

Treatment of Presbyopia With Conductive Keratoplasty®

Six-Month Results of the 1-Year United States FDA Clinical Trial

Marguerite B. McDonald, MD,* Daniel Durrie, MD,† Penny Asbell, MD,‡ Robert Maloney, MD,§ and Louis Nichamin, MD||

Purpose: To provide 6-month results of a 1-year clinical trial evaluating conductive keratoplasty (CK) for the treatment of presbyopic symptoms in emmetropic and hyperopic eyes.

Methods: A total of 143 patients with presbyopic symptoms were enrolled in this 1-year United States FDA clinical trial and treated to improve near vision in 1 eye (unilateral treatment). In addition, 33 fellow eyes were treated to improve distance vision (bilateral treatment). For near vision correction, the target refraction was up to -2.0 D in the nondominant eye, and for distance vision correction, 0.0 D. Enrolled patients had a preoperative spherical equivalent of plano to +2.00 D, no more than 0.75 D of refractive astigmatism, and were 40 years of age or older. No retreatments were performed.

Results: Of the eyes treated for near, 77% had uncorrected near vision of J3 or better at 6 months postoperatively. A total of 85% of all patients had binocular distance UCVA of 20/25 or better along with J3 or better near, a combination that represents functional acuity for a presbyope. Sixty-six percent of eyes treated for near had a manifest refractive spherical equivalent (MRSE) within ± 0.50 D of intended at 6 months. In 89% of eyes, the MRSE changed 0.05 D or less between 3 and 6 months postoperatively. After month 1, the incidence of variables associated with safety was 1% or lower. Seventy-six percent were very satisfied or satisfied with their procedure.

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From the *Southern Vision Institute, New Orleans, Louisiana 70115; †Durrie Vision, PA, Overland Park, Kansas; ‡Mt Sinai Medical Center, New York, NY; §Maloney Seibel Vision Center, Los Angeles, CA; and ||Laurel Eye Clinic, Brookville, PA.

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The nature of the procedure was explained to all participating patients, and they all signed informed consent forms before undergoing the procedure. These data have not been previously published.

Reprints: Marguerite B. McDonald, MD, Southern Vision Institute, 2820 Napoleon Avenue, New Orleans, LA 70115 (e-mail: margueritemcdmd@aol.com).

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Conclusions: CK appears to be very safe and effective in producing functional visual acuity in presbyopic eyes up to 6 months following the procedure. Patient satisfaction with the procedure is similar to that of monovision LASIK.

Key Words: presbyopia, conductive keratoplasty, CK, thermokeratoplasty, refractive surgery, hyperopia

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Presbyopia is a problem attributed to age-related loss of accommodation. At age 20, the crystalline lens is soft and deforms easily with contraction of the ciliary muscles. Average amplitude of accommodation at that age is 11.0 ± 2.0 D.¹ At age of 40, however, average accommodation has decreased to 6.0 ± 2.0 D, and, at age 52, it is down to 2.5 ± 1.5 D. A person unable to maintain 3.0 D of accommodation for any length of time is considered to have symptoms of presbyopia.²

Near vision has been improved or restored in presbyopic eyes with bifocal spectacles or monovision contact lenses³⁻⁶ and with refractive surgery. Refractive surgery procedures include those that steepen the cornea by means of the excimer laser,⁷⁻¹⁰ the holmium:YAG laser,¹¹ or radiofrequency energy.^{12,13} Procedures that expand or relax the sclera^{14,15} intra-corneal implants,¹⁶ multifocal IOLs,^{17,18} and accommodative IOLs^{19,20} have also been used. Some of these procedures are actively being investigated and appear promising, but others are controversial and have questionable efficacy, safety, or both.

