Supplement to

Cataract & Refractive Surgery TODAY

March 2005

# The State of Cataract and Refractive Surgery

**Our fourth annual review of the latest developments in cataract and refractive surgery.**

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# The Future Looks Bright

*Cataract & Refractive Surgery Today* is pleased to present its fourth annual edition of "The State of Cataract and Refractive Surgery." Each spring, we reflect on the highlights of the previous year and look ahead to anticipated developments in order to summarize the current status of these two ophthalmic specialties.

As the articles herein illustrate, 2004 was an interesting year. IOL technologies continued to attract attention as more research was conducted on accommodative, phakic, aspheric, microincisional, and blue-light–blocking IOLs as well as on conceptual phakic and pseudophakic designs. In tandem with expanded IOL options, calculating corneal power after refractive surgery remains a hot topic. Wavefront technology made more headlines as a potential therapeutic treatment for a variety of indications. Also, cataract surgeons were pleased to see capsular tension rings gain FDA approval. Now, we have this unique technology to stabilize the capsular bag apparatus and allow for in-the-bag IOL implantation.

The past year was also marked by happenings outside of the clinical arena. Most notably, ophthalmology lost one of its greatest innovators, Charles Kelman, MD. He will forever remain a role model for his drive, innovative spirit, and variety of life-long pursuits at the highest levels. Another story that continues to dominate the news publications is scope-of-practice delineations between ophthalmology and optometry. The AAO, ASCRS, ASOA, and other organizations continue to champion the concept of structured education and tutored in-house training as the most appropriate ways to prepare a surgeon for patient care.

We have much to look forward to in 2005, with both specialties expecting exciting advancements. Read on to be inspired!

**—John F. Doane, MD, FACS**

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# The Year in Review

*A snapshot of 2004's biggest news stories.*

### CHARLES KELMAN, MD, DIED

Cataract surgery pioneer, Charles Kelman, MD, died June 1 of lung cancer. He was best known for inventing phacoemulsification and making cataract surgery an outpatient procedure, but was also responsible for many other notable contributions.
Dr. Kelman was honored by President George H.W. Bush in 1992 with the National Medal of Technology, and he was inducted to the National Inventors Hall of Fame in Akron, Ohio, last May. Posthumously, Dr. Kelman was awarded the 2004 Albert Lasker Medical Research Award for Clinical Medical Research.

### SCOPE OF PRACTICE FOR OPTOMETRISTS

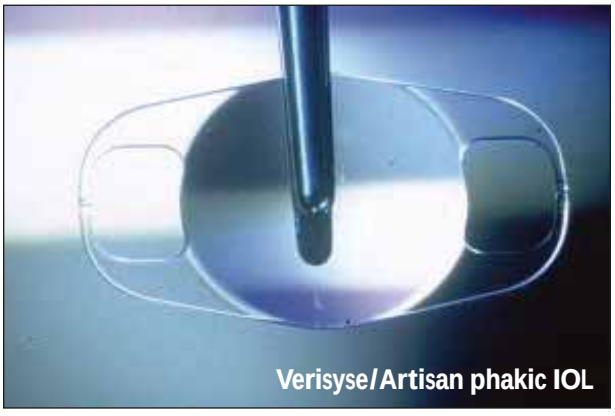
Last year was a contentious one between optometrists and ophthalmologists. During 2004 alone, 12 states plus Alaska, Hawaii, and Puerto Rico ruled on legislation that was intended to broaden optometrists' medical privileges. Some of the most publicized proceedings in this debate occurred in Oklahoma, where Governor Brad Henry signed legislation in October that granted optometrists permission to practice scalpel eye surgery. In response, the AAO vowed to contest the ruling.

Much of the medical privileges controversy last year also centered around the Department of Veterans Affairs (VA), because of the system's history of providing surgical education and training for optometrists. In August 2004, the VA issued a revised directive that allowed optometrists to perform laser surgery only if the optometrist's state licensure allowed it and only under the supervision of an ophthalmologist. Then, on December 17th, the VA rescinded that directive and replaced it with VHA Directive 2004-070, which ensures that only ophthalmologists will be permitted to perform therapeutic laser eye surgery.

Various ophthalmic interest groups, including the AAO, are involved in ongoing efforts to combat any and all optometric scope-of-practice expansion. Activists have called upon ophthalmologists nationwide to increase their involvement in the issue politically and financially to a level equal to or greater than that of optometrists'.

### VERISYSE/ARTISAN PHAKIC IOL RECEIVED FDA APPROVAL

Advanced Medical Optics, Inc. (AMO; Santa Ana, CA) and Ophtec USA, Inc. (Boca Raton, FL), a subsidiary of Ophtec BV (The Netherlands), received FDA approval in September for the Verisyse/Artisan phakic IOL for use in patients with myopia. The approval marked the official introduction of the first phakic IOL to the US market.



Verisyse/Artisan phakic IOL

The lens is indicated for the reduction or elimination of myopia in patients aged 21 and older who fall within the myopic range of -5.00- to -20.00D. The lens is manufactured and distributed by Ophtec BV under the trade name Artisan in all markets with the exception of North America and Japan. Global distribution rights to the phakic IOL were acquired by AMO in 2002, and the company markets it under the Verisyse brand. The lens is now exclusively available through AMO in North America and Japan.

### INTRALASE WENT PUBLIC

Intralase Corp. (Irvine, CA) announced its first public offering of 6,636,314 common stock shares, priced at $13 per share, On October 7, 2004. A portion of the offering, totaling 336,314 shares, was sold on behalf of particular selling stockholders of Intralase, although the company received no profit from the sale of the stocks. The Nasdaq National Market listed the shares under "ILSE." The stock's value as of February 22 was $19.06.

### A BIG YEAR FOR AMO

In April 2004, Advanced Medical Optics, Inc. (AMO; Santa Ana, CA) announced that it had acquired the ophthalmic surgical business of Pfizer Inc. (New York, NY). The purchase included the Healon line of viscoelastic products, the Ceeon and Tecnis IOLs, and the Baerveldt glaucoma shunt, as well as various related manufacturing and research facilities.

Then, on November 9, 2004, AMO and Visx, Incorporated (Santa Clara, CA), jointly announced AMO's acquisition of Visx. The goal of the acquisition was to create the world's leading refractive surgical business. The transaction is expected to finalize within the first quarter of 2005. The newly combined company will carry the Advanced Medical Optics name and be headquartered in Santa Ana, California.

Under the terms of the definitive $1.27 billion accord, Visx stockholders will receive 0.552 shares of AMO stock and $3.50 in cash for every share of Visx common stock they own, or a total value of $26.52 per share of Visx common stock, based upon the closing price of AMO's common stock on November 8th. The total consideration is approximately 29 million shares of AMO stock and $184 million in cash.

### STEVEN POST LASIK TRIAL OVERTURNS AND THEN RECOVERS

On April 19, 2001, United Airlines pilot Steven Post filed a lawsuit against University Physicians Inc. (UPI) for a LASIK procedure that left Post unable to continue flying. A 10-day trial resulted in a record $4 million jury verdict in Post's favor, but in November 2002, the Honorable Kenneth Lee, of the Arizona Superior Court of Pima County, granted Defendant UPI a new trial and set aside the jury's verdict. Judge Lee's decision was based on newly discovered evidence presented by the Plaintiff's expert witness, Jeffrey Machat, MD, at a post-trial evidentiary hearing during which Dr. Machat changed his standard-of-care opinion.

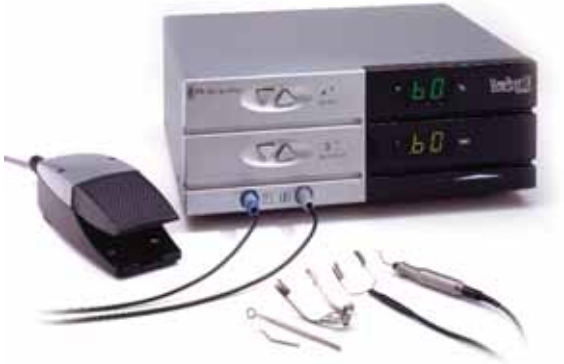
Plaintiff Post subsequently appealed that decision to the Arizona Court of Appeals. In an unpublished Memorandum Decision on February 1, 2004, that court overturned Judge Lee's decision to throw out Plaintiff Post's $4 million verdict. Nevertheless, the record $4 million verdict was not automatically reinstated as a result of the Appellate Court's reversal. Rather, the case was remanded by the Appellate Court to the state superior court, where the Plaintiff filed a Motion to Reinstate the Judgment, the Defendant UPI filed a Renewed Motion for a New Trial, and the Plaintiff filed a Motion to Correct a Mathematical Error.

On October 28, 2004, Judge Lee ruled on these pending motions; he denied the Defendant's Renewed Motion for a New Trial, granted the Plaintiff's Motion to Reinstate the May 14, 2002, judgment in favor of the Plaintiff, and granted the Plaintiff's Motion to Correct a Mathematical Error, awarding the Plaintiff taxable costs against the Defendant in the amount of $44,569.71.

Although the jury originally awarded $4 million against the Defendant, it apportioned fault of 85% to the Defendant and 15% to the Plaintiff. However, with back interest, the judgment against Defendant UPI totals $4,306,738.06.

### CK GAINED FDA APPROVAL FOR PRESBYOPIA

Refractec Inc. (Irvine, CA) announced on March 22nd that the FDA approved the Viewpoint CK System for performing the Nearvision CK (conductive keratoplasty) procedure for the temporary improvement of near vision in emmetropic and hyperopic presbyopes. The system uses radio waves to reshape the cornea. The FDA's approval was based on 12-month clinical follow-up data in which NearVision CK demonstrated effectiveness in significantly improving a patient's near vision.



**Viewpoint CK System**

Of the 150 patients studied, 98% could see J5 in the treated eye, and 87% could see 20/20 at distance and also read J3. No serious, sight-threatening, or unanticipated safety events were reported. ■

# IOL Selection for the Weakened Capsular Bag

*Certain designs and materials may be preferable for pseudoexfoliation.*

**BY DAVID F. CHANG, MD**

Devices designed to help stabilize the loosened capsular bag during phacoemulsification include (1) capsular tension rings (CTRs; Morcher GmbH, Stuttgart, Germany [distributed in the US by FCI Ophthalmics, Inc., Marshfield Hills, MA], and OPHTEC, Groningen, the Netherlands), (2) the Ahmed capsular tension segment (Morcher GmbH), and (3) capsule retractors such as the Mackool Cataract Support System (Duckworth & Kent Ltd., Hertfordshire, England, and Impex, Staten Island, NY). Thanks to these devices and to techniques such as phaco chop, surgeons are frequently able to preserve the capsular bag despite the multiple challenges posed by weakened zonules. The surgeon, however, is then faced with a new set of decisions. Is the capsular bag suitable for the long-term support of an IOL? Which IOL should be used? Is a CTR or other implantable device, such as a Cionni modified CTR (Morcher GmbH), necessary? The same questions must be considered for all eyes with pseudoexfoliation (PXF) in light of the increasing incidence of late, spontaneous dislocation of the capsular bag.[1-4]

## SPONTANEOUS DISLOCATION OF THE CAPSULAR BAG

At the 2000 Annual Meeting of the AAO, Mamalis et al[1] reported their initial series of nine patients with PXF who presented with late, spontaneous dislocation of the capsular bag. These dislocations occurred between 5 and 10 years after the original surgery. The investigators' case series comprised eight PMMA IOLs and one plate haptic silicone IOL, and it was published in *Ophthalmology* 1 year later.[2] I reported on two cases of spontaneous dislocation in PXF patients with three-piece silicone IOLs.[3] At the 2002 AAO Annual Meeting Spotlight on Cataracts Symposium, Alan Crandall, MD, of Salt Lake City updated his series, which numbered 19 patients at that time.[4]

I was impressed by the contraction of the capsulorhexis in the four patients whom I have managed with

