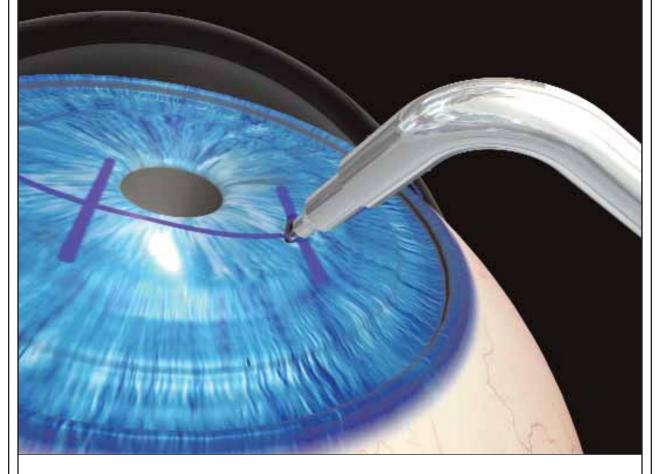
NearVision CK Pearls and pitfalls for managing presbyopia.



n 2002, Refractec, Inc. (Irvine, CA) made its conductive keratoplasty radiofrequency procedure, NearVision CK, widely available to refractive surgeons in the US. Originally FDAapproved to treat hyperopia, the technology initially suffered low adoption rates

due to its seemingly limited applications and delayed "wow" factor. Today's NearVision CK is a very different procedure, thanks to the new LightTouch technique that helps make it easier to perform and delivers more reproducible, immediate results. The procedure is finding its niche as a fast, effective, low-risk refractive technology for a wide range of applications, from presbyopia and astigmatic correction to postsurgical rescues and enhancements.

As part of a lively cocktail reception hosted at the famed Tao restaurant in Las Vegas during the 2006 AAO meeting, a panel of experienced surgeons described how NearVision CK is helping them grow their practices by serving an array of refractive and cataract patients. The following monograph is based on the presentations from that evening. Those considering adding CK to their clinical services will find a wealth of relevant information.

-Richard L. Lindstrom, MD

CK: A Versatile Tool for the Modern Practice

How I position this procedure now.

BY RICHARD L. LINDSTROM, MD

Since NearVision CK (Refractec, Inc., Irvine, CA) was first approved by the FDA for hyperopia in 2002, more than 150,000 procedures have been performed. Many clinicians do not see the value in this technology, but others use it for a wide range of indications. Although my early experience with NearVision CK was mixed, I have since fit the procedure into my practice and now consider it a versatile and valuable treatment option. I want to encourage other surgeons to take a second look at this procedure.

A SLOW START

I was involved in the early FDA clinical trials for CK to treat hyperopia, and I consult for Refractec, Inc. After the CK trials concluded, my partners and I at Minnesota Eye Consultants struggled to position the procedure in our practice. CK certainly had a spectacular safety profile, and it worked well for low levels of hyperopia; however, I achieved better hyperopic outcomes with the excimer laser. Eventually, we used CK to treat hyperopes who had dry eyes or thin corneas that excluded them from LASIK surgery. My partners and I have since discovered that CK is a versatile tool that has many applications for select groups of patients.

CK'S VERSATILITY

A Presbyopic Treatment

As ophthalmologists learn more about presbyopia, many are using NearVision CK as a form of blended vision to treat these patients. Patient awareness about presbyopic treatments is still developing, and most presbyopes simply buy a cheap pair of over-the-counter reading glasses instead of exploring surgical treatments. My colleagues and I are happy to perform NearVision CK for presbyopia, we just have not had many patients requesting it. We have been treating many more myopia, hyperopia, and astigmatism patients than presbyopes. This trend is starting to change, however, thanks to the recent ruling by the Centers for Medicare and Medicaid Services on presbyopia-correcting IOLs as well as nation-

TABLE 1. NEARVISION CK'S SAFETY PROFILE

- · Unsurpassed safety profile; no loss of BCVA
- No induction of dry eye
- No weakening of structural integrity of cornea
- No lawsuits to-date

