Surgical correction of presbyopia

Richard S. Davidson, MD, Deepinder Dhaliwal, MD, D. Rex Hamilton, MD, Mitchell Jackson, MD, Larry Patterson, MD, Karl Stonecipher, MD, Sonia H. Yoo, MD, Rosa Braga-Mele, MD, Med, FRCSC, Kendall Donaldson, MD, MS, for the ASCRS Refractive Cataract Surgery Subcommittee

Presbyopia is the most common refractive disorder for people older than 40 years. It is characterized by a gradual and progressive decrease in accommodative amplitude. Many surgical procedures for the correction of presbyopia exist, with additional procedures on the horizon. This review describes the prevalent theories of presbyopia and discusses the available surgical options for correction.

Financial Disclosure: Proprietary or commercial disclosures are listed after the references.

J Cataract Refract Surg 2016; 42:920–930 © *2016 ASCRS and ESCRS*

The term *presbyopia* originates from the Greek word "presbyteros," meaning elder. It is the most common refractive disorder in people older than 40 years and manifests as a gradual and progressive decrease in accommodative amplitude. The underlying cause remains unclear and is likely multifactorial. Three main etiologic categories exist[1]: lens- and capsule-based theories, which focus on the decreasing capsule elasticity and increasing stiffness/sclerosis of the aging lens; extralenticular theories, which consider a decrease in ciliary body contractility to be the main cause of presbyopia; and the geometric theory, in which presbyopia is thought to be due to a decrease in the distance between the equatorial edge of the lens and the ciliary body, which in turn causes a decrease in zonular tension. Some overlap exists between the first and third categories.

This review describes the prevalent theories of presbyopia and discusses currently available surgical options for correction.

PHYSIOLOGY OF ACCOMMODATION AND PRESBYOPIA

Accommodation is the ability of the eye to change its optical power to focus from distant to near objects. The amplitude of accommodation is greatest in early childhood, with 15 diopters (D) or more of accommodation attainable. This ability declines with age in a linear fashion universally and predictably. A change in the shape of the crystalline lens is responsible for the change in the optical power during accommodation. Ciliary muscle contraction alters zonular tension to effect this change. However, there is no consensus on the precise mechanism. Two prevailing theories exist: Helmholtz (described by Michaels[2] and Fincham[3]) and Schachar.[4] Others have expanded and elaborated these theories with debate over the exact mechanism[5,6]; many agree on some movement of the lens and ciliary body complex toward or away from the sclera during accommodation.

The lens grows continuously throughout life, and the equatorial diameter increases approximately 20 μm a year.[1] Schachar[4] believes the effective force that the ciliary muscle can apply to the lens equator decreases in a linear fashion with age and is the primary etiology of presbyopia. This is the genesis of his concept of scleral expansion surgery to treat presbyopia.

SURGICAL OPTIONS FOR PRESBYOPIA CORRECTION

Corneal Options

Monovision Monovision is a concept familiar to many in the eye-care field who treat patients complaining of presbyopia. With monovision, 1 eye (usually dominant) is corrected for distance vision and the other eye is corrected for near vision. Whether fitting a patient with contact lenses, determining the best target

Submitted: September 26, 2015.
Final revision submitted: January 23, 2016.
Accepted: January 26, 2016.

University of Colorado Health Eye Center, University of Colorado School of Medicine, Aurora, Colorado, USA.

Corresponding author: Richard S. Davidson, MD, University of Colorado Health Eye Center, 1675 North Aurora Court, Aurora, Colorado 80045, USA. E-mail: richard.davidson@ucdenver.edu.

Published by Elsevier Inc.
http://dx.doi.org/10.1016/j.jcrs.2016.05.003
0886-3350

for laser in situ keratomileusis (LASIK) surgery, or counseling patients about their options for cataract surgery, discussion and consideration of monovision is integral to the decision-making process.[7] The selection of monovision surgical correction through laser vision correction or monofocal intraocular lens (IOL) implantation during cataract surgery is critical to achieving patient satisfaction.

Evaluation for monovision correction must include a thorough patient history, comprising the patient's prior experience with contact lens use; specifically, any experience with monovision or multifocal contact lenses. Because some patients may not tolerate the anisometropia induced by monovision, a contact lens trial can be undertaken to simulate the proposed refractive target prior to surgery. Evaluation is optimally performed in a real-life situation instead of an artificial simulation such as the examination room. Both multifocal and monovision contact lens users tend to be more tolerant of blur and are more amenable to permanent surgical monovision correction. Additionally, it is helpful to use a questionnaire or alternative interview process designed to ascertain a patient's daily visual needs, both professional and extracurricular. A patient's leisure activities, such as golf, tennis, recreational or commercial piloting, or other activities involving extremely acute depth perception and stereopsis, may preclude the ability to tolerate monovision.[7]

Blended vision or mini-monovision is an excellent option for many presbyopic patients. This approach aims for −1.00 to −1.25 D in the nondominant eye and plano in the dominant eye. Patients generally adjust to this degree of anisometropia with little difficulty. In addition, blended vision maintains distance vision of approximately 20/40; thus, patients experience little effect on distance acuity and minimal induction of photic phenomena (eg, glare and halos at night). Patients can also retain some useful stereopsis.

Ideally, the surgical outcome in patients having monovision correction provides a high degree of spectacle independence with minimal neuroadaptation to induced anisometropia. In cases in which the patient is not satisfied with the visual outcome or is unable to adapt to the anisometropia, laser vision correction provides a minimally invasive option for conversion to bilateral distance correction or enhancement of the distance eye. Patients with monovision appear to be more sensitive to changes in their distance eye, making them more likely to request enhancement for small refractive errors.

As with any refractive procedure, patients must have reasonable expectations of their postoperative vision. These expectations should be clearly explained before the surgical procedure, and the patients should sign a special consent confirming their refractive target preoperatively so both patient and surgeon are in agreement with the surgical plan.

Conductive Keratoplasty Conductive keratoplasty (CK) (Viewpoint CK System, Refractec, Inc.) was U.S. Food and Drug Administration (FDA) approved in 2004 as a noninvasive treatment for mild to moderate hyperopia (+0.75 to +3.00 D).[8,9] It uses radio waves to adjust the contour of the cornea by shrinking the corneal collagen around a radioactive probe. Basically, the procedure is designed to steepen the central cornea, creating a hyperprolate contour and thus increasing refractive power.