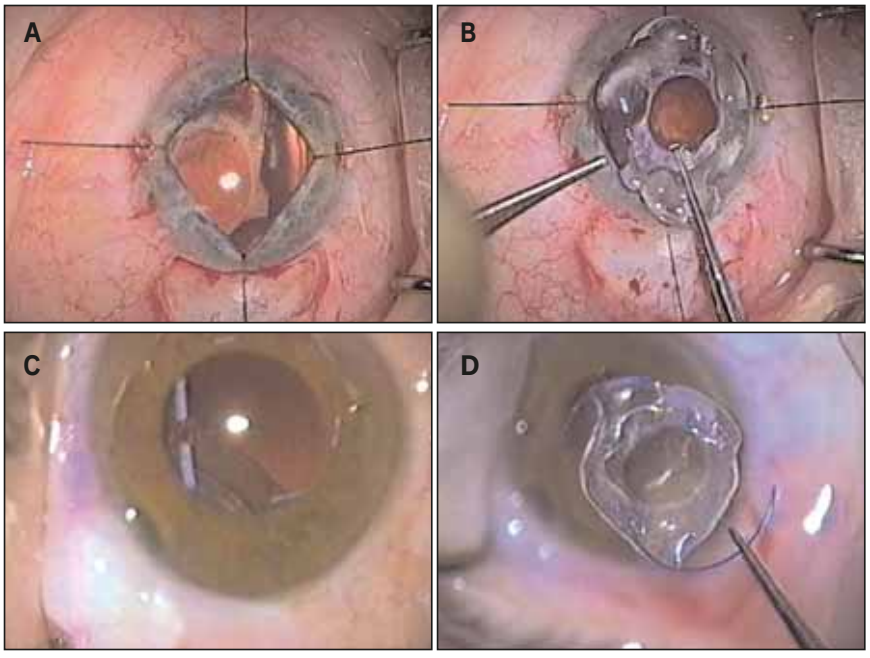



**Figure 1. After late posterior dislocation of a bag with a PMMA IOL (A), the explanted bag-IOL complex showed capsulorhexis contraction and the Soemmering's ring (B). Following late posterior dislocation of a capsular bag with a silicone IOL (C), the explanted bag-IOL complex showed capsulorhexis contraction (D).**

this complication. I was the primary surgeon for three of them (Figure 1). Exaggerated contraction of the capsulorhexis is usually an indication of weak zonules.[5-7] It also seems likely, however, that capsulophimosis and extensive anterior capsular fibrosis exerted excessive centripetal strain on the already weakened zonules in these eyes.

Given that the capsulorhexis technique was not widely adopted until the early 1990s, and considering the 5- to 10-year latency for this complication, it makes sense that we surgeons are seeing an increasing frequency and growing awareness of this complication during the past few years. In assessing the risk of delayed spontaneous bag dislocation in PXF, however, what is not known is the denominator. Complicating any evaluation of preventive measures is the fact that dislocation may take more than 10 years to occur. Nonetheless, I believe it is possible to make rational choices based upon our current knowledge of IOL design and materials.

### *CTRs AND PXF*

Does every patient with PXF require a CTR? This decision is controversial, and the extent of zonular deficiency should be a determinant. Significant zonular weakness would certainly be a reasonable indication for a CTR. Many PXF patients, however, exhibit no intraoperative evidence of zonular laxity, and I do not think that a CTR is necessary in such cases. Nevertheless, there are several surgical and IOL design objectives that make sense for any patient with PXF.

> "One should specifically examine the anterior capsular reaction at the final 1-month postoperative visit in patients with PXF."

Thorough cortical cleanup is especially important in PXF eyes. Although the circumferential anterior capsular overlap of the optic edge is desirable, an excessively small-diameter capsulorhexis must be avoided in these patients. IOLs with optic diameters smaller than 6 mm should be avoided for this reason. Following IOL implantation, a small capsulorhexis can be secondarily enlarged if necessary. After obliquely cutting one edge with a long Vannas scissors, I re-tear the opening under viscoelastic.

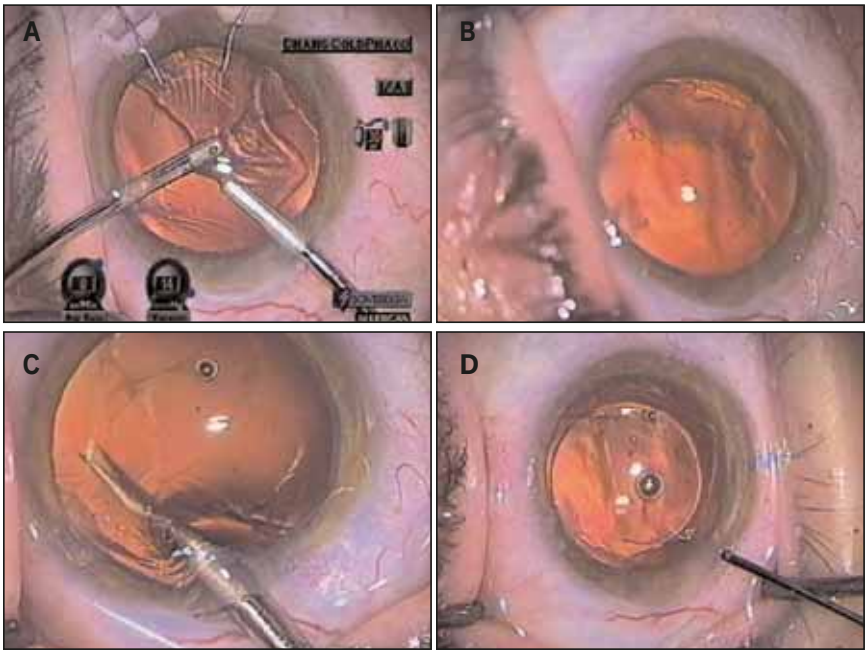



**Figure 2. Mackool capsule retractors supported a nasal area of large zonular dialysis during bimanual cortical I/A (A). Despite the preservation of the capsular bag, a large nasal zonular dialysis was visible after the removal of the capsule retractors (B). The surgeon used long Vannas scissors to make multiple radial cuts in the nasal capsulorhexis edge (C). The surgeon placed a 13.5-mm-long, foldable silicone IOL in the sulcus, with the haptic axis oriented 90° from the zonular defect (D).**

Because hydrophobic acrylic IOLs are associated with less anterior capsular fibrosis when compared with silicone lenses,[8,9] I believe that the former material is preferable for PXF eyes. Three-piece lens designs with broad, stiff PMMA haptics are able to exert the maximum centrifugal tension against the capsular fornices. They are preferable to the soft, floppy single-piece haptics for this reason. At the most recent AAO Annual Meeting, Da Reitz Pereira et al[10] reported on a large retrospective study comparing the single-piece and three-piece AcrySof IOLs (Alcon Laboratories, Inc., Fort Worth, TX). With a single surgeon and identical capsulorhexis sizing, the single-piece AcrySof group demonstrated a significantly higher incidence of capsular contraction syndrome. Three percent of the single-piece AcrySof group required a

YAG anterior capsulotomy for this condition versus none of the three-piece group. One should probably avoid silicone plate haptic IOLs in PXF eyes, because of these lenses' haptic design and higher tendency for anterior capsular fibrosis.

"If a CTR is not available, there are other options to consider. As an alternative to enlarging a small-diameter capsulorhexis, one could make relaxing incisions in the capsulorhexis edge after placing the IOL in the bag."

Finally, one should specifically examine the anterior capsular reaction at the final 1-month postoperative visit in patients with PXF. If there already are signs of early contracture and fibrosis, prophylactic YAG relaxing cuts in the capsulorhexis edge should be considered.

In any eye in which the surgeon notes intraoperative signs of zonular laxity, the placement of a CTR is prudent. The goals would be to (1) prevent capsulophimosis, (2) reduce centripetal zonular stress by resisting capsulorhexis contraction, and (3) avoid IOL decentration caused by asymmetric capsular fibrosis. There are numerous situations, however, where a CTR alone might not afford sufficient long-term capsular support. Such cases include eyes with a large zonular dialysis or severe, diffuse circumferential weakness. It is for these eyes that the Cionni modified CTR or the Ahmed capsular tension segment were designed. Unfortunately, neither device is currently FDA-approved in the US.

If a CTR is not available, there are other options to consider. As an alternative to enlarging a small-diameter capsulorhexis, one could make relaxing incisions in the capsulorhexis edge after placing the IOL in the bag. With a temporal incision, I would orient the haptics along the horizontal axis (3- to 9-o'clock position) and make two opposing cuts in the capsulorhexis edge superiorly and inferiorly (12- and 6-o'clock positions). The cuts should not extend too far peripherally, because they merely need to prevent the sphincter-like contraction of the capsulorhexis margin.

Finally, one could place the IOL in the sulcus (Figure 2). The sulcus diameter can be estimated by adding 1.5 mm to the white-to-white horizontal corneal diameter. Thus, the typical foldable IOL of 13 mm in overall length is too short for a corneal diameter of 12 mm or greater. STAAR Surgical Company (Monrovia, CA) makes a 13.5-mm foldable silicone IOL (model AQ 2010 V) that is my preference for sulcus placement. The IOL power should be reduced by 0.50 to 1.00 D from that calculated for capsular bag placement.[11] The single-piece AcrySof is not only too short for sulcus placement, but it has thicker, sharp-edged haptics that can cause pigment dispersion. If sulcus placement is elected because of a severe zonular dialysis, one should consider making multiple relaxing cuts in the capsulorhexis edge to avoid extensive and asymmetric bag contracture with avulsion of the remaining hemisphere of weak zonules.

## CONCLUSION

Whereas excellent results may be obtained with a wide range of IOL materials and designs in routine cases, eyes with weak zonules are at greater risk for delayed IOL subluxation, dislocation, and capsulophimosis. Surgeons should strive to minimize anterior capsular fibrosis and capsulorhexis contraction through a combination of surgical technique and IOL selection. ■

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# Microincisional Lenses

*Thin IOLs and bimanual microincisional cataract surgery are paving the way for smaller injectable IOLs.*

BY MATTEO PIOVELLA, MD; FABRIZIO I. CAMESASCA, MD; AND BARBARA KUSA, MD

In the past year, cataract surgeons may have often wondered whether the frenzy about bimanual microincisional cataract surgery is warranted. The main purpose for microincisional cataract surgery is to prepare the way for injectable IOLs, with implantation through progressively smaller incisions. Several types of these new IOLs are now available, and studies on many others are underway. The time of rigid and standard foldable IOLs could be coming to an end. One-year follow-up of thin IOL implantation is providing us with interesting and positive results.

> "One-year results demonstrated a mean visual acuity of 20/23 with a mean spherical equivalent correction of -0.19 ±0.68 D."

## WHY A THIN IOL?

The Thinoptx lens (Thinoptx, Abingdon, VA) is a hemacrylic (18% water), one-piece, plate-haptic, rollable IOL. This thermoplastic, 11.2-mm–wide lens has a thickness of 350 to 400 µm, depending on the power of the IOL. Thus, its thickness is one-fifth that of a standard IOL. The Thinoptx lens can easily be inserted through an incision of approximately 2 mm. Multiple 50-µm high steps and the combination of front and back IOL surface powers make the Thinoptx a refractive lens (Figure 1). Folding and insertion are now facilitated by improved injectors that prevent lens damage. Slightly warmed in BSS, the Thinoptx IOL can be easily placed in the injector. The shape of the folded IOL is uniformly cylindrical. Due to the thermoplastic properties of its material, this IOL does not expand abruptly as it exits the injector, and it requires 20 seconds for complete unfolding.

The haptics of the IOL are designed to roll and absorb forces, thus providing optimal centration (Figure 2). Because in-the-bag rotation of the IOL may damage the capsule, we recommend first positioning the IOL on the desired axis while it is in the anterior chamber. One can then insert it into the bag by gently folding the IOL's haptics. The plate haptics feature special, teardrop-shaped fenestration holes that also allow the surgeon to easily determine which side of the IOL should face anteriorly.

