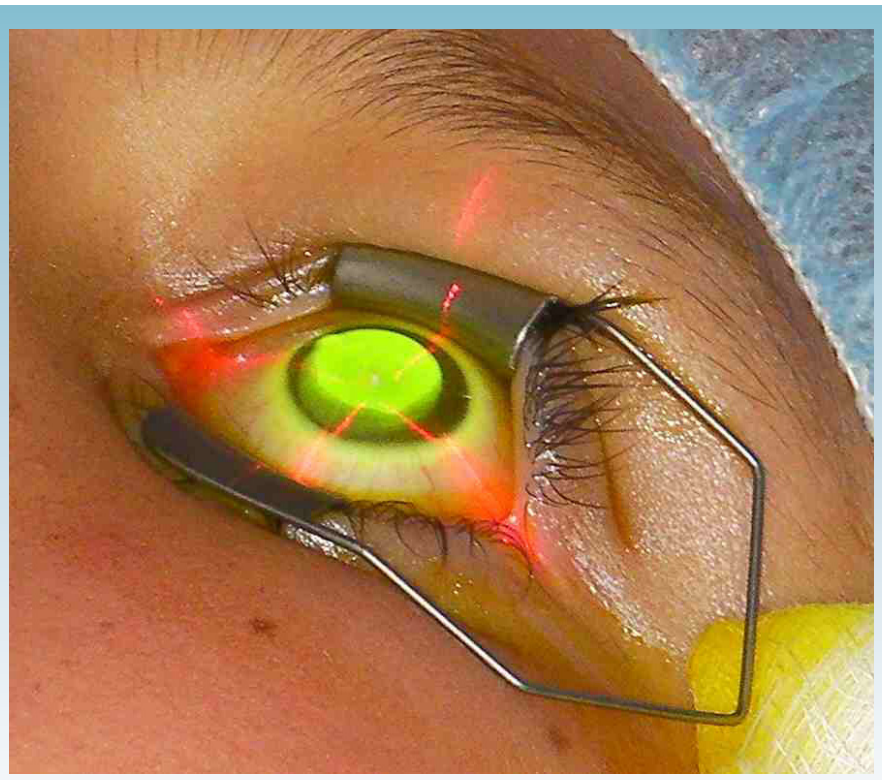
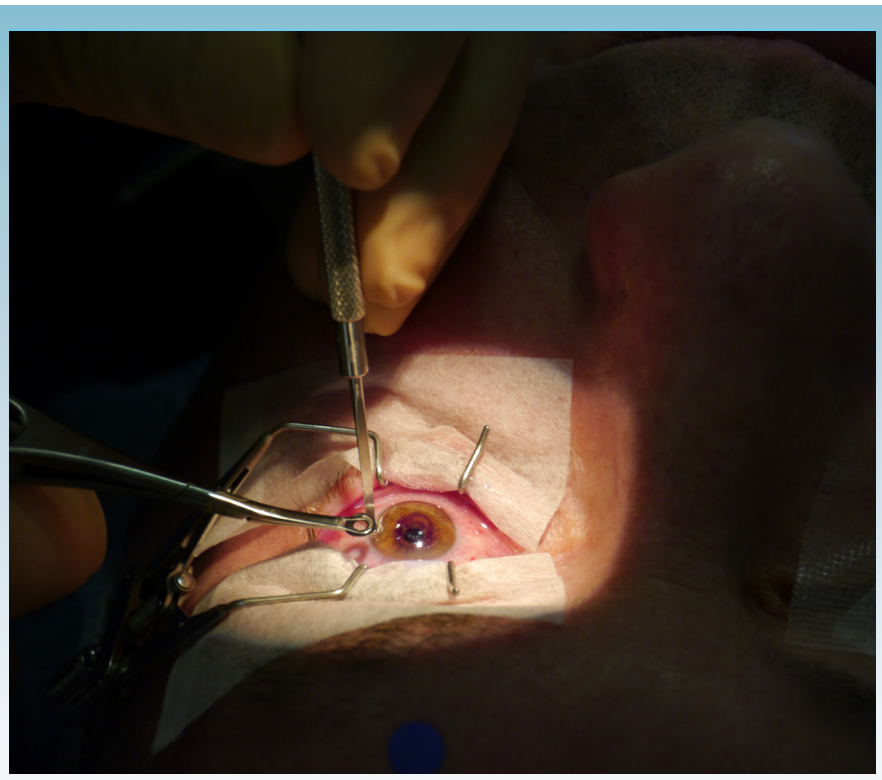
What's more minimally invasive than LASIK?