Of the laser procedures that modify corneal shape, monovision hyperopic laser in-situ keratomileusis (H-LASIK) has been the most successful, although use of H-LASIK for monovision is off-label and involves all of the risks of flap creation, severing of corneal nerves that causes dry eye, night time starbursts, reduced contrast sensitivity, and possibility of diffuse lamellar keratitis.²¹⁻²⁶ In monovision surgery, the patient has 1 eye corrected for near tasks, and the other eye is left uncorrected or has distance vision sharpened to serve as the distance eye. Success depends on interocular suppression of blur. This effect has been defined as the ability of the ocular system to suppress detrimental blurred information from the

defocused eye so that it does not interfere with the in-focus image in the other eye. For example, the image from the near eye is suppressed for distance binocular vision. The suppression occurs regionally between corresponding retinal areas.²⁷

Conductive keratoplasty® (CK®) is a nonablative, radiofrequency-based, collagen-shrinking procedure that has been approved by the Food and Drug Administration for the correction of mild to moderate spherical hyperopia in people over the age of 40. Radiofrequency energy is delivered through a fine tip inserted into the peripheral corneal stroma in a ring pattern outside of the visual axis. When a series of 8 to 32 treatment spots are placed in up to 3 rings in the corneal periphery (6-, 7-, and 8-mm optical zones), striae form between the spots and create a band of tightening. This causes a steepening of the central cornea and corrects hyperopic refractive error.

Because corneal steepening can add power to the cornea and improve near vision, a multicenter study is being conducted to evaluate CK for the treatment of presbyopic symptoms in emmetropic and hyperopic eyes. This is an interim report of a 6-month follow-up of what will be a 12-month study.

METHODS

Study Design

The study is a prospective, consecutive series, multicenter clinical trial (FDA phase 3) evaluating the safety and efficacy of the ViewPoint™ CK system for improvement of near vision in emmetropic and hyperopic eyes with the conductive keratoplasty (CK®) procedure. The 5 participating centers are a mix of university and private practice settings. Patients with a desire for presbyopic correction were screened for eligibility. A total of 150 consecutive patients were to be enrolled and followed for 1 year. Patient enrollment was phased, such that 50 patients were enrolled and underwent the CK procedure initially. The 3-month postoperative data were reviewed on these 50 patients before an additional 100 patients were enrolled and treated.

Eligible patients were treated to correct up to 2.0 D of presbyopia. To be eligible for the study, patients had to have a preoperative spherical equivalent (SE) from plano (considered as +0.5 to -0.5 D) to +2.0 D and less than or equal to 0.75 D of refractive astigmatism, as determined by cycloplegic refraction. Screening for eligibility included a history of monovision contact lens wear or success with a contact lens trial of monovision.

In addition, we used a preoperative assessment tool called the "loose lens test" to demonstrate the effects of CK to the candidate in 3 to 5 minutes of chair time. Based on nominal corrections with CK, lenses of 3 different dioptric powers were used: (1) a +0.75 D lens for a +0.8 D correction with 8 CK

spots, (2) a +1.50 D lens for a +1.36 D correction with 16 CK spots, and (3) a +2.00 D lens for a +1.8 D correction with 24 CK spots. If a patient could not find a satisfactory endpoint, we did not proceed with the surgery. No other preoperative monovision contact lens trial was administered.

Following screening, study protocol criteria were followed to develop a treatment plan for each patient that considered patient age, accommodative amplitude, and desired distance for near correction. The target refraction was up to -2.0 D (myopic endpoint) in the nondominant eye. Emmetropic patients were treated unilaterally in the nondominant eye with an intended correction of up to 2.0 D (target of -1.0 to -2.0 D) to attain near vision in that eye. Hyperopic patients were treated bilaterally: the nondominant eye was treated up to 3.0 D (target of -1.0 to -2.0 D) to provide near vision, and the dominant eye was treated with a correction of up to 2.0 D (target of plano) to improve distance vision.

Patients

Institutional Review Board approval was obtained at each clinical center that participated in the multicenter trial. A total of 143 patients at 5 centers in the United States who met eligibility requirements were enrolled consecutively into the study and signed informed consent forms. Of the 176 enrolled eyes, 143 eyes have been treated for near vision correction, and 33 eyes for distance correction.

Examination Methods

The preoperative and postoperative examinations for all eyes included manifest and cycloplegic refractions; uncorrected and best spectacle-corrected visual acuity for near and distance (monocular and binocular); slit lamp, preoperative pachymetry, and central keratometry; computerized corneal topography; and mesopic and photopic contrast sensitivity with and without glare. A postoperative patient satisfaction questionnaire was administered, and patient spectacle dependence was evaluated.