Safety data from Presbyopia Study	Mo 12	Mo 24
Loss ≥ 2 lines BCVA-D or -N	0%	0%
BCVA-D worse than 20/40	0%	0 %
 Increase > 2,00D cyl 	0%	0 %
• Pre-op BCVA-D ≤ 20/20 to > 20/25	0%	0%
BCVA-N worse than J3	0 %	0 %

wide marketing efforts put forth by ophthalmologists and IOL manufacturers. Physicians in many markets are seeing more patients seeking an alternative to drugstore reading glasses, and I am happy to have CK to offer presbyopes. I believe CK gives most emmetropic presbyopes a good outcome with the best risk/benefit ratio of any presbyopia-correcting treatment currently available (Table 1).

A Rescue/Enhancement Procedure

A lot of ophthalmologists are now offering presbyopia-correcting IOLs, and every so often, we must rescue an eye that underresponds to a near vision correction. NearVision CK is a great tool for such a rescue procedure because it enhances near vision with the smallest impact on distance vision and has an exceptional safety profile. My partners and I also perform CK enhancements over previous LASIK procedures. As I mentioned, we also occasionally treat hyperopes whose corneas are either too dry or too thin for hyperopic LASIK.

Astigmatic Treatments

I find CK to be such an effective tool for correcting astigmatism that I have suggested that the company explore and develop this application further. Many surgeons

TABLE 2. RESULTS OF A SMALL SERIES OF CK-A PATIENTS

- 10 patients
- 2 spots at 7-8mm optical zone on flatter meridian (operating microscope ring mire)
- Range of effect: 0.50-2.00D (6-18 months postoperatively)
 - Mean effect: 1.10D
- Complications: None
- Conclusion: CK-A effective in reducing postcataract surgery astigmatism

do not like performing corneal relaxing incisions because they are invasive and somewhat unpredictable. As an alternative, they can charge an extra fee and correct astigmatism with CK intraoperatively during refractive lens surgery (*see*, Intraoperative CK for Astigmatism). CK can also be used to treat mixed and hyperopic astigmatism postoperatively (Table 2). In some patients, I have combined CK with Intacs (Addition Technology Inc., Des Planes, IL) to treat early keratoconus. In this procedure, I round the cornea with CK to reduce the astigmatism, treat with Intacs, and then sometimes treat residual refractive error with PRK. CK can also be somewhat effective as an enhancement tool with multifocal IOLs when astigmatism persists after surgery.

To treat astigmatism with CK, I place two treatment spots, with one on each side of the flattest meridian, which will easily correct 1.00D of astigmatism at minimal risk to the patient. If the astigmatism is still undercorrected, I add more spots. I find the LightTouch technique (explained later in this monograph) most effective.

NearVision CK FOR VISUAL FUNCTION

I almost always start a NearVision CK procedure with an eight-spot treatment, or else two spots for astigmatism. Another reason I continue to use CK is that it enhances patients' visual function, not just their refractive error. In fact, if I use CK in the nondominant eye for near, a little bit of cylinder is OK—it increases depth of focus. I do not readily advocate the Strauss loose lens test where a +1.25D loose lens is placed over the nondominant eye in an

INTRAOPERATIVE CK FOR ASTIGMATISM

My partner, Elizabeth Davis, MD, has used CK intraoperatively to treat astigmatism on a series of patients. She starts the operation by treating the astigmatism with two spots of CK at the 8-mm optical zone in the flatter meridian. She marks the flatter meridian using gentian violet and an 8-mm RK marker. Dr. Davis then performs phacoemulsification. She has achieved excellent outcomes so far. attempt to simulate the effect of CK. I found that it poorly represents CK. I have been searching for a preoperative trial that better simulates CK's effect, and the answer may be placing a PureVision multifocal contact lens (Bausch & Lomb, Rochester, NY) on the eye with a +0.50D power and a +1.00D add. I suggest this approach for surgeons whose patients have been scared away from CK by the Strauss loose lens test.