## CLINICAL RESULTS

Presently, we are following a group of 40 eyes of 35 patients who received the Thinoptx IOL. The mean, final incisional width, calculated with a caliper measurement of the internal tunnel after IOL insertion, was 2.37 ±0.36 mm. One-year results demonstrated a mean visual acuity of 20/23 with a mean spherical equivalent correction of -0.19 ±0.68 D. Endothelial cell counts decreased by an average of 9.2% at

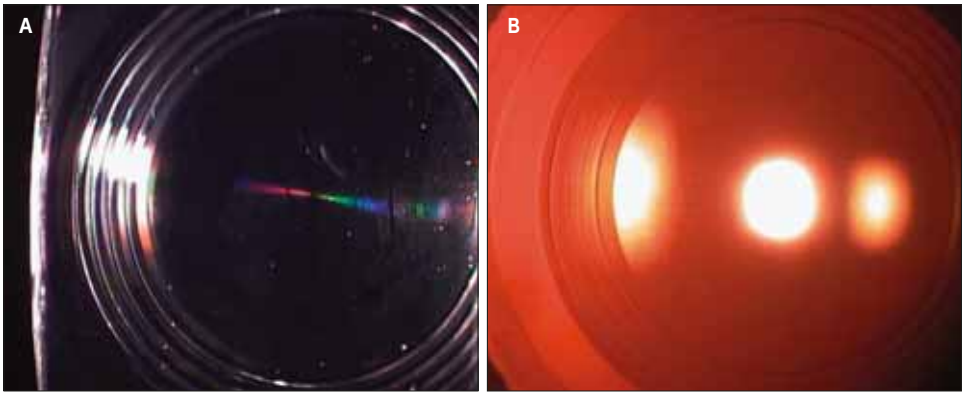


**Figure 1. The high-magnification image shows the multiple 50-µm high steps that, together with the combination of front and back IOL surface powers, make the Thinoptx a refractive lens (A). After insertion, the Thinoptx lens is shown with the retinal red reflex in a fully dilated eye (B).**

1 year. Interestingly, the amount of coma and spherical and higher-order aberrations, measured at 1 year with the WASCA Analyzer (Carl Zeiss Meditec AG, Jena, Germany), were not significantly greater when compared with normal population values.

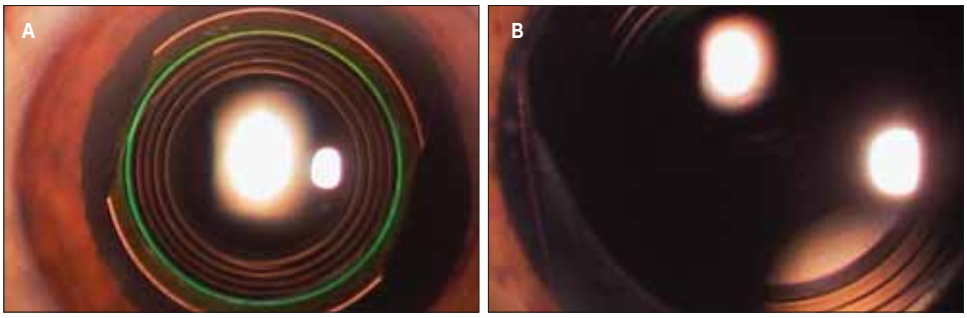


**Figure 2. The Thinoptx IOL demonstrates good centration and stability, even with a fully dilated pupil (A). The inserted lens is viewed with high magnification (B).**

We are presently evaluating other factors, such as the frequency of posterior capsular opacification. The Thinoptx lens, due to its peculiar shape, lacks a square edge, and thus the frequency of posterior capsular opacification appears to be higher than with square-edge IOLs such as the Sensar (Advanced Medical Optics, Inc., Santa Ana, CA). Nonetheless, the posterior capsular opacification rate appears to be much lower when compared with rigid PMMA IOLs.

## SURGICAL TECHNIQUE

For our study, we used topical anesthesia and the following instrumentation: 1.3-mm–wide sapphire knives for the microincisional tunnel and sideport, coaxial forceps for the capsulorhexis, and 0.9-mm phaco microincisional tips. We also used a separate irrigation source through a sideport incision. The two most critical steps of microincisional cataract surgery are (1) creating the incision and (2) making the capsulorhexis. Tunnel creation must respect a delicate balance: a tunnel too short may easily lead to iris chafing or prolapse, and the insertion of surgical instruments through a small tunnel may be difficult when its three planes are very steep.

Due to limited tunnel width, the capsulorhexis must be performed with forceps that do not open in the usual way (without the proper instrument, grasping and guiding the capsulorhexis is difficult). A new generation of 23-gauge coaxial rhexis forceps that work like vitrectomy instruments is presently available, and they make this step similar to the usual 3.4-mm tunnel situation. Microincisional phaco tips are now available with a 0.9-mm outside diameter, and they may also be carbon-coated to reduce friction and heat generation during surgery. A 0.9-mm microincisional phaco tip without an irrigation sleeve requires a 1.3-mm incision. Irrigation is provided through 1.1-mm sideport, and newly designed instruments presently provide both the irrigation and the chopper functions. A chopper with a front opening for irrigation will ensure better irrigation and chamber stability compared with a side-irrigating chopper. Because the small incision constrains movement of the phaco tip, most surgeons performing bimanual microincisional surgery presently adopt a phaco chop technique. It is possible, however, that a completely new surgical technique will be developed to maximize the advantages offered by bimanual microincisional surgery. Finally, the I/A step is performed with bimanual, Buratto-style cannulas.

We believe that caution must be applied when choosing instrumentation for bimanual microincisional surgery. Several generations of instruments have evolved over the course of 1 year. It is therefore desirable to select the newest instruments that incorporate the latest technical improvements.

## CONCLUSION

Bimanual microincisional cataract surgery adds a certain degree of surgical complexity and therefore increases surgical and phaco times. A learning curve definitely exists to safely mastering this new technique. We believe ultrathin, injectable IOLs will end these efforts on the part of transitioning surgeons and instrument companies.

In our hands, the Thinoptx IOL makes bimanual microincisional surgery a worthwhile endeavor. ■

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# Bimanual Microincisional Phacoemulsification for Brunescent Nuclei

*A safer procedure than conventional phacoemulsification.*

**BY HIROSHI TSUNEOKA, MD**

In bimanual phacoemulsification, the phaco tip comes into direct contact with tissue at the incision site during ultrasound operation. At one time, I considered this procedure difficult to implement for a very hard nucleus. However, I have found that the advent of the Whitestar Technology (Advanced Medical Optics, Inc., Santa Ana, CA) and the new irrigating chopper produced by Microsurgical Technology, Inc. (MST; Redmond, WA), allows me to use bimanual phacoemulsification to emulsify even dense nuclei more safely than conventional phacoemulsification.

## *HOW TO PREVENT COMPLICATIONS*

When using bimanual phacoemulsification to emulsify and aspirate a hard nucleus, I have found the following points helpful for avoiding complications during surgery.

Because emulsifying a hard nucleus requires operating ultrasound at a higher power and for a longer duration than with ordinary nuclei, ophthalmologists need special technology, such as Whitestar Technology, to prevent thermal burns and other injuries at the incision site. For a clean incision even after the emulsification and aspiration of a hard nucleus, surgeons must choose the optimal incision size for that procedure.

In my experience, posterior capsular rupture is primarily due to destabilization of the anterior chamber because of an inadequate flow of infusion solution through the sideport. In particular, during the final stage of nucleofractis, the posterior capsule tends to rise and can accidentally be aspirated by the phaco tip. It is necessary to ensure an adequate flow of infusion solution through the sideport to stabilize the anterior chamber during surgery. Also, aspiration flow and pressure should be set at lower levels than during ordinary surgery in order to prevent postocclusion surge.

Because this procedure requires the use of a large-gauged irrigating chopper for nucleofractis, surgeons need to select the best possible nucleofractis technique for hard nuclei. The technique should (1) cause little dispersion of hard nuclear fragments, (2) make it easy to avoid posterior capsular rupture, and (3) be simple to perform, even with a large-gauged chopper.

**Tip No. 1. To prevent injury at the incision site, use the appropriate incision size (1.4 mm).** Reducing the incision to 1.2 mm in order to stabilize the anterior chamber depth and prevent posterior capsular rupture increases the risk of thermal burn at the incision site,

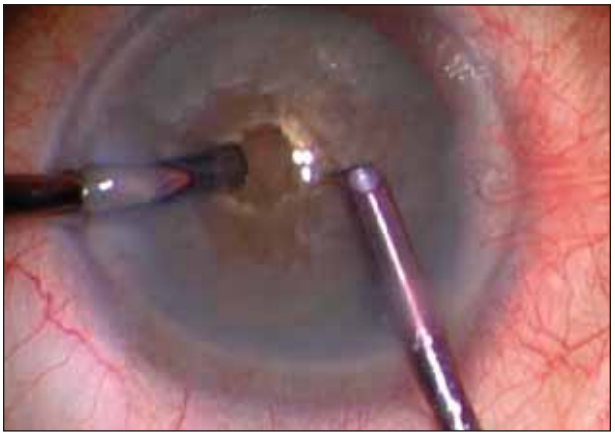

**Figure 1. The author digs a deep, large crater with a 20-gauge sleeveless phaco tip. At this stage (mode 1), the aspiration flow rate and pressure are set low, and the hard section of the nucleus is emulsified without the phaco tip's being completely occluded. Incomplete occlusion prevents thermal burn, despite the high ultrasound power setting.**

**TABLE 1. ASPIRATION FLOW RATES AND PRESSURE SETTINGS FOR A VERY HARD NUCLEUS**

| | Aspiration Flow Rate (mL/min) | Maximum Aspiration Pressure (mm Hg) | Bottle Height (cm) |
|---|---|---|---|
| Mode 1 (Crater) | 20 | 60 | 75 |
| Mode 2 (Vertical Chop) | 25 | 250 | 75 to 85 |
| Mode 3 (Divided Nuclei) | 22 | 140 | 80 to 90 |

even with ultrasound oscillation in Whitestar mode. A smaller incision means an increased risk of hydration of the tissue around the incision, because friction between the tip and the incision wall irritates the corneal tissue and produces hydration. Also, the circular deformation of the incision persists even after the surgeon withdraws the phaco tip, a problem that makes the incision less likely to self-seal.

Widening the incision to 1.4 mm, however, allows fluid to leak through the incision to cool the tissue and the phaco tip and therefore prevent a thermal burn. The extra space between the tip and tissue also increases clearance so that, even when the tip is moving from side to side during the procedure, less pressure is applied to the surrounding corneal tissue. This in turn reduces the deformation and hydration of the incision site.

**Tip No. 2. Use an irrigating chopper to ensure adequate infusion flow.** In order to improve the stability of the anterior chamber, it is necessary to increase the flow of the infusion solution through the sideport incision. The Duet irrigating chopper (Microsurgical Technology, Inc.) has a wide opening at the front end of the cannula that permits an infusion flow rate of 50 mL/min with the infusion bottle at a height of 85 cm. Also, the strong outflow of the infusion solution from the chopper's tip can be used to blow back the posterior capsule. Surge-induced posterior capsular rupture during the final stage of phacoemulsification can be avoided by directing the chopper's aperture toward the posterior capsule.

**Tip No. 3. The best surgical technique is the crater and vertical chop.** In using bimanual phacoemulsification to emulsify and aspirate a brunescent nucleus, the surgical procedure must (1) provide prolonged ultrasound operation without thermal burn at the incision site, (2) avoid injury to the corneal endothelium resulting from the dispersion of small, hard nuclear fragments into the anterior chamber, (3) divide the nucleus easily, even when the surgeon uses a large-gauged chopper, and (4) be unlikely to cause posterior capsular rupture. After comparing a variety of techniques for emulsification and aspiration, I have concluded that the crater and vertical chop method is best for brunescent nuclei.

