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Radial keratotomy for the optical rehabilitation of mild to moderate keratoconus: More than 5 years' experience

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PURPOSE. *To present the authors' long-term experience of radial keratotomy (RK) for the optical rehabilitation of patients with mild to moderate keratoconus – central corneal thickness of greater than 400 µm and without apical scarring.*

METHODS. *In this observational, noncomparative series of cases, all consecutive patients with mild or moderate keratoconus, treated by RK between 1990 and 2002, with at least 1 year follow-up were included. A total of 170 eyes of 96 patients were investigated. Mean follow-up was 42.08 ± 28.14 months. Visual acuity, refraction, corneal curvature, central corneal thickness, and complications were evaluated.*

RESULTS. *In all of the control visits, mean uncorrected and best spectacle corrected visual acuities were better than preoperative values ($p<0.0001$). Preoperative myopic spherical refraction decreased significantly ($p<0.0001$), and remained relatively unchanged throughout the follow-up ($p=0.43$). A small but statistically significant decrease from baseline was observed in astigmatism ($p=0.038$), which almost disappeared 1 year after the surgery ($p=0.47$). The surgery produced a statistically significant flattening of the corneal curvature ($p<0.0001$). Central corneal thickness did not change significantly ($p>0.05$) in either control visit. In 33 eyes (19.4%), re-deepening of the incisions was required. In 3 eyes (1.8%) penetrating keratoplasty was performed, due to disease progression in 2 eyes (1.2%) and acute traumatic hydrops in 1 eye (0.6%). In 4 eyes (2.2%) microperforation, in 2 eyes (1.2%) macroperforation, in 1 eye (0.6%) infectious keratitis, and in 1 eye (0.6%) hyperopic shift occurred.*

CONCLUSIONS. *RK surgery was found to be a reasonable option for the rehabilitation of a selected group of keratoconus patients in the early or moderate stages. (Eur J Ophthalmol 2006; 16: 376-84)*

KEY WORDS. *Keratoconus, Radial keratotomy*

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INTRODUCTION

The optimal rehabilitation of keratoconus usually depends on the disease severity and may also include some invasive treatment modalities. In advanced stages of the disease, because of the development of severe corneal irregular astigmatism, progressive stromal thinning, and apical stromal scarring, penetrating keratoplasty will ultimately become necessary in order to improve the visual acuity (1, 2). In the mild to moderate disease stages, on the other hand, contact lenses (even spectacles in some cases) are usually tried as the initial therapeutic option with variable degrees of success (3). For the optical rehabilitation of contact lens intolerant patients, however, a number of surgical treatment modalities have become necessary. They include incisional keratotomy, photore-

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fractive keratectomy (PRK), laser-assisted *in situ* keratomileusis (LASIK), epikeratoplasty, and intrastromal ring implantation (4-10).

Some contradictory case reports (most of them were negative) were published in the medical literature describing the results of radial incisional keratotomy (RK) procedure in keratoconus (11-16). Since 1990, we have been performing RK in patients with keratoconus in order to reduce the astigmatism and myopic refractive error and thus improve the visual acuity. Between 1995 and 2002, we have limited our patient selection criteria with patients in mild and moderate stages (central corneal thickness equal to or greater than 400 µm), because of the complications encountered in patients with advanced stages of keratoconus and the changing trends in ophthalmic surgery. We have also adjusted the optic zone size and number of radial incisions with respect to the spherical myopic error. In eyes with high amounts of astigmatism, we preferred the use of oblique optic zones and adjust them with respect to the axis of astigmatism.

In this study, we present our experience of more than 5 years (starting from 1990) in patients with mild to moderate keratoconus – central corneal thickness of greater than 400 µm and without apical scarring. Although it had an observational, noncomparative case series design without incorporation of a control group, our study is different from short case reports with respect to strict patient selection criteria, surgical protocol, much larger number of eyes involved, and longer follow-up.

METHODS

The study was designed to include all the consecutive eyes presenting with central keratoconus and treated by RK in Beyoglu Eye Education and Research Hospital between 1990 and 2002. Preoperative examination was performed at least 1 month after the discontinuation of contact lens wear in patients already wearing them and included the following:

- Uncorrected visual acuity (UCVA) at Snellen.
- Objective and subjective phoropter refraction.
- Best spectacle corrected visual acuity (BSCVA) at Snellen.
- Keratometry by using a Javal type keratometer.
- Corneal topography with a computerized device.
- Corneal thickness with ultrasonic pachymeter in central and peripheral cornea.
- Axial length measurement with A-scan biometry.
- Biomicroscopy for detection of corneal scarring, or other pathologies.
- Intraocular pressure measurement by using applanation tonometer.
- Retinal examination after pupillary dilatation.