PATIENT COUNSELING AND FOLLOW-UP

Surgeons are growing more comfortable with setting realistic expectations for patients regarding the current technologies available for presbyopia. Myopic LASIK's outcomes are extraordinary: patients are happy on the first day after surgery. Surgeons who implant multifocal or accommodating IOLs know that this refractive approach does not produce immediate results, and that patients and physicians may have to work a little harder at their visual recovery. Because CK also has a longer visual recovery period than LASIK, patients must be advised of this preoperatively so that they are comfortable with the postoperative recovery time frame.

Because the effect of NearVision CK takes a few weeks to stabilize, patient follow-up can be lengthier than for other treatments. Although we still see CK patients on the first postoperative day, this appointment is more for the patient's peace of mind, because safety is not an issue with these patients. After the 1-day follow-up, however, I do not see CK patients again until 4 to 6 weeks postoperatively. Again, it is important to explain to the patient that his or her vision may still be adjusting at 2 to 3 weeks after a CK treatment.

AN ONGOING TREATMENT

Patients and physicians alike must understand that NearVision CK is a titratable procedure. When I first started performing CK, I visited Antonio Mendez, MD, in Tijuana, Mexico, to learn about his experience with the procedure. His best advice was to perform CK titratably. He suggested first delivering a reasonable treatment that would satisfy the patient initially, but to set the patient's expectations to receive enhancements. You are not going to perform CK in an eye only once in the patient's lifetime. As patients age, their presbyopia will worsen, their astigmatism may change, and they will need additional treatments. I tell my presbyopic patients that a single CK treatment will let them read comfortably for 1 to 3 years, after which they may need an enhancement. Nevertheless, the procedure is so easy and its safety profile is so high that most patients are quite comfortable with its titratable nature. As an ongoing treatment option, NearVision CK can be a good value for patients and surgeons.

(Continued on page 52)

Building a Presbyopic Practice

Setting the stage for comprehensively managing the presbyope.

BY H. L. "RICK" MILNE, MD

he stage is now set for US ophthalmologists to become presbyopic surgeons. With multifocal implants debuting under a lot of media attention, many presbyopes are asking their ophthalmologists how they can rid themselves of reading glasses. Having implanted approximately 750 multifocal IOLs, I do not think these lenses are a good starting point for the plano presbyope. Because it is minimally invasive and has a superb safety record, NearVision CK (Refractec, Inc., Irvine, CA) is an excellent introductory surgical procedure for this demographic.

SUCCEEDING WITH NEARVISION CK

I have positioned my practice to serve presbyopes by continuously advertising these services in my community (my staff and I use all forms of media in which we always identify ourselves as a presbyopia-focused practice). Because of this approach, we had 100 patients on a waiting list for the multifocal implants before they gained FDA approval.

To embrace NearVision CK correctly, you first have to understand what it can and cannot do. I use it to treat hyperopia (up to +1.50D), emmetropic presbyopes, and in the eyes of patients who have previously undergone LASIK and now want to regain some near vision. NearVision CK also works well as a rescue procedure for patients who have multifocal implants and are unhappy with +1.00 or +0.75D residual refractive error.

Second, you must market NearVision CK, and my staff and I do this primarily internally. I tell my patients about the vision my wife and I have after undergoing NearVision CK. I still have J1+ vision in my right eye after undergoing CK almost 3 years ago. Also, my staff and I encourage our happy NearVision CK patients to brag to their families and friends about their outcomes, and we get many referrals that way. In addition, my staff focus on delivering good customer service by trying to overdeliver on what outcome we have told the patient to expect.

Furthermore, some of our former LASIK patients are now emmetropic presbyopes, and it is interesting how

many of them embrace this procedure. In particular, many myopes whom I treat with LASIK return a few years later because they are now presbyopic. When I offer these patients the choice of a laser enhancement or NearVision CK, most choose CK.

