Best Practices

in Integrated Care

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BAUSCH + LOMB

Best Practices in Integrated Care

This ongoing series, now in its third year, is featured in each issue of *AOC* and its sister publication, *CRST*. The articles will clarify how eye care providers can best work together to provide patient-centered care of the highest quality possible.

HOW TO PRESENT RLE TO PATIENTS IN THREE SIMPLE STEPS

Take the challenge out of discussing dysfunctional lens syndrome.

BY GEORGE O. WARING IV, MD

What was once a challenging patient consultation for refractive surgery can now be streamlined. During the past decade, my colleagues' and my approach to educating patients on their conditions and our understanding of how best to serve their needs has evolved. Years ago, when presbyopic patients would present for LASIK to reduce their dependence on reading glasses and bifocals, we would recommend a refractive lens exchange in cases where there was early lenticular opacity and/or hyperopia. Not infrequently, patients were taken aback at the suggestion of a lens-based procedure. For many years, we performed LASIK in these individuals, and frequently they would come back within 5 to 7 years complaining that their LASIK had "worn off."

Enter the concept of the *dysfunctional lens syndrome* (DLS) and the use of advanced diagnostics to aid in its detection and proper staging.

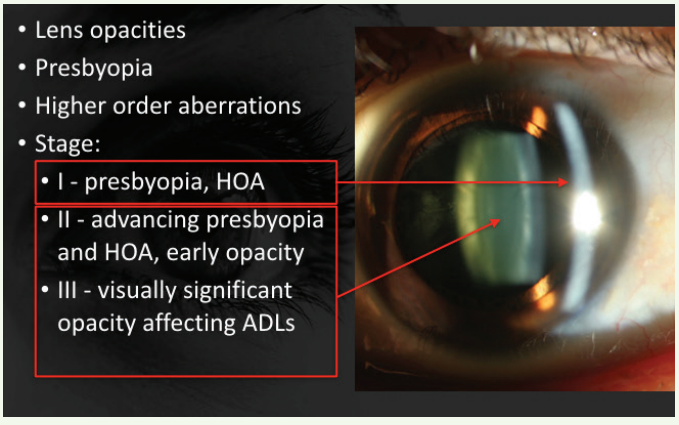

Figure 1. The use of DLS in decision making.

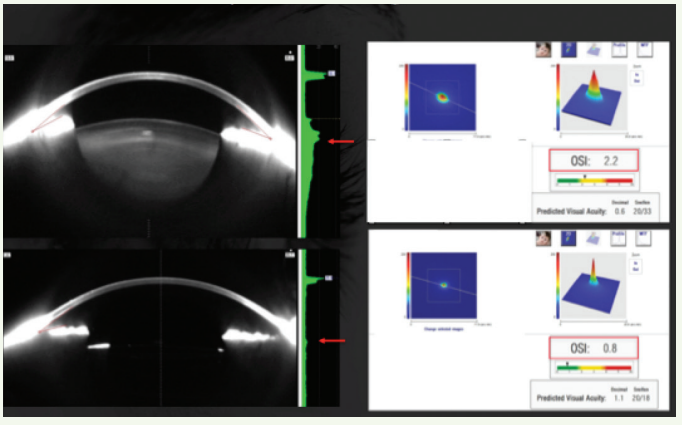

Figure 2. Ocular scatter index (right) before and after refractive lens exchange.

WHAT TO KNOW

Below I outline three tips on how to present refractive lens exchange to patients.

Tip No. 1: Use an advanced ocular analysis and include a digital "lens-centric" examination. With this approach, we often find that baby boomers presenting for LASIK do not have clear lenses; instead, they have DLS, a clinical entity that has been overlooked and inadequately characterized for years. The term *dysfunctional lens syndrome* characterizes a spectrum of changes that occur ubiquitously with age and that include presbyopia, lens opacification, decreased retinal image quality, and higher-order aberrations.[1] Part of the rationale behind the terminology DLS is to avoid the use of others such as *very early cataract* or *precataract*. These terms can seem dismissive, implying that the patient's only option is to wait for the early cataract to ripen or for a precataract to become a cataract, delaying surgery by 5 to 10 years.

