Long-term results of conductive keratoplasty for low to moderate hyperopia

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PURPOSE: To assess the long-term safety, efficacy, predictability, and stability of conductive keratoplasty (CK) for the treatment of low to moderate hyperopia and to evaluate the impact of the procedure on the quality of vision.

SETTING: University of Crete, Medical School, Vardinoyannion Eye Institute of Crete, Crete, Greece.

METHODS: In this prospective nonrandomized noncontrolled single-center study, 38 eyes of 26 patients (13 women and 13 men) were treated for hyperopia with a Refractec ViewPoint CK system and followed for 30 months. Preoperatively, the mean manifest refraction spherical equivalent (MRSE) was +1.89 diopters (D) ± 0.6 (SD) (range +1.00 to +3.25 D), and the mean follow-up was 30.9 ± 1.1 months. All eyes were treated with the regular CK nomogram for the treatment of spherical hyperopia. The treatment consisted of 8 to 32 spots applied to the periphery of the cornea. Mean age was 50.3 ± 8.8 years (range 31 to 71 years). All treated eyes were analyzed for safety, efficacy, predictability, and stability.

RESULTS: At 12 months, the MRSE was −0.06 ± 0.8 D and at 30 months was −0.02 ± 0.7 D. At 30 months, the mean MRSE was within ±0.50 D in 68%, within ±1.00 D in 92%, and within ±2.00 D in all eyes. At 30 months, uncorrected visual acuity was 20/20 or better in 52.5% and 20/40 or better in 89% of eyes. No eye lost 2 or more Snellen lines or had an induced cylinder of 2.00 D or greater. The procedure did not cause statistically significant changes in contrast sensitivity.

CONCLUSION: Results show that CK for low to moderate hyperopia is a safe, effective, predictable, and stable procedure.

Over the past decade, thermokeratoplasty procedures for the correction of low hyperopia have evolved greatly. Thermokeratoplasty techniques are considered more friendly to the cornea than photoablative procedures, because the central clear optical zone of the cornea remains intact. Thermokeratoplasty techniques today include laser thermal keratoplasty (LTK) with a holmium:YAG laser, both contact and noncontact;[1–7] continuous-wave diode LTK;[8] and conductive keratoplasty (CK).[9–13]

Nevertheless, laser in situ keratomileusis (LASIK) remains the most popular technique for the correction of low to moderate hyperopia[14–23] with photorefractive keratectomy (PRK)[24–27] and recently reported laser-assisted subepithelial keratectomy (LASEK)[28] for low hyperopic errors.

Conductive keratoplasty, which is a thermokeratoplasty procedure, is used for the correction of low to moderate hyperopia with or without astigmatism using high-frequency (radio frequency, 350 kHz), low-energy current (data on file, Refractec). The procedure was first used by Mendez and Mendez Noble[9] in 1993.

Controlled-released energy is delivered within the stroma of peripheral cornea with a keratoplasty tip (Keratoplast, Refractec) inserted to the depth of 500 μm (data on file, Refractec). The technique uses electrical properties of the corneal tissue. The tissue temperature rise

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is induced by electric impedance in the flow of energy through collagen fibrils, causing collagen shrinkage when the temperature reaches 65°C.

The treatment probe is inserted into the cornea in a spot-by-spot manner, each time completing circles of 8 spots starting at the 6.0 mm optical zone and expanding if demanded by the nomogram to the 7.0 mm and 8.0 mm zones. These 3 circles of treatment can be combined with intermediate spots at the 7.0 mm zone to increase the effect of the treatment. The described nomogram is used for treatment of low to moderate hyperopia. Adding extra spots to the flat meridian of astigmatism enables a surgeon to treat an astigmatic component as well as to perform a series of customized operations such as in cases of previously decentrated ablation, corneal trauma, or even keratoconus.[12]

We report the 30-month results of CK for the correction of low to moderate hyperopia, the impact of the technique on the quality of vision in contrast sensitivity, and the results of subjective patients' evaluation.

PATIENTS AND METHODS

In a prospective nonrandomized noncontrolled single-center clinical study, 38 eyes of 26 patients (13 women and 13 men) were treated for hyperopia with CK. The treatment was performed with a ViewPoint CK system (Refractec). A detailed informed consent was obtained from the entire patient group prior to surgery. The approval of the Ethical Board Committee for the study was attained. Mean age of the patients was 50.3 years ± 8.8 (SD) (range 31 to 71 years). Treated eyes had +1.00 to +3.25 diopters (D) of hyperopia and 0.75 D or greater of cylinder (cycloplegic refraction). The intended refraction was plano in all cases.

Protocol

None of the patients had existing or chronic ocular or systemic diseases, a history of ocular surgery or trauma, a steroid-responsive increase in intraocular pressure (IOP), or unstable, progressive hyperopia. Contact lens users (there were no hard contact lens wearers in this study) were advised to discontinue their contact lens use 21 to 30 days prior to the preoperative evaluation and the procedure. The participants had to have a clear cornea image in the slitlamp microscope examination and undistorted mires in the central keratometry examination. Eyes with ultrasound pachymetry readings of 550 µm at the 6.0 mm zone and eyes with an uncorrected distance visual acuity of 20/32 or better were excluded from the study.