MANAGING THE PRESBYOPE

When evaluating presbyopic patients for a NearVision CK treatment, you must know their history, particularly whether they have undergone a laser vision correction or other ocular procedure. Then, I discuss their available corrective options. I show them a picture of how the eye works and explain that their crystalline lens is aging and will continue to age. I present the option of either treating their crystalline lens or trying a less expensive corneal procedure on just one eye that would restore their near vision without significantly compromising their distance vision (NearVision CK disrupts distance vision less than laser monovision treatments and contact lens wear¹). Most patients choose NearVision CK, knowing that they will need a multifocal implant in the future. At least 10 patients whom I treated 4 years ago with NearVision CK now have multifocal implants.

When patients choose NearVision CK, I make sure they understand that they will need future retreatments and eventually other corrective procedures as their eyes continue to age. I describe their options for future treatments, including laser procedures, NearVision CK, and multifocal implants. I explain that I offer a substantial discount for future procedural upgrades. A significant percentage of presbyopes elect subsequent NearVision CK treatments.

MY NOMOGRAM

In general, I use laser vision correction on patients aged 18 to 55 who fit that procedure's parameters. NearVision CK suits 45- to 60-year-olds who have a refractive error of between -0.75 to +1.00—that is NearVision CK's "sweet spot" for happy patients. I use IOLs in patients over the age of 55 or whose refractions are more than +6.00D or -6.00D.

THE LIGHTTOUCH TECHNIQUE

The proper technique is important with NearVision CK. I do not prefer the term *LightTouch*, because many surgeons do not apply enough pressure when delivering the NearVision CK treatment spots and actually pull the probe away from the eye during the procedure. The key is to use consistent and equal amounts of pressure with each radiofrequency (RF) pulse delivered. I also dry the cornea very well before I begin the treatment, because a meniscus of fluid on the corneal surface can make it difficult to tell how much I am indenting the cornea when I apply the RF pulse. A dry cornea makes the striae more visible.

To start, I push the CK probe firmly into the cornea, then I release the pressure. I press in a few more times, and then I try to stop the probe at a 2-mm indentation. Once the RF energy discharges, the cornea will contract away from the probe slightly. Unfortunately, I have seen surgeons pull the probe away as the cornea starts contracting, which causes the procedure to regress significantly. Keeping the probe depressed throughout the pulse will deliver the treatment at full depth.

PERFORMANCE

I performed a retrospective study of the 12- to 18month data of 81 patients I treated with LightTouch. The eyes that received eight spots at 8mm had a 0.75D effect at both 6 months and 1 year. Their loss of effect from 6 to 12 months was 0.25D, but their near visual acuity was still better than J2 at 1 year. The eyes that received eight treatment spots at 7mm had an effect of 1.50D at 6 months and 1.30D at 12 months, with a visual acuity of better than J2 at 12 months. The eyes that received 16 treatment spots (eight at 7mm and eight at 8mm) had 2.00D of effect at 6 months, 1.75D at 12 months, and also saw better than J2 at 12 months (Table 1). As my LightTouch nomogram continues to evolve, these are the outcomes I have come to expect at 1 year after an initial NearVision CK treatment.

I was interested to learn how many patients I had to retreat with CK for additional near vision between the 6and 12-month period. The total number was 10% of those 81 patients, which I think is a fair representation of enhancement rates during this time period. Some of the retreatments were necessary because, after the LightTouch technique first debuted, I pressed the probe too lightly and inadvertently undertreated some eyes.