Tip No. 2: Use a DLS grading scale to educate patients on their condition and to suggest the best procedure for them. My colleagues and I recently presented a grading scale for DLS that has been useful in clinical decision-making for a lens- or cornea-based procedure and for educating patients on their condition.[2] In stage 1 DLS, the patient has lost the ability to adequately accommodate but still has excellent image quality with a relatively clear lens. In this situation, a cornea-based procedure is often the best choice, unless the patient has a significant degree of hyperopia. In stage 2 DLS, the lens has developed some early opacification, resulting in decreased image quality and higher-order aberrations. In this situation, a lens-based procedure is often the most appropriate choice. In stage 3 DLS, the lens opacities affect the patient's daily activities and meet subjective and objective insurance-based criteria for a diagnosis of cataract (see Figure 1 and *DLS by Stage*).

As I explain to patients with stage 2 DLS, their situation is similar to looking through two dirty windshields, one in front of the other. We can clean (focus) the outer windshield (the cornea) with LASIK, but the inner windshield (the crystalline lens) is still cloudy. Therefore, in patients with DLS, it makes more sense to exchange the aging crystalline lens for an appropriately selected IOL instead of performing LASIK now and cataract surgery years later. Although we do perform clear lens exchange in younger patients with large degrees of hyperopia, stage 2 dysfunctional lenses are not clear; hence the use of the term *dysfunctional lens replacement* or *refractive lens exchange* and not *clear lens exchange*.

Tip No. 3: Give patients a digital tour of their eyes. Herman Snellen described visual acuity in 1863, but practitioners now have advanced diagnostics that measure functional vision and quality of vision. A patient may have a visual acuity of 20/20 but diminished retinal image quality. Combining the use of dilated Scheimpflug imaging and associated densitometry with double-pass wavefront technology (AcuTarget HD; AcuFocus), we take patients on a digital tour of their eyes, showing them their dysfunctional lens and the correlating light scatter. The AcuTarget HD generates an ocular scatter index, which provides patients with a score for their quality of vision and also demonstrates the light scatter as it falls on the retina (Figure 2).

Ray-tracing technologies like the iTrace (Tracey Technologies) are also being developed to quantify internal aberrations and derive a dysfunctional lens index. I find that showing patients the light scatter (point spread function) and increased ocular scatter index helps them to understand the value of addressing the source of the problem, the aging crystalline lens, with a single procedure, while also preventing the future formation of cataracts.

CONCLUSION

In our experience, patients who come in for a LASIK consultation and are found to have stage 2 DLS respond well to being told they are candidates for laser vision correction, as we

DLS BY STAGE

now have lasers to treat both the cornea and the internal lens. Furthermore, during the refractive consultation, we emphasize to all patients that DLS is a normal part of the aging process and that no action is required. For patients with stage 2 DLS who wish to pursue surgery to treat presbyopia, dysfunctional lens replacement/refractive lens exchange is presented as an option. Patients appreciate this as a treatment option, because we educate them appropriately. As with all surgical procedures, we outline the relative risks and benefits of each technique. ■

1. Waring GO IV. Diagnosis and treatment of dysfunctional lens syndrome. *CRST*. March 2013;13(3):36-38.
2. Waring GO IV, Rocha KM, Durrie DS, Thompson VM. Use of dysfunctional lens syndrome grading to guide decision making in the surgical correction of presbyopia. Paper presented at: ASCRS/ASOA Symposium & Congress; May 10, 2016; New Orleans, Louisana.

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Best Practices in Integrated Care

CORNEAL INLAYS: A CLINICAL PRIMER

Corneal inlays expand the options for correcting presbyopia. Here is what optometrists should know about these devices.

