

CONDUCTIVE KERATOPLASTY FOR THE CORRECTION OF HYPEROPIA*

By Penny A. Asbell, MD, Robert K. Maloney, MD (BY INVITATION), Jonathan Davidorf, MD (BY INVITATION), Peter Hersh, MD (BY INVITATION), Marguerite McDonald, MD (BY INVITATION), Edward Manche, MD (BY INVITATION), AND the Conductive Keratoplasty Study Group (BY INVITATION)

ABSTRACT

Background/Purpose: Conductive keratoplasty (CK) is a surgical technique that delivers radio frequency (350 kHz) current directly into the corneal stroma through a Keratoplast tip inserted into the peripheral cornea at 8 to 32 treatment points. A full circle of CK spots produces a cinching effect that increases the curvature of the central cornea, thereby decreasing hyperopia. We report here the 12-month results of a 2-year, prospective, multicenter US clinical trial conducted to evaluate the efficacy, safety, and stability of CK.

Methods: A total of 233 patients (401 eyes) with preoperative hyperopia of +0.75 to +3.00 D and ≤ 0.75 D of astigmatism (mean preoperative manifest refractive spherical equivalent = $+1.76 \text{ D} \pm 0.60$) were enrolled into the study at 13 centers and underwent CK treatment.

Results: Twelve-month postoperative data are available on 203 eyes for safety and stability and 171 eyes for safety, stability, and efficacy. A total of 91% had uncorrected visual acuity (UCVA) of 20/40 or better, and 51% had UCVA of 20/20 or better. Manifest refractive spherical equivalent was within ± 0.50 D in 58%, within ± 1.00 D in 91%, and within ± 2.00 D in 99%. The mean change in residual refraction was $0.26 \text{ D} \pm 0.49$ between 3 and 6 months, $0.09 \text{ D} \pm 0.37$ between 6 and 9 months, and $0.13 \text{ D} \pm 0.39$ between 9 and 12 months.

Conclusions: One-year data show safety and efficacy of CK in the treatment of hyperopia. Changes in residual refractive error after CK appeared to be small, suggesting that a stable refraction could be achieved by 6 months.

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INTRODUCTION

Thermal techniques to correct hyperopia by steepening the central cornea date back to the work of Lans in the 19th century. Hot-wire thermokeratoplasty, a technique from the Soviet Union in which corneal spots were heated to 95% of corneal depth, produced unpredictable, unstable, and unsafe results.¹⁻⁴ Modern surgical procedures now include thermokeratoplasty-based techniques: pulsed, noncontact holmium:YAG laser keratoplasty (non-contact LTK, Hyperion System, Sunrise Technologies, Fremont, California);⁵⁻¹³ contact Ho:YAG laser thermal keratoplasty (LTK) (Holmium 25, Technomed, Baesweiler, Germany);¹⁴⁻¹⁶ diode laser thermal keratoplasty (DTK,

Rodenstock, ProLaser Medical Systems, Inc, Dusseldorf, Germany);^{17,18} and conductive keratoplasty (Refractec, Inc, Irvine, California).¹⁹ Excimer laser-based techniques include photorefractive keratectomy (PRK)²⁰⁻²⁵ and laser in situ keratomileusis (LASIK).²⁶⁻³²

THE CONDUCTIVE KERATOPLASTY PROCEDURE

The CK procedure performed with the ViewPoint CK System is designed to treat spherical, previously untreated hyperopia of +0.75 to +3.00 D. Treatment of presbyopia, astigmatism, and residual hyperopia following LASIK or other refractive procedures is another potential application.

Conductive keratoplasty (CK) delivers radiofrequency (350 kHz) current directly into the corneal stroma through a probe inserted into the peripheral cornea at eight or more treatment points. Localized heating of collagen is the result.²⁶ Increasing dehydration of collagen increases resistance to the flow of the current, making the process self-limiting. A thermal model predicts a cylindrical footprint approximately 150 μm to 200 μm wide by 500 μm deep that extends to approximately 80% of the depth of the midperipheral cornea at each treated spot

*From the Department of Ophthalmology, Mount Sinai Medical Center, New York, New York (Dr Asbell); Maloney Vision Institute, Los Angeles, California (Dr Maloney, Dr Davidorf); the Cornea and Laser Vision Center, Teaneck, New Jersey (Dr Hersh); the Refractive Surgery Center of the South, New Orleans, Louisiana (Dr McDonald); and Stanford University School of Medicine, Palo Alto, California (Dr Manche). Supported by Refractec, Inc, Irvine, California. Drs Asbell, Davidorf, Maloney, Manche, and Hersh participated as clinical investigators in this FDA phase III study sponsored by Refractec, Inc. Dr McDonald is a paid medical monitor for the US multicenter trial of Conductive Keratoplasty for Refractec, Inc.