Treatment with CK is based on the effect of heat on the biomechanical properties of the cornea. At 55°C to 65°C, collagen dehydrates and retracts but returns to its original configuration on cooling. At temperatures above 70°C to 100°C, collagen completely denatures, resulting in permanent changes. Circular applications of 8 spots are created by repeated insertion of the probe at optical zones of 6.0 mm, 7.0 mm, or 8.0 mm circumference, determined by a preset nomogram, for a total of 8, 16, 24, or 32 spots. Shrinking the peripheral collagen has a tightening effect on the midperipheral cornea.

The efficacy of CK was validated in a prospective consecutive case series by Stahl,[10] which showed safe, effective results at 1 year in a series of 10 emmetropic presbyopic patients who had CK in their nondominant eye. Patients had a mean preoperative near acuity of Jaeger (J) 10. Postoperatively, 90% of patients achieved a mean uncorrected near visual acuity (UNVA) of J1 and 100% achieved a UNVA of J3 or better. No eye lost corrected visual acuity at distance or near. Treated eyes lost a mean 2.2 lines ± 2.0 (SD) of uncorrected distance visual acuity (UDVA) but gained a mean 8.7 ± 2.0 lines of UNVA. Effects were sustained at the 1-year follow-up.[8–10] Although patients reported glare and halos during the early postoperative period, high levels of satisfaction and spectacle independence for near were reported 1 year postoperatively.[8–10] Despite these encouraging results, patients having CK tend to experience significant regression over time, with some patients reverting to their preoperative refractive state.[11] Currently, CK is not commonly performed because of the lack of long-term stability; however, some surgeons perform it in select patients to enhance near vision.

Corneal Inlays The concept of the corneal inlay has been around for more than 60 years. The original idea, synthetic keratophakia, was proposed by Barraquer in 1949 (described by Waring and Klyce[12]). Corneal inlays have evolved over the past 20 years, with more dramatic advancements occurring since

Table 1. Characteristics of 3 types of corneal inlays.

Type of Inlay	Example	Optics	Structure and Composition	Appproval Status
Corneal reshaping	Raindrop (Vue+/Presbylens) (Revision Optics, Inc)	Steepens central cornea; hyperprolate anterior cornea increases depth of focus	Transparent hydrogel, 2.0 mm diameter, 32 μm in center, no refractive power	Phase II trials
Refractive	Flexivue Microlens (Presbia, Inc) InVue (Biovision AG, Neoptics AG)	Clear refractive inlay with index of refraction different from that of the cornea, creating multifocal cornea	Transparent hydrophobic acrylic, 1.6 mm aperture, 3.2 μm wide 15 μm thick, refractive power of ring +1.5 to +3.5 D	Phase II trials
Small aperature	Kamra (ACI 7000, Acufocus, Inc)	Pinhole effect increases depth of field	Opaque, 1.6 mm aperture, 8400 holes (5-11 μm), 5 μm thin, 3.8 mm diameter	FDA approved

FDA = U.S. Food and Drug Administration

the introduction of femtosecond laser technology, which facilitates intracorneal placement.[13] Earlier inlay models were challenged with biocompatibility issues; however, recent models are thinner and more porous with high levels of oxygen permeability and minimal reactivity within the corneal stroma.[A] Early models were derived from the pinhole optical effect, which increased the depth of field.

Although not all corneal inlays have been approved by the FDA for use in the U.S., several models have been implanted with good results throughout the world. The 3 types of corneal inlays—corneal reshaping inlays, refractive inlays, and small-aperture inlays (Table 1, Figure 1)—are based on different optical principles and work through different mechanisms to increase the depth of focus, thus inducing a form of pseudoaccommodation. All appear to result in an improvement in UNVA.

The primary advantage of corneal inlays compared with other forms of surgical presbyopia correction is that they are additive; that is, no tissue is removed. This makes them easier to remove or reverse. Corneal inlays can be used in conjunction with laser refractive surgery or cataract surgery or can be removed later for other forms of presbyopia correction.

Kamra Inlay The Kamra inlay (Acufocus, Inc.) recently received FDA approval in the U.S. It is commercially available in 49 countries, and close to 20 000 inlays have been implanted worldwide.[14] There are more data supporting the efficacy and safety of this inlay than of any other inlay at this time. The small-aperture, microperforated opaque inlay is made of polyvinylidene fluoride. It comprises approximately 8400 pinholes that allow micronutrients to freely permeate the structure. Studies show that the inlay has been tolerated and is biocompatible at least 2 years postoperatively, with no signs of scarring or vascularization.[15] The opaque inlay may be visible in light-colored eyes, whereas the other inlay types are clear. Aside from the aesthetic issue, the opaque nature of the inlay may be a barrier to performing

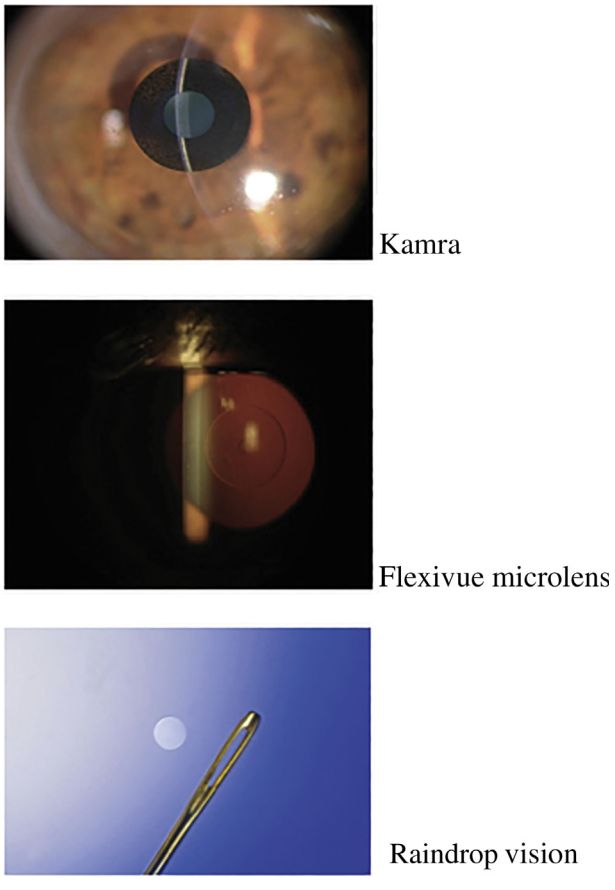

Figure 1. Three types of corneal inlays.

subsequent cataract or retina surgery. The inlay relies on the principle of pinhole optics to increase depth of focus by blocking unfocused light.