The ViewPoint™ CK System (study device) used to perform the CK procedure and the surgical procedure were previously described.^{12,13}

RESULTS

Accountability and Demographics

A total of 143 patients (176 eyes) were enrolled and treated with CK. One hundred forty-three eyes were treated for near vision correction, and 33 eyes for distance correction (Table 1). Patients treated for near correction were an average of 53 years old, and those treated for distance an average of 54 years; 96% of all patients were white, and 60% were female. The mean intended correction for eyes treated for near was 2.0

TABLE 1. Demographic and Baseline Information

	Treated for Near	Treated for Distance
Number of patients/eyes	143/143	33/33
Mean age (years) (SD)	53.1 (4.8)	54.1 (4.6)
Range	44 to 71	44 to 61
Intended correction		
Mean (SD)	2.01 D (0.62)	1.22 D (0.34)
Range	0.75 D, 3.00 D	0.75 D, 2.00 D
Target		
Mean (SD)	-1.46 D (0.36)	0.00 (0.00)
Range	-2.25 D, -1.00 D	0.00, 0.00
Total 176 eyes of 143 patients.		

D, and the mean target refraction was -1.46 D. For eyes treated for distance, the mean intended correction was 1.22 D, and the mean target refraction was 0.0 D. Follow-up at 6 months is 83/176 (47%) (Table 2). All eyes were treated once (no retreatments).

Visual Acuity

Of the eyes treated for near, 87/130 (67%) and 47/73 (64%) had UCVA-N of J2 or better at 1 month and 6 months, respectively; 101/130 (78%) and 56/73 (77%) had J3 or better, and 120/130 (92%) and 65/73 (89%) saw J5 or better (Fig. 1).

For binocular UCVA (all treated eyes), at 1 month and 6 months, respectively, 87/129 (67%) and 49/73 (67%) had 20/20 or better distance acuity and J2 or better near acuity, compared with 7/137 (5%) who had this uncorrected binocular acuity preoperatively; 106/129 (82%) and 62/73 (85%) had 20/25 or better distance and J3 or better near, compared with 13/137 (9%) who had this binocular acuity preoperatively; and 123/129 (95%) and 67/73 (92%) had 20/32 or better distance and J5 or better near, compared with 72/137 (30%) preoperatively (Fig. 2).

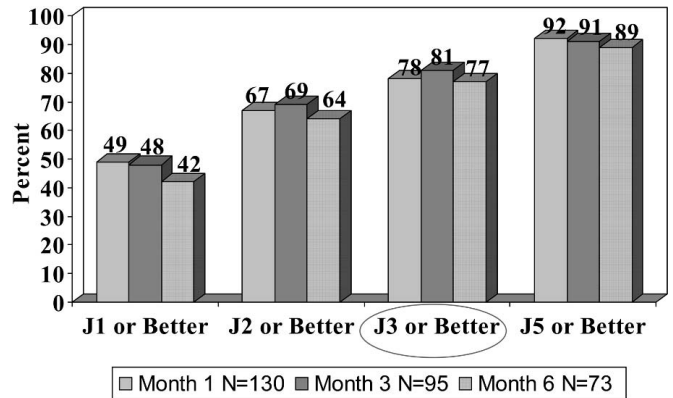


FIGURE 1. Uncorrected visual acuity in the eyes treated for near vision.

Accuracy and Stability

At 6 months, 48/73 (66%) of the eyes treated for near had a manifest refractive spherical equivalent (MRSE) within 0.5 D of intended correction, 65/73 (89%) within 1.0 D, and 73/73 (100%) within 2.0 D (Fig. 3).

In the eyes treated for near, 85% and 89% changed 0.05 D or less between 1 and 3 months and between 3 and 6 months, respectively (Fig. 4). The MRSE mean change per month was 0.06 D between 1 and 3 months and 0.04 D between 3 and 6 months. Total change per interval was 0.14 D between 1 and 3 months and 0.17 D between 3 and 6 months.

Safety

Safety results are summarized in Table 3. After month 1, the incidence of variables associated with safety was 1% or lower. At 1 month, 1% (2/160) of all treated eyes lost more than 2 lines of BSCVA; this incidence fell to 0% by the third and sixth months. Loss of 2 lines (3/160) occurred in 2% at month 1 and dropped to 1% at months 3 and 6. There were no cases of BSCVA worse than 20/40, increases of 2.00 D or over 2.00 D of cylinder, or eyes that had 20/20 or better BSCVA preoperatively that had worse than 20/25 postoperatively.