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(data on file, Refractec, Inc, Irvine, California). Striae form between the treated spots, creating a band of tightening that increases the curvature of the central cornea, thereby decreasing hyperopia.

This study reports the 1-year results of a 2-year, multicenter, prospective clinical trial to evaluate the safety, efficacy, and stability of CK to treat low to moderate hyperopia. Institutional Review Board approval was obtained at every study site prior to study inception.

US CLINICAL TRIAL OF CONDUCTIVE KERATOPLASTY

SYSTEM EQUIPMENT

The Viewpoint CK system consists of a radiofrequency energy-generating console (Fig 1); a handheld, reusable,



FIGURE 1

The ViewPoint conductive keratoplasty system: console, probe, and a choice of two lid specula that act as the electrical return path.

pen-shaped handpiece attached by a removable cable and connector; a speculum that provides a large surface for an electrical return path; and a foot pedal that controls release of radiofrequency energy. Attached to the handpiece is the Keratoplast tip, a single-use, sterile, disposable, stainless-steel, penetrating tip, 90 μm in diameter and 450 μm long, that delivers the current directly to the corneal stroma (Fig 2). At the very distal portion of the tip is a Teflon-coated stainless-steel stop (cuff) that assures correct depth of penetration (0.5 mm). The energy level default is 60% of 1 W and the exposure time default is 0.6 seconds. These parameters are set on the console so that each foot pedal excursion delivers the same level and duration of energy to the Keratoplast tip.

PATIENT SELECTION

The nature of the procedure was explained to all partici-



FIGURE 2

The conductive keratoplasty Keratoplast tip (90 mm wide, 450 mm long) shown next to a 7-0 suture.

pating patients, and they signed informed consent forms prior to undergoing the procedure. Patients treated in the study had +0.75 to +3.00 D of spherical hyperopia, ≤ 0.75 D of refractive astigmatism, and a peripheral pachymetry reading at the 6 mm optical zone of not less than 560 μm . Visual acuity was correctable to at least 20/40 in both eyes. Hard or rigid gas permeable lenses were discontinued for at least 3 weeks and soft lenses for at least 2 weeks prior to the preoperative evaluation. Hard contact lens wearers had 2 central keratometry readings and 2 manifest refractions taken at least 1 week apart. The manifest refraction measurements did not differ from the earlier measurements by more than 0.50 D in either meridian. Keratometry mires were regular.

Patients not eligible for CK treatment in the study were those with active ocular disease, corneal abnormality, progressive or unstable hyperopia, history of previous refractive surgery, or other significant ocular or physical history.

EXAMINATIONS

Preoperative examinations included a manifest and cycloplegic refraction, uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA) (distance and near), slit-lamp and funduscopic examination, applanation tonometry, central keratometry, ultrasonic pachymetry, and computerized corneal topography. Postoperative examinations were performed on days 1 and 7 and on months 1, 3, 6, 9, and 12.

TREATMENT

One drop of topical anesthetic was administered 2 or 3 times at 5-minute intervals, and the patient was monitored for degree of anesthesia. Pilocarpine was not administered. The CK lid speculum was inserted to provide corneal exposure and an electrical return path. Care was taken to ensure that the lid drape (if used) did not prevent direct contact of the lid speculum and eyelid, which would disrupt the electrical current return path. The fellow eye was

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taped closed. The operating microscope was positioned over or in front of the eye to be treated.