The examination protocol for all patients at each examination included manifest refraction (fogging technique), cycloplegic refraction, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), computerized corneal topography, slitlamp microscopy, dilated fundus examination, central and peripheral (6.0 mm optical zone) ultrasound pachymetry, contrast sensitivity test, measurement of IOP (with Goldmann applanation tonometry), and a questionnaire with subjective patient evaluation of the quality of vision (after surgery). Follow-up examinations were scheduled for 1 and 24 hours after surgery, followed by examinations at 1, 3, 6, 9, 12, 24, and 30 months.

Measurements of manifest and cycloplegic refractions at distance were performed using a Snellen chart. Cycloplegic refraction was measured after at least 2 applications of cyclopentolate 1% drops 10 minutes apart, 30 minutes after the first application. Computerized corneal topography was performed with EyeSys Premier topography unit (EyeSys Technologies, version 3.1) and with a C-scan corneal topography unit with ray tracing (Technomed GmbH). Corneal thickness (central and peripheral) was measured with ultrasound pachymetry (DGH 5100 Technology, Inc). Monocular contrast sensitivity function was measured with a CSV 1000 contrast sensitivity chart (Vector Vision).

Attempted correction was based on cycloplegic refraction. In all eyes, the number of spots for the spherical hyperopic component was selected in accordance with a standard Refractec nomogram for spherical hyperopia treatment. The patients received a total number of 8 to 32 spots of treatment at the circles of the 6.0 mm, 7.0 mm, and 8.0 mm zones.

Surgical Procedure

Both unilateral and bilateral treatments were performed. All procedures were done by the same surgeon (I.G.P.) with a ViewPoint CK system. All procedures were performed under topical anesthesia. A drop of propocaine 0.5% was administered in the operative eye 15 minutes before the procedure followed by a second application right before the surgery. Eyes were prepped with povidone–iodine (Betadine), and lids were retracted with a ViewPoint CK speculum.

Careful attention was paid to marking the 6.0 mm, 7.0 mm, and 8.0 mm optical zones on the center of the cornea with a CK ViewPoint marker. The surface was irrigated with a balanced salt solution and then dried with a fiber-free sponge. According to the marking, the spots were applied to the cornea starting with a circle at the 6.0 mm optical zone and followed when necessary by circles of spots at the 7.0 mm and 8.0 mm zones as advised by the nomogram. The treatment spots were applied to the cornea with the Keratoplast tip placed perpendicular to the corneal surface. All eyes were treated with the standardized setting of 350 kHz, 60% power for 0.6 seconds per spot. As soon as the procedure was completed, drops of tobramycin 0.3% (Tobrex) and a drop of flurbiprofen sodium 0.03% (Ocuflur) were administered. One hour after surgery, all patients had a slitlamp microscope examination.

Treatment After Surgery

After surgery, the patients received a treatment of tobramycin 4 times a day for 2 weeks with flurbiprofen sodium 0.03% 4 times a day for the first 2 days after surgery. Patients were encouraged to use a drop of artificial tears 5 to 6 times a day for the first 2 weeks after surgery.

Statistical Analysis

Statistical evaluation of the results was performed as means, standard deviations, ranges, and confidence intervals (CIs). Ninety-five percent CI limits were calculated for differences in mean results. The differences between the groups (preoperative group, 1-, 3-, 6-, 9-, 12-, and 30-month postoperative groups) were assessed by analysis of variance (1-way) followed by the

Student-Newman-Keuls post hoc multiple comparisons tests. *P* values less than 0.05 were considered statistically significant. Dioptric power matrix, as suggested by Kaye and Harris,[29] was used to perform quantitative analysis of refractive data.

RESULTS

Slitlamp Microscopy

Slitlamp microscopy 24 hours after surgery revealed a white zone of stromal edema surrounding each spot of treatment. Corneal opacities corresponding with each treatment spot were observable by slitlamp microscopy during the whole follow-up period. Folds in Descemet's membrane were detectable on slitlamp microscopy in all eyes. Fluorescein staining demonstrated a small epithelial defect corresponding to the treatment spot. The epithelial defect healed during the first 48 to 72 hours after surgery.

Efficacy

The percentage of eyes with a UCVA better than 20/40 and 20/25 were also analyzed to represent the treatment's efficacy. Values of UCVA before and after surgery are demonstrated in Figure 1. Preoperatively, the mean UCVA was 0.42 (20/40) ± 0.22, with a range 0.2 to 0.9 (20/100 to 20/25). One month after surgery, UCVA reached a mean of 0.78 (20/32) ± 0.25, with a range 0.2 to 1.2 (20/100 to 20/16). Starting 3 months after surgery, the mean UCVA measurement was improved up to 0.84 (20/25) ± 0.27. At 12 months, the mean UCVA was 20/20 or better in 19 of 38 eyes (50%) and 20/40 or better in 34 eyes (89%). At 30 months, 20 of 38 eyes (52.5%) had a UCVA of 20/20 or better and 25 eyes (68%) had a UCVA of 20/25 or better. Uncorrected visual acuity of 20/40 or better was achieved in 34 of 38 eyes (89%). Mean UCVA at this period was 0.9 (20/25) ± 0.29, with a range 0.2 to 1.2 (20/100 to 20/16).