USING NEARVISION CK BEFORE AND AFTER IOLS

With refractive and especially diffractive implants, if the postoperative refraction is not within 0.50D of the target, the patient will likely be unhappy. If the patient does not want to spend the extra money to correct a multifocal

TABLE 1. THE AUTHOR'S LIGHTTOUCH NOMOGRAM Chart rev. Chart rev. LightTouch nomogram 6 months 12 months 8 @ 8 mm 1.00 D 0.75 D 0.75 D 8 @ 7 mm 1.75 D 1.50 D 1.30 D 16 (7, 8 mm) 2.25 D 2.00 D 1.75 D

implant, I suggest the Presbyoptics procedure developed by Y. Ralph Chu, MD, of Edina, Minnesota. Presbyoptics involves performing NearVision CK after an IOL implantation so as to leave the patient slightly hyperopic in his distance eye and slightly myopic in his near eye. CK is then performed to give the cornea a multifocal effect on top of these monofocal IOLs. This procedure produces a highly satisfactory effect and is less disruptive to the patient's distance vision than monovision with implants.

IOL CALCULATIONS AFTER NEARVISION CK

To date, I have performed refractive IOL implantation on a small number of my patients whom I previously treated with a NearVision CK procedure. In data from a small set of these patients, eight of the nine eyes achieved outcomes within 0.60D of their expected final refractive error. I use the IOLMaster (Carl Zeiss Meditec Inc., Dublin, CA) with no variations to calculate patients' treatments. I am completely confident in this device. The Pentacam (Oculus, Inc., Lynnwood, WA) was designed for eyes that underwent a myopic treatment, not a hyperopic one.

SUMMARY

I am pleased to offer NearVision CK to patients. People are comfortable with the procedure, and it has a high satisfaction rate for restoring near vision and also rescuing other procedures. For now, NearVision CK is a threshold procedure—it gets risk-averse individuals into the practice for a high-benefit, low-risk surgery. Ophthalmologists need to let patients know that NearVision CK is available as part of an expanding armamentarium of presbyopic treatments.

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NearVision CK: A "Utility Player" for Treating Presbyopia

How I am growing my presbyopia practice with this procedure.

BY MICHAEL GORDON, MD

Some refractive procedures can be called *utility* players, because they fill various roles and pinch hit when other treatments falter. I consider NearVision CK (Refractec, Inc., Irvine, CA) a utility player. In addition to being my treatment of choice for plano presbyopes, NearVision CK is also an effective postoperative rescue procedure for presbyopic, LASIK, IOL, and astigmatic patients.

RETURNING TO CK

In my comprehensive refractive practice in San Diego, I have performed over 20,000 LASIK procedures and was one of the first surgeons in the US to use NearVision CK. When it debuted in 2002, CK was a different procedure than it is now. Inserting the probe into the cornea required more pressure than today's LightTouch technique. At the time, I was biased against thermokeratoplasty, and I was unimpressed by the original procedure's results.

Approximately 2 years ago, I started to think more about presbyopia's potential market, and I wanted to expand my presbyopic treatments. At the same time, early results with the LightTouch technique were being presented, and I realized that NearVision CK is the safest procedure performed in ophthalmology. The

TABLE 1. POST-LASIK CLINICAL TRIAL RESULTS: SAFETY			
	1 Month n = 63	3 Months n = 60	
Loss of >2 Lines BSCVA-D	0%	0%	
BSCVA-D worse than 20/40	0%	0%	
Preop BSCVA-D ≤20/20 to >20/25	0%	0%	
Increase >2.00 D cylinder	0%	0%	

"I realized that NearVision CK is the safest procedure performed in ophthalmology."

LightTouch technique increases the procedure's predictability and stability.

FOCUSING ON PRESBYOPIA

Consider the typical baby boomer who underwent LASIK surgery 10 years ago because he was enamored with the idea of not having to wear glasses. He is now 50 years old and can no longer read unaided. The surgeon must weigh his options. Relifting the patient's LASIK flap raises myriad considerations: Is the flap large enough? Will the hinge be damaged? Should the flap be lifted or cut? Should the eye receive a surface treatment? If this is a cataract patient, should the surgeon implant an IOL, implant piggyback lenses, or perform a lens replacement? All of these options carry significant risks. NearVision CK is the simplest, safest, and probably the most effective option available, and as a comprehensive refractive surgeon, I wanted to have every presbyopia-correcting tool available to offer my patients.