TABLE 2. Study Patient Accountability

	Month 1		Month 3		Month 6	
	Number	%	Number	%	Number	%
Available for analysis	162/176	92%	112/176	64%	83/176	47%
Discontinued	0/176	0%	0/176	0%	1/176	1%
Missed visit	3/176	2%	0/176	0%	0/176	0%
Patient has not reached 6-month postop time point	11/176	6%	64/176	36%	92/176	52%

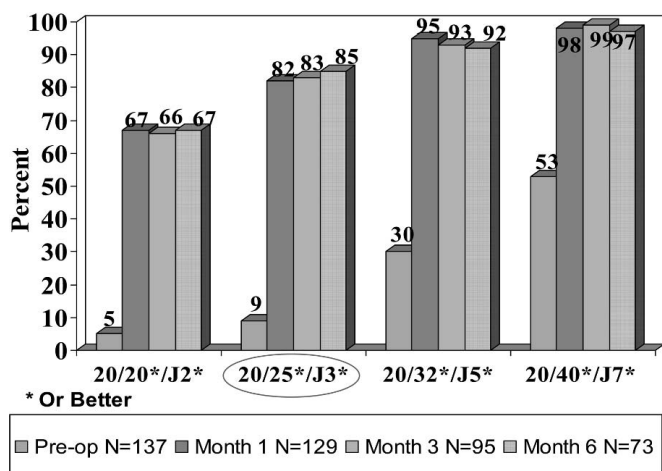


FIGURE 2. Binocular uncorrected visual acuity for distance and near in all treated eyes.

Postoperative increases in absolute cylinder were generally 1.50 D or less and decreased with time (Table 4). Figure 5 shows that the 27% of eyes with cylinder of 1.00 D to 1.75 D at month 1 had decreased to 8% by month 6. No intraoperative complications or adverse events occurred during any of the surgeries.

Vision Quality and Patient Satisfaction

Of the patients who had eyes treated for near, 71% and 72% reported extreme or marked improvement in vision at 1 and 6 months postoperatively, respectively (Table 5). Moderate and slight improvement was reported by 26% and 24%, respectively. A total of 82% and 76% reported being very satisfied or satisfied with their outcome at 1 and 6 months postoperatively, respectively (Table 6).

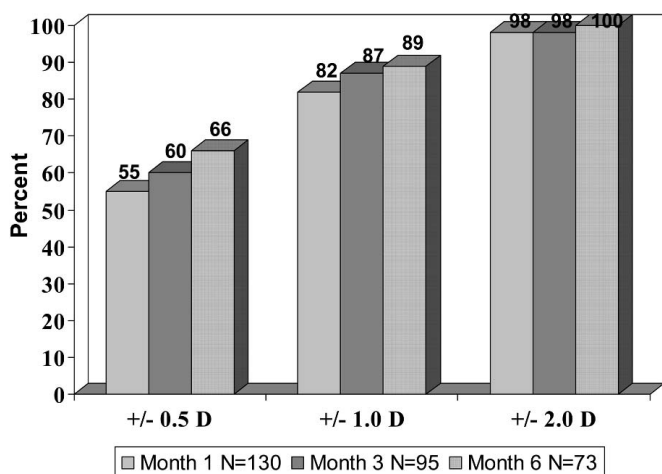


FIGURE 3. Accuracy from target refraction in the eyes treated for near.

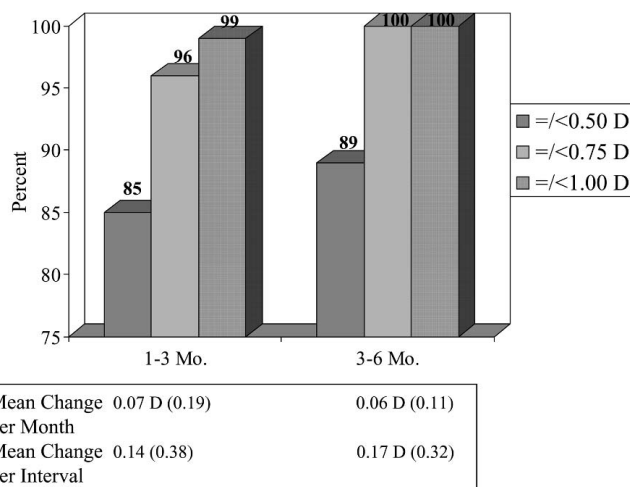


FIGURE 4. Stability of the manifest refractive spherical equivalent through 6 months postoperatively. Eyes with consecutive visits treated for near.