The patient was reminded to fixate on the light from the microscope during corneal marking. The eight-intersection CK marker was dampened with gentian violet or rose bengal stain, and the marker's crosshair was centered over the center of the pupil. The marker makes a circular mark at the 7 mm optical zone, with hatch marks indicating the 6 and 8 mm optical zones. Light pressure was applied on the marker to mark the cornea. If gentian violet was used, the cornea was irrigated with balanced salt solution to remove excess ink. The surface of the cornea was dried thoroughly with a fiber-free sponge to avoid dissipation of applied energy by a wet surface.

The Keratoplast tip was examined under the microscope to ensure it was not damaged or bent prior to application. The appropriate treatment parameters were set on the console, and the eye was treated with the appropriate number of treatment spots, as specified in the nomogram (Fig 3). For example, to correct +1.00 D to +1.625 D of hyperopia, 16 treatment spots were placed: 8 at the 6 mm

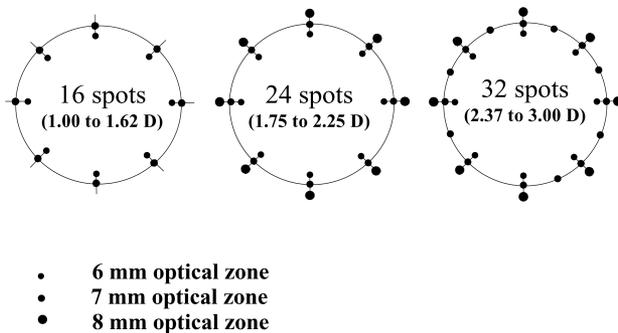


FIGURE 3

Nomogram showing number and location of treatment spots.

optical zone and another 8 at the 7 mm optical zone. When treating +0.75 D to +0.875 D (8 spots), treatment was applied only at the 7 mm optical zone.

To treat each spot, the tip of the delivery probe was placed at the treatment mark on the cornea, perpendicular to the corneal surface. Light pressure was applied until the tip penetrated the cornea down to the insulator stop. The foot pedal was depressed to apply the radio frequency energy. The tip was cleaned with a fiber-free sponge after each treatment spot to remove any tissue debris, taking care not to damage the tip. As specified by the study protocol, intraoperative keratometry was performed at the slit lamp to check for any induced cylinder.

POSTOPERATIVE CARE

One drop of a topical ophthalmic antibiotic solution and 1 drop of an ophthalmic nonsteroidal anti-inflammatory

drug were administered and continued for up to 3 days. Topical corticosteroids were not used.

CLINICAL TRIAL RESULTS

PATIENT DATA

The patients' demographic and baseline information is shown in Table I. A total of 361 eyes were treated with the

TABLE I: DEMOGRAPHIC AND BASELINE INFORMATION

Multicenter Study Investigators	20 surgeons at 13 centers in US
Refractive error treated	+0.75 D to + 3.00 D, ≤ 0.75 D cylinder
Intended refraction	Plano
Retreatments	None
Patients' characteristics	Age: 55 ± 6.4 years (range, 40 to 74) Female, 58%; male, 42% Caucasian, 81%
Mean preoperative MRSE	+1.82 \pm 0.60 D
Range	+0.75 D to +3.00 D
Median MRSE	+1.75 D
Mean preoperative CRSE	+1.76 \pm 0.60 D
Range	+0.75 D to +3.25 D

CK, conductive keratoplasty; CRSE, cycloplegic refractive spherical equivalent; MRSE, manifest refractive spherical equivalent.

current nomogram for CK (Fig 3), and an additional 29 were treated with an earlier nomogram that had a tendency to undercorrect. The 29 eyes treated with the earlier nomogram were excluded from analysis of efficacy variables. Thus data from 397 eyes were evaluated for efficacy, safety, and stability variables, and 401 were evaluated for stability and safety variables (Table II). Preoperatively, UCVA for distance was 20/40 or worse in 81% of the eyes, and UCVA for near was J5 or worse in 95%.