I also had to re-examine my knowledge and beliefs about presbyopia and remember that the disease is progressive. Many presbyopes are plano or latent hyperopes who become manifest hyperopes. For example, a person treated for presbyopia with NearVision CK at age 45 may not be able to read unaided by age 50. His degradation does not mean that the CK procedure undercorrected or regressed, but simply that the individual's latent hyperopia has become manifest. Thus, treating presbyopia becomes an investigative process for the surgeon: is the patient suffering from surgical regression or disease progression? Is his or her latent hyperopia becoming manifest?

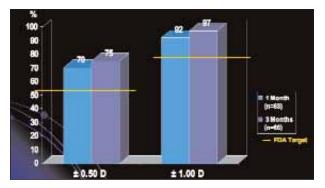


Figure 1. Post-LASIK clinical trial results: predictability of MRSE $\pm 0.50D$ and $\pm 1.00D$.

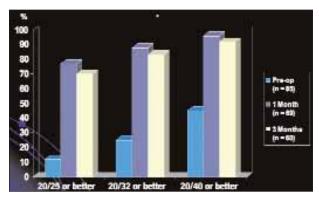


Figure 3. Post-LASIK clinical trial results: UCVA-intermediate (MN read).

"GETTING-AROUND" NEAR VISION

When my patients ask what their vision will be like after a NearVision CK procedure, I talk to them about functional near vision. "Getting-around" near vision, as I call it, does not mean patients can read a book 8 hours straight, but it allows them to read a menu in a restaurant and view a golf scorecard, their computer screen, wristwatch, cell phone, and their automobile's dashboard. A high percentage of NearVision CK patients achieve functional "getting-around" near vision.

CLINICAL TRIAL: POST-LASIK PATIENTS

Although I have been treating post-LASIK presbyopes off-label with NearVision CK for 2 years with great success, Refractec, Inc., is seeking expanded FDA labeling for NearVision CK to treat post-LASIK presbyopes. I am participating in this prospective, multicenter clinical trial that involves 150 eyes of 150 emmetropic presbyopes who had previously undergone myopic LASIK surgery. These patients' MRSEs must be \pm 0.50D, and their original myopic corrections had to be between -1.00 and -6.00D. Their residual pachymetry had to be greater than 400µm centrally and greater than 560µm peripherally. We have targeted 1.25D of add via an eight-spot

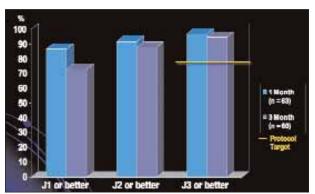


Figure 2. Post-LASIK clinical trial results: UCVA-near.

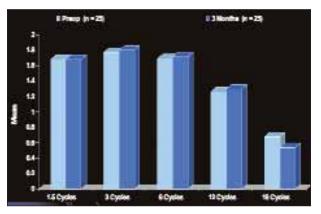


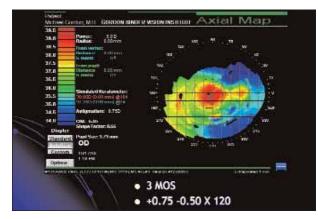
Figure 4. Post-LASIK trial results: mesopic contrast sensitivity.

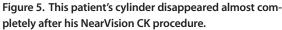
treatment at 8mm (these parameters give the best effect in postoperative corneas). The patients' ages ranged from 41 to 63 years. The mean time between their LASIK surgeries and their CK surgeries was 5.1 years, and their mean pre-LASIK MRSEs were -3.38D.

Interim results show that the procedure's safety results are excellent. By 3 months (n=60), no patient had lost more than two lines of distance BSCVA or had distance BSCVA worse than 20/40. No patient with better than 20/20 vision preoperatively saw worse than 20/25 postoperatively, and none had more than 2.00D of induced cylinder (Table 1). The procedure's predictability (Figure 1) and efficacy exceeded the FDA's targets (Figures 2 and 3). Also, myopic contrast sensitivity both with and without glare showed no statistical difference between preoperative and postoperative measurements (Figure 4).