First, I emulsify and aspirate as much of the hard, central portion of the nucleus as possible without fully occluding the phaco tip (Figure 1). This approach prevents heating of the phaco tip and also reduces the likelihood

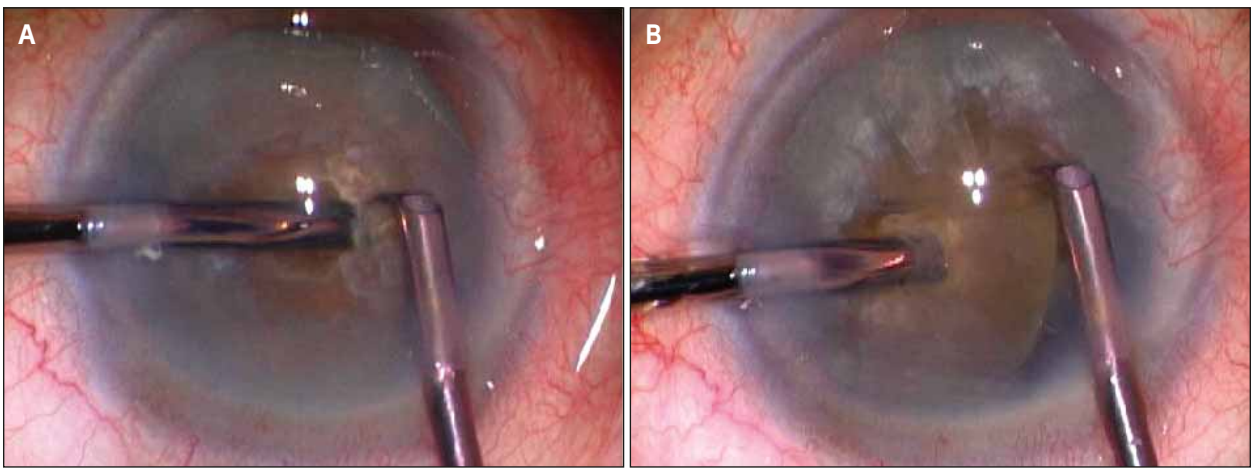


**Figure 2. When the crater is sufficiently deep , the author presses and digs the phaco tip firmly into the crater wall. At this stage (mode 2), it is important to raise the setting of aspiration pressure to high so as to occlude the phaco tip completely and operate ultrasound in Whitestar mode or a similar pulse mode. After the author divides the nucleus into several fragments using the vertical chop technique (A), he draws the fragments into the center (B). This process also requires high aspiration pressure.**

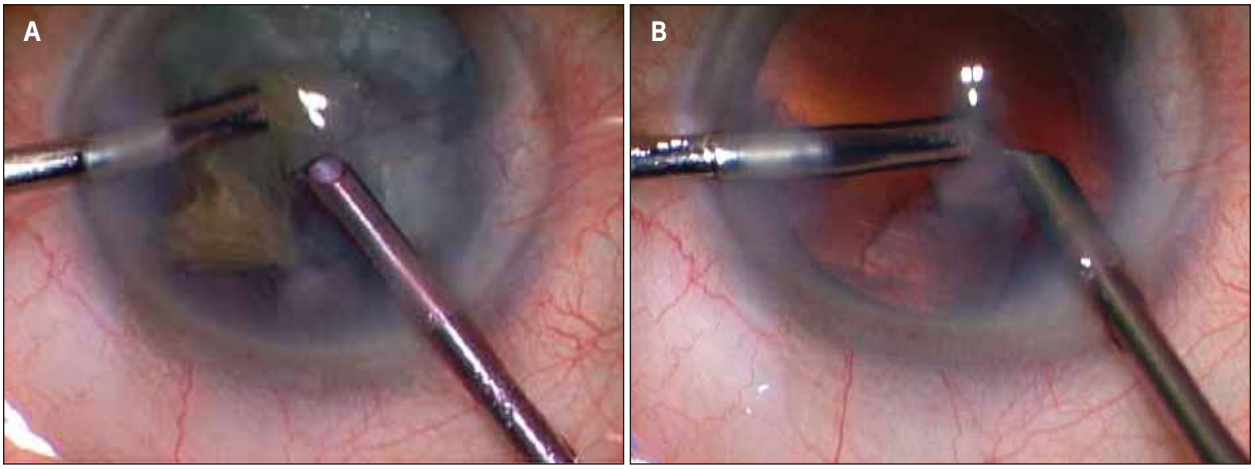


**Figure 3. After the author draws the divided fragments into the center (A), he reduces the high aspiration pressure to 140 mm Hg. Once he emulsifies and aspirates the free nuclear fragments and epinucleus, he uses the strong flow of irrigating solution to press against the posterior capsule near the phaco tip by directing the opening of the irrigating chopper toward the posterior capsule (B).**

of hard nuclear fragments' dispersing into the anterior chamber. Crater and vertical chop allow nucleofractis with minimal movement of the large irrigating chopper, so the sideport incision is less traumatized. I consider this technique to be more useful than the original phaco chop method.

**Tip No. 4. Avoid posterior capsular rupture by lowering the aspiration settings (Table 1).** Recently, it has become popular in phaco surgery to elevate the infusion bottle and use high settings for the aspiration flow rate and pressure in order to perform the surgery quickly. Such high settings, however, can elevate IOP and produce turbulence and surge within the anterior chamber. To minimize the invasiveness of bimanual phaco surgery, surgeons need to reduce these settings and emulsify and aspirate the nucleus without disturbing the anterior chamber.

In bimanual phacoemulsification, I have found it possible to achieve the same level of efficiency as in traditional phacoemulsification with lower settings of aspiration pressure. For an ordinary nucleus, I now set the infusion bottle at between 75 and 80 cm, the aspiration flow rate at 24 mL/min, and the maximum aspiration pressure at 160 mm Hg in mode 2. For a brunescent nucleus, I set the infusion bottle at 75 to 85 cm, the aspiration flow rate at 25 mL/min, and the maximum aspiration pressure at 250 mm Hg in mode 2 (Figure 2). During the final stage of phacoemulsification, the posterior capsule is prone to elevation and rupture, so during mode 3 I reduce the aspiration flow rate and maximum aspiration pressure and slightly elevate the infusion bottle (Figure 3). I also direct the opening of the irrigating chopper downward so that the infusion flow presses down on the posterior capsule and helps prevent posterior capsular rupture. This feature is one advantage of bimanual phaco surgery.

### *RECENT RESULTS WITH BRUNESCENT NUCLEI*

Since May 2003, I have used the procedures mentioned earlier (a 1.4-mm incision, the Duet irrigating chopper, low aspiration settings, and the crater and vertical chop methods) in bimanual phacoemulsification on 48 eyes with brunescent nuclei. My mean rate of endothelial cell loss is 9.8%, and I have had no instances of posterior capsular rupture. I attribute these results to my maintaining a sufficient volume of infusion solution through the sideport incision and to the strong flow of infusion solution from the irrigating chopper. The solution can be used to press down on the posterior capsule near the phaco tip.

In particular, because I have seen no instances of thermal burn at the incision site in bimanual phacoemulsification, I believe that this procedure is safer than conventional phaco surgery in cases of very hard nuclei. ■

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# The Capsular Tension Ring: Indications for Use

*The most appropriate uses for the CTR based on investigative and clinical experience.*

**BY I. HOWARD FINE, MD**

I served as Medical Monitor for the US clinical trial of the Morcher GmbH (Stuttgart, Germany) capsular tension ring (CTR), and I have performed approximately 350 surgeries with the device. The experience my colleagues and I gained from the FDA trial gave us surgical insights into using the CTR. Indications for its use presently involve between 2% and 5% of all cataract surgeries.

## *INDICATIONS*

### Systemic Conditions

The CTR is indicated for all cases of compromised zonular integrity. This condition appears in many congenital, metabolic, and endocrine disorders such as Marfan syndrome, Marchesani's syndrome, scleroderma, homocystinuria, spherophakia, porphyria, hyperlysinemia, hyperlipoproteinemia, and sulfite oxidase deficiency.

### Preoperative Findings

Several preoperative conditions necessitate using a CTR during surgery. All patients with pseudoexfoliation receive a ring, because it makes surgery safer and promotes long-term IOL centration. Patients with high myopia (whose axial lengths are greater than 26 mm) benefit greatly from the use of the device, as do patients who show any phacodonesis at the slit lamp examination. Obvious subluxation of the lens or missing zonules would also require a CTR.

I also use the implant in all postvitrectomy patients, because I believe it helps to fortify the capsule during surgery. Additionally, the device may help guide the final position of the IOL with respect to centration as well as the anterior/posterior locations.

Furthermore, I employ a CTR in all of my patients who previously underwent glaucoma filtration surgery, because most of them have had a shallow or flat anterior chamber postoperatively, which stretches and weakens the zonules. Any patient who has undergone an RK procedure with more than eight incisions also receives a CTR, because in this type of surgery, physicians make the incisions as deep as possible. Thus, a significant percentage of these patients have micro- or macroperforations, which may make the chamber shallow and also stretch and weaken the zonules.

Finally, I use the device in most cases of previous ocular trauma, because there is frequently unknown damage to the ocular apparatus.

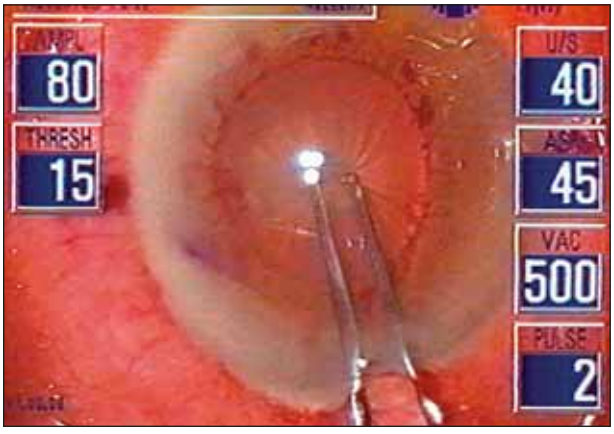


**Figure 1. Wrinkling of the capsule while it is being pinched by capsulorhexis forceps is a sign of weak zonular status.**

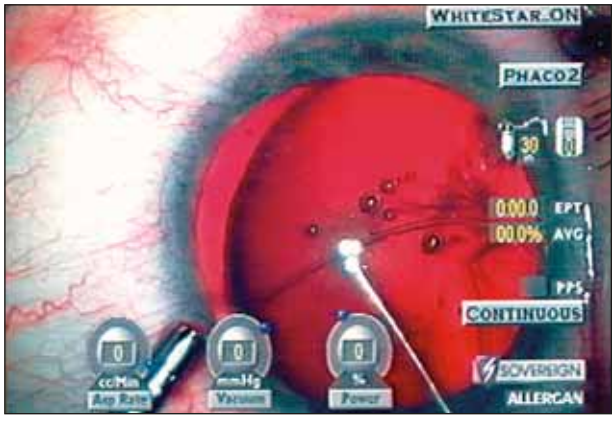


**Figure 2. The author demonstrates bimanual, microincisional insertion of the CTR.**

### Intraoperative Use

One intraoperative signal of weak zonules is wrinkling of the capsule while using the forceps during the capsulorhexis (Figure 1). I also recommend the use of the device in all cases of intraocular zonular damage, such as when the ophthalmologist dialyzes the bag during surgery.

### Contraindications

I refrain from using a CTR in cases of questionable capsular bag integrity and for posterior polar cataracts that might have an opening in the posterior capsule.

## *IMPLANTATION TECHNIQUE*

During the FDA trial, my colleagues and I always inserted the CTR after gentle cortical cleaving hydrodissection but prior to phacoemulsification. The ring can be implanted with forceps or with the Geuder AG injector (Heidelberg, Germany) through a 2.5-mm incision. I use an injector to implant the ring and then perform bimanual microincisional surgery. This type of surgery uses two sideport incisions to conduct phacoemulsification. I inject the ring through the left-hand sideport incision (the injector requires a 2.5-mm incision) and control its intraocular movements through the right-hand sideport incision with a Lester hook (Katena Products, Inc., Denville, NJ) (Figure 2).

### SIZING

I recommend that axial lengths greater than 26 but less than 30 mm receive a medium-sized CTR. Axial lengths greater than 30 mm warrant a large ring, and those less than 26 mm need a small ring.

## *PHACOEMULSIFICATION TECHNIQUE*

In most cases, if I believe that the zonular apparatus is strong enough, I perform horizontal chopping, because it enables me to purchase the nucleus in the golden demarcation ring and lift it when I embed the tip for chopping. I slip the horizontal chopper under the capsulorhexis, into the golden ring, and then I pull the endonucleus toward me as I lift it slightly. At the same time that I embed the bevel-down phaco tip, I hold and chop the nucleus, so as not to transmit a downward force to the capsular bag. Horizontal chopping also retains the vector forces within the plane of the capsule. I usually hydrodissect extremely dense lenses out of the bag before phacoemulsifying them (I prefer bimanual microincisional phacoemulsification). ■

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### REIMBURSEMENT FOR CAPSULAR TENSION RINGS

**By Kevin J. Corcoran, COE, CPC, FNAO**

Recently, the FDA approved the capsular tension ring (CTR) developed by Morcher GmbH (Stuttgart, Germany) and distributed within the US exclusively by FCI Ophthalmics, Inc. (Marshfield Hills, MA; (800) 932-4202). Prior to this approval, reimbursement was hampered because the product was experimental or investigational in the US.

Filing a claim for this prosthetic device is now possible, but there is no specific code with which to report the CTR. For now, the ambulatory surgery center (ASC) or hospital outpatient department may report the CTR using a miscellaneous HCPCS code: L8699, *prosthetic implant, not otherwise specified*. The surgeon should not file a claim for the device that is supplied by the facility where the procedure is performed but should instead bill for the surgical procedure alone (ie, CPT code 66982, *complex cataract surgery*).