BY J. CHRISTOPHER FREEMAN, OD, FAAO

Presbyopia can be a frustrating experience for patients, especially those who have been emmetropic their entire lives and suddenly face the progressive loss of near vision. Patients who have had refractive surgery may have an extra level of anxiety because they may believe their surgery is "wearing off."

There have been few lasting surgical choices for correcting presbyopia until recently. The FDA approvals of the Kamra Corneal Inlay (AcuFocus) and Raindrop Near Vision Inlay (ReVision Optics) have made available a new approach to restoring near vision in presbyopic patients. With these approvals and at least one other corneal inlay also in development (see *Corneal Inlays: Just the Facts*), eye care professionals may finally have viable and potentially permanent fixes for presbyopia to offer to their patients.

KAMRA AND RAINDROP

Although the Kamra was the first corneal inlay to gain FDA approval in April 2015, the concept behind corneal inlays dates back to the 1940s.[1] The Kamra design features a small aperture in the central optical zone; the resulting pinhole effect enhances the patient's depth of field. With the Kamra inserted in a corneal pocket in the nondominant eye, patients achieve improved near vision in that eye without having to sacrifice distance visual acuity as they would with monovision. On the other hand, there is a slight decrease in acuity in the implanted eye relative to the untouched emmetropic dominant eye.[1]

The ideal patient for a Kamra inlay has a slightly myopic refraction in the range of -0.50 D to -1.00 D, with a "sweet spot" around -0.75 D. The optical effect of extending the depth of field in a slightly myopic eye is to enhance near vision while also slightly improving distance acuity, as the pinhole masks much of the distance blur inherent to the small amount of myopia. In some settings, a Kamra inlay may be paired with LASIK, as the pocket created for the inlay does not necessarily interfere with flap creation; however, this is an off-label use of the device.

The Raindrop inlay has a different mechanism of action. It creates an aspheric, hyperprolate cornea that is slightly myopic in the center of the visual axis, with a decrease in the amount of myopia toward the edge of the inlay. The result is, reportedly, an optical effect similar to that of a multifocal lens, with continuous viewing zones for near, intermediate, and distancevision with less effect on distance vision compared with monovision. However, according to the FDA, in clinical trials there was a mild decrease in distance visual acuity in the Raindrop eye.

Eyes with refractions ranging from emmetropic to slightly hyperopic tend to receive the greatest benefit from the Raindrop inlay. Because the Raindrop is placed under a flap in the cornea, and because most surgeons prefer not to recut a flap, use of the Raindrop would seem to preclude the use flap-based refractive surgeries. Patients with previous LASIK surgery may have to seek other options for correction of presbyopia.

PRE- AND POSTOPERATIVE MANAGEMENT

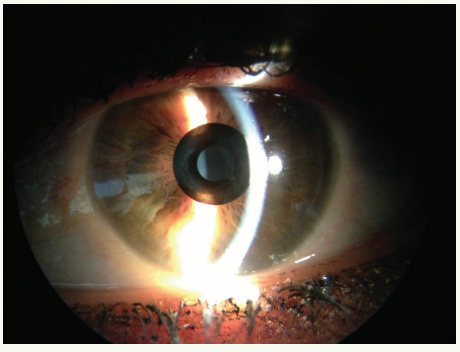
Although the category of corneal inlays is new, many of the principles for preoperative preparation and counseling and for postoperative care are similar to those for other refractive procedures. Patients can expect to have some fluctuation in vision in the immediate postoperative period; eye dryness and mild discomfort are not uncommon. The surgery may induce some swelling of the cornea; thus, halo or glare might be noticed during the healing period. Most visual symptoms resolve, and patients should achieve their final vision by about 3 months after surgery.