There was a statistically significant difference in UCVA measurements before and after surgery ($F = 13.468$, $df = 5164$, $P < .001$). After surgery, the differences among the postoperative 3-, 6-, 9-, 12-, and 30-month groups were not statistically significant.

Safety

Before surgery, the mean BSCVA was 1.03 (20/20) ± 0.15, with a range 0.5 to 1.2 (20/40 to 20/16). There was no statistically significant difference in the BSCVA values between the preoperative and postoperative measurements ($F = 0.096$, $df = 5166$, $P < .993$). No eye lost 2 Snellen lines or more or had an induced cylinder of 2.00 D or greater. The BSCVA was better than 20/40 in all the treated eyes.

The distribution of BSCVA line change is shown in Figure 2. Fourteen percent of eyes gained 1 Snellen line, whereas a loss of 1 line was observed in 14% of eyes 12 months after surgery. At 30 months, the lines gained/lost did not differ from the 12-month measurements. Seventy-two percent of eyes had no change in BSCVA at 30 months.

Absolute change in refractive cylinder observed after surgery is demonstrated in Table 1. Increase of cylinder up to 1.75 D was mostly observed at the first examinations after surgery. The induced cylinder values decreased gradually during the whole follow-up period (Table 1). Dioptric power matrix analysis of preoperative versus postoperative sphere, astigmatism, and its axis as they co-vary is demonstrated in Table 2, as is the refractive surgical effect.

Predictability

Predictability was evaluated by the mean postoperative manifest refraction spherical equivalent (MRSE) and the

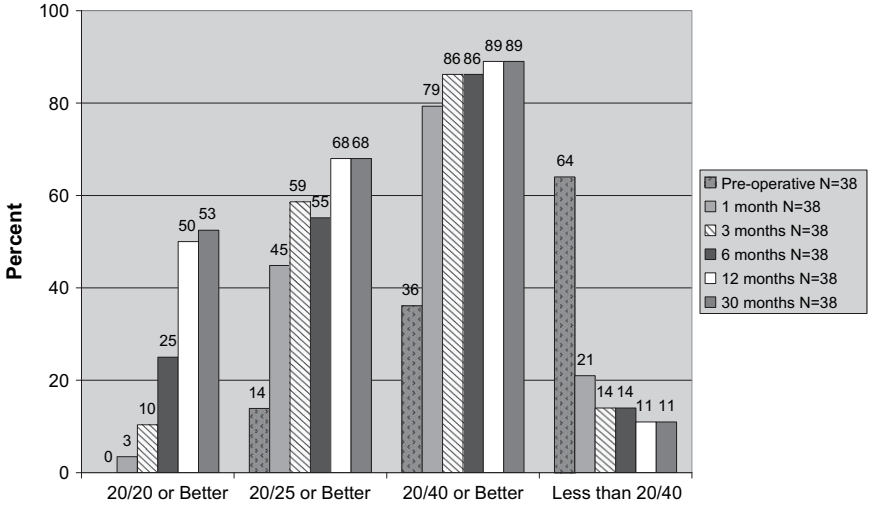

Figure 1. Efficacy: UCVA after surgery.

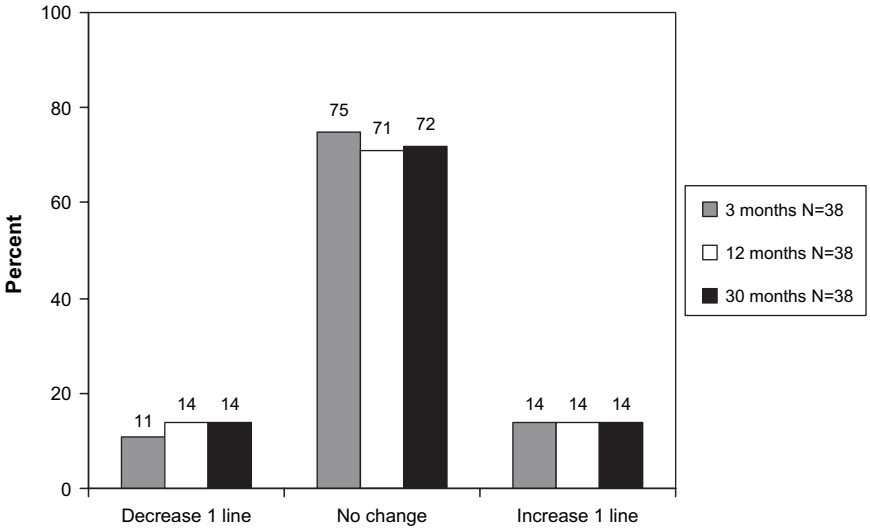

Figure 2. Safety: change in BSCVA compared with preoperatively.

percentage of eyes within ±0.50 D and ±1.00 D of emmetropia. Before surgery, the mean MRSE was +1.9 D ± 0.6 (range +1.00 to +3.25 D). Attempted MRSE versus achieved MRSE is demonstrated in Figure 4. At 12 months, the mean MRSE was −0.06 D ± 0.8 and at 30 months, −0.02 D ± 0.7. At the last follow-up examination (30 months after surgery), it was measured within ±0.50 D of plano in 26 of 38 eyes (68%), within ±1.00 D in 35 eyes (92%), and within ±2.00 D in all eyes (Figure 3).