Patient satisfaction with the procedure was very high. At 3 months, 85% of the CK-after-LASIK patients were either satisfied or very satisfied. More interestingly, they noticed no difference in the quality of their depth perception preoperatively to postoperatively. In summary, patients experienced no adverse effects, they achieved a mean effect of 1.45D \pm 0.536D at 1 month, had no

NearVision CK =





change in contrast sensitivity, and their near vision exceeded all the FDA's targets.

OTHER CK OPPORTUNITIES

NearVision CK represents a tremendous opportunity for physicians in large cataract practices to target patients with monofocal IOLs who desire gettingaround near vision. Another application for CK is treating astigmatism. For this purpose, NearVision differs from laser astigmatic treatments or limbal-relaxing incisions, which relax the steeper meridian. CK instead tightens the cornea in order to steepen the flat meridian. The nomogram is still being perfected, but two spots delivered on opposite sides of the cornea at 9mm seems to effectively treat 2.00D of cylinder.

One particular patient of mine presented with almost 4.00D of cylinder. He had undergone many different refractive surgery procedures since 1997. I treated him with NearVision CK, and his cylinder virtually disappeared. At 3 months, this patient was extremely happy (Figure 5).

NEW SCREENING METHOD FOR CANDIDATES

Traditional screening methods do not accurately convey CK's effect on patients' near vision. Although loose lenses appear to work satisfactorily, patients respond negatively when they hold the lens or look through the phoropter. A contact lens trial can be misleading, because I do not think that a +0.50 or a +1.00D lens does CK justice. A CK patient's topography is much different. Jack Holladay, MD, of Houston studied Pentacam (Oculus, Inc., Lynnwood, WA) images of the corneas of CK patients. He found that the central cornea had less effect, giving the cornea a multifocal, aspheric, prolate shape. David Geffen, OD, a partner in my practice, thought that perhaps this prolate shape had more in

common with a multifocal contact lens than with a single monofocal contact lens. After performing standard visual acuity tests and wavefront aberrometry on 10 patients, Dr. Geffen fitted all with a standard monofocal contact lens and then a PureVision multifocal lens (Bausch & Lomb, Rochester, NY) in their nondominant eyes. After fitting, he repeated the same visual acuity and wavefront tests. Dr. Geffen found that the result with the multifocal contact lens much more closely simulated what the patient would experience with NearVision CK. This is now our practice's standard CK screening tool.

CK IN MY PRACTICE

Last year, I performed 65 NearVision CK procedures, of which 35 were post-LASIK. All of the post-LASIK patients achieved J3 or better and 20/25 or better. My staff and I are now mining our database for post-IOL/post-LASIK CK candidates in order to focus our practice on treating presbyopia. At a time when LASIK volumes are flat or falling, our CK volume increased more than 25% last year. I think this is a safe, effective, useful procedure that benefits surgeons as well as patients.

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(Continued from page 47)

CK FOR THE MODERN PRACTICE

In summary, NearVision CK can be a good procedure for surgeons building a presbyopia practice. One particular selling point is its extraordinary safety profile. I enjoy being able to look patients in the eye and tell them that there is almost no chance that they will suffer an adverse reaction secondary to CK. None of my patients has experienced a significant loss of vision, nor did any patient in any of the clinical trials for CK.

If you think of CK as a titratable, versatile tool, you will likely find a significant number of good candidates in your practice, perhaps between five and 10 per month. CK has a relatively low barrier to entry, and I would personally encourage anyone doing any type of cataract or refractive surgery to try it. I think you will find CK a valuable addition in your practice.

Richard L. Lindstrom, MD, is Founder and Attending Surgeon of Minnesota Eye Consultants and Adjunct Professor Emeritus at the University of Minnesota in Minneapolis. He is a consultant for Refractec, Inc. Dr. Lindstrom may be reached at (952) 888-5800; rllindstrom@mneye.com.