Managing preoperative dry eye disease is important for any ocular surgical procedure, but the stakes might be slightly higher in corneal implant procedures, especially for those involving the Kamra. The corneal surface is a powerful but underappreciated source of refractive influence in the eye, but, in an optical system that depends on a unilateral implant, any perception of degradation in quality of vision may be heightened because the other eye cannot compensate. In the case of Kamra patients, because they are looking through a fine pinhole in the implanted eye, any associated loss of acuity in the central zone could offset the

CORNEAL INLAYS **THE BASIC FACTS**

KAMRA INLAY

Manufacturer: AcuFocus
Status: FDA approved April 2015



Design Specs

Polyvinylidine difluoride material; 6 µm thick; overall diameter 3.8 mm with a central annulus of 1.6 mm; 8,400 microperforations arranged in a pseudorandom pattern allow nutrient flow

Concept

Uses pinhole optics, by blocking peripheral rays of light to enhance depth of focus

Target Eye

Nondominant

Surgical Procedure

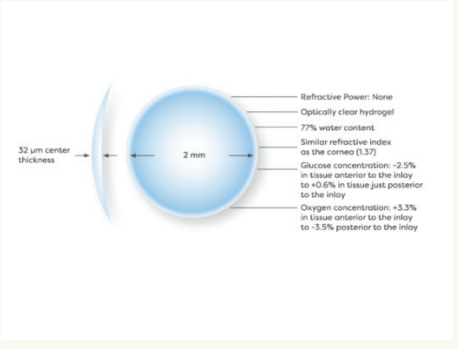
Implanted in a pocket at least 200 µm from the corneal surface

Clinical Trial Data

In 507 patients (age, 45-60 years) with manifest refraction spherical equivalent (MRSE) of -0.75 to +0.50 D, mean near vision improved from J8 to J2; mean distance UCVA of 20/20 was maintained, and binocular contrast sensitivity and visual fields were clinically unaffected.[1,2]

RAINDROP NEAR VISION INLAY

Manufacturer: ReVision Optics
Status: FDA approved June 2016



Design Specs

Hydrogel material with water content and refractive index similar to the cornea; 30 µm thick; diameter 2 mm

Concept

Creates greater depth of focus by increasing central curvature of the cornea

Target Eye

Nondominant

Surgical Procedure

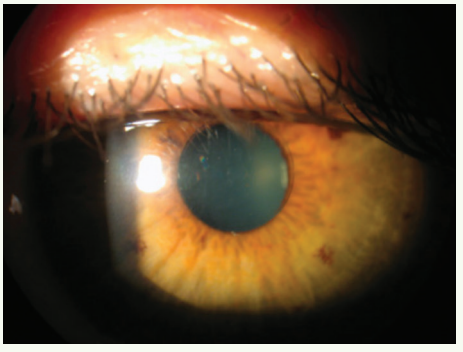
Implanted under a femtosecond laser-created flap at 30% of central corneal thickness

Clinical Trial Data

In 343 patients, average near UCVA improved by 5 lines in the treated eye at 12 months; 93% of patients achieved 20/25 near UCVA or better; intermediate UCVA improved by 2.5 lines, and distance UCVA decreased by 1.2 lines; blurred vision (1%), glare (2%), and halo (4%) were the most commonly reported side effects.[3,4]

FLEXIVUE MICROLENS

Manufacturer: Presbyia
Status: Approved in 42 countries; investigational in US



Design Specs

Hydrophilic acrylic polymer; available in nine refractive powers; diameter 3.2 mm, with a 1.6-mm central zone focused for distance; peripheral annulus provides focus for near

Concept

Multiple viewing zones allow the eye to focus at varying depths

Target Eye

nondominant

Surgical Procedure

Implanted into a femtosecond laser-created corneal pocket, potentially performed in-office under topical anesthesia; investigational studies exploring use in conjunction with LASIK

Clinical Trial Data

A 3-year clinical trial has enrolled 421 emmetropic patients; trial expected to be completed in 2018.