There was a statistically significant difference in MRSE between the preoperative and postoperative groups ($F = 43.160$, df = 5 166, $P<.001$). At 30 months, no eye was undercorrected by 1.00 D or greater of hyperopia and 3 of 38 eyes (7.8%) were overcorrected by 1.00 D or greater.

Stability

All eyes were evaluated for stability (mean diopter change in MRSE over time). Only the data of the patients who followed all the scheduled follow-up examinations were included in this analysis. The MRSE changed by 0.06 D between 3 and 6 months after surgery, 0.01 D between 6 and 12 months, and 0.04 D between 12 and 24 months postoperatively. Stability was achieved 6 months after surgery. Distribution of MRSE in the course of the follow-up is demonstrated in Figure 5.

Complications and Adverse Events

No complications occurred during the 38 surgeries, and no sight-threatening complications were reported postoperatively. Moderate discomfort and foreign-body sensation were reported in 13 of 38 eyes (34%). These symptoms resolved in all eyes in the first 72 hours after surgery. Light sensitivity in the first 48 hours was reported in 26 of 38 eyes (68%). Blurred distance vision was observed during the whole follow-up period in 1 eye of 38 (2.6%) with intended overcorrection. In 1 eye (2.6%) with induced

Table 1. Absolute change in refractive cylinder (follow-up examinations (N = 38 eyes)).

	Number (%)				
Cylinder Increase (D)	1 Month	3 Months	6 Months	12 Months	30 Months
1.25 to 1.75	13 (34.2)	12 (31.5)	7 (18.4)	6 (15.7)	5 (13.1)
1.00	4 (10.5)	5 (13.1)	3 (7.9)	2 (5.2)	2 (5.2)

Table 2. Dioptric power matrix analysis (Kaye and Harris[29]).

Parameter	F11	F12	F22	DET	TRACE	Sphere	Cylinder	Axis
Preoperative	2.022224	−0.0128	2.102776	4.252	4.125	2.02	0.08	8.81
Postoperative	−0.1488	0.011831	0.122506	−0.018	−0.026	−0.15	0.27	177.51
RSE	−2.17105	0.02463	−1.98027	4.299	−4.151	−2.17	0.20	172.76