DISCUSSION

Presbyopia is the most frequently occurring refractive error, and the number of presbyopes grows yearly. This is a result of the aging of the “baby-boomer” generation, the 76 million Americans born between 1946 and 1964, and the estimated 10 million persons who have immigrated to the United States.^{28,29} Despite the high prevalence, surgical solutions for presbyopia are few and often imperfect. Scleral procedures generate much skepticism and debate over efficacy and permanence. Clear lens extraction and implantation of a multifocal intraocular lens in phakic patients has not had wide appeal. The AT-45 Crystalens accommodative IOL (eyeonics, Aliso Viejo, California) was recently approved by the United States FDA for surgical treatment of presbyopia, but, like multifocal implants, it also requires crystalline lens removal.

Outcomes of monovision LASIK (hyperopic LASIK procedure with myopic endpoint in 1 eye) have not been widely reported, but the available reports are favorable.^{9,10} Typically, the dominant eye is corrected for distance vision,

TABLE 3. Summary Safety Variables: All Treated Eyes

Safety Variable	Month 1 (n = 160)	Month 3 (n = 112)	Month 6 (n = 83)
>2 lines lost BSCVA	1%	0%	0%
2 lines lost BSCVA	2%	1%	1%
BSCVA worse than 20/40	0%	0%	0%
Increase >2.00 D cylinder	0%	0%	0%
If preop BSCVA 20/20 or better, and post-op 20/25 or worse	0%	0%	0%

TABLE 4. Absolute Change in Cylinder: All Treated Eyes

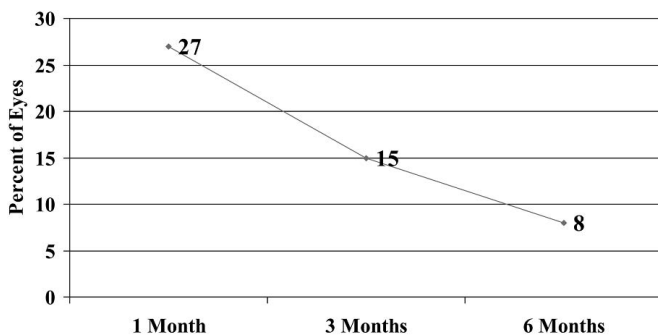
Increase	Month 1 (N = 160)	Month 3 (N = 112)	Month 6 (N = 83)
>2.00D	0%	0%	0%
2.00D	0%	0%	0%
1.75D	1%	0%	0%
1.50D	3%	1%	1%
1.25D	7%	6%	5%
1.00D	16%	8%	2%

and the nondominant for near. The typical induced anisometropia is from 1.00 D to 2.00 D.

Although monovision does not increase accommodation, a corneal steepening procedure that compensates for presbyopic symptoms would be expected to be a popular alternative to reading spectacles. However, this has not been the case. Fewer than 5% of the United States presbyopic population has had a LASIK monovision procedure (R. Lindstrom, Binkhorst Lecture: Presbyopic correction from a surgeon’s perspective, American Society of Cataract & Refractive Surgery annual meeting, San Francisco, 2003), possibly because the LASIK procedure lacks appeal for older patients. These over-40 patients may be more risk-averse and do not wish to undergo a procedure they consider an extreme remedy for their presbyopic symptoms.

Furthermore, the low adoption rate of H-LASIK may indicate that surgeons, as well as patients, are not comfortable with this procedure. Hyperopic LASIK requires skill in the use of a microkeratome and excimer laser, creation of a large flap, perfect centration, and an ablation profile with smooth transition zones. Healing problems, dry eyes, and diffuse lamellar keratitis need careful follow-up and treatment.

As a nonablative, nonincisional procedure that does not require creation of a flap and uses radiofrequency energy to steepen the central cornea, CK avoids LASIK-related prob-



*All eyes with cylinder increase of 1.00 D to 1.75 D

FIGURE 5. Mean change in induced cylinder over time.