by Matt Young and Gloria D. Gamat EyeWorld Contributing Writers



Patient undergoing accelerated crosslinking with the KXL II system

Source: Peter Hersh, MD



Patient undergoing vision correction surgery with the KAMRA inlay

Source: Jeffery J. Machat, MD

PiXL, KAMRA, and—for extreme refractive error—the Visian ICL

Ophthalmologists will forever push the envelope to achieve a smaller surgical footprint.

That's why LASIK isn't the endgame of refractive surgery, but rather the beginning of the beginning. As far as minimally invasive refractive surgery goes, this is especially true.

Advancements in technology and refractive surgical techniques have brought about a wide range of refractive correction procedures that are even more minimally invasive. Here we look at two of the latest advancements and a third (the Visian ICL, STAAR Surgical, Monrovia, Calif.) that is standing the test of time to provide a minimally invasive LASIK alternative for extreme refractive error.

Non-invasive, topography-guided crosslinking

In corneal refractive surgery, refractive errors are corrected through techniques that reshape the cornea either by surgery or by laser treatment. When corneal crosslinking with riboflavin and ultraviolet-A (UVA) was introduced, it provided an option that reshapes the cornea by changing its biomechanical structure. The standard technique was designed to stabilize the progression of ectatic corneal disorders such as keratoconus and corneal ectasia. However, basic science and clinical research have expanded the potential utilities of crosslinking. Today, accelerated crosslinking using higher power UV sources can reduce procedure time from 30 minutes to 3 minutes or less. In addition, Photorefractive Intrastromal Crosslinking (PiXL) using the KXL II System (Avedro, Waltham, Mass.) can address topography irregularities and refractive errors as well.

"PiXL is a topography-guided crosslinking," said **Peter Hersh, MD**, Cornea & Laser Eye Institute – Hersh Vision Group, Teaneck, N.J. "The KXL II System incorporates eye tracking to properly pattern and apply the UVA energy needed."

"PiXL has two goals," Dr. Hersh said. "In irregular corneas, such as in keratoconus, we can use topography both to guide the power and the pattern of the UV light on the cornea to obtain crosslinking individualized to the patient's corneal irregularity, and for refractive surgery, we are able to pattern the energy in order to correct lower degrees of nearsightedness, farsightedness, and astigmatism."

PiXL is extremely non-invasive, according to Dr. Hersh.

"Unlike LASIK or PRK, which are removing tissue, [PiXL] doesn't violate the tissue per se, but it changes the shape of the cornea on a biomechanical basis," he said. "It is a new kind of platform where we are changing the corneal biomechanics and corneal microarchitecture in order to correct refractive error."

While LASIK is most suitable for higher degrees of myopia, PiXL best suits patients with lower degrees of refractive error.