For best results, patients should start with emmetropia. If they are not emmetropic, LASIK can be performed to achieve emmetropia. One month after the LASIK procedure with a 100 µm flap, a corneal pocket is made in the nondominant eye at a depth of 200 µm using a femtosecond laser and the inlay is inserted into the pocket.

The patient should be told to expect a period of neuroadaptation, which may be longer in older patients. The inlay may also induce some glare and halos and should probably not be used in patients who are highly dependent on night driving.

The complications of this inlay are primarily related to the LASIK flap or pocket and include dry eye and epithelial ingrowth. Centration of the inlay may be challenging and for this primary reason, the learning curve is slower than that for other laser refractive procedures. The inlay seems to provide acceptable visual outcomes with a significant increase in near vision and minimal loss of distance vision.[16]

Raindrop Near Vision Inlay The Raindrop near vision inlay (Revision Optics, Inc.) is a small-diameter uniform clear hydrogel lens with a hyperprolate shape and no refractive power. It is intended to reshape the anterior curvature of the cornea (causing central steepening) to enhance near and intermediate vision. Although the inlay itself has no refractive power, it produces a variable power from the center to the periphery, similar to the effect of a multifocal IOL.

The inlay is freely permeable, enabling nutrients to pass through readily. It is currently placed under a femtosecond laser flap; however, it will soon be placed in a femtosecond laser–created pocket. Although the inlay is intended for unilateral use in the nondominant eye, it has been placed bilaterally with good results. Bilateral staged implantation 6 months apart seems to increase near vision an additional line with a minimal decrease in distance vision. The inlay has been implanted in phakic and pseudophakic patients with good results.[17]

Flexivue Microlens The Flexivue microlens (Presbia, Inc.) is a hydrophilic acrylic clear refractive inlay with an index of refraction that differs from that of the cornea. The small hole in the center of the inlay provides distance vision, and the peripheral ring creates a slight myopic shift inducing a multifocal effect, providing the patient with good distance and near vision. The inlay has excellent biocompatibility and nutrient permeability, and because it is a clear disk, it does not obstruct the light entering the eye.

The inlay is currently being implanted in emmetropic presbyopic patients only, and they are in Phase 3 of the FDA clinical trial.[B] Theoretically, the inlay will eventually be combined with LASIK surgery to correct the patient's refractive error as well as the presbyopia. It is being implanted in a femtosecond laser–created pocket, similar to the implantation of the Kamra inlay. The inlay has the Conformité Européenne (CE) mark in Europe and is also available in South America; however, only about 1000 inlays had been implanted as of March 1, 2014.[16]

Summary of Corneal Inlays In the U.S., corneal inlays are now available as an option for presbyopic patients. Although corneal inlay treatments for presbyopia may not be ideal, they have many desirable attributes, including reversibility, repeatability, and minimally invasive surgical implantation, while providing improvements in near vision without significant loss of distance vision. Disadvantages include a potential decrease in contrast sensitivity and a small decrease in distance visual acuity. Corneal inlays may induce corneal aberrations that create difficulties with subsequent IOL choice and power calculations. They may also affect visibility for further cataract or retinal surgery. Given the natural progression of presbyopia, most patients may eventually need reading glasses again if their accommodative needs surpass what the inlay can provide. Patient satisfaction will be increased by providing patients with realistic expectations before surgery (Figure 2).

Excimer Laser Multifocal Ablations (Presbyopic Laser In Situ Keratomileusis) The current flying-spot excimer lasers have enormous flexibility in the type of ablation patterns available for reshaping the cornea. Myopic astigmatic, hyperopic astigmatic, and mixed astigmatic patterns have been used for many years to create a stigmatic focal point to achieve crisp uncorrected visual acuity at a given distance. The stigmatic nature of that focal point can be traded for an elongated focal range at the expense of vision quality by exploiting spherical aberration (Figure 3).

The first multifocal corneal ablation was reported by Moreira et al.[18] using photorefractive keratectomy to treat myopia. Over the subsequent 20 years, although many ablation profiles were tried in various trials around the world, 2 main techniques emerged: peripheral and central presbyopic LASIK. These techniques are the most robust in providing functional uncorrected distance and near vision while minimizing the inevitable loss of contrast sensitivity and concomitant quality of vision inherent in creating a multifocal cornea. Implementing these techniques depends on

Advantages of Corneal Inlays	Disadvantages of Corneal Inlays
Reversible Repeatable Minimally invasive Easily modifiable Able to use in conjunction with laser vision correction Do not need a cataract	• Issues with oxygen permeability • Decrease in contrast sensitivity • Decrease in light entering eye • Decrease in quality of distance vision • Provides near vision in only one eye Must tolerate monovision first • Questionable complete reversibility Possible permanent corneal alterations • Questionable biocompatibility Mild interface reactions Neuroadaptation issues Procedural issues – centration may be tricky Glare/halos

Figure 2. Advantages and disadvantages of corneal inlays.

the unique capabilities of the excimer laser platform on which they were developed. At the time of this publication, neither technique has been approved by the FDA for clinical use in the United States.

Peripheral (Central-Far and Peripheral-Near) Peripheral presbyopic LASIK creates a central oblate zone for distance vision surrounded by a steeper, more prolate peripheral annulus for near vision. An early version, known as the PARM technique,[19] started with a hyperopic ablation to create the hyperprolate asphericity required for the peripheral near zone. This was followed by a central 4.0 mm myopic ablation for distance vision (Figure 4).