EFFICACY

Twelve months postoperatively, UCVA was 20/20 or better in 87 (51%) of 171 eyes, 20/25 or better in 125 (73%) of 171 eyes, and 20/40 or better in 156 (91%) of 171 eyes. Near UCVA increased an average of 6 Jaeger lines. Mean

TABLE II: ANALYSIS OF PATIENT DATA

EYES	NO.
Patients treated	233
Eyes treated	401
Total treated within protocol (no deviations)	397
Total treated prior to nomogram modification	29
Total treated with current nomogram	372
Evaluated for safety and stability variables	401
Evaluated for all variables (Efficacy, safety, stability)	397
Available at 12 months for stability and safety analyses	203
Available at 12 months for safety, efficacy, and stability analyses	171

manifest refractive spherical equivalent (MRSE) values showed 99 (58%) of 171 within ± 0.50 D of plano, 156 (91%) of 171 within ± 1.00 D, and 169 (99%) of 171 within ± 2.00 D (Fig 4). A summary of the efficacy results with conductive keratoplasty at 12 months is shown in Table III.

TABLE III: SUMMARY OF EFFICACY RESULTS WITH CONDUCTIVE KERATOPLASTY COMPARED WITH FDA GUIDELINES FOR REFRACTIVE SURGERY PROCEDURES

	FDA GUIDELINE	6 MONTHS (N=350)	9 MONTHS (N=340)	12 MONTHS (N=171)
UCVA $\leq 20/20$	50%	40%	50%	51%
UCVA $\leq 20/25$	Not stipulated	63%	74%	73%
UCVA $\leq 20/40$	85%	86%	93%	91%
MRSE ± 0.50 D	50%	56%	64%	58%
MRSE ± 1.00 D	75%	83%	87%	91%
MRSE ± 2.00 D	Not stipulated	97%	99%	99%

FDA, Food and Drug Administration; MRSE, manifest refractive spherical equivalent; UCVA, uncorrected visual acuity.

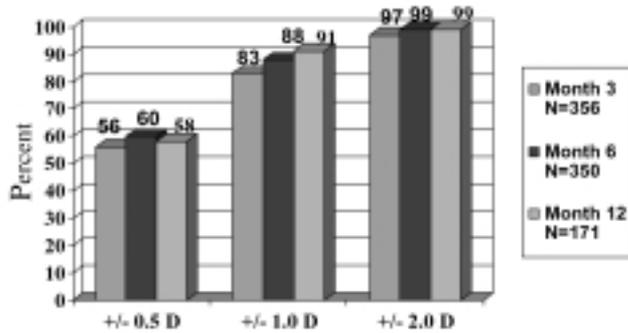


FIGURE 4

Accuracy of achieved refraction 3, 6, and 12 months following conductive keratoplasty treatment.

One hour after treatment, the opacities at each treatment spot were visible by slit lamp as small surface leukomas, with a band of striae connecting the treatment spots (Fig 5).

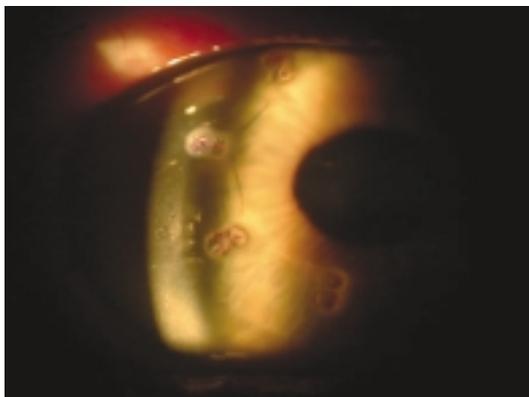


FIGURE 5

Leukoma visible by slit-lamp 1 hour following conductive keratoplasty treatment.

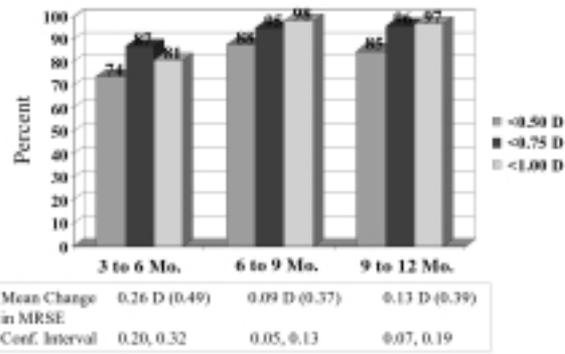


FIGURE 6

MRSE stability through 12 months in patients with consecutive visits.