Claims for miscellaneous codes generally require supporting documentation to facilitate payment. Useful information includes a description of the device and its purpose, a statement concerning FDA approval, an invoice showing the cost of acquiring the device, and the pertinent regulation that warrants additional reimbursement. Under the Medicare law SSA §1833(i)(2)(A), a prosthetic device such as the CTR is a benefit to the patient and merits separate reimbursement when it is not specifically part of the ASC facility fee, as with an IOL. The coverage rule may be found in the *Medicare Carriers Manual* at MCM §2265.4, which states in part: "Prosthetic devices, other than intraocular lenses (IOLs), whether implanted, inserted, or otherwise applied by covered surgical procedures, are covered, but are not included in the ASC facility payment amount."

In the future, a new HCPCS code identifying CTRs would help expedite claims processing. Corcoran Consulting Group is assisting FCI Ophthalmics, Inc., with the application process for a new code. Although such an effort has a good chance of success, it is difficult to predict exactly when a new HCPCS code may be published.

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# Therapeutic Wavefront

*Enhancements may benefit unhappy patients.*

BY STEPHEN G. SLADE, MD, FACS, AND KERRY D. SOLOMON, MD

A broad spectrum of patients may benefit from therapeutic applications of customized corneal correction, including those with refractive errors after previous RK, automated lamellar keratoplasty, or penetrating keratoplasty; individuals whose LASIK procedures failed, involving those who have had multiple enhancements; and people who suffered traumatic injury after an uneventful surgery.

It is difficult to generalize about such a diverse group of patients, but, in our experience, approximately two-thirds of these complicated retreatment cases can benefit from customized ablations. However, identifying which two-thirds, as well as finding a solution for the remaining one-third, continues to challenge refractive surgeons. Fortunately, although Customcornea surgery with the Ladarvision system (Alcon Laboratories, Inc., Fort Worth, TX) cannot help every therapeutic case, we find that it very rarely worsens the problem. Typically, a poor outcome primarily happens due to improper patient selection criteria.

## PATIENT SELECTION

Before considering performing a wavefront-guided therapeutic treatment, it is important to rule out potential sources of the visual symptoms or reduction in best-corrected vision that are not related to higher-order aberrations and will not be affected by a customized correction.

The examination should include a refraction and an attempted correction with glasses. The physician should evaluate the eye's corneal topography and ocular surface, including corneal staining, to rule out dry eye-related problems, ocular surface disease, or other pathology. An overrefraction with a hard gas permeable contact lens can help distinguish between corneal surface irregularities and opaque transmission defects. Finally, the surgeon should consider whether pupil size is contributing to the patient's symptoms and whether Alphagan (Allergan Inc., Irvine, CA) will provide any relief. It is surprising how often other conditions can cause or contribute to a patient's complaints.

> "Careful relifting of a previous LASIK flap is preferred because it reduces the likelihood of induced astigmatism."

## SURGICAL TIPS

Several factors contribute to the success of a therapeutic ablation. The eye should not be excessively dry during wavefront capture. Additionally, it is essential to lift the previous LASIK flap, if possible. Careful relifting, rather than recutting, is preferred because it reduces the likelihood of induced astigmatism. When recutting is necessary, creating the new flap with the Intralase femtosecond laser (Intralase Corp., Irvine, CA) seems not to introduce the trefoil that a microkeratome does.

Although formal studies for the FDA approval of Customcornea for retreatments are ongoing, sharing anecdotal information from complicated cases helps all of us better understand the results we can expect from customized therapeutic ablations. Some of our recent therapeutic cases indicate what this technology can accomplish.

| | Preoperative OS | 1 month postoperatively OS |
|---|---|---|
| RMS | 1.03 | 0.40 |
| Higher-order aberration | 0.27 | 0.17 |
| Spherical equivalent | 0.08 | 0.01 |
| Coma | 0.19 | 0.11 |

**Figure 1. These were the Ladarwave (Alcon Laboratories, Inc.) values in a patient with a 6-mm pupil. According to the authors, in the right patient, therapeutic Customcornea surgery with the Ladarvision system can improve quality of vision.**

## DR. SLADE: MIXED ASTIGMATISM

My colleagues and I treated a 37-year-old white male with mixed astigmatism. Following conventional LASIK, the patient had 2.00D of against-the-rule cyl-

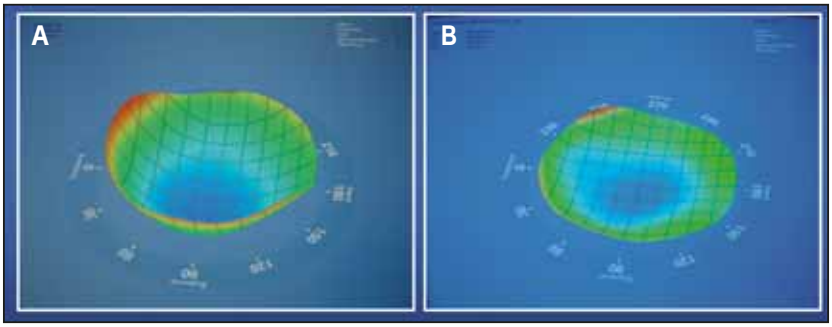


**Figure 2. After undergoing a Customcornea enhancement procedure, a patient's UCVA increased from 20/25 preoperatively (A) to 20/15 postoperatively (B).**

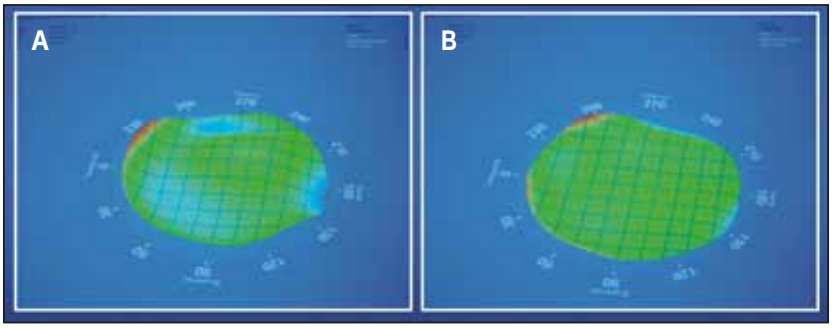


**Figure 3. Following therapeutic wavefront Customcornea surgery, a patient's total higher-order aberrations can be reduced (preoperative, A; postoperative, B).**

inder. Nevertheless, his visual symptoms of glare and halos were significantly worse than would be expected from his postoperative refraction. Six months after undergoing therapeutic Customcornea surgery, he had gained two lines of BSCVA, and his photopic and mesopic contrast sensitivity had improved significantly. Furthermore, we were able to reduce the amount of his total higher-order aberrations by 32%, with spherical aberrations being the most notably affected. The patient is very happy with his surgical results.

In general, I would say we are able to correct coma, spherical aberration, secondary astigmatism, and tetrafoil quite well. Trefoil has proven more difficult to address, but, fortunately, it also seems to cause less visual distortion than some of the other aberrations.

### *DR. SOLOMON: SYMPTOM RESOLUTION IN AN EMMETROPE*

A 35-year-old white male underwent a conventional procedure with the Visx Star (Visx Inc., Santa Clara, CA) laser in February 2002 for the correction of fairly typical myopic astigmatism. Postoperatively, his UCVA was 20/20, but he was very unhappy. The patient complained of double vision, ghosting, and glare in his left eye, especially at night but also sometimes during the day. Topography revealed a well-centered ablation and no irregular astigmatism. His ocular surface was healthy.

After a Customcornea enhancement in March 2003, the patient's UCVA improved from 20/25 to 20/15. Total higher-order aberrations were reduced from an RMS of 0.27 to 0.17, and spherical aberration was almost completely eliminated (Figures 1 through 3). Most importantly, his quality-of-vision problems were resolved, and the patient claims to have better vision than he has ever experienced.

### *NO PATIENT LEFT BEHIND*

We believe that wavefront-guided treatments like Customcornea represent a paradigm shift in laser vision correction. We have moved from improving Snellen acuity to improving quality of vision. The ultimate effect of this change has been to raise the bar in terms of our surgical expectations. We now look not only for good Snellen acuity, but also a flatter wavefront, good contrast sensitivity, and other quality-of-vision improvements.

Even more exciting is that, for the first time, we can begin to address the patients who were "left behind" after previous refractive surgery.

Therapeutic customized retreatments have a great deal of potential. As clinicians, we should be selective about which patients should receive the procedure and should first certainly rule out simpler contributors such as ocular surface disease. However, in the right patients, the technology can achieve the quality of vision patients desire from refractive surgery. ■

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# Calculating Corneal Power After Refractive Surgery

*New methods for determining the estimated true corneal power of an eye that has undergone RK, PRK, LASIK, LASEK, or conductive keratoplasty.*

**BY KENNETH J. HOFFER, MD, FACS**

This article reviews some of the methods proposed to calculate or estimate the true power of the cornea in eyes that have undergone corneal refractive surgery. The first methods I touch on have been well discussed during the past decade and have worked well, but there are newer ideas not yet thoroughly tested by independent studies that are worth considering.

The problem we have is determining the true optical central power of the cornea using present instrumentation. Keratometers and topography units measure the curvature too peripherally and miss the very central, flat part of the cornea. The result is an overestimation of the corneal power that, when entered into the IOL power formula, produces an overly weak IOL power and thus a hyperopic refractive result. The methods described herein are intended to better estimate the true power of the altered cornea.

### CLINICAL HISTORY METHOD

The earliest and most simplistic method of corneal power calculation is the Clinical History Method, which was proposed by Jack Holladay, MD, of Bellaire, Texas, and which I converted into a formula. The method is based on the idea that refractive surgery has changed the corneal power and that this refractive change must be added to the presurgical power of the cornea in order to estimate its present power.

Here is what you need to obtain:

1. A preoperative average K reading (Kp).
2. A preoperative spherical equivalent refractive error (Rp, before refractive corneal surgery).
3. A postoperative spherical equivalent refractive error (Ro, after the eye has healed following refractive surgery and visual acuity has stabilized but before cataract formation).

To calculate the eye's estimated corneal power (K), use the formula: K = Kp + Rp - Ro. Remember to add algebraically; minus a minus equals a plus.

Vertex-correcting the refractions is no longer recommended by Dr. Holladay or me, based on studies showing that doing so only creates a more hyperopic result clinically.[1]

### CONTACT LENS METHOD

The Contact Lens Method was first described by Frederick Ridley[2] of London, later by Joseph Soper[3] of New York, and more recently published by Dr. Holladay.[4] I transformed the method into a formula.[5] The method is based on the concept that, if a hard PMMA contact lens of known base curve (eg, 35.00 D) and known power (eg, plano) is placed on the cornea and the refraction does not change, the effective power of the cornea must be 35.00 D. If the power is different from plano and/or the difference in refraction is not zero, the formula will calculate the power. This method is limited to cataractous eyes with a minimum BCVA of 20/80. The method will not work in eyes that are not able to be refracted.

Here is what you need to obtain:

1. A hard PMMA (not RGP) contact lens with a base curve (B) close to the estimated K reading and with a known power (P, easier if plano). You can obtain a set of various plano contact lenses from Eye Scan Consulting (Decatur, GA).
2. A bare manifest refraction without a contact lens (Rb).
3. A manifest overrefraction with a contact lens (Rc).

To calculate the eye's estimated corneal power (K), use the formula: K = B + P + Rc - Rb. Again, remember to add algebraically and keep in mind that Dr. Holladay and I no longer recommend vertex-correcting the refractions.

The two methods described thus far are automatically available on Hoffer programs, including the Palm OS version.

### SHAMMAS NO HISTORY METHOD

In 2003, John Shammas of Lynwood, California, proposed a formula that only requires the postoperative average K reading obtained from a manual keratometer.[6] I call it the *Shammas No History Method*.

Here is what you need to obtain:

Only the postoperative, manual average keratometry reading (Ko).

To calculate the eye's estimated corneal power (K), use the formula: K = 1.143 X (Ko) - 6.8.

Warning: The Shammas No History Method has not been tested for accuracy on a large, reported series.

### MALONEY TOPOGRAPHY METHOD

Robert Maloney, MD, of Los Angeles has been using a formula I call the *Maloney Topography Method*.

Here is what you need to obtain:

Only the postoperative simulated central K reading from the topography unit (Kt).

To calculate the eye's estimated corneal power (K), use the formula: K = [376/(337.5/Kt)] - 5.5.

Warning: The Maloney Topography Method has not been tested for accuracy on a large, reported series.