F11, F12, F22 = matrix components; RSE = refractive surgical effect

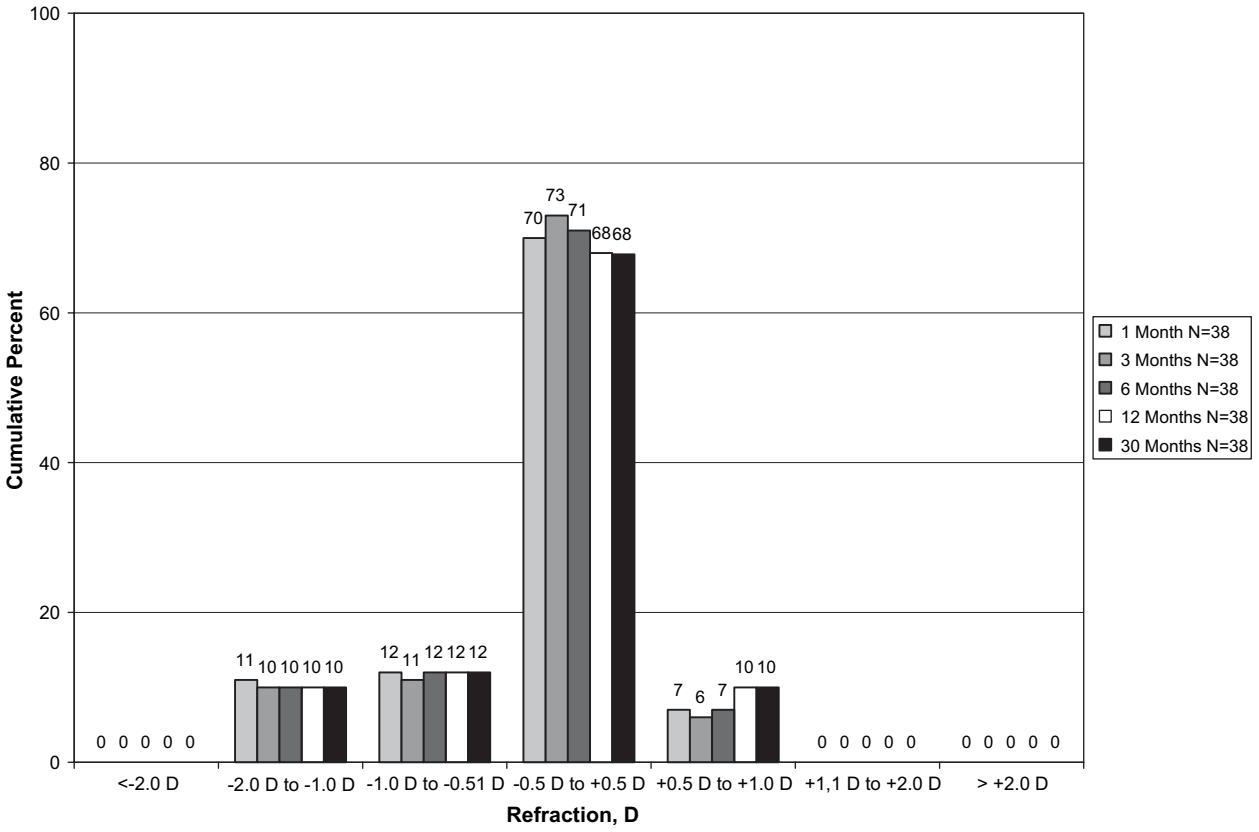

Figure 3. Predictability.

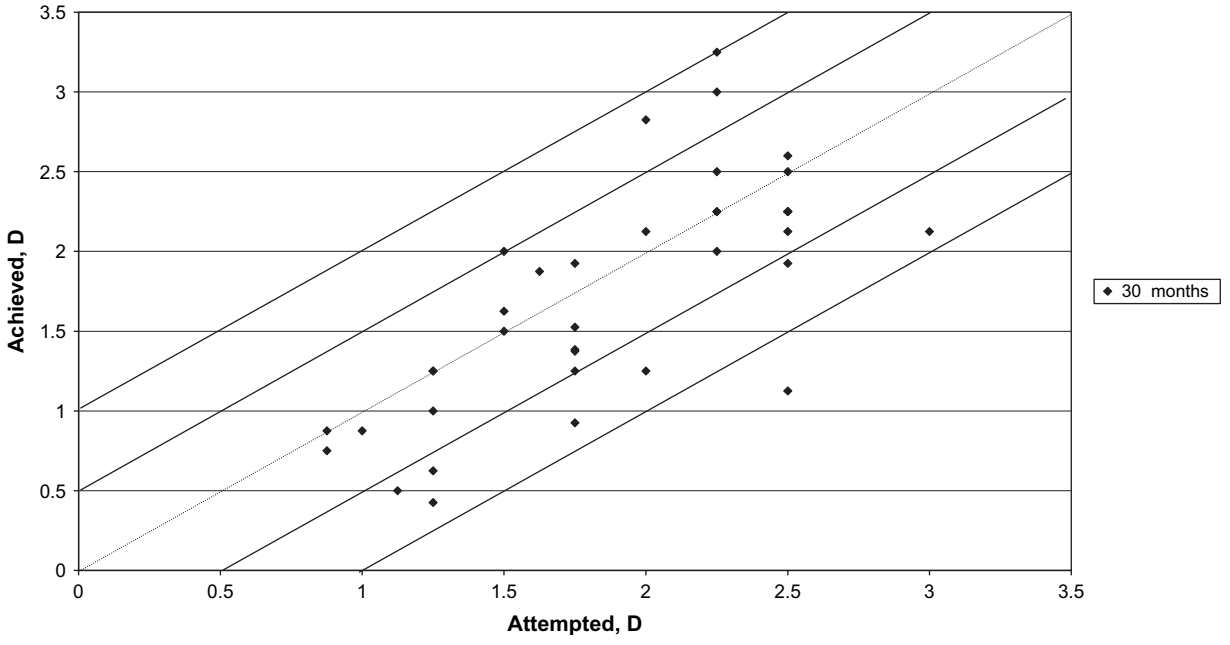

Figure 4. Scattergram of attempted versus achieved MRSE.

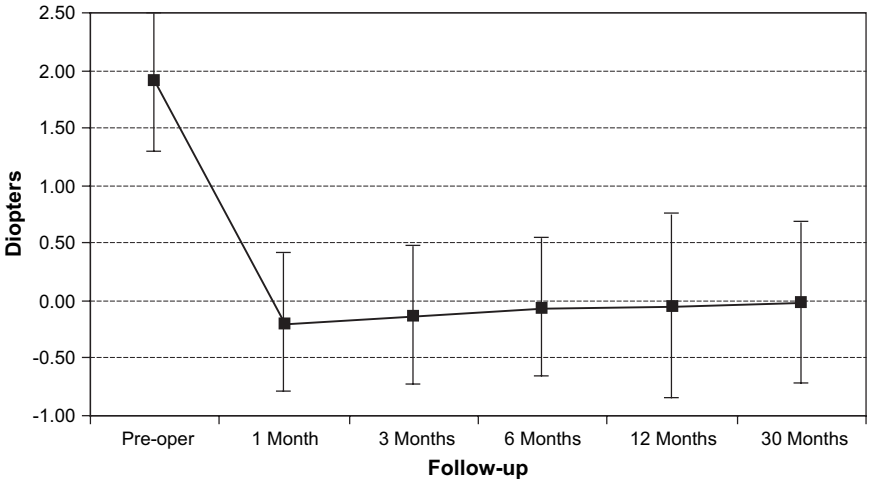

Figure 5. Mean MRSE during the follow-up period.

cylinder, the patient complained of starbursts up to 9 months after surgery. No retreatments were performed.