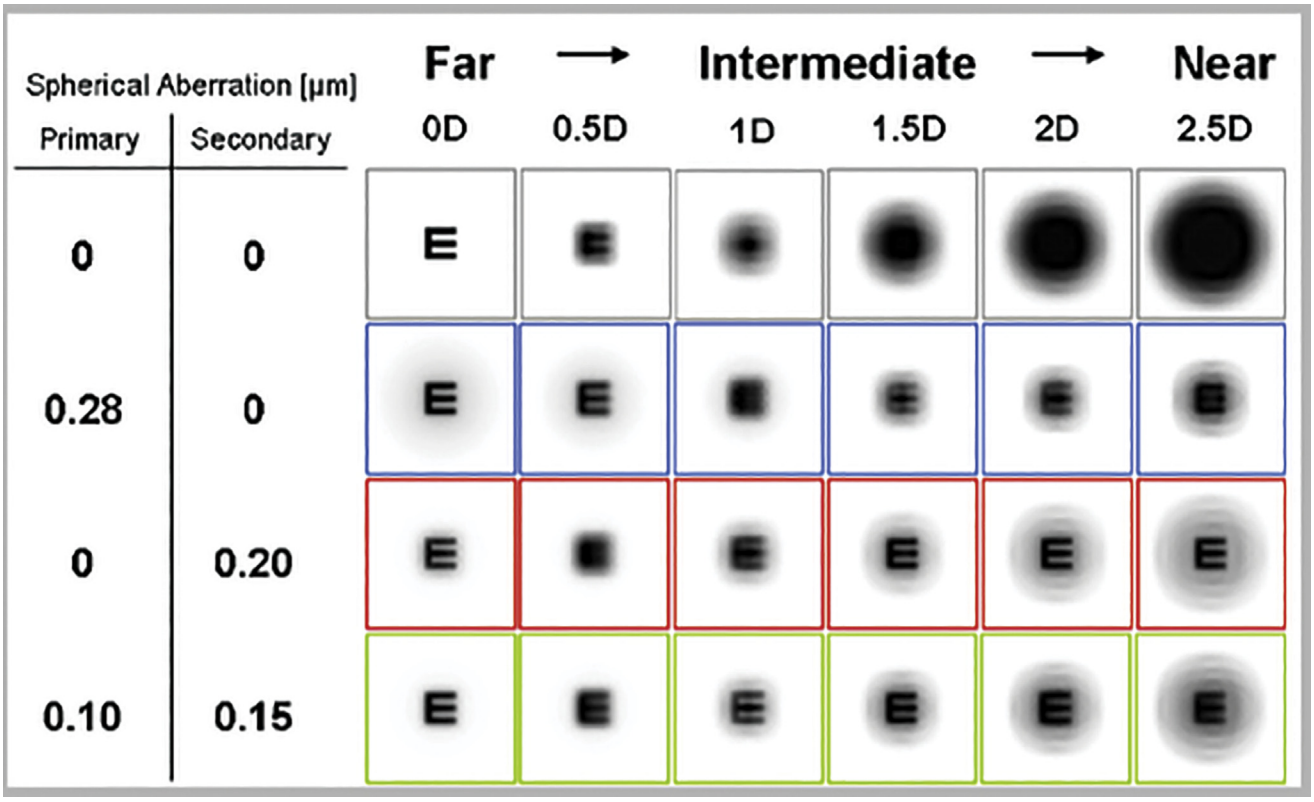

Figure 3. Spherical aberration tradeoff between depth of field and visual quality. In the emmetropic eye with no spherical aberration, the distant image is the most stigmatic and the most crisp (*upper left E*). The image quality degrades rapidly; however, when the object moves closer (*E's to the right in the first row*), when spherical aberration is present in various amounts, the quality remains useful over a wider range of distances (*E's on rows 2 through 4*). (Image from the University of Rochester Advanced Physiological Optics Laboratory. Available at: http://www.cvs.rochester.edu/yoonlab/research/pa.html. Accessed February 8, 2016).

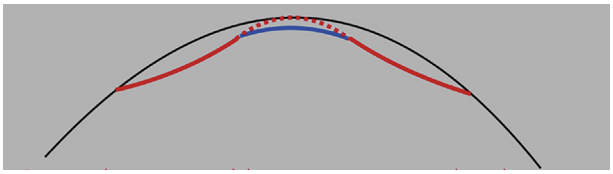

Figure 4. Peripheral (central-near, peripheral-far) presbyopic LASIK. Step 1 (*red*): Hyperopic ablation creates peripheral near zone. Step 2 (*blue*): Small optical zone central myopic ablation creates central distance zone.

Peripheral presbyopic LASIK uses a wavefront-guided algorithm to reduce unwanted aberrations, with an initial large optical zone to treat a myopic correction. Subsequent midperipheral aspheric ablations are added to create increasing myopia in the peripheral cornea. Finally, a demyopization treatment is added to the central 4.0 to 5.0 mm to ensure distance correction in the central cornea.

The major limitation of the peripheral presbyopic LASIK technique is the relatively large amount of tissue removal required to create the hyperprolate shape. Because of this, peripheral presbyopic LASIK is better suited to hyperopic than myopic presbyopic eyes. In addition, the technique requires an excimer laser that compensates for the cosine effect—the loss of fluence, which occurs with the more oblique incident beam inherent to treating the peripheral cornea.

Epstein et al.[20] reported a series of 103 patients treated with standard LASIK in the dominant eye for distance and peripheral presbyopic LASIK in the nondominant eye, creating a sort of "super monovision."[21] With all eyes followed for at least 1 year, 92% of myopic patients and 89% of hyperopic patients reported spectacle independence. Binocular UDVA was at least 20/20 in 67.9% of hyperopic patients and 70.7% of myopic patients. Binocular UNVA at 40 cm was at least 20/20 in 71.4% and 65.3%, respectively. Higher-order aberrations increased by more than 50% in both hyperopic and myopic groups, with 14.3% of hyperopic eyes losing 1 line of CDVA.

Central (Central-Near and Peripheral-Far) Central presbyopic LASIK creates a small optical zone of central steepening for near vision surrounded by a relatively flatter peripheral zone for distance vision. One advantage of this technique is that the central area of steepening can be applied following a hyperopic or myopic initial treatment for distance correction without a significant increase in overall tissue removal (Figure 5).

The main limitation of central presbyopic LASIK is difficulty determining the optimum axis for centration: visual axis, pupil center, or corneal vertex. As a result, this technique is prone to inducing coma-like aberrations, which degrade quality of vision.

Alió et al.[22] reported 6-month results in 25 patients with hyperopic astigmatism and presbyopia treated bilaterally with central presbyopic LASIK. Sixty-four percent of patients had a UDVA of 20/20 or better. Seventy-two percent had a UNVA of 20/40 or better. Twenty-eight percent lost a maximum of 2 lines of CDVA. There were significant mean decreases in contrast sensitivity in spatial frequencies of 3, 6, 12, and 18 cycles per degree.