STABILITY

Postoperative MRSE values within ± 0.50 , ± 1.00 , and ± 2.00 D of plano are shown in Fig 6. The mean change in residual refraction for eyes with all consecutive follow-up visits was 0.26 D \pm 0.49 (CI = 0.20, 0.32) between 3 and 6 months; 0.09 D \pm 0.37 (CI = 0.01, 0.17) between 6 and 9 months; and 0.13 D \pm 0.39 (CI = 0.07, 0.19) between 9 and 12 months.

SAFETY

No significant events occurred intraoperatively, and there were no treatment-related adverse events. No remarkable postoperative changes were seen in loss of BSCVA or induced cylinder (Table IV).

DISCUSSION

Surgical correction of hyperopia has been a greater challenge to ophthalmology than surgical correction of myopia because of the impermanence of surgical effect

TABLE IV: SUMMARY OF SAFETY RESULTS WITH CONDUCTIVE KERATOPLASTY

CHANGE IN SAFETY VARIABLE	POSTOPERATIVE VISIT				
	1 MO (N=390)	3 MO (N=392)	6 MO (N=387)	9 MO (N=376)	12 MO (N=203)
2 Lines loss of BSCVA	6%	5%	4%	3%	0.50%
>2 Lines loss of BSCVA	2%	1%	0.50%	0.50%	0%
BSCVA worse than 20/40	0%	0%	0%	0%	0%
Increase >2.00 D cylinder	3%	2%	1%	<1%	0.50%
BSCVA <20/25 if better than 20/20 preoperatively	4%	2%	<1%	<1%	0%

BSCVA, best spectacle corrected visual acuity

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(regression). Conductive keratoplasty is a new, nonablative method for the correction of mild to moderate hyperopia that uses electrical current to generate heat in the cornea. Stromal tissue provides resistance to the flow of the current, resulting in gentle, controlled tissue heating and collagen dehydration and contraction. The process is self-limiting, since resistance to the flow of current increases with increasing dehydration of collagen. Unlike Fyodorov's original "hot needle keratoplasty" technique, the CK delivery needle stays cool as collagen is heated.

Contraction of collagen following its dehydration has been shown to be a function of temperature and time.³³ Under steady-state laboratory conditions, collagen heated in the range of 55°C to 65°C dehydrates and contracts but can still regain its original configuration upon cooling. Above 75°C, collagen denatures completely. Thus the temperature "window" for collagen contraction without complete denaturation under steady-state conditions is approximately 65°C.³³⁻³⁵

However, because thermokeratoplasty is a dynamic (not steady-state) process, the state of collagen while undergoing thermokeratoplasty can be inferred, but not exactly defined, through these steady-state temperature studies. According to a thermal model, the CK targeted treatment zone reaches a temperature consistent with optimal shrinkage (65°C to 75°C) and produces a cylindrical footprint that has almost no axial gradient.³³

Histologic studies have shown that the footprint extends to approximately 80% of the depth of the midperipheral cornea (data on file, Refractive, Inc, Irvine, California). Deep thermal penetration in the treatment zone (without damaging the endothelium) is desirable for permanent collagen shrinkage,³⁴ which is expected to reduce postoperative regression. Early ultrasound biomicroscopic (UBM) studies of patients following CK treatment have shown a consistent cylindrical footprint in the cornea 0.51 mm deep, a depth that would extend to 90% of the depth of most corneas (P. Asbell, preliminary UBM data, Mount Sinai School of Medicine, April 2001). In contrast to the CK technique, the Hyperion noncontact LTK technique generates the greatest amount of heat at the surface of the cornea because of the high absorption of light energy in water. The Ho:YAG beam is attenuated as it passes through the cornea so that the heat energy diffuses radially and axially into the tissue. The result is a cone-shaped collagen shrinkage zone (conical footprint),⁶ with corneal denaturation decreasing from top to bottom. While studies have not been published on the depth of the LTK footprint, the penetration is believed to be more shallow. Deep penetration with a conical configuration could be expected to cause surface damage.

As a nonexcimer laser technique for correcting hyperopia, CK preserves the central cornea and does not induce

flap-related complications. The decreased complexity of the procedure compared with LASIK results in the need for fewer staff members. The range of correction, however, is limited to low hyperopia, and the surgeon must turn to LASIK, phakic IOL implantation, clear lens extraction, or other procedure for patients outside of the treatment range of CK.