***After looking at all of the preceding methods, you should choose the lowest K reading from those you have calculated to use in the formula and then employ the Aramberri Double-K Method (see next method).***

### ARAMBERRI DOUBLE-K METHOD

In 2001 (oral communication), Jaime Aramberri, MD, of San Sebastian, Spain, had the eminently sound idea that the postsurgical flatter K reading should not be used in modern, theoretic formulas to calculate the estimated position of the IOL (estimated lens position [the visual axial distance from the front of the cornea to the principle plane of the IOL] or anterior chamber depth).[7] This concept is based on the fact that the flattening and thinning of the corneal surface has not changed the biometric measurements of the anterior chamber structures; that is, the cornea has not changed its distance relationship with the crystalline lens and iris. I call Dr. Aramberri's method the *Aramberri Double-K Method*.

Here is what you need to do:

1. Use the preoperative K reading (Kp, eg, 43.50 D) in the part of the formula that predicts the estimated lens position (anterior chamber depth).
2. Use the postoperative (Ko, eg, 35.00 D) in the part of the formula that calculates the IOL power.

Presently, this option is only available on the Hoffer Programs version 2.5.

Warning: The Aramberri Double-K Method has not been tested for accuracy on a large, reported series.

### IANCHULEV APHAKIC OR REFRACTION METHOD

In mid-2003 (oral communication), Sean Ianchulev, MD, of Los Angeles proposed a method of calculating the IOL power for postrefractive surgery eyes that does not require the axial length or average K reading. I call this the *Ianchulev Aphakic or Refraction Method*. It is based on the concept of determining the aphakic refraction of the eye with a handheld autorefraction device immediately after cataract removal in the OR. After using this method on a series of eyes, Dr. Ianchulev was able to propose a formula to convert the refraction obtained into an IOL power based on the A-constant of the lens to be used. This method could also be used for normal eyes but would require a clear cornea after cataract removal and the availability of a full inventory of lens powers in the OR.

Here is what you need to do (no axial length, K readings, or formulae needed):

1. After the cataract is removed in the OR,
   - reinflate the eye with BSS,
   - move the microscope out of the way,
   - perform handheld autorefraction,
   - obtain the refraction (Rx, eg, 10.50 D sphere), and
   - know the A-constant (A) of the IOL to be used (eg, 119.2).
2. Calculate the IOL power (P) using the formula: P = 2.02 X Rx + (A-118.4). For example, P = 2.02 X (10.5) + (119.2-118.4) = 22.01.

Basically, the formula is twice the aphakic refraction with an adjustment for the difference in the A-constant from 118.4, the A-constant of the lens Dr. Ianchulev used in his study.

Warning: The Ianchulev Aphakic or Refraction Method has not been tested for accuracy on a large, reported series.

### CONCLUSION

I hope you find these methods useful in determining the best IOL power for your postrefractive surgery patients, whose situation has yet to be resolved precisely. Remember to warn your patients that none of these methods can guarantee the desired, healed refractive result and that they may need to undergo a lens exchange, implantation of a piggyback lens, or some other surgical adjustment.

To view and download calculations, visit www.EyeLab.com. ■

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*Peer-Reviewed Literature:*

# Amniotic Membrane Transplantation

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Amniotic membrane transplantation (AMT) has been successfully applied to treat various kinds of ocular surface disease. Its application is expanding in many ophthalmologic fields.

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## THE AMNIOTIC MEMBRANE DEFINED

The amniotic membrane is the innermost layer of placental membrane. It was first used in 1910 in skin transplantation.[1] Since then, the use of amniotic membrane has expanded in many surgical fields, including brain and genito-urinary tract surgery. The first ophthalmic application to treat ocular surface disorders was reported in the 1940s.[2] The application of AMT in the management of ocular surface disorders is ever increasing. In this review, we will discuss its biologic properties, mechanism of action, and applications in ophthalmology, as well as define existing problems in its application.

## BIOLOGIC PROPERTY

Amniotic membrane, which is derived from fetal ectoderm, is a translucent membrane consisting of five layers starting from the innermost layer: (1) epithelium; (2) basement membrane; (3) compact layer; (4) fibroblast layer; and (5) spongy layer. Its thickness varies from 0.02 to 0.50 mm. It lacks blood vessels or a direct blood supply.[3]

Amniotic membrane produces a large number of cytokines, of which Interleukins 6 and 8 are predominant.[4] Expression of these cytokines increases in the presence of IL-1ß, TNF-alpha, and bacterial lipopolysaccharide. Studies reveal that human amniotic membrane preserved at -80°C for 1 month retains the presence of EGF, TGF-alpha, KGF, HGF, bFGF, TGF-ß1, TGF-ß2, endothelin-1, leukotrines, and carbonic anhydrase isoenzymes CA-1 and CA-2. These proteins are hypothesized to contribute to immune-mediated defense mechanisms during pregnancy.[5]

According to the literature, amniotic membrane does not express HLA-A, B, or DR antigens, so immunological rejection after transplantation is rare.[6] Additionally, amniotic membrane is also believed to have antimicrobial and antifibroblastic activity properties and cell migration/growth-promoting activity.[7,8]

## THE FUNCTIONS OF AMT

### Positive Effects

Amniotic membrane executes its functions via multiple mechanisms. Many experimental and clinical studies[8-10] have demonstrated that AMT can promote corneal re-epithelialization, which is its most important function. Two other important effects include anti-inflammatory properties and fibrosis prohibition.

### Promoter of Re-Epithelialization

The presence of a normal substrate is essential for normal proliferation, differentiation, and migration of epithelial cells. Lee and Tseng[9] reported successful re-epithelialization of 10 out of 11 cases of persistent epithelial defect by AMT. They postulated that amniotic basement membrane plays an important role in epithelial differentiation, the migration of epithelial cells, and the adhesion of basal epithelial cells.

**Inhibitor of Inflammation and Scarring**

Amniotic membrane executes anti-inflammatory and antifibrotic effects. Studies show that amniotic membrane induces a downward regulation of transforming growth factor ß, which is an important fibroblastic activator in wound healing.[8] Amniotic membrane may also act as an anatomical barrier because its stromal layer is avascular, and blocks new vessels from growing.

> "Ocular surface disorders including chemical or thermal burns, Stevens-Johnson syndrome, and cicatricial pemphigoid constitute an indication for AMT."

Additionally, antiangiogenic and antimicrobial properties of amniotic membrane are reported in the literature. Kim and Tseng[10] demonstrated that rabbit corneas with limbal stem cell deficiency and total keratectomy were less likely to become revascularized if covered with amniotic membrane.

## *THE USE OF AMNIOTIC MEMBRANE IN OPHTHALMOLOGY*

**Ocular Surface Reconstruction in Stem Cell Deficiency**

The Kim and Tseng study[10] has led to successful applications in various ocular surface diseases. Cicatrizing diseases of the ocular surface associated with acute or chronic stem cell loss constitute an indication for AMT. These ocular surface disorders include chemical or thermal burns, Stevens-Johnson syndrome, and cicatricial pemphigoid. Shimazaki et al[11] reported the first clinical applications of the membrane in patients with the aforementioned conditions in 1997.

Tseng et al[12] applied the membrane in the treatment of 31 eyes of 26 patients with partial and total stem cell deficiency. The majority of these patients had chemical burns or Stevens-Johnson syndrome. Other patients presented with contact lens-induced keratopathy, aniridia, atopy, and iatrogenic stem cell disease.

**Application in Persistent Epithelial Defects**

AMT was reported to be successful in patients with persistent epithelial defects.[13] Heiligenhaus et al[14] reported that AMT was applied to promote the healing of acute ulcerative and necrotizing herpetic keratitis. In these studies, AMT shows great promise in acute ulcerative and necrotizing ocular surface diseases.

**Conjunctival Reconstruction**

The conjunctiva is an integral part of the ocular surface. Most procedures employing amniotic membrane in reconstruction of the ocular surface involve both the cornea and conjunctiva. Amniotic membrane has been used as an alternative to a conjunctival autograft in the treatment of pterygia. Ma et al[15] compared amniotic membrane grafts with conjunctival autografts and topical mitomycin C in 80 eyes of 71 patients with primary pterygia. They found no differences in recurrence rates in the three groups. Because conjunctival autografts have limited success, and administration of mitomycin C increases risk of complications, AMT was suggested as the preferred procedure.

**Other Ophthalmic Applications of AMT**

Pires et al[16] reported that AMT was used effectively for the treatment of symptomatic bullous keratopathy. During the follow-up period of 33.8 weeks after AMT, 90% of the 50 patients studied with intolerable pain preoperatively became pain-free postoperatively. Anderson et al[17] used amniotic membrane in 16 eyes after surgically removing the calcified deposits in band keratopathy. Rodriguez-Ares et al[18] reported on AMT application in the repair of a large scleral perforation in a patient with Marfan's syndrome. Wang et al[19] and Dua et al[20] used amniotic membrane after PRK. Wang et al found that the corneal haze score in the amniotic-membrane-covered group was significantly less than in the control group 7 to 12 weeks postoperatively. Amniotic membrane is applied as a substrate and a stem cell niche for cultivating autologous corneal epithelial cells for ocular surface reconstruction.[21,22] Results in these instances demonstrated that the sterilized, freeze-dried amniotic membrane retained most of the physical, biological, and morphologic characteristics of cryopreserved amniotic membrane. Consequently, it is a useful biomaterial for ocular surface reconstruction.

## *COMPLICATIONS WITH AMT*

As the use of amniotic membrane in ophthalmic surgery has become widespread, complications have rarely been reported in published studies. Most of the reported complications, such as persistent inflammation and suture granuloma, are not specific to the membrane.[23] Failure to achieve the intended effect with amniotic membrane is perhaps the most significant drawback. Another, less significant undesirable effect is the residual subepithelial membrane that persists in some

cases.[23] The incidence of this complication should decrease as ophthalmologists' experience increases, thereby enhancing appropriate patient selection.

The potential danger of the spread of viruses and bacteria should not be overlooked. Because amniotic membrane from a single donor is often used in several patients, the risk of single donor infections to multiple recipients is real. Adequate donor screening, handling, and storage, as well as frequent microbiological tests should be performed in order to avoid or minimize this risk.

## BOTTOM LINE

Amniotic membrane has many unique properties that can aid the treatment of different ocular surface disorders. AMT can promote normal epithelialization of the cornea and conjunctiva and prevent excessive fibrosis during ocular surface reconstruction. It is an effective alternative in the treatment of many challenging ocular surface disorders. Although AMT holds great promise and its application is expanding in many ophthalmologic fields, it is not the panacea. Surgical failures and potential risks with its applications are inevitable. A comprehensive understanding of amniotic membrane's biologic properties, action mechanisms, and associated risks is helpful for appropriate patient selection. ■

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# Accommodating IOLs: Emerging Concepts and Designs

*Steps toward providing excellent distance, intermediate, and near UCVA.*

**BY SAMUEL MASKET, MD**

With respect to pseudophakia, accommodating IOLs are both the hope for and the wave of the future. Cataract surgeons' goal has long been to provide unaided, high-quality distance, intermediate, and near vision postoperatively. Although the concept of surgically emptying the capsular bag and refilling it with an accommodating polymer that matches the behavior of the juvenile lens has received consideration for many years, its actualization remains elusive today. Ophthalmologists' work toward that goal will involve many intermediate steps. Presently, the field is on the brink of a new era in accommodating IOL technology. This article considers the currently available lenses as well as those devices that are in varying stages of development. Because this is an ever expanding field, all present examples cannot be addressed. Rather, present design concepts are considered in group styles. I make no attempt to include all products under development.

> "An IOL's true accommodative function should be based upon the Helmholtz theory of accommodation."

## ACCOMMODATIVE FUNCTION AND EFFECT

I believe that an IOL's true accommodative function should be based upon the Helmholtz theory of accommodation. Accordingly, a truly accommodating IOL requires one or both of these transient and reversible changes: (1) anterior movement of the optic and (2) increased optical power of the IOL. It follows, then, that accommodating IOLs must be dynamic. As a result, they are most likely to depend on the long-term flexibility of the capsular bag in order to function properly. For this reason, surgeons will likely need to modulate postoperative reactions of the lens epithelial cells in order to reduce the tendency for fibrometaplasia, typically observed for the anterior subcapsular lens epithelial cells

(Courtesy of Advanced Medical Optics, Inc.)