Patient Selection Presbyopic LASIK is most appropriate for patients early in the presbyopic process. With the significant improvement of multifocal IOL technology in recent years and the relatively low risk of clear lens exchange in the hyperopic population, the transient nature of presbyopic LASIK makes it a less attractive option for the hyperopic presbyopic patient. For myopic presbyopic patients in whom clear lens exchange carries some risk for retinal complications, presbyopic LASIK may be a safer alternative. Other good candidates for presbyopic LASIK are patients with previous monofocal IOL implantation who desire spectacle independence.

In summary, excimer laser multifocal ablations have limited application in the treatment of presbyopia, primarily because of their inherent transient nature and relatively high incidence of quality of vision loss. The lack of standardization of the technique across multiple excimer laser platforms and the relatively low number of high-quality clinical trials make it unlikely that the techniques will gain wide acceptance, particularly in the U.S. because of the lack of FDA-approved

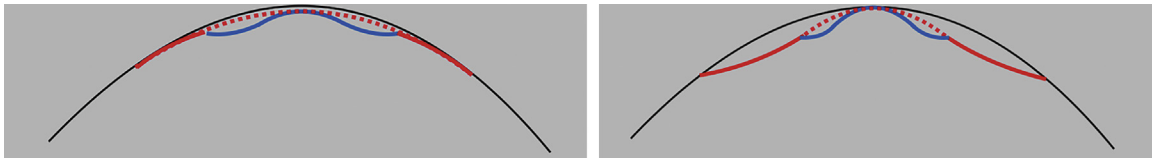

Figure 5. *Left*: Central (central-far, peripheral near) presbyopic LASIK for myopia. Step 1 (*red*): Myopic ablation creates peripheral distance zone. Step 2 (*blue*): Additional small optical zone central hyperopic ablation creates central near zone. *Right*: Central (central-far, peripheral near) presbyopic LASIK for hyperopia. Step 1 (*red*): Hyperopic ablation creates peripheral distance zone. Step 2 (*blue*): Additional small optical zone central hyperopic ablation creates central near zone.

protocols. Although some experts describe the procedure as reversible, the absence of FDA-approved topography-guided excimer laser protocols make this claim clinically impractical in the U.S.

INTRAOCULAR LENS–BASED OPTIONS

Cataract surgery or clear lens extraction provides another opportunity for the surgical correction of presbyopia. As previously discussed, monovision and blended vision (mini-monovision) are options for patients to achieve increased spectacle independence with cataract surgery. Multifocal or accommodating IOLs are options with the potential to dramatically improve a patient's spectacle independence, but patient selection is critical.

Multifocal Intraocular Lenses

Multifocal IOLs are designed with concentric zones or rings in the lens that focus light from 2 distances, enabling patients to see both distant and near targets. However, they are not suitable for every patient and potential candidates have to be carefully selected through extensive preoperative screening.[23]

All multifocal IOL patients should have preoperative topography to look for evidence of irregular astigmatism. Multifocal IOLs are not well-suited to patients with high degrees of regular astigmatism, irregular astigmatism, or other forms of corneal dystrophies or degenerations that can compromise quality of vision.

Similarly, optimum macular and optic nerve function is essential for a patient to adapt to the optics of multifocal IOLs, which result in a reduction in the modulation transfer function, clinically manifesting as a decrease in contrast sensitivity. Multifocal IOLs should not be implanted in high-risk surgical cases with the potential for complications.[23]

When an appropriate candidate is identified, preoperative counseling should be used to set appropriate realistic expectations, advising the patient of potential visual side effects (such as glare and halos) and potential limitations at certain distances or in certain lighting situations. Significant time should be taken preoperatively to avoid postoperative disappointments. Understanding a patient's lifestyle demands and their visual expectations will help ensure that the selected IOL will achieve the patient's goals for surgery.

Multifocal IOLs are exquisitely sensitive to residual refractive error. Therefore, accurate preoperative biometry is essential.[23,24] Corneal power can be assessed in several ways including with devices that measure the anterior corneal surface, posterior corneal surface, or both using various topographic and tomographic technologies.[25,26] We have recently learned that posterior corneal astigmatism can significantly affect the refractive outcome.[13] Therefore, a device that uses Scheimpflug tomography to measure the anterior and posterior corneal surfaces may be more accurate than manual keratometry and Placido topography, which assess only the anterior surface. The most precise method to measure posterior corneal astigmatism directly and incorporate it into the assessment of total corneal power is being investigated and factored into product development.[25] It is also important to center and align the IOL on the visual axis; however, in most instances, the IOL will center itself in the capsular bag regardless of where the surgeon places it.

Multifocal IOLs require proper centration and function best in patients with minimal astigmatism and a nearly emmetropic refractive result. Thus, astigmatism management with multifocal toric IOLs, limbal relaxing incisions, arcuate incisions, or postoperative bioptics is crucial. The use of femtosecond lasers in cataract surgery has the potential to improve IOL centration through creation of a well-centered, perfectly circular capsulorhexis for IOL centration in the capsular bag, although it is currently unclear whether this truly results in better visual outcomes. The recent FDA approval of a toric multifocal IOL (Restor toric, Alcon Surgical, Inc.) will also enable us to offer spectacle independence to more patients. In cases with residual postoperative refractive error, laser vision correction provides a mechanism for enhancing results and improving patient satisfaction.[27,28]

Although our options for multifocal IOLs are limited (Restor and Restor toric and Tecnis multifocal, Abbott Medical Optics, Inc.) in the U.S., several IOL platforms, such as trifocal designs, extended depth of focus IOLs, and toric multifocal IOLs, used in other parts of the world are promising technologies for future application. In addition, IOLs that allow the correction of refractive errors postoperatively may be excellent options for patients. Despite technologic advancements, patient selection and patient education are ultimately the keys to success with this technology.

Accommodating Intraocular Lenses

Accommodating IOLs are designed to replicate physiologic accommodation by changing the refractive power of the eye through contraction of the ciliary muscle, changing vitreous pressure, or reducing the diameter of the capsular bag.[29] Unlike multifocal IOLs, which require the brain to distinguish between a distant image and a near image at the same time, accommodating IOLs have a single point of focus. The accommodating IOL is designed to provide

excellent distance and intermediate vision and functional near vision.