In the multicenter clinical trial reported here, the efficacy results exceeded all Food and Drug Administration guidelines for performance of refractive surgery procedures. At 1 year after treatment, 51% of the study eyes showed 20/20 or better UCVA and 91% showed 20/40 or better. Regression following the CK procedure was low and decreased with time. Mean MRSE was within ± 0.50 D in 58% and within ± 1.00 D in 91%. During the last two intervals (6 to 9 months, 9 to 12 months), the MRSE refraction changed 0.09 D and 0.13 D, respectively. The refraction appeared to stabilize by 6 months. Since we performed no retreatments, our stability results reflect actual corneal refractive stability over the 1-year follow-up.

Leukomas visible by slit-lamp postoperatively were small because CK delivers energy deep into the stroma rather than on the surface. The striae between treatment zones remain visible at 3, 6, and 12 months, as reported by the United States CK clinical trial investigators, and suggest that the effect of treatment on the stroma is long-lasting.

The safety profile following CK was similar to that of LTK and is likely due to the preservation of the visual axis in both procedures. In comparison, hyperopic PRK²⁰⁻²⁵ and hyperopic LASIK studies^{26-32,36} have commonly demonstrated a two-line or greater loss of BSCVA of 5% to 6%.

SUMMARY

The refractive effect stabilized by approximately 6 months in this ongoing 2-year, prospective clinical study of the CK technique for correcting low to moderate spherical hyperopia. Postoperative visual acuity and predictability of refraction were excellent and met or exceeded the results reported for PRK or LASIK for low hyperopia. The stability results surpassed those reported with the noncontact LTK method. The CK technique spares the visual axis, has an excellent safety profile, and does not involve removal of any corneal tissue. The 2-year data from this ongoing trial should help to confirm current findings.

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DISCUSSION

DR ROGER F. STEINERT. Until recently, refractive surgery procedures have concentrated on the correction of myopia and myopic astigmatism. However, the 1997 Baltimore Eye Study showed a distribution of refractive errors that approached a normal distribution, with as many hyperopic as myopic eyes in the range of +6D to -6D (Fig 1)¹. In North America alone, 150 million potential patients are 40 or more years of age. Thirty-five percent of these patients are between +1 and +3.0D. Therefore, over 50 million individuals are potential candidates for one of the thermal approaches to correction of low hyperopia. In the USA today, techniques available for the correction of low hyperopia are photorefractive keratectomy (PRK) and laser in-situ keratomileusis (LASIK), capable of correcting both spherical and astigmatic errors; laser thermokeratoplasty, capable of correcting low

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Hyperopic Patient Distribution

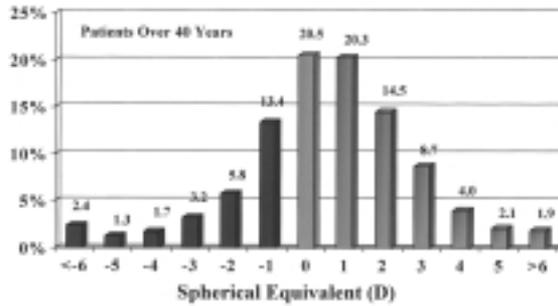


FIGURE 1
Distribution of refractive errors (adapted from reference 1)

spherical hyperopic errors utilizing the non-contact Sunrise Technology holmium laser; and clear lens extraction with implantation of an intraocular lens.

In PRK and LASIK, the excimer laser recontours the cornea by removing corneal stroma through the process of photoablation, in a pattern that is ideally equal and opposite to the refractive error of the eye. In non-contact holmium laser thermokeratoplasty, the patient typically receives 8 simultaneous laser applications as a ring of spots at 6.0 mm on the cornea, followed by 8 spots at 7.0 mm, with each spot consisting of 7 pulses delivered over 1.4 seconds.

Dr. Asbell has nicely summarized key results through 12 months of a different form of thermokeratoplasty. As we have just heard, in conductive keratoplasty, heat is generated through radiofrequency current, applied to the corneal stroma through a pinpoint probe inserted into the peripheral cornea to a depth of approximately 450 microns. The probe is manually applied to the cornea, puncturing the stroma following a pattern imprinted by the prior application of a marker indicating optical zone size and spacing of the applications. In the presentation of the study results, several limitations must be noted. Although the results are reported at 12 months follow-up, only 96 out of 361 treated eyes are available. In the manuscript provided for review, the reason for the low followup was not stated. Presumably, some patients have not yet reached the 12 month followup interval, but no data are presented about the number of patients lost to followup, the number undergoing retreatment, and other possible reasons for failure to achieve the 12 month followup category.