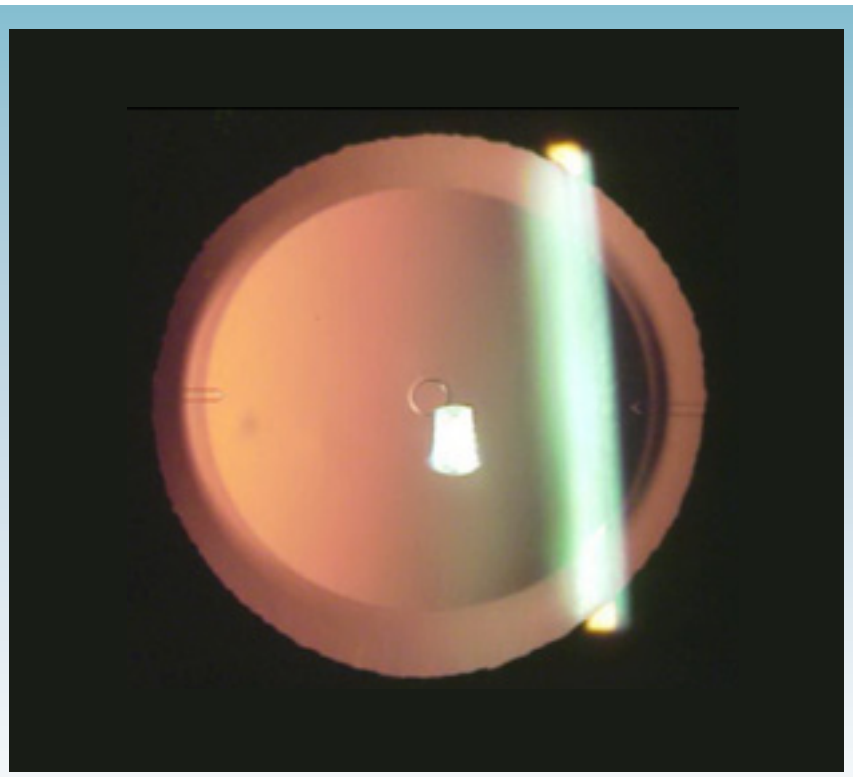
"It is a standalone procedure for lower degrees of hyperopia, myopia, or astigmatism," Dr. Hersh explained. "But we also see that it might have a good place as an enhancement procedure in post-cataract surgery, where there is a residual refractive error that can be corrected in a non-invasive way."

PiXL provides ophthalmic surgeons with an enhancement tool that can proceed without much intervention. However, experts are still defining the limits.

Corneal inlays over multifocal ablation

In the last 10 years, several generations of corneal inlays have been developed and refined. Made of an inert material called polyvinylidene fluoride (PVDF), the KAMRA corneal inlay (AcuFocus, Irvine, Calif.) is a disc-shaped inlay that is 6 microns thick, 3.8 mm in diameter and has a 1.6 mm opening.

"The KAMRA corneal inlay has 8,400 tiny perforations throughout the inlay in a pseudo randomized pattern," said **Jeffery J. Machat, MD**, chief medical director, Crystal Clear Vision, Toronto. "Weighing only as much as a crystal of salt, it is an incredibly refined type of inlay that works on extending the range



With the new V4c model of the Visian ICL that has a central hole, no iridectomies or iridotomies are needed. The surgery is faster, easier, and less traumatic compared to previous models that needed peripheral iridectomies/iridotomies.

Source: Alaa El Danasoury, MD

of focus of the eye using pinhole or small aperture optics."

In the clinical practice, it is more well known that changing the power of the eye means changing the shape of the cornea with lasers, like LASIK and PRK, or changing the power of the eye internally with a lens implant.

Corneal inlays work with a different mechanism.

"Instead of being a lens that changes the power of the eye, this is an optical principle that increases the depth of focus," said **Daniel S. Durrie, MD**, founder and president, Durrie Vision, Overland Park, Kan.

"You will have a large range [of vision]. That's what made this popular to patients and doctors," he said.

Its minimally invasive characteristic is another reason KAMRA is gaining popularity among patients and doctors. The procedure is straightforward, easy to put in and easy to remove as well.

"It takes 60 seconds or less to remove," Dr. Machat said.

Results of FDA clinical trials, which evaluated whether the KAMRA inlay can be removed from the cornea and allow patients' vision to return to the preoperative state, have shown that patients did recover within one line of their best corrected vision after the inlay was removed.

"I think it is a comfort level for both surgeons and patients that it is removable and the patients' corneas tolerated the surgery to put it in and the surgery to take it out. The good news is that in well-selected patients, the removal rate is running 1% or less," Dr. Durrie said.

KAMRA provides a long-lasting, minimally invasive option to presbyopes who otherwise have healthy corneas.

"For this procedure, you need to have clear media," Dr. Machat said. "Any sort of scarring or problem on the cornea, even a mere dry eye, any sort of irregularity or early cataract change in the lens disqualifies a patient from getting the inlay."

"[Patients] need to have a good tear film, and we need to make sure that they don't have a cataract," Dr. Durrie said. "The age group for

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this is patients in their 40s, 50s, and sometimes 60s—the same age group that could be developing a cataract. We are narrowing down the optics of the eye. We look through the small aperture optics. If patients have cataract or dry eye, they don't get nearly as good of a result."