1. Durrie D. The effect of different monovision contact lens powers on the visual function of emmetropic presbyopia patients (an American Ophthalmological Society Thesis). *Trans Am Ophthalmol Soc.* 2006;104:366-401.
2. Jalali S, Aus der Au W, Shaarawy T. AcuFocus corneal inlay to correct presbyopia using femto-LASIK. One year results of a prospective cohort study. *Klin Monbl Augenheilkd.* 2016;233(4):360-364.
3. Whitman J, Dougherty PJ, Parkhurst GD, et al. Treatment of presbyopia in emmetropes using a shape-changing corneal inlay: one-year clinical outcomes. *Ophthalmology*. 2016;123:466-475.
4. Kilcoyne J. Treatment of presbyopia. Paper presented at: OIS @ AAO 2015; November 12, 2015; Las Vegas, NV. Available at: http://ois.net/ois-aao-2015/presentations. Accessed April 18, 2016.

value of the presbyopic correction. In addition, a dry corneal surface is known to affect the accuracy of biometric readings. Therefore, it is vital to detect and address existing dry eye disease during evaluation and screening to avoid treating inappropriate candidates.

IN THE PIPELINE

The Kamra and Raindrop corneal inlays represent proofs of two principles that pave the way for future development in the category of corneal inlays. However, just as each of these inlays depends on different optical designs to restore near vision, one other inlay on the horizon uses yet another optical principle to address loss of accommodation.

The Flexivue Microlens (Presbyia) is approved for use in 42 countries but does not yet have the FDA's nod. Much like a multifocal lens, the Flexivue has multiple viewing zones with differing refractive power adds. Similar to the other inlays, it is intended for use in the nondominant eye. It creates a slight myopic shift, so the ideal candidate appears to be an individual with emmetropia to mild hyperopia. The lens is available in nine refractive powers, which could add a customizable approach to the correction of presbyopia, including exchange for a more powerful inlay as presbyopia advances. Early clinical results and data from outside the United States appear promising.

With any surgical procedure, appropriate candidacy and discussion of perioperative expectations is integral to success. Corneal inlays offer tremendous potential to permanently address a source of refractive error that can be extremely frustrating for patients, one that only promises to grow in prominence with the aging of the population. With more patients coming into the clinic, eye care practitioners would do well to understand the options so that they can refer patients appropriately. ■

1. Arlt E, Krall E, Moussa S, et al. Implantable inlay devices for presbyopia: the evidence to date. *Clin Ophthalmol.* 2015:14;(9):129-37..
2. Barraquer JI. Modification of refraction by means of intracorneal inclusions. *Int Ophthalmol Clin.* 1966;6(1):53-78.

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SMILE OFFERS VIABLE ALTERNATE TO LASIK

Patients' preferences may ultimately determine the success of this procedure.

BY STEPHEN G. SLADE, MD

Over the years, LASIK has garnered some unfortunate press and a negative image—undeservedly so, in my opinion—despite advances in the past 25 years that have improved outcomes and made the surgery safer. It is worthwhile to keep in mind, however, that the LASIK market originally grew because of patients' demand for the procedure. Patients' preferences will continue to drive the future of refractive surgery. Indeed, refractive surgery is still very much desired by many patients, and they might welcome new options that offer similarly excellent results.

In the interest of giving patients more options for refractive correction, the recent FDA approval of small-incision lenticule extraction (SMILE) for myopia is a welcome addition to the refractive surgery repertoire. In this technique the VisuMax femtosecond laser (Carl Zeiss Meditec) is used to cut a small lenticule that is then extracted. Investigations to date suggest that SMILE provides safety and efficacy outcomes at least comparable to those of LASIK. It uses a different approach to modifying the optical system, however, which may confer benefits including potentially faster healing, if not faster visual recovery.

The laser SMILE procedure is performed in four stages:
- the underside of the lenticule is cut
- the sides of the lenticule are cut
- the upper border of the lenticule is cut
- an opening incision is created

The patient is then moved to the microscope, where the surgeon removes the lenticule through the opening incision.