This study appears to analyze many bilaterally treated eye results as if they were independent events. A total of 231 patients were enrolled in the study, yet 390 eyes were reported within protocol and 361 eyes treated with the current nomogram. Because the results in a given patient may be correlated between the 2 eyes, separate reporting

of first eye results is important.

In addition, the reported postoperative refractions are manifest refractions only. No cycloplegic refractive results are given. Residual accommodation may be present in patients under 55 years of age, especially when the residual hyperopia is relatively small.

I have attempted to compare the publicly available results from the pre-market approval submissions to the FDA by Sunrise Technology and Alcon Summit Autonomous Technology.

The demographics of the 3 groups appear similar, although the range of treatment in the LASIK group was considerably larger, up to +6D (Fig 2).

Demographics

	CK	LTK	LASIK
MRSE	+1.76	+1.69	
Range	+0.5 to +3.25	+0.75 to +2.5	
CRSE	+1.82		+2.68
Range	+0.75 to +3.0		+1 to +6
Mean age	55	56.1	
Range	40-74	40-78	
Female	58.4%	59.6%	

FIGURE 2
Demographics of laser vision correction study eyes.

Looking solely at uncorrected visual acuity (UCVA) at 6 and 12 months, CK has the edge over LTK but not LASIK for 20/20 or better UCVA, despite the inclusion of higher hyperopic corrections in the LASIK group (Fig 3).

Curiously, predictability is comparable in the 3 procedures, however. Predictability usually closely correlates with UCVA unless irregular astigmatism is present (Fig 4).

Stability of hyperopic corrections, particularly thermal procedures, is a major concern. I could obtain somewhat comparable data for stability within 1 D over post-

Effectiveness UCVA

	CK		LTK	LASIK
	6m	12m	12m	6m
≥ 20/20	46%	55%	37%	50%
≥ 20/25	65%	76%		69%
≥ 20/40	90%	91%	86%	93%

FIGURE 3
Three uncorrected visual acuities (UCVA).

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Accuracy MRSE

	CK		LTK	LASIK
	6m	12m	12m	6m
+/- 0.5 D	60%	55%	57%	66%
+/- 1.0 D	88%	91%	83%	87%

FIGURE 4

Percentage of patients within 0.5 and 1.0 diopters of target manifest refraction spherical equivalent (MRSE).

operative intervals. Of note, CK and LTK look comparable after 3 months, while LASIK is more stable than LTK in the period from 1 to 3 months. CK data in this early interval are not given. One is left wondering whether LASIK is more stable in the first 3 months than either thermal procedure (Fig 5).

As the principal measure of safety, the thermokerato-

Stability MRSE Change \leq 1D

	CK	LTK	LASIK
1 to 3 months		82%	96.4%
3 to 6 months	96%	94.8%	
	94.2%		
9 to 12 months	97%		
6 to 12 months		94.3%	
12 to 18 months		96.8%	
18 to 24 months		100%	

FIGURE 5

Stability measured by percentage of patients with \leq 1 diopter change in manifest refraction spherical equivalent (MRSE) at postoperative intervals.

plasty procedures do, in the long run, have few patients who lose best spectacle-corrected visual acuity. Despite surgical creation of a flap, LASIK results seem comparable (Fig 6).

In summary, Dr Asbell and her coworkers have demonstrated preliminary efficacy, predictability and safety of the Refractec conductive keratoplasty device in a subset of eyes at 6 and 12 months. At these intervals, the results seem comparable to LASIK with the Autonomous scanning excimer laser and the Sunrise LTK procedure, with the exception of better UCVA at the 20/20 level for the CK and LASIK patients than the LTK patients. Early

Safety Change in BSCVA

	CK		LTK	LASIK
	6m	12m		6m
Loss > -2 lines	1%	0	0	0
-2 lines	4%	0	0	4%
-1 line			0	21%
0			98.6%	54%
Gain +1line			0	17%
+2 lines			1.4%	3%
> +2 lines			0	1%

FIGURE 6

Change in best-spectacle corrected visual acuity (BSCVA) compared to preoperative value.

stability with LASIK appears better than with LTK; we don't have CK stability data before 6 months.