The following criteria must have been met in all study eyes during initial evaluation in order to be considered eligible for the RK procedure:

- Central corneal thickness greater than 400 µm (mild or moderate keratoconus).
- No apical scarring.
- No ocular diseases other than keratoconus.
- Poor visual acuity with spectacles.
- Contact lens intolerance or not willing to wear contact lenses.
- Patients were informed about the procedure and an informed consent was obtained.

Prior to the surgery, the target refraction aiming to be corrected by the RK procedure was determined. The objective refraction under cycloplegia was taken as the surgical target if reproducible objective and subjective refraction testing could be performed. For those eyes without any reliable and reproducible refraction testing, the targeted correction for spherical refraction (myopia) was determined by considering the influences of both axial length and keratometry using the following formula:

Target for myopia (diopters) = (average keratometry – 43.5) –3 x (axial length – 23.5).

This formula provided only an approximation of targeted correction. It was derived by one of the authors (OFY), taking the average keratometry and axial length measurements of the population into consideration (17).

The target for surgical correction of astigmatism was determined by keratometry.

All of our patients operated with this technique had central keratoconus. Patients with eccentric keratoconus, whose refraction could not be precisely determined or in whom the radial cuts needed to be placed asymmetrically (i.e., some of them very near the limbus and very short in length while the others crossed the papillary axis), were regarded as not eligible for RK procedure.

Surgical treatment protocol involved the following:

- Centripetal Russian style radial incisions were made by using 30° diamond blades with a dull vertical back edge.
- The Thornton optical zone markers (from 3.0 mm to 5.0 mm in quarter mm steps), radial 6 line, and 8 line low

profile markers were used for corneal marking before making incisions.
- Incision depth was adjusted to 100% of the thinnest pachymetric reading.
- Number of incisions and central optic zone (ZO) diameter were selected according to the calculated target for myopia by using a special nomogram developed by one of the authors (OFY):
  - Eight incisions for myopia less than 4 diopters.
  - Ten incisions for myopia equal to or greater than 4 diopters.
  - Fine adjustment by changing ZO sizes between 3.0 mm and 6.0 mm.
- In cases of myopia less than 8 diopters, oblique ZO with minimum and maximum diameters between 3.0 mm and 6.0 mm were chosen, in order to reduce the astigmatism together with the spherical refractive error. In eyes with myopia of greater than 8 diopters, a circular ZO of 3.0 mm with 10 radial incisions were performed and no attempt was made to address astigmatism.
- The difference between the larger and smaller radii of oblique ZO was proportional to the amount of astigmatism.
- Oblique ZO axis was oriented according to the axis of preoperative astigmatism.
- No tangential or arcuate incision was made.
- Peripheral re-deepening was performed in eyes with myopia over 10 diopters by deepening the peripheral part of the incisions (outside the central 7 mm) by setting a blade depth of 600 µm.

The surgical treatment was performed under topical or general anesthesia depending on the cooperation of the patient. Both eyes were treated at the same session if they were both considered eligible for the RK procedure.

At the end of surgery, the incisions were copiously irrigated from debris by 27 Gauge blunt tip irrigating cannula. The eyes were patched during the first 24 hours. Postoperative treatment regimen included topical antibiotics and artificial tear substitutes five times daily during the first week and then were gradually tapered and discontinued after the first month.

The first control visit was performed the day after surgery. In cases of any microperforation occurring during surgery, a Seidel test was performed in order to detect any leakage. Patching was continued in these cases until the Seidel test became negative. Eyes with anterior chamber shallowing and hypotony were closely followed and suturing of the perforation site was performed if the situation did not improve.

Routine control visits were scheduled at the end of the first week, first month, third and sixth months, and then yearly afterwards. UCVA, refraction, BSCVA, and keratometry were recorded in each of the control visits. Corneal topography and pachymetry were repeated annually. The complications were recorded at each control visit.

Patients with at least 1 year of follow-up were included in this study. During the follow-up visits, the following parameters were recorded and compared with preoperative data:
- Refraction (sphere, astigmatism, spherical equivalent [SE]).
- Visual acuity (UCVA, BSCVA) (converted to logMAR scale during averaging and statistical analysis).
- Corneal curvature (CC) (minimum, maximum, mean, dose).
- Central corneal thickness.
- Complications.

Statistical analysis was performed by using the computer software SPSS for Windows Release 8/0 and repeated measures analysis of variance (ANOVA) test. Surgically induced astigmatism was calculated by vector analysis method, using preoperative and postoperative refractive data (18).

RESULTS

A total of 246 eyes with keratoconus underwent RK procedure in our institution between 1990 and 2002. Seventy-six eyes were dropped because of insufficient follow-up (less than 1 year) and finally 170 eyes of 96 patients were included in the current study. Seventy-four of our patients had bilateral operation, while 22 patients were operated unilaterally. The mean age of those patients was 26.58 ± 8.59 years (range 10–63 years). Fifty-four of the patients were male and 42 of them were female. Baseline characteristics of the patients are shown in Table I.