With the KAMRA—an outpatient procedure that takes about 10 minutes with topical anesthetic—vision recovery can be quite rapid. However, patient reactions vary. While some can read fine print the next morning, others take about 4–6 weeks as their tear film stabilizes and any edema resolves centrally.

"In 15% of these patients, improvement of vision can be seen in 3–4 hours, and it does continue to improve after the first week," Dr. Durrie said. "There is an adaptation period to their vision whereby patients are more comfortable in their new vision after 1 month than 1 day after the surgery."

The surgical development of the KAMRA has been going on for a decade now. In the process, ophthalmic surgeons have learned who's a good candidate and have perfected how to do the surgery. The procedure performed well enough in the early studies done on patients to continue developing it.

"What is great about FDA clinical trials is that we can look at the long-term data (up to 5 years) and now know the best candidates and what the best surgical technique is," Dr. Durrie said. "We now know the best femtosecond laser settings and where to center the inlay. We did not know this when we started clinical trials."

The key to this procedure's success, Dr. Durrie said, is not just good patient selection and good technique, but also patient education.

"To make sure that expectations are aligned, patients need to understand that this procedure doesn't make them see instantly, and it doesn't make their eyes younger," Dr. Durrie said. "But it does give them the ability to have a broader function of vision for both near and distance. The main thing is that this is a new optical principle and that's what makes it exciting. We are now going to have a different tool when evaluating options for patients."

The Visian ICL for extreme—and low—refractive error

Patients with low to extremely high refractive errors, dry eyes and thin corneas do not qualify for LASIK. Instead, the Visian ICL could be more appropriate.

"The Visian ICL can correct a wide range of refractive errors, between –18.0 and +6.0 D," said **Alaa El Danasoury, MD**, medical director and chief of the refractive surgery department, Magrabi Hospitals & Centers. "It also corrects astigmatism up to 6.0 D. This range covers most patients with ametropia. The main prerequisite for ICL implantation is an anterior chamber depth of 3.0 mm or more, measured from the endothelium. Other criteria include stable refraction and healthy endothelium."

Although glaucoma, keratoconus, and retinal dysfunction are relative contraindications for the procedure, the most important exclusion criterion for Visian ICL is a shallow anterior chamber (less than 3.0 mm), Dr. El Danasoury said.

Considered a minimally invasive procedure, the Visian ICL is performed routinely under topical anesthesia.

"The implant can be inserted through a small incision, less than 3 mm, and it entails minimal manipulation of the intraocular tissue," he said. "With the new V4c model that has a central hole, no iridectomy or iridotomies are needed. It is an

additive procedure so it can be partially reversed and the lens can be easily exchanged if needed."

Similar to laser vision correction, the procedure is done in an outpatient setting.

"In experienced hands the whole procedure takes less than 3 minutes, which minimizes the risk of infection," Dr. El Danasoury said.

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Compared to other refractive correction procedures, the Visian ICL may be a better option for patients with myopia above 7.0 D because of the better quality of vision, elimination of the risk of ectasia and flap complications, refractive stability, and preservation of the crystalline lens and accommodation.

"For moderate myopia (between 5.0 and 7.0 D) I personally prefer the Visian ICL because of better predictability, less night vision complaints, and less postoperative chair time," Dr. El Danasoury said. "In many cases with low myopia (between 1.0 and 4.0 D) I still prefer the Visian ICL if the topography and/or tomography show any degree of suspicion or in cases of borderline corneal thickness. With the ICL there is no risk of surprises that we sometimes see with laser correction."

Although there are some areas warranting refinement (i.e., ICL sizing), the current available methods, according to Dr. El Danasoury, are good enough for about 95% of the cases. Further, in the rare cases with oversizing or undersizing, the ICL can be easily exchanged for a smaller or larger lens.

"Modern phakic IOLs gained a solid place in refractive surgery over the last 3 decades; the main debate that was ongoing for the last 10–15 years—which phakic IOL is better?—is now resolved, and most of the phakic IOL surgeons agree that posterior chamber IOLs are the closest to ideal because of their long-term safety, stability inside the eye, ability to correct astigmatism, better cosmesis, and higher patient satisfaction," he said. **EW**

Editors' note: Dr. Hersh has financial interests with Avedro. Drs. Machat and Durrie have financial interests with AcuFocus. Dr. El Danasoury has financial interests with STAAR Surgical.

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