Currently, the only 2 FDA-approved accommodating IOLs in the U.S. are the Crystalens Advanced Optics monofocal IOL and the astigmatism-correcting version, the Trulign toric IOL (both Bausch & Lomb). The Crystalens has a 5.0 mm silicone optic and is designed to provide approximately 1.0 D of monocular accommodation, which is intended to provide near, intermediate, and distance vision with decreased dependency on spectacles.[C]

The Trulign toric version was FDA approved for 3 cylinder powers: 1.25 D, 2.00 D, and 2.75 D measured at the IOL plane. In the FDA trial of 210 patients, 97.8% of patients had distance and intermediate visual acuity of 20/40 or better postoperatively and 70% had a UNVA of 20/40.[C]

An advantage of accommodating IOLs compared with multifocal IOLs is that more patients are candidates for these IOLs because patients with other ocular pathology are generally excluded as candidates for multifocal IOLs. In addition, patients with accommodating IOLs tend to experience less glare and halos and less decrease in contrast sensitivity postoperatively.[29]

A disadvantage of accommodating IOLs is that the ability to truly accommodate and see near targets appears to be somewhat variable. To ensure that patients will obtain functional near vision with an accommodating IOL, many surgeons undercorrect (by approximately 0.75 D) the nondominant eye of the patient. Dhital et al.[30] have shown better near and intermediate visual acuities with accommodating IOLs than with monofocal IOLs. They believe this is due to depth of focus and not IOL movement. Zamora-Alejo et al.[31] also showed that the Crystalens HD had some benefit for intermediate visual function compared with a monofocal IOL; however, there were no signs of accommodation in either group.

SCLERAL-BASED PRESBYOPIA OPTIONS

Scleral-based presbyopia surgery developed from the theory that the lens is under increased equatorial zonular tension during accommodation and any procedure that increases the distance between the lens equator and the ciliary muscle should improve accommodation. The Helmholtz lenticular theory of accommodation has endured through various modifications as technological advances have enabled us to understand the anatomy of the extralenticular elements involved in accommodation.[1,2] Understanding the relationship between the ciliary body, vitreous, zonular fibers, and anterior hyaloid face is essential to comprehend the current scleral-based presbyopia surgical options.[32] Detorakis and Pallikaris[33] showed ocular rigidity to be correlated with loss of accommodation. The Croft et al. study[34] showed that the ciliary muscle does not lose the ability to contract with age but does lose the ability to move forward and centripetally with age, perhaps because of an increasingly inelastic posterior attachment. The loss of muscle movement with age is sufficient to explain losses in centripetal lens movement and in accommodative amplitude and may be involved in the pathophysiology of presbyopia.[34,35] Goldberg[36] has further supported this model of accommodation with the generation of a computer model to support the complex anatomy involving the ciliary body, zonular apparatus, anterior and posterior capsule, and lens.

Past scleral techniques include silicone implants in radial incisions,[37] anterior ciliary sclerotomy with and without collagen,[38,39] and erbium:YAG laser radial sclerectomy.[40] None are currently being used because of variable outcomes and risks such as anterior segment ischemia and scleral macroperforations.

Currently, 2 procedures that treat presbyopia by altering the scleral and ciliary body anatomy based on the aforementioned concepts have received the CE mark and are being studied in clinical trials. The trials are enrolling phakic patients between 45 years and 60 years with good distance visual acuity (20/25 or better) and normal ocular anatomy and without chronic systemic diseases, previous ocular surgery, or inflammatory ocular conditions.

The first of the 2 technologies is the Presview scleral implant (Refocus Group); FDA data are being collected.[D] Refocus developed this scleral implant and the associated procedure to treat presbyopia. During the procedure, 4 small, clear plastic scleral implants are placed in a circular pattern just below the surface of the sclera. The implants function by lifting or vaulting the sclera. The scleral vaulting also lifts the underlying ciliary muscles surrounding the crystalline lens. Lifting the ciliary muscles increases the circumlental space, thus tightening the zonular fibers that hold the IOL in place. With proper tension on the zonular fibers, the ciliary muscles can manipulate and change the shape of the IOL to focus on near objects.

The procedure has been performed in 330 primary eyes and 315 fellow eyes (total 645; mean preoperative UNVA 20/73). The mean age of the cohort was 54.3 years. The mean manifest refraction spherical equivalent of the cohort was +0.28 D. To date, 324 patients have been followed for 3 months, 179 for 12 months, and 80 for 24 months. At 3 months, the percentage of patients reporting excellent or acceptable bilateral intermediate vision while viewing

the computer improved from 24% preoperatively to 87%. The percentage of patients reporting excellent or acceptable vision while reading newspapers improved from 4% preoperatively to 76%; at 24 months, 73% of patients still reported excellent or acceptable vision. Other fine near tasks such as reading prices and medicine labels also improved by 59% and 57%, respectively, at 3 months. At 24 months, 83% of the patients were able to perform most near activities without reading spectacles and 89% rated their near vision as better to significantly better than preoperatively. Distance vision is not affected by this procedure; 99% of the patients reported excellent or acceptable vision for distance tasks (the same as preoperatively).[E] Data collection on this group is continuing at the 24-month mark and will continue out to 36 months.

The second of the technologies is the Laser ACE system (Ace Vision Group). This procedure differs from the Presview procedure in that it uses the Visiolite erbium:YAG laser (Ace Vision Group) to ablate 600 μm laser spots in the sclera, which are presumed to facilitate contraction of the ciliary muscle by decreasing scleral resistive forces based on the previously discussed studies. Nine laser spots are delivered in a diamond matrix pattern to each oblique quadrant. Proprietary materials are used to promote healing to maintain the desired effect. Current clinical trials are being performed outside the U.S. Outcomes in 15 patients in a prospective single-center 12-month trial were presented at the European Society for Cataract and Refractive Surgeons.[F] All 15 patients achieved some improvement in near and intermediate visual acuity, with a mean of 4 lines of improvement in reading vision. The mean increase in accommodative amplitude was 1.5 D, and patient satisfaction was at the 90% level, with stereoscopic acuity remaining intact.

Both of the 2 procedures have shown improvement in UNVA and high patient satisfaction. The Presview procedure is closer to the approval process, with active patients being recruited in FDA trials. Both procedures have obtained the CE mark, and patients with follow-ups of more than 3 years are being recorded.

CONCLUSION

The surgical correction or elimination of presbyopia remains a major goal in ophthalmology. Currently, there is no perfect option but several options can provide spectacle independence for some patients; however, all the options reflect a compromise compared with pre-presbyopic emmetropia. Presbyopia is a universal problem that many have attempted to solve through a variety of physiologic approximations to recreate the natural physiology of a young eye with true accommodative amplitude. Achieving complete spectacle independence with restoration of accommodation is an enormous task; however, many of the evolving modalities are moving us toward achieving this goal.