One eye with preoperative UCVA of 0.9 was operated since his fellow eye had been previously operated, and he requested an operation on that eye, too. This was one of the first cases in our clinic and at that time RK procedure was performed with the concept of stopping the progression of the disease permanently.

During the RK, eight incisions were performed in 89 eyes (52.4%) and 10 radial incisions in 81 eyes (47.7%) (Fig. 1). Oblique optic zone was selected in 86 eyes (50.6%). Average optic zone diameter was 3.6 ± 6.8 mm.

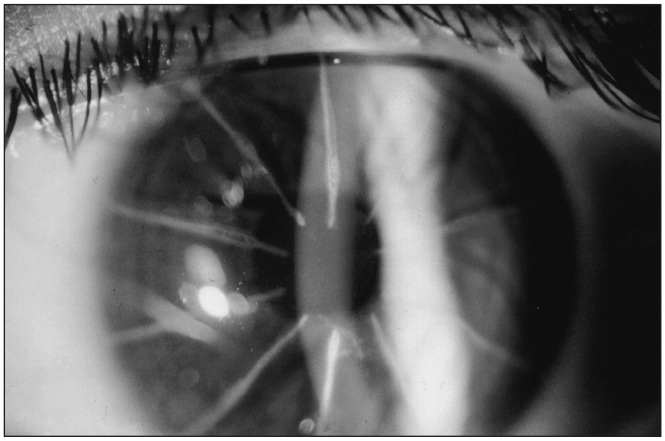

Fig. 1 - *Postoperative biomicroscopy of a patient.*

Mean follow-up was 42.08 ± 28.14 months (range 12–128 months). It was at least 12 months in 129 eyes (75.9%), 24 months in 93 eyes (54.7%), 36 months in 67 eyes (39.4%), 48 months in 43 eyes (25.3%), and 60 months in 29 eyes (17.1%).

Change in visual acuity

Mean UCVA was found to be improved significantly following RK surgery (p<0.0001). Mean UCVA recorded at the sixth month control visit approached (and even slightly improved upon) the preoperative BSCVA. The gain in UCVA was not transient and remained unchanged throughout the rest of the follow-up (p=0.14, repeated ANOVA test).

BSCVA also increased significantly at the sixth month control visit (p<0.0001) and remained about the same until the last follow-up (p=0.31, repeated ANOVA test).

Only 2 eyes (1.2%) were found to lose more than two lines of BSCVA at the sixth month visit. At the last control visit, 10 eyes (5.9%) had similar amount of drop in BSCVA. At the sixth month visit, BSCVA increased at least two Snellen lines in 48 eyes (28.2%) (Tab. II).

TABLE I - BASELINE CHARACTERISTICS OF THE PATIENTS

	Mean ± SD	Range
Central corneal thickness (μm)	489.7±48.6	400–632
Axial length (mm)	23.52±1.11	21.51–26.21
Corneal curvature (diopters)		
Minimum	47.65±4.20	38.5–60
Maximum	50.17±4.88	41–64
Average	48.87±4.09	40.38–62
Refraction (diopters)		
Sphere	-4.79±4.32	-22.75 to +4.00
Cylinder	-3.00±2.08	-8.00 to 0
Spherical equivalent	-6.21±4.68	-25.63 to 0
Visual acuity (Snellen)		
BSCVA	0.40±0.47	0.04–1.0
UCVA	0.10±0.31	0.01–0.9

UCVA = Uncorrected visual acuity in decimal scores; BSCVA = Best spectacle-corrected visual acuity in decimal scores

Change in refraction

Myopic spherical refraction decreased significantly at the sixth month visit as compared with the baseline (p<0.0001). In all of the remaining control visits, it remained statistically different from the preoperative data. Some fluctuations were observed in spherical refraction after the sixth month, but they were not statistically significant (p=0.43, repeated measures ANOVA).

The formula for targeted refractive spherical correction was used in 25 eyes, in which any reliable and reproducible refraction testing could not be done. In those eyes, the mean targeted myopic correction was calculated to be 4.48±3.75 D. At the postoperative sixth month visit, mean spherical refraction of those eyes was 0.81±0.85 D (p=0.07).

Six months after the RK procedure, a small but statistically significant decrease from baseline was observed in astigmatism (p=0.038). This improvement in astigmatism was transient, however, and almost disappeared 1 year after the surgery (p=0.47). Repeated measures ANOVA test also revealed that any statistically significant long term reduction of astigmatism could not be induced by the RK surgery (p=0.21). By vector analysis, the surgically induced astigmatism was found to be 2.40 D at 15° at the sixth month postoperatively.