LASIK currently has a broader range of treatable hyperopic spherical correction, and also can treat simultaneous astigmatism. Another challenge to adoption of the CK procedure may be the large installed base of excimer lasers and microkeratome-trained surgeons.

Needless to say, good long-term results are fundamental to the success of any treatment modality. In refractive surgery today, however, the hearts and minds of patients are won by the vision on day 1, week 1 and, to some extent, at the first month after surgery. The results at these intervals are already collected in studies of these devices, but they are rarely reported because the emphasis of the FDA with its conventional reporting intervals has been on intermediate and longer term followup. However, our understanding of the clinical implications of refractive techniques also requires reporting of the key results in these early periods.

REFERENCE

1. Katz J, Tielsch JM, Sommer A. Prevalence and risk factors for refractive errors in an adult inner city population. *Invest Ophthalmol Vis Sci* 1997;38:334-340.

[Editor's note] DR DOUGLAS D. KOCH questioned the assertion that the residual refractive error was stable after 6 to 9 months. He felt that regression may continue after that and pointed out that even a 20% regression was clinically significant in cases that were treated for only 1 to 2 diopters of hyperopia. He pointed out that one of the clinical photographs showed whitening and probable necrosis of the corneal epithelium. Similar degrees of overheating in the stroma could produce necrosis of keratocytes and stimulate a wound healing response.

Conductive Keratoplasty for the Correction of Hyperopia

DR IVAN R. SCHWAB asked if endothelial cell damage or loss was studied.

DR PENNY A. ASBELL. I will try to answer the questions in order. Should the 2 eyes be analyzed separately? Generally device trials do not necessitate separate eye analyses as drug trials do since there is no drug-transfer effect. In the phase III multicenter study on conductive keratoplasty (CK), 12 month data from 401 eyes of 233 patients were combined for analysis. The FDA prior to the initiation of the study approved this method.

Why weren't cycloplegic refractions reported? For entry into the phase III CK study, patients were to have no more than 0.50 difference between their preoperative manifest and cycloplegic refractions. The patients (mean age of 55) were non-accommodating hyperopes, and the manifest and cycloplegic refractions were similar.

Should not residual refractions be reported as +/-0.50 diopters when small refractive corrections are being made? Results of the study were reported for +/-0.50 and +/-1.00 diopters of the intended plano correction.

In response to the question about the post-operative day 1 results and the "wow" effect, there is about a 0.75 diopter initial overshoot after the surgery so CK patients read J1 right away but don't immediately have 20/20 distant vision. Different refractive procedures have different advantages and disadvantages. Conductive keratoplasty has outcomes similar to those after LASIK, but unlike LASIK it spares the visual axis, does not cut corneal

nerves, and is an easier procedure to perform. Patients are not disappointed with the lack of the "wow" effect if the surgeon makes sure they understand what to expect and talks about the tradeoffs with them.

How many patients were lost to follow-up? One patient was discontinued because he was not treated. Accountability at follow-up visits ranged from 95% at month 12 to 98% at month 6. Lack of accountability at any visit was due to a missed visit, which occurred for less than 3% of the patients at any follow-up visit.

Does CK induce astigmatism? At 1 month following CK, the incidence of induced cylinder of 2.00 diopters or greater was 3%; at 1 year it was 0.5%. This is similar to induced cylinder data reported after Sunrise Hyperion laser thermal keratoplasty. Some level of induced cylinder is intrinsic into all hyperopia procedures since peripheral corneal flattening and central corneal steepening brings any peripheral irregularity to the center.

Is there data on CK treatment for astigmatism? Treatment of astigmatism with CK is now being studied. Data will be available in early 2002.

Is there information on wound healing following CK? I have presented photomicrographs of the bovine cornea following CK; they show good healing 1 week after surgery. A study reported to the American Society of Corneal and Refractive Surgery showed that the CK procedure did not significantly change endothelial cell counts in the central or peripheral cornea despite penetration of treatment to approximately 80% of the corneal depth.