REFERENCES

1. Werner L, Trindade F, Pereira F, Werner L. Physiology of accommodation and presbyopia. Arq Bras Oftalmol 2000; 63:503–509. Available at: http://www.scielo.br/pdf/abo/v63n6/en_9615.pdf. Accessed February 8, 2016
2. Michaels DD. Visual Optics and Refraction: A Clinical Approach, 3rd ed. St. Louis, MO, CV Mosby, 1985; Chap. XVIII
3. Fincham EF. The mechanism of accommodation. Br J Ophthalmol Monogr Suppl 1937; 8
4. Schachar RA. Cause and treatment of presbyopia with a method for increasing the amplitude of accommodation. Ann Ophthalmol 1992; 24:445–447; 452
5. Wilson RS. Does the lens diameter increase or decrease during accommodation? Human accommodation studies: a new technique using infrared retro-illumination video photography and pixel unit measurements. Trans Am Ophthalmol Soc 1997; 95:261–267; discussion, 267–270 Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1298362/pdf/taos00004-0284.pdf. Accessed February 8, 2016
6. Glasser A, Kaufman PL. The mechanism of accommodation in primates. Ophthalmology 1999; 106:863–872
7. Farid M, Steinert RF. Patient selection for monovision laser refractive surgery. Curr Opin Ophthalmol 2009; 20:251–254
8. U.S. Food and Drug Administration. Premarket approval. Summary of Safety and Effectiveness Data. ViewPoint™ CK System. PMA P010018. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/P010018b.pdf. Accessed February 8, 2016
9. McDonald MB, Durrie D, Asbell P, Maloney R, Nichamin L. Treatment of presbyopia with conductive keratoplasty®; six-month results of the 1-year United States FDA clinical trial. Cornea 2004; 23:661–668. Available at: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.506.2327&rep=rep1&type=pdf. Accessed February 8, 2016
10. Stahl JE. Conductive keratoplasty for presbyopia: 1-year results. J Refract Surg 2006; 22:137–144
11. Moshirfar M, Anderson E, Hsu M, Armenia JM, Miflin MD. Comparing the rate of regression after conductive keratoplasty with or without prior laser-assisted in situ keratomileusis or photorefractive keratectomy. Middle East Afr J Ophthalmol 2012; 19:377–381. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3519124/?report=printable. Accessed February 8, 2016
12. Waring GO IV, Klyce SD. Corneal inlays for the treatment of presbyopia. Int Ophthalmol Clin 2011; 51:51–62
13. Lindstrom RL, MacRae SM, Pepose JS, Hoopes PC Sr. Corneal inlays for presbyopia correction. Curr Opin Ophthalmol 2013; 24:281–287
14. Yılmaz ÖF, Alagöz N, Pekel G, Azman E, Aksoy EF, Çakır H, Bozkurt E, Demirok A. Intracorneal inlay to correct presbyopia: long-term results. J Cataract Refract Surg 2011; 37:1275–1281
15. Seyeddain O, Riha W, Hohensinn M, Nix G, Dexl AK, Grabner G. Refractive surgical correction of presbyopia with the AcuFocus small aperture corneal inlay: two-year follow-up. J Refract Surg 2010; 26:705–715