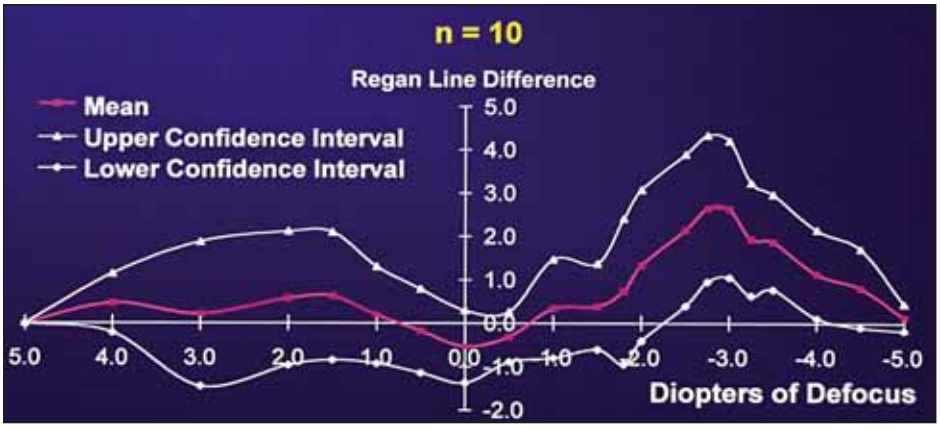
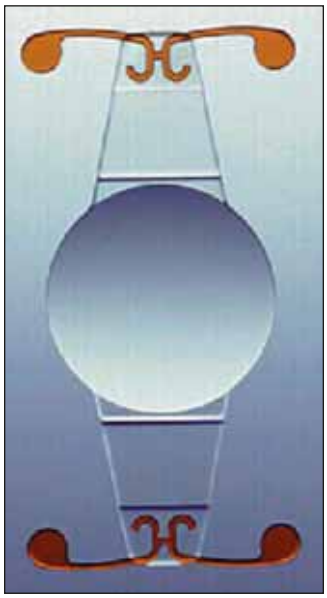



**Figure 1. The defocus curve is used to determine the accommodative or pseudoaccommodative function of an IOL.**

after implant surgery. Additionally, it is important to recall that these postoperative changes vary with the nature of the implant material and its contact with the anterior capsule.

Another consideration is the methodology for measuring the accommodative effect of an IOL. Patients with monofocal IOLs demonstrate a small degree of accommodation that is probably related to artificial or pseudoaccommodative effects such as corneal asphericity, which produces a multifocal cornea. Alternatively, corneal astigmatism may also provide for degrees of pseudoaccommodation. It is generally accepted that patients with monofocal IOLs may generate between 0.50 and 1.50 D of pseudoaccommodation after surgery. Strictly measuring postoperative near visual acuity may therefore be misleading, because a degree of pseudoaccommodation exists in most patients. This caveat may be of particular importance in patients who have small or miotic pupils; similar to all optical systems, the eye with a small pupil has an increased depth of focus.



(Courtesy of Eyeonics, Inc.)

**Figure 2. The Crystalens features a 4.5-mm, fixed-power optic with grooved plate haptics designed to allow flexibility and accommodation.**

Researchers have employed several automated devices in their efforts to demonstrate either anterior movement of an IOL or a change in optical power on attempted accommodation—high-resolution anterior segment ultrasound biomicroscopy in the former case and a variety of new automated refractors and wavefront analyzers in the latter. Automated devices have yet to be standardized, however, and there appears to be no consensus as to the best objective means for determining true accommodative function. As a result, distance defocus curves have become an accepted tool for measuring the accommodative and pseudoaccommodative effects of IOLs. In fact, this system was employed for the FDA approval of the Array multifocal lens (Advanced Medical Optics, Inc., Santa Ana, CA). This method appears to be the most useful until such a time as objective tools are standardized and widely accepted (Figure 1).

## DESIGN CONCEPTS FOR ACCOMMODATING IOLs

### Single Fixed Optic, Flexible Haptic Support System

In accordance with the Helmholtz theory, one concept for an accommodating lens design (and the simplest) would be a fixed-power single optic with a dynamic, flexible haptic support system. The flexible haptic would allow the optic to move anteriorly during the accommodative effort and thereby increase the effective power of the lens. Such a design system is currently employed in the Crystalens (Eyeonics, Inc., Aliso Viejo,

(Courtesy of Visiogen, Inc.)

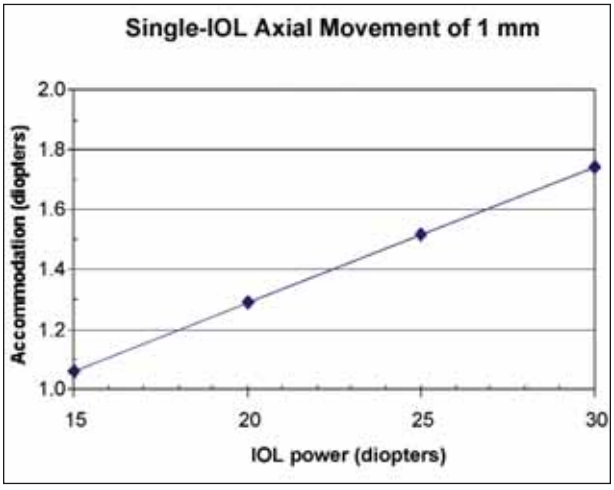



**Figure 3. This chart reveals the degree of accommodation generated by anterior movement of the IOL. Note that higher dioptric powers induce greater accommodation than do lower-powered lenses of this design.**

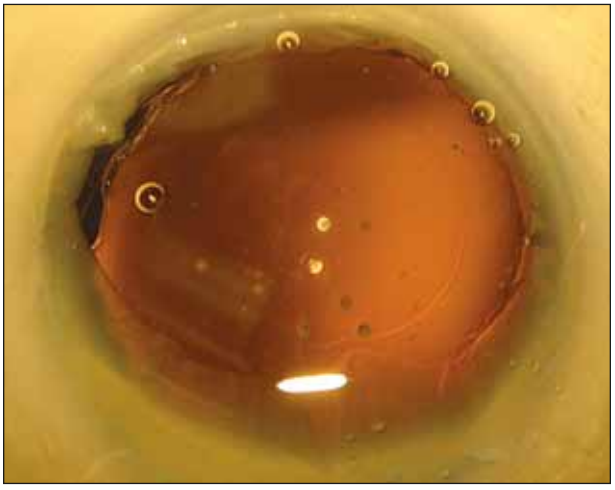


**Figure 4. A SmartIOL filled the capsular bag of an autopsied human eye. After implantation through a 3-mm incision, the cornea was excised, revealing a 6-mm capsulorhexis and a well-centered implant.**

## ACCOMMODATING IOLs IN DEVELOPMENT

**Sarfarazi Twin-Optic Elliptical Accommodating IOL (Bausch & Lomb Surgical, Rochester, NY)**

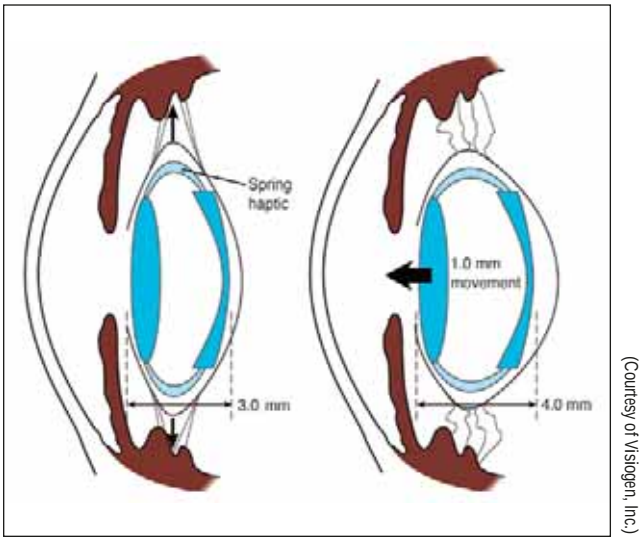
- Designed to mimic the optical changes of the crystalline lens during accommodation
- Dual-optic design features a positively powered anterior lens joined to a negatively powered posterior optic
- Foldable
- Human implantation has been scheduled

**[A developmental accommodating IOL] (Quest Vision Technologies [Tiburon, CA], and Advanced Medical Optics, Inc. [Santa Ana, CA])**

- Has been implanted in primate and cadaver eyes; no human implantations to date
- Has myopic configuration in the resting state and an anterior position in the accommodative state
- Being tested in both near and distance vision resting states
- Features a balloon-shaped haptic that is shaped like the capsular bag
- During disaccommodation, the zonules pull the capsule so that the lens flattens

**Kellan Tetraflex IOL (Lenstec, St. Petersburg, FL)**

- Made of hydroxyethylmethacrylate with a UV filter
- Haptic design facilitates movement of the optic
- Injectible through a 1.6-mm cartridge
- Features a 5.75-mm optic with square edges
- Currently being implanted throughout Europe and the Middle East
- CE Marked as a posterior chamber aphakic lens
- Available in + 5.00 to + 36.00 D




(Courtesy of Visiogen, Inc.)

**Figure 5. This concept for an accommodating IOL system uses dual optics in a truly telescopic design. During rest (left), the optics are close together, and the "springs" maintain potential energy. With accommodation (right), the springs exhibit kinetic energy, and the optics separate, thus increasing the optical power of the lens system.**

CA), which the FDA recently approved for implantation. The lens is made of silicone with a 1.43 index of refraction, has a 4.5-mm optic, and features grooved plate haptics. In the investigational FDA clinical trials, the Crystalens allowed approximately 70% of the subjects to remain free of spectacles (Figure 2).

Similar devices have been used in Europe. One is the Akkommodative 1CU lens (HumanOptics AG, Erlangen, Germany), which is made of a hydrophilic acrylic material. A number of similar lens designs are under consideration at this time.

## EXPECTATIONS

It is worth mentioning that matching the expectations of patients is difficult with any IOL but with pseudoaccommodating IOLs in particular. People's demands of the early accommodating IOLs are likely to be unrealistic. Although sophisticated in their knowledge, patients often misunderstand the state of the art regarding IOLs. They have been influenced by the hyperbole surrounding LASIK correction, and they expect to fully eliminate their spectacle use after lens-related surgery. Ophthalmologists must be careful in dealing with unrealistic expectations regarding the optical outcomes of surgery, including spherical, toric, and accommodative visual function.

One drawback to this design concept is that lenses of lower power will generate less accommodation with anteroflexion than will higher-powered IOLs. Figure 3 demonstrates a considerable difference in the achieved increase in IOL power with higher-dioptric lenses and 1 mm of anteroflexion. In addition, it has recently been suggested that lenses of this design characteristically move less than 1 mm anteriorly upon accommodative effort, as determined by ultrasound biomicroscopy.[1] Although simple in design, IOLs of this type are unlikely to be successful over a wide range of dioptic powers. In addition, the flexibility of the capsular bag remains an important aspect of performance for this lens design.

(Courtesy of Visiogen, Inc.)

**Figure 6. The Visiogen Synchrony IOL.**

### Dynamic Optic

Another accommodative IOL concept is a dynamic optic that increases power but maintains its position with accommodation. This design requires flexibility of the optic. One example, the SmartIOL (Medennium, Inc., Irvine, CA), consists only of a full-sized, 9.5-mm diameter by 3.5-mm optic made of a thermodynamic, hydrophobic acrylic material. This IOL is designed to fill the entire capsular bag (Figure 4). Accommodative forces are transmitted to the capsular bag from the ciliary body and, in turn, to the pliable IOL. With accommodative effort, the lens increases its anterior/posterior dimension, thus increasing optical power.

The SmartIOL requires continued flexibility of the capsular bag. Considering the nature of the lens' hydrophobic acrylic material, its tacky surface, and the fact that it fills the capsular bag, however, it seems likely that the amount of posterior capsular opacification and capsular fibrosis will be limited. Another feature of this lens, given its flexibility and thermodynamic properties, is that it will be implantable through a 3-mm incision, although the IOL is equivalent to the size of the normal human lens.

A second dynamic optic lens, the Power Vision IOL (Power Vision, Santa Barbara, CA), does not change position within the eye during accommodation. Based upon the use of applied microfluidics, this lens—theoretical at this time—has a peripheral fluid reservoir. Upon accommodative stimulation, an actuator triggers microscopic pumps to move fluid from the periphery to the center of the lens, thereby increasing its anterior/posterior dimension and, hence, its optical power. As accommodation relaxes and the stimulus to near vision decreases, fluid is pumped back from the central to the peripheral aspect of the IOL, thus altering its optical power to the distance mode.

Although lenses with a single, dynamic optic have yet to be implanted in humans, they are likely to achieve a greater degree of accommodative power than lenses with a fixed-power optic and flexible haptics.