TABLE 5. Subjective Assessment of Vision Quality: Eyes Treated for Near

Improvement	Month 1 (N = 130)	Month 3 (N = 96)	Month 6 (N = 75)
Extreme/marked	71%	74%	72%
Moderate	18%	18%	13%
Slight	8%	6%	11%
None	2%	2%	4%
Not reported	1%	1%	0%

lems. CK does not invade the central cornea, cause flap-related complications, compromise the integrity or structure of the cornea (CK involves no incisions), cause dry eye (corneal nerves are not severed) or central haze, and has a larger effective optic zone compared with that obtained with H-LASIK using the VISX S2 excimer laser.³⁰ In addition, CK can be performed in the office setting with only topical anesthesia, is technically easier to perform than LASIK, and involves use of a portable unit that is much less expensive than most other refractive surgery platforms.

The US Food and Drug Administration has recently granted approval of CK for the temporary reduction of mild to moderate (+0.75 D to +3.00 D) previously untreated spherical hyperopia in patients aged 40 or older. The CK procedure has also been used internationally and in the United States to treat astigmatism (one or more treatment spots placed in selected locations on the peripheral cornea steepen the meridian in which they are placed),³¹ correction of hyperopia induced by previous refractive procedures, and the treatment of presbyopia. After correction for near in 1 eye with CK, a phenomenon called “blended vision” has been observed. The hypothesis is that CK presbyopic correction differs from monovision because there appears to be less compromise of distance vision binocularly, contrast sensitivity, or depth perception than with other methods. Contact lens monovision is known to compromise distance vision and contrast sensitivity, whereas correction for near in 1 eye with CK does not appear to do so. The blended vision effect is currently under investigation by means of comparison studies with contact lens monovision.

TABLE 6. Patient Satisfaction: Eyes Treated for Near

Satisfaction	Month 1 (N = 131)	Month 3 (N = 96)	Month 6 (N = 75)
Very satisfied/satisfied	82%	84%	76%
Neutral	11%	13%	19%
Dissatisfied/very dissatisfied	7%	3%	5%

The present multicenter study, conducted with the rigor required of FDA submission studies, evaluated the safety and efficacy of CK for reducing the symptoms of presbyopia. Six months postoperatively, 77% of examined eyes had J3 or better monocular UCVA, and 85% of patients had binocular UCVA of 20/25 or better distance along with J3 or better near, a combination that represents functional acuity for a presbyope.

Only 9% of the treated eyes had this level of uncorrected binocular acuity preoperatively. Furthermore, 92% of the CK-treated eyes had an uncorrected binocular vision of 20/32 and J5, which also allows a high degree of uncorrected visual function. One-, 3-, and 6-month binocular visual acuity values were similar, suggesting that most patients achieved functional vision by 1 month postoperatively.

Accuracy to target was good, with 66% of eyes within 0.50 D of intended correction. Accuracy values appeared to improve with time: 55% of eyes were within 0.50 D at 1 month, which increased to 66% by month 6. In this study accuracy to within 0.5 D of target refraction was slightly below that achieved in H-LASIK studies. These mostly showed accuracy to within 0.5% of 61% to 79%.^{13,32-37}

Follow-up was too short for meaningful determination of refractive stability, but the change in SE decreased from 0.07 D per month in the first 2 months to 0.06 D per month for months 3 to 6. Follow-up to 3 years and beyond is needed for accurate evaluation of stability.

Other mechanical steepening procedures, such as non-contact holmium:YAG laser thermal keratoplasty (LTK), appeared promising in the 1990s, but longer-term data showed disappointing predictability and stability.^{11,38} Choi and associates proposed that LTK's decline in refractive effect over time is based on shallow penetration because of the strong absorption of 2.1- μm Ho:YAG laser light (the wavelength used by LTK) by water, and corneal tissue is 75% water by mass.³⁹ They demonstrated that penetration depth of holmium YAG laser light in water is 360 μm , or approximately 60% of a typical corneal thickness of 600 μm .

Furthermore, LTK holmium YAG laser treatment has been shown to produce the greatest amount of heat at the surface of the cornea and lesser amounts deeper in the stroma. The lesion resulting from treatment is cone-shaped^{39,40} and shallower than that of a CK-treated spot. The CK lesion (footprint), on the other hand, is cylindrical and approximately 80% deep, as shown in a pig histology study.¹² Clinical studies of CK used to treat hyperopia have shown better stability at 12 months than was shown by LTK treatment.¹³ Unfortunately, follow-up in the LTK clinical studies for FDA submission ended at 18 months, and longer follow-up data are not available for comparison with LTK.