16. Dexl AK, Jell G, Strohmaier C, Seyeddain O, Riha W, Rückl T, Bachernegg A, Grabner G. Long-term outcomes after monocular corneal inlay implantation for the surgical compensation of presbyopia. J Cataract Refract Surg 2015; 41:566–575
17. Barragan Garza E, Chayet A. Safety and efficacy of a hydrogel inlay with laser in situ keratomileusis to improve vision in myopic presbyopic patients: one-year results. J Cataract Refract Surg 2015; 41:306–312
18. Moreira H, Garbus JJ, Fasano A, Lee M, Clapham TN, McDonnell PJ. Multifocal corneal topographic changes with excimer laser photorefractive keratectomy. Arch Ophthalmol 1992; 110:994–999
19. Avalos Urzua G. Presbyopia treatment with LASIK PARM (Presbyopia Avalos Rozakis method). In: Garg A, Hoyos JE, Avalos Urzua G, Pinelli R, Mehta KR, Piovella M, eds, Mastering the Techniques of Presbyopia Surgery. New Delhi, India, Jaypee Brothers, 2006; 167–174
20. Epstein RL, Gurgos MA. Presbyopia treatment by monocular peripheral presbyLASIK. J Refract Surg 2009; 25:516–523. Available at: http://glacialblog.com/userfiles/15/file/0-54464400-1302229773.pdf. Accessed February 8, 2016
21. Waring GO, Dougherty PJ, Chayet A, Fischer J, Fant B, Stevens G, Bains HS. Topographically guided LASIK for myopia using the Nidek CXII customized aspheric treatment zone (CATz). Trans Am Ophthalmol Soc 2007; 105:240–246; discussion 247–248 Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2258119/pdf/1545-6110_v105_p240.pdf. Accessed February 8, 2016
22. Alió JL, Amparo F, Ortiz D, Moreno L. Corneal multifocality with excimer laser for presbyopia correction. Curr Opin Ophthalmol 2009; 20:264–271
23. Braga-Mele R, Chang D, Dewey S, Foster G, Henderson BA, Hill W, Hoffman R, Little B, Mamalis N, Oetting T, Serafano D, Talley-Rostov A, Vasavada A, Yoo S; for the ASCRS Cataract Clinical Committee. Multifocal intraocular lenses: relative indications and contraindications for implantation. J Cataract Refract Surg 2014; 40:313–322
24. Rajan MS, Keilhorn I, Bell JA. Partial coherence laser interferometry vs conventional ultrasound biometry in intraocular lens power calculations. Eye 2002; 16:552–556. Available at: http://www.nature.com/eye/journal/v16/n5/pdf/6700157a.pdf. Accessed February 8, 2016
25. Findl O, Kriechbaum K, Sacu S, Kiss B, Polak K, Nepp J, Schild G, Rainer G, Maca S, Petternel V, Lackner B, Drexler W. Influence of operator experience on the performance of ultrasound biometry compared to optical biometry before cataract surgery. J Cataract Refract Surg 2003; 29:1950–1955
26. Koch DD, Ali SF, Weikert MP, Shirayama M, Jenkins R, Wang L. Contribution of posterior corneal astigmatism to total corneal astigmatism. J Cataract Refract Surg 2012; 38:2080–2087
27. de Vries NE, Webers CAB, Touwslager WRH, Bauer NJC, de Brabander J, Berendschot TT, Nuijts RMMA. Dissatisfaction after implantation of multifocal intraocular lenses. J Cataract Refract Surg 2011; 37:859–865
28. de Vries NE, Nujits RMMA. Multifocal intraocular lenses in cataract surgery: literature review of benefits and side effects. J Cataract Refract Surg 2013; 39:268–278
29. Ang RE, Martinez GA, Cruz EM, Tiongson AA, Dela Cruz AG. Prospective evaluation of visual outcomes with three presbyopia-correcting intraocular lenses following cataract surgery. Clin Ophthalmol 2013; 7:1811–1823. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3788698/pdf/opth-7-1811.pdf. Accessed February 8, 2016
30. Dhital A, Spalton DJ, Gala KB. Comparison of near vision, intraocular lens movement, and depth of focus with accommodating and monofocal intraocular lenses. J Cataract Refract Surg 2013; 39:1872–1878
31. Zamora-Alejo KV, Moore SP, Parker DGA, Ullrich K, Esterman A, Goggin M. Objective accommodation measurement of the Crystalens HD compared to monofocal intraocular lenses. J Refract Surg 2013; 29:133–139
32. Lütjen-Drecoll E, Kaufman PL, Wasielewski R, Ting-Li L, Croft MA. Morphology and accommodative function of the vitreous zonule in human and monkey eyes. Invest Ophthalmol Vis Sci 2010; 51:1554–1564. Available at: http://iovs.arvojournals.org/article.aspx?articleid=2165290. Accessed February 8, 2016
33. Detorakis ET, Pallikaris IG. Ocular rigidity: biomechanical role, in vivo measurements and clinical significance. Clin Experiment Ophthalmol 2013; 41:73–81
34. Croft MA, McDonald JP, Nadkami NV, Lin T-L, Kaufman PL. Age-related changes in centripetal ciliary body movement relative to centripetal lens movement in monkeys. Exp Eye Res 2009; 89:824–832
35. Croft MA, Nork TM, McDonald JP, Katz A, Lütjen-Drecoll E, Kaufman PL. Accommodative movements of the vitreous membrane, choroid, and sclera in young and presbyopic human and nonhuman primate eyes. Invest Ophthalmol Vis Sci 2013; 54:5049–5058. Available at: http://iovs.arvojournals.org/article.aspx?articleid=2129052. Accessed February 8, 2016
36. Goldberg DB. Computer-animated model of accommodation and presbyopia. J Cataract Refract Surg 2015; 41:437–445
37. Fukasaku H, Marron JA. Anterior ciliary sclerotomy with silicone expansion plug implantation: effect on presbyopia and intraocular pressure. Int Ophthalmol Clin 2001; 41:133–141
38. Hamilton DR, Davidorf JM, Maloney RK. Anterior ciliary sclerotomy for treatment of presbyopia; a prospective controlled study. Ophthalmology 2002; 109:1970–1976; discussion by RF Steinert, 1976–1977
39. Malyugin B, Antonian S, Lohman BD. Anterior ciliary sclerotomy using collagen T-shaped implants for treatment of presbyopia. Ann Ophthalmol 2008; 40:130–136
40. Lin JT, Mallo O. Treatment of presbyopia by infrared laser radial sclerectomy [letter]. J Refract Surg 2003; 19:465–467. Available at: http://www.healio.com/ophthalmology/journals/jrs/2003-7-19-4/%7B5df5ea21-a836-47b4-8009-de028efbbd8e%7D/treatment-of-presbyopia-by-infrared-laser-radial-sclerectomy. Accessed February 8, 2016

OTHER CITED MATERIALS

A. Kent C. Inlays and presbyopia: the next frontier. Rev Ophthalmol 2014; 21(2):24–28. Available at: http://www.reviewofophthalmology.com/content/i/2746/c/46512/. Accessed February 8, 2016
B. U.S. National Institutes of Health Clinical Trials. Investigation of the Presbia Flexivue Microlens™. NCT02110472. Available at: https://clinicaltrials.gov/ct2/show/NCT02110472?term=Flexivue&rank=1. Accessed February 8, 2016
C. U.S. Food and Drug Administration. Data on file for Bausch & Lomb Crystalens HD and Trulign Toric Intraocular Lenses
D. U.S. National Institutes of Health Clinical Trials. Trial of the PresView Implant for the Improvement of Near Vision in Presbyopic Patients. NCT01933750. Available at: https://clinicaltrials.gov/ct2/show/NCT01933750?term=Presview&rank=2. Accessed February 8, 2016
E. Stonecipher KG, "Results From a Multi-Center US Clinical Trial for the Surgical Treatment of Presbyopia," poster presented at the XXXI Congress of the European Society of Cataract and Refractive Surgeons, Amsterdam, the Netherlands,

October 2013. Abstract available at: http://escrs.org/amsterdam2013/programme/posters-details.asp?id=19810. Accessed February 8, 2016

F. Hipsley A, Rowen S, "LaserACE Procedure to Restore Dynamic Accommodation: Clinical Trial Results up to 1-Year Follow-up," poster presented at the XXXI Congress of the European Society of Cataract and Refractive Surgeons, Amsterdam, the Netherlands, October 2013. Abstract available at: http://escrs.org/amsterdam2013/programme/posters-details.asp?id=19793. Accessed February 8, 2016

FINANCIAL DISCLOSURES

Dr. Davidson is on the Advisory Board for Alcon Laboratories, Inc. (LenSx). Dr. Hamilton is on the Speakers Bureau for Alcon Laboratories, Inc., Abbott Medical Optics, Inc., Reichert Technologies, and Ziemer USA, Inc. Dr. Jackson is a consultant to Bausch & Lomb, Lensar, Inc., and Acevision Group. Dr. Stonecipher is a consultant to Alcon Laboratories, Inc. and Bausch & Lomb and is on the Medical Advisory Board for Alcon Laboratories, Inc. (LenSx). Dr. Yoo is a consultant to Alcon Laboratories, Inc. and Optimedica Corp. Dr. Braga-Mele is a consultant to Alcon Laboratories, Inc., and Allergan Corp. No other author has a financial or proprietary interest in any material or method mentioned.

First author:
Richard Davidson, MD

University of Colorado Health Eye Center, University of Colorado School of Medicine, Aurora, Colorado, USA