Contrast Sensitivity

The analysis included changes in the contrast sensitivity function curve at the spatial frequencies of 3, 6, 12, and 18 cycles per degree (cpd) under scotopic conditions (only the chart illuminated). There were no statistically significant changes in spatial frequencies between preoperative and postoperative measurements.

By 9 months after surgery, 3 of 38 patients (7.9%) experienced a decrease in contrast sensitivity function at low spatial frequency of 3 cpd and 8 of 38 (21%) experienced an increase of 1 or more lines at the same frequency.

At the spatial frequencies of 6 and 12 cpd, almost no change in contrast sensitivity was recorded in the early or late in the follow-up period.

At the high spatial frequency of 18 cpd, an increase in contrast sensitivity lines was observed in 44% of the eyes by the 9-month examination and was observed through the whole follow-up period. Summarizing, there was a tendency toward improvement in contrast sensitivity at spatial frequencies of 3 cpd and 18 cpd, even by the 9-month interval, but this tendency was not statistically significant.

Subjective Evaluation

On the patient a questionnaire concerning postoperative quality of vision, the scale of satisfaction was set from 1 to 4, where 1 corresponded to poor quality of vision; 2, indifferent outcome; 3, moderate improvement of quality; and 4, high improvement in quality of vision. The results are demonstrated in Table 3.

Twelve months after surgery, patients reported moderate to high improvement in quality of vision in 21 of 38 eyes (52%) a number that increased by the end of the follow-up period up to 58% (22 of 38 eyes). Only 1 patient reported poor quality of vision at 12 months because of starburst phenomenon, a symptom that was not reported at 30 months.

DISCUSSION

Efficacy

High levels of UCVA were achieved early in the follow-up. A mean UCVA value of 20/40 was increased to 20/32 starting at 1 month. This measurement stabilized at 3 months and remained at a mean of 20/25 throughout the follow-up period. At 12 months, the UCVA was 20/20 or better in 19 of 38 eyes (50%) and 20/40 or better in 34 eyes (89%). At 30 months, 20 of 38 eyes (52.5%) had a UCVA of 20/20 or better and 25 (68%) had a UCVA of 20/25 or better. Uncorrected visual acuity of 20/40 or better was achieved in 34 eyes (89%).

Compared with PRK corrections, the observed results are better than in reviewed studies. Pietilä and coauthors[25] reported an efficacy of 20/20 or better in 6.3% and 20/40 or better in 67%; Vinciguerra and coauthors[27] mentioned a mean of 0.37 (20/50 to 20/63). Only Jackson and coauthors[26] reported equal or better than CK results after PRK (20/25 or better in 80% and 20/40 or better in 88%). Another study by the same author reports a UCVA of 20/25 or better in 70% of eyes at 12 months and the same results up to 18 months.[30]

Autrata and Rehurek[28] reported 2-year results of PRK and LASEK for hyperopia that after 2 years. The UCVA was of 20/40 or better in 81% in the PRK group and 91% in the LASEK group. No PRK eye had a UCVA

Table 3. Subjective patient assessment of quality of vision after CK (N = eyes).

	Number (%)		
Quality of Vision	1 Mo (%)	12 Mo (%)	30 Mo (%)
Poor	1 (2.6)	1 (2.6)	0
Indifferent	10 (26.2)	6 (15.7)	7 (18.4)
Moderate improvement	5 (13.1)	7 (18.4)	8 (47.3)
High improvement	5 (13.1)	14 (36.8)	14 (36.8)

better than 20/20, but 6% LASEK eyes had a UCVA of 20/15.

The achieved efficacy of 20/20 or better (52.5%) is equal to or better than that reported in LASIK studies. Portellinha and coauthors[31] reported a mean UCVA of 20/20 or better in 41%, Attia and coauthors[32] in 12%, and Arbelaez and Knorz[15] in 42%.

When compared with LTK corrections of hyperopia, CK demonstrated overall higher efficacy. Alió and coauthors[7] reported UCVA of 20/20 or better in 47% of eyes and 20/40 or better in 72% at 15 months; Koch et al.[2] reported a mean value of 20/63. Pop[33] reported a UCVA of 20/20 or better in 24% of the treated eyes. A recent study of noncontact LTK for hyperopia with a 2-year follow-up[34] described better efficacy results than other LTK reports. At 2 years, UCVA was 20/40 or better in 100% of eyes and 20/20 or better in 84%.

Lin and Manche[13] reported UCVA of 20/20 or better in 64% having CK and UCVA of 20/40 or better in 95% of the treated eyes at 2 years. A CK study by McDonald et al.[10] reported higher efficacy levels of 20/20 or better than those observed in this study (57% versus 52.5%); the results on lower efficacy levels are similar (20/40 or better in 93% versus 89%). Pallikaris et al.[12] reported 1-year results of a UCVA of 20/20 or better in 50% of the treated eyes. Mendez and Mendez Noble[9] reported that all except 1 of the treated eyes had an UCVA range of 20/20 to 20/30 at 1 year.