In a phase 3 trial, 327 of 328 eyes treated with SMILE achieved 20/40 or better vision 6 months postoperatively, and 88% of eyes achieved 20/20 or better. Issued related to loss of suction, and complications such as dry eye and moderate to severe glare and halo, were seen with rates comparable to those reported after LASIK.[1]

As one of the investigators in that trial, I had the opportunity to learn about this procedure and what advantages it may offer in certain patients, and I share some of these insights in this article.

PATIENT SELECTION

Patient selection is important for the success of any surgery. As SMILE is rolled out commercially, we will undoubtedly learn more about the nuances of who may benefit from it the most. For now, we know that SMILE has the potential to fix myopia and astigmatism, although it is now approved only for correction of myopia between -1.00 and -8.00 D.

(I was the medical monitor of a trial looking at SMILE for the treatment of myopic astigmatism; that study has been completed, and results have been submitted to the FDA. I am not able to share specific data, but I can say that the outcomes were very promising.)

To date, close to 600,000 SMILE procedures have been performed worldwide, with outcomes equal to and in some cases superior to those of LASIK. Any patient who would be a candidate for myopic LASIK would likely be equally suitable for SMILE. However, the features of SMILE and how it is performed may make it a more desirable option for some patients.

DRY EYE

Compared with LASIK, fewer corneal nerves are truncated during the SMILE procedure, so there appears to be a theoretical reduction of risk postoperative dry eye. Equally, those with preoperative dry eye may experience easier healing after SMILE than after LASIK.

RISK FOR ECTASIA

Whereas LASIK procedures require creation of a corneal flap around 270° for access the stromal bed, in SMILE the entrance incision is 45° to 60.° Moreover, more of Descemet membrane is preserved in SMILE relative to LASIK, leaving more of this strongest part of the cornea intact. As refractive surgeons are well aware, with proper patient selection LASIK does not cause ectasia, but in a cornea prone to ectatic changes it can hasten its onset. Because less tissue is disturbed in SMILE, the procedure appears to offer better postoperative corneal biomechanical integrity than LASIK.

VERY HIGH MYOPIA

SMILE is not a dose-dependent procedure. That is to say, with LASIK, the higher the refractive error treated, the more laser stromal ablation must be applied, leading to longer procedures with more energy application, in which the flap and cornea are exposed longer to drying conditions.

With SMILE, on the other hand, anterior and posterior laser cuts are made, and the only variable is how far apart to place them; the same amount of energy is applied to low and high myopes alike, in the same span of time. As a result, although a typical scattergram of LASIK outcomes tends to get a greater spread of results among very long eyes, a scattergram of similar patients with SMILE would demonstrate tighter clustering around the mean, indicating more consistent outcomes.

PATIENT PREFERENCE AND THE FUTURE

Although SMILE may be preferred over LASIK for clinical reasons in certain cases, patient preference will most often be the determining factor in which option patients select. If the experiences in Europe and Asia with SMILE are an indication, the desire to avoid a flap-based procedure will be important to some patients; others will be attracted by the novelty of SMILE, the latest refractive surgery offering; still others may be wary because of LASIK's previous bad press and eager to try something new and different. When LASIK was introduced 25 years ago, it offered outcomes similar to those of PRK, but it became the favored option for correcting vision due to popular demand. In the ensuing time, advances such as eye tracking capabilities, femtosecond laser flap creation, and wavefront-guided ablation have greatly improved the safety and efficacy of LASIK. In most cases, SMILE will yield outcomes comparable to those with the most advanced LASIK techniques and technologies, so it will be interesting to see how the court of popular demand rules in terms of patient preference.

In the near term, a review by the FDA of clinical data on SMILE in myopic astigmatism is anticipated, and ongoing research is exploring SMILE techniques for correction of hyperopia. It is hoped that these developments will complement the success of SMILE for myopia and add to our ability to give patients the final vision they want. These advances provide good options for patients today, and they establish a platform that can be further improved to offer even better options in the future. ■

1. FDA approves VisuMax Femtosecond Laser to surgically treat nearsightedness [press release]. US Food and Drug Administration. September 13, 2016. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm520560.htm. Accessed January 19, 2017.

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