### Dual Optics

With a dual-optic, telescoping IOL, spring-like haptics separate a high-plus anterior lens from a posterior minus lens (Figure 5). The one-piece, dual-optic lens rests within the capsular bag. In the nonaccommodative phase, the tension of the capsular bag and zonules keeps the two optics in close proximity while the spring devices are collapsed and

### MULTIFOCAL IOLs

Until recently, the Array (Advanced Medical Optics, Inc., Santa Ana, CA) has been the only multifocal IOL available for use in the US. This pseudoaccommodative lens is considered to be a zonal progressive multifocal. Because light energy is divided between distance and near, the patient experiences a loss of contrast sensitivity and a reduction in vision quality resulting from halos and glare. For this reason, the IOL has not achieved a large market share, although it is available worldwide. A recent meta-analysis of the literature suggested that slightly fewer than 50% of patients implanted with this device are able to maintain spectacle-free vision for all ranges and that many experience some degradation of vision quality.[1] Although other pseudoaccommodating IOL designs are under FDA investigation at this time, the limits of this form of technology cannot be ignored, and lenses that provide a full range of accommodation and high-quality vision will likely supercede pseudoaccommodating IOLs.

1. Leyland M, Zinicola E. Multifocal versus monofocal intraocular lenses in cataract surgery: a systemic review. *Ophthalmology.* 2003;110:1789-1798.

exhibit potential energy. With accommodative effort, the zonules relax, the capsular bag expands, and the springs express kinetic energy. This change allows the optics to separate as the anterior plus lens moves forward, thus producing a higher optical power that yields accommodation.

Visiogen, Inc. (Irvine, CA), has developed the Synchrony IOL, a dual-optic, single-piece, silicone device with an index of refraction of 1.43 (Figure 6). This lens has been implanted in approximately 60 eyes outside the US and appears to generate 2.50 D of accommodation, as measured by distance defocus curves.[2] It will enter US FDA clinical trials this year.

## CONCLUSION

All ocular surgeons await the development of a surgical method for replacing the aging crystalline lens with a polymer that behaves exactly like the juvenile human lens without compromising the capsular bag's clarity and flexibility. While the creation of those polymers is underway, some of the IOL designs described in this article will move patients toward the goal of spectacle independence and establish lens-related procedures as the dominant form of refractive surgery. ■

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## CRYSTALENS: ONE YEAR AFTER APPROVAL

**By John F. Doane, MD, FACS**

During the first year after the FDA approved the Crystalens Accommodative IOL (Eyeonics, Inc., Aliso Viejo, CA), 13,000 lenses have been implanted in the US. Interestingly, 25% of this number were implanted in November and December 2004, a fact that suggests the lens' growth potential. Currently, there are 140 ophthalmologists in the US who are fully credentialed to implant the IOL in patients. The average selling price for the Crystalens procedure, including lens implantation and cataract removal, is approximately $4,500, a figure that requires patients to pay an out-of-pocket premium beyond the surgical fee covered by their insurance companies. To date, Medicare beneficiaries have not been candidates for Crystalens implantation because they cannot pay out of pocket for a surgical upgrade. Discussions are ongoing with the Centers for Medicare and Medicaid Services about the organization allowing beneficiaries to upgrade to this technology at the beneficiaries' expense.

Eyeonics, Inc., plans to maintain its current business model of marketing the Crystalens as an out-of-pocket elective procedure. Based on the current figures, the retail gain for practitioners using the lens is as follows: 13,000 lenses implanted at the average retail price of $4,500 equals approximately $58.5 million. Dividing that figure by 140 fully credentialed clinical sites means approximately $420,000 of revenue per site. Thus, the Crystalens' business model has the potential to generate a substantial profit for ophthalmic practices.

The company expects the lens' adoption rate to increase. It has nine credentialing courses scheduled for 2005 and also requires onsite credentialing, where practitioners must bilaterally implant 20 eyes of 10 patients under close proctoring.

### PERFORMANCE REVIEW

Many surgeons are interested in the Crystalens' 3-year FDA results. The 3-year data for distance UCVA shows that 100% of the 124 recipients have maintained acuities of 20/40 or better, 97.1% see 20/25 or better, and 88.6% see 20/20 or better. According to the near UCVA results, 100% are at J3, 91.4% see J2, 77.1% are at J1, and 25.7% see J1+. The bilateral distance-corrected intermediate vision results are 100% at J1 and 97.1% at J1+. These results are culled from 12 centers and 17 surgeons who participated in the FDA clinical trial.[1]

In a nutshell, the Crystalens Accommodating IOL attempts to provide distance, intermediate, and near vision. In the 3-year study, more than 90% of the patients achieved 20/25 or better bilateral UCVA for distance, nearly 100% attained 20/25 or better J1 for intermediate vision, and more than 70% achieved bilateral near UCVA with an ability to read J1 at 12 to 36 months after implantation.

The company intends the Crystalens to add value to ophthalmologists' treatment options, and its fast adoption rate in the last 2 months of 2004 signals that clinicians recognize its worth.

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1. Data available from Eyeonics, Inc.

# Measuring Pseudophakic Accommodation

*An evaluation of available methods.*

**BY CAMERON F. PARSA, MD**

Accommodation is but one component of the synkinetic near reflex triad, which also comprises convergence and miosis. It is important to remember this triad when attempting to measure accommodation as well as to recognize that blocking convergence (eg, by monocular occlusion) decreases both accommodation and miosis.[1] Whereas the ability to accommodate decreases with age, miosis increases as a result of decreased sympathetic activity while convergence remains relatively unchanged. This article evaluates available subjective and objective methods for measuring accommodation.

## DONDER'S "PUSH-UP" METHOD

Although this subjective method is historically considered to identify the near point of accommodation, it more accurately measures the near depth of field, which is dependent on a variety of factors and not accommodation alone. Donder's method could more precisely be described as providing a means for determining the near point of acuity rather than of accommodation.

An individual's depth of field, in addition to his accommodative ability, depends on varying pupil size (both as a part of the reflex triad and in response to light) and on the eye's inherent optical aberrations and multifocality. The diameter of the entrance pupil is equally important as the amount of dioptric defocus in the formation of blurred ocular imagery, and one must account for the former when making any assessment of a patient's depth of focus.[2] Even eyes with perfectly centered, monofocal, pseudophakic lenses may demonstrate significant multifocality as a result of corneal effects.[3] Depth of field and near visual acuity also depend significantly on neural processing, an effect not yet fully understood or quantifiable but important in final image appreciation.[2] For instance, neural processing may sometimes select the least blurred image presented to the retina rather than the image of highest contrast.[4]

"Donder's method could more precisely be described as providing a means for determining the near point of acuity rather than of accommodation."

## OBJECTIVE MEASURES OF TRUE ACCOMMODATION

### Dynamic Retinoscopy

Although first described by Edward Jackson, MD,[5] in 1895 and despite being simple to perform, dynamic retinoscopy is nonetheless fairly unfamiliar to most ophthalmologists.[6-10] This technique should not be confused with near retinoscopy, which may be used to measure distance refraction rather than accommodation.

Using an ordinary retinoscope, when the examiner observes the retinoscopic reflex of a distance-corrected eye without additional lenses, "with" movement is observable. When the patient switches fixation from distance to an object placed beneath the peephole of the retinoscope, the beam broadens to neutralization as full accommodation occurs. Near targets placed close to the patient in front of the retinoscope produce "against" movement (Figure 1).

Dynamic retinoscopy readily detects the degree and speed of accommodation as well as the presence of irregular light reflexes due to corneal or lens aberrations' inducing multifocality.

### Infrared Optometers Using the Scheiner Principle

Because infrared optometers provide refractive measurement through only a small portion of the eye's optics, the alignment of the various measuring apertures with the patient's pupil is critical. Sampling only a small portion of the pupil for the refractive measurement means that small amounts of optical irregularities that are present may render the results unrepresentative of the eye's optics as a whole.[11]

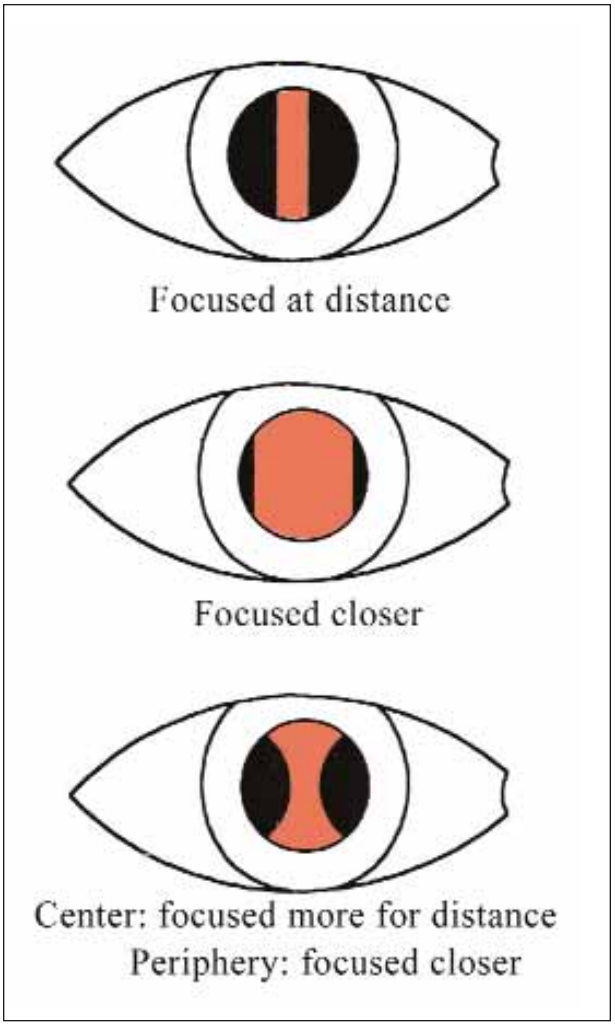


**Figure 1. "With" movement of the retinoscopic red reflex is observable when a patient wearing distance correction looks at a distance fixation target (top). As the patient switches fixation to a closer target, the reflex broadens. If the target is placed just below the retinoscope's peephole, neutralization occurs when accommodation is complete (middle). If spherical aberration is present, multifocality is observable; the central, narrower part of the red reflex indicates rays more focused for distance whereas the broader, peripheral portion is more focused for near (bottom).**

Newer versions of infrared optometers use photoretinoscopy (such as the PowerRefractor[12] [PlusOptix, Nürnberg, Germany]). They offer the advantage of rapidly measuring the refraction at distance as well as binocularly. These instruments calculate an average refraction for the entire pupil, however, and do not provide any information on multifocality. Because devices are calibrated for the smaller amount of aberrations present when the lens is in a relaxed state, they underestimate the degree to which accommodation increases the amount of aberrations.[13]

### Wavefront Analysis

Wavefront calculations have demonstrated that Donder's push-up method may have identified as accommodation what could be attributed to corneal multifocality induced by surgery in some pseudophakes.[3] Devices based on the principle of Hartmann-Shack aberrometry are now available for clinical use. They measure the shape of the wavefront of light as it exits the eye from an effective point source on the retina. These aberrometers are able to determine multifocal refractive states across the pupil,[14] both before and during accommodation, and the difference in these values is the exact measure of true accommodation. Best results are obtained with a large, dilated pupil,[15,16] such as is achieved through the administration of phenylephrine without affecting accommodation.[17]

Using Hartmann-Shack aberrometry, researchers have demonstrated small but significant degrees of accommodation in patients who recently received hinged, accommodating IOLs.[18]

## CONCLUSION

Several investigators have emphasized the importance of selecting the appropriate test for the variable to be measured, be it optical image quality, optical image appreciation, or actual accommodation.[7,19,20] Although related, these terms designate distinct entities. For example, multifocality affects optical image quality, whereas neural processing (both retinal and cortical) strongly influences optical image appreciation.[2,4]

In order to measure a dynamic process such as accommodation, the clinician must employ a test that measures the dynamic change that occurs within the eye as opposed to image or acuity appreciation endpoints, which are multifactorial. Without the ability or means to control for other factors involved in acuity (eg, variation in pupil size, multifocal optics, neural processing), attempts to measure accommodation through acuity testing will be unreliable. At present, dynamic retinoscopy is the most readily available, reliable, and practical objective

method for assessing accommodation, although it is difficult to quantify. The recent availability of Hartmann-Shack aberrometers for performing wavefront analysis adds an objective, quantitative, and observer-independent tool to clinicians' armamentarium. ■

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