The CK procedure appeared very safe. No intraoperative complications or adverse events occurred during any of the

surgeries. Two eyes (1%) lost more than 2 lines of BSCVA at 1 month, but the percentage was 0 at 3 and 6 months. The 27% of eyes with cylinder of 1.00 D to 1.75 D at month 1 had decreased to 8% by month 6. Thus, induced cylinder appeared to decrease with time.

Quality of vision, as evaluated by the patients, was high and stable from 1 to 6 months postoperatively. Only 2% of patients at month 1 and 4% at month 6 reported no improvement. A total of 76% reported being very satisfied or satisfied with their CK procedure, and 19% reported being neutral.

There is no good single measure to quantify success with a monocular treatment, and patient satisfaction has been used as a proxy for success.¹⁰ The satisfaction percentages and visual results after CK are comparable to rates reported in other studies with different modalities.⁷⁻¹⁰ However, the criteria to define success and satisfaction in these studies were different from those used in this study, and comparisons are therefore not parallel. The age of the patients, amount of attempted correction, amount of induced anisometropia, and patient selection (and especially rejection criteria) for study participation were also different and would have an effect on success and satisfaction rates.

Before monovision refractive surgery, contact lenses were the standard modality when uncorrected distance and near acuity was desired. A 1996 literature review showed that monovision contact lenses for presbyopia were an effective and reasonable modality given proper patient selection and screening.⁶ They reported a mean 73% success rate with monovision contact lenses. Similar good results have been reported with PRK monovision surgery. A 1999 study of 21 patients by Wright and associates showed 71% with binocular 20/20 visual acuity at near and 86% patient satisfaction on a scale of 1% to 100% satisfaction.⁸ Satisfaction rates in this study of monovision PRK appear higher than those we report here with monovision CK. However, a very different scale was used to determine satisfaction, so comparisons are not parallel. Furthermore, fewer risks for the benefits are found with a non-laser, minimally invasive procedure that does not invade the central cornea or cause postoperative haze, such as CK, when compared with a surface-ablating procedure such as PRK.

In a retrospective study of patient records from 1995 to 1998, Jain and associates showed 88% patient satisfaction with LASIK or PRK monovision surgeries in presbyopes.¹⁰ Patient satisfaction was not rated on a scale but was recorded as a comment in the patients' charts. This, as well as the retrospective nature of this study, lowers the quality of these data. Goldberg⁹ reported on a retrospective study of monovision LASIK performed between 1998 and 1999 on patients 40 years of age or older (mean age not reported). Patients rated their satisfaction on a scale of 1 (least satisfied) to 10 (most satisfied). The mean satisfaction score was 8.5. Keeping in mind that the techniques for assessing surgical success and patient satisfaction with H-

LASIK were highly varied, CK surgery appears to produce similar satisfaction to LASIK with less risk of complications.

Patient selection and education are important for success with CK presbyopia surgery. We suggest excluding patients with previous corneal surgery, epithelial or endothelial compromise, keratoconus or pellucid degeneration, significant dry eye or problems with the tear film, and corneas with topographies that suggest a potential for induced cylinder. Patients' expectations should be realistic. The surgeon should explain that hyperopia and presbyopia are progressive conditions that will lead to a need for reading glasses with time. However, the advantages gained from the procedure will be retained, and the need for near correction will probably be delayed. Furthermore, reading vision may vary with lighting conditions. Patients should also understand that the CK procedure does not restore accommodation but simply compensates for its loss.

The "loose lens test" was a valuable tool for identifying CK candidates as well as for informed consent. It helped patients realize that the goal of treatment is improved vision for daily life and that decreased vision for fine detail (compared with the fine detail obtained with reading spectacles) is the trade-off. Long-term follow-up data on the value of this test are not yet available.

In conclusion, in 2002 conductive keratoplasty was shown to be effective and safe in the treatment of low to moderate hyperopia in a prospective study with 400 eyes.¹³ The study reported here demonstrated that CK treatment need not be limited to hyperopia correction. This interim report of 6-month follow-up of a 12-month study suggests that symptoms of presbyopia can also be decreased with CK effectively and safely.

At 6 months, functional visual acuity at distance and near (20/25 or better and J3 or better) was attained in 85% of the patients. The CK procedure appears to be a very effective solution for improving near vision for presbyopic patients.

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