Predictability

Thirty months after surgery, the mean MRSE was −0.02 ± 0.7 D. At the latest examination (30 months), the MRSE was within ±0.50 D of plano in 26 of 38 eyes (68%), within ±1.00 D in 35 eyes (92%), and within ±2.00 D in 100% of treated eyes. These results stabilized 3 months after surgery.

Predictability of CK demonstrated in this study exceeds the results achieved with most of PRK corrections. For instance, Vinciguerra and coauthors[27] reported 31% of the eyes within ±1.00 D of intended refraction, and Pietilä and coauthors[25] reported 40% of eyes within ±1.00 of plano and 20% within ±0.50 D. However, Jackson and coauthors[26] reported results similar to ours for predictability within ±1.00 of plano (88%) and 80% of the treated eyes within ±0.50 D at 12 months after surgery. Another PRK study by Jackson et al.[30] reported 80% eyes were within ±0.50 D of plano and 98% were within ±1.00 D at 24 months. A hyperopic LASEK study by Autrata and Rehurek[28] reported that 78% of eyes were within ±0.50 D of plano at 2 years.

Concerning predictability of the refractive outcome, we observed results as good as or better than those obtained with hyperopic LASIK.[14–22] In this comparison group, Reviglio et al.[18] reported on predictable results for low to moderate (up to +6.00 D) hyperopia. At the end of the follow-up, 88% of the treated eyes within ±1.00 D of intended refraction. Arbelaez and Knorz[15] reported similar spherical equivalent (SE) refraction results within ±1.00 D 12 months after surgery in low to moderate hyperopia groups (91% and 85%, respectively). Esquenazi and Mendoza[21] reported that 24 months after surgery, 74% of treated eyes were within ±1.00 D of intended refraction, which is lower than our results.

Compared with LTK, CK demonstrated higher predictability than in most LTK studies. Nano and Muzzin[4] reported 46% of the eyes within ±1.00 D of plano. Twelve months after surgery, initial SE refraction was reduced by only half (+2.50 ± 0.87 D was reduced to +1.25 ± 0.96 D). Alió and coauthors[7] reported 57.8% of the treated eyes within ±1.00 D of intended refraction. The majority of surgeons performing LTK agree on the low predictability of the technique.[3–7] However, a recent LTK study by Rocha et al.[34] reported high predictability; 92% of the eyes were within ±0.50 D of plano, and 100% within ±1.00 D 2 years postoperatively.

Compared with results in other studies of CK, the present results demonstrate a bit higher predictability of MRSE, especially in the group of eyes within ±0.50 D of intended refraction (68%). Lin and Manche[13] reported 64% of eyes within ±0.50 D of plano and 91% within ±1.00 D at 24 months. Mendez and Mendez Noble[9] reported 50% of treated eyes within ±0.50 D and 90% within ±1.00 D at 1 year, whereas McDonald et al.[10] reported a mean MRSE within ±0.50 D in 46% (13 of 28 eyes), within ±1.00 D in 93% (26 of 28 eyes), and within ±2.00 D in 100%.

Stability

Stability was evaluated as a mean diopter change in MRSE during the follow-up period. No statistically significant difference was observed between the mean values over the follow-up period. The mean MRSE changed 0.50 D or less in 34 of 38 eyes (90%) between 3 and 6 months after surgery, 35 eyes (93%) between 6 and 12 months, and 100% of eyes between 12 and 30 months. The absolute changes

were 0.06 D between 3 and 6 months after surgery, 0.01 D between 6 and 12 months, and 0.04 D between 12 and 24 months. The SE refraction stabilized between 3 and 6 months after surgery.

Compared with PRK corrections, CK demonstrated more stable results, as shown in the present study and previously published CK studies. Pietilä and coauthors[25] reported that although most eyes were relatively stable at 3 months, regression was a constant finding with PRK for hyperopia. Jackson and coauthors[26] reported that slight regression was observed after PRK and a regression with a mean of +0.31 D in another study with an 18-month follow-up.[30]

Conductive keratoplasty achieved even higher stability values than hyperopic LASIK.[14–23] Esquenazi and Mendoza[21] reported regression less than 0.50 D at 1 year. Similar results were reported by Arbelaez and Knorz.[15] Zadok et al.[16] reported significant regression of low to moderate hyperopia after LASIK, whereas another study by Zadok and coauthors[23] reported higher levels of regression in the low hyperopia group by the 18-month postoperative period.

Conductive keratoplasty stability results exceed by far the ones achieved with LTK treatment.[3–7] Ever since LTK technology was introduced, regression has been a major topic of discussion.[35,36]

Eggink and coauthors[5] reported regression and low predictability of the effect. Instability of refraction persisted up to 1 year after treatment. Reports of regression were supported by another study by Eggink and coauthors.[6] Nano and Muzzin[4] reported 1-year results of LTK treatment in 182 eyes; the retreatment rate was in the first 9 months after surgery.

Attia and coauthors[32] reported LASIK for recurrent hyperopia after LTK performed in 50 eyes; regression was 100% in 15 eyes, 75% in 22 eyes, and 50% in 7 eyes. In another LTK study of 57 eyes with naturally occurring hyperopia by Alió and coauthors,[7] regression of the effect was evident in all eyes and was total in 31.5% of eyes by the end of the follow-up period. Retreatment rate was 19.2%.

A 2-year CK study by Lin and Manche[13] reported a low and decreasing regression rate of +0.024 D per month between 12 and 24 months. In our study, the mean total regression between 12 and 30 months was +0.04 D. In McDonald et al.,[10] the achieved levels of stability were similar to ours. In our study, the longest study to date on CK, the MRSE changed less than 0.50 D between 12 and 30 months in 100% of the treated eyes.

Safety

No sight-threatening complications were observed intraoperatively or postoperatively. Complaints after surgery included discomfort and foreign-body sensation in one-third of the eyes during the first 3 days, accompanied by light sensitivity in two thirds of the patients. Other complaints (blurred distance vision and starbursts) had to do with the achieved refractive outcome and were recorded in only 2 eyes.

In the present study, no eye lost 2 Snellen lines or more, and all eyes had a BSCVA of 20/40 or better. In PRK studies, Pietilä and coauthors[25] and Vinciguerra and coauthors[27] reported on much higher percentages than in CK studies, a loss of BSCVA of 2 lines or more (6.6% and 7%, respectively).

In a LASIK study, Zadok and coauthors[23] reported a 3.9% decrease in the BSCVA; Zadok et al.[16] reported a line loss of 1.4% only in the moderate hyperopia group. Reviglio et al.[18] reported no loss of 2 or more Snellen lines. Arbelaez and Knorz[15] reported similar results at 12 months after surgery in a low to moderate hyperopia group. Lindstrom et al.[20] reported a 2% line loss, whereas Esquenazi and Mendoza[21] reported that 24 months after surgery, 5% of the treated eyes lost 2 or more Snellen lines. Laser thermal keratoplasty studies[2–7,37] mostly reported induced cylinder and rarely reported loss of 2 Snellen lines or more.

In this study, none of the patients had 2.00 D or greater induced cylinder. Induced cylinder of 1.00 to 1.75 D was seen in 31.5% of eyes (12 of 38) at 3 months, a percentage that decreased to 15.7% (6 of 38 eyes) at 12 months. At 30 months, induced cylinder of 1.00 to 1.75 D was observed in 5 of 38 eyes (13%). We believe that the reported values of induced cylinder are the major safety setbacks of CK. With CK, an increase in cylinder occurs if the cornea is not marked properly prior to surgery or when spots are not applied symmetrically according to the marking.

In a 2-year CK study by Lin and Manche,[13] 12% had an induced cylinder greater than +1.00 D; none had more than +1.75 D. At 24 months, no eye had induced cylinder greater than +0.75 from baseline. These results are better than the ones that we report. In McDonald et al.[10] at the end of the follow-up, induced cylinder of 1.00 D to 1.75 D was seen in 11.8% of eyes and none of the patients experienced an increase of 2.00 D or more of cylinder. In our study 13% had an increase of 2.00 D.

Contrast Sensitivity

We analyzed quality of vision achieved after CK treatment using contrast sensitivity and subjective evaluation of the patients. We did not observe statistically significant changes at any spatial frequencies postoperatively. An insignificant increase in contrast sensitivity values was observed at 3 and 18 cpd spatial frequencies. We did not observe significant changes in lost or gained contrast sensitivity lines in different phases of the follow-up.

The fact that no significant contrast sensitivity loss was observed is encouraging because a loss of contrast sensitivity lines is common after other refractive procedures. The reported findings are similar to reports in our previous CK study with a 1-year follow-up.[12]

After LASIK, Montés-Micó and Charman[38] reported that contrast sensitivity before surgery at all frequencies did not differ from that 6 to 12 months after surgery. Holladay and coauthors,[36] however, reported worsening in functional vision after LASIK because the target contrast diminished and pupil size increased. Arbelaez and Knorz[15] also reported that alterations in the corneal curvature after hyperopic LASIK caused significant optical aberrations, which led to a loss of contrast sensitivity. After PRK for hyperopia, Stevens and Ficker[39] reported a significant decrease in contrast sensitivity. After LTK, Koch et al.[2] reported that mean contrast sensitivity values were essentially unchanged compared with preoperative values in all groups.

The results of subjective patients' evaluation of the quality of vision after surgery were satisfying. None of the treated patients reported poor quality of vision at 30 months. Moderate to high improvement in preoperative quality of vision was reported in more than 84% of cases (22 of 38 eyes), whereas indifferent outcome was reported in 7 eyes (18.4%). Our results on subjective evaluation by the patients are similar to the results by Lin and Manche[13] and McDonald et al.[10]

In conclusion, the demonstrated efficacy, predictability, stability, and safety of CK are not lower but often higher than those of the currently used refractive procedures. It is important that 30 months postoperatively, the levels of stability remained high. The most concerning issue for beginning CK surgeons is induced cylinder. It decreases with time but can also be managed with an enhancement procedure (CK or LASIK retreatment). The characteristics of the technique are encouraging, especially if we take into account that CK is minimally invasive.

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