Astigmatic decomposition revealed that with-the-rule component of this astigmatism was 0.16 D, while against-the-rule component was 2.24 D (18).

The most obvious and greatest changes were observed in SE after RK procedure. As compared with the preoperative baseline, the myopic SE decreased and approached towards emmetropia after the sixth month visit (p<0.0001) and remained approximately the same throughout the rest of follow-up (p=0.03, repeated measures ANOVA) (Tab. III).

Safety

Postoperatively at the last follow-up, 15 eyes (9.2%) lost 2 or more lines of BSCVA, 68 eyes (41.7%) gained ≥ 2 lines of BSCVA, while 80 eyes (49.1%) remained stable within ±1 Snellen line of BSCVA.

The safety index, which is defined by mean postoperative BSCVA divided by mean preoperative BSCVA, was found to be 1.54 at the last control visit.

Efficacy

Postoperatively at the last follow-up, 120 eyes (73.6%) had 20/40 or better BSCVA.

The efficacy index, which is defined by mean postoperative UCVA divided by mean preoperative BSCVA, was found to be 1.54 at the last control visit.

Stability

Stability evaluation was done on the 119 eyes that were examined both at the postoperative 12th month and at the last follow-up visit.

At the last follow-up, 87 eyes among the 119 eyes (73.1%) were within ±1.00 D of the SE of manifest refraction at the postoperative 12th month, whereas 32 eyes (26.9%) had ≥1.00 D change in SE of manifest refraction.

Change in corneal curvature

The minimum, maximum, and mean corneal curvature values were reduced and corneas were flattened by RK surgery. The biggest flattening was found between the baseline and the sixth month visit for all of the keratometric parameters ($p<0.0001$). Repeated measures ANOVA test, however, revealed that a small but progressive flattening continued throughout the rest of follow-up ($p=0.28$, $p=0.32$, and $p=0.21$ for minimum, maximum, and mean corneal curvature, respectively) (Tab. IV). Preoperative and postoperative corneal topography of a patient is seen in Figure 2, A and B.

Progression of keratoconus

Keratoconus progression was analyzed by investigating the postoperative course (the difference between the sixth

TABLE II - CHANGE OF VISUAL ACUITY

Follow-up (n/%)		UCVA		BSCVA	
		logMAR	Snellen	logMAR	Snellen
Baseline	(170/100)	0.99±0.51	0.10±0.31	0.30±0.32	0.41±0.48
6th month	(121/71.2)	0.37±0.34*	0.42±0.46*	0.23±0.26†	0.59±0.55†
12th month	(129/75.9)	0.40±0.36	0.39±0.44	0.22±0.22	0.60±0.60
24th month	(93/54.7)	0.38±0.31	0.42±0.49	0.21±0.17	0.62±0.68
36th month	(67/39.4)	0.31±0.27	0.49±0.54	0.17±0.18	0.68±0.66
48th month	(43/25.3)	0.44±0.36	0.36±0.44	0.23±0.19	0.59±0.65
60th month	(29/17.1)	0.34±0.37	0.46±0.42	0.13±0.11	0.74±0.78
Last visit	(163/95.9)	0.40±0.51	0.39±0.31	0.20±0.18	0.63±0.66

*p<0.05, †p<0.0001, n = Number of patients examined at each visit; UCVA = Uncorrected visual acuity in decimal scores; BSCVA = Best spectacle-corrected visual acuity in decimal scores

TABLE III - CHANGE IN REFRACTION

Follow-up (n/%)		Sph (D)	Cyl (D)	Axis	SE
Baseline	(170/100)	-4.79±4.31	-3.00±2.08	101.8±62.1	-6.21±4.68
6th month	(121/71.2)	-0.72±2.54*	-2.18±2.79†	100.7±62.0	-1.92±2.75*
12th month	(129/75,9)	-0.59±3.00	-2.58±1.87	100.7±63.5	-1.82±3.33
24th month	(93/54.7)	-0.25±2.84	-2.46±1.80	96.3±60.7†	-1.53±2.92
36th month	(67/39.4)	0.10±1.84	-2.54±1.62	98.6±61.1†	-1.16±1.92
48th month	(43/25.3)	-0.54±2.67	-2.50±2.48	81.8±61.9†	-1.86±3.17
60th month	(29/17.1)	-0.03±1.82	-2.60±1.57	64.3±58.9	-1.34±2.21
Last visit	(163/95.9)	-0.43±2.70*	-2.37±1.90*	91.9±61.6	-1.59±2.96*

Sph (D) = Spherical error in diopters; Cyl (D) = Cylindrical error in diopters; SE = Spherical equivalent, *p<0.05, †p<0.0001

month visit and last control) of corneal curvature and refraction following RK procedure.

Progression of more than 2 diopters could be demonstrated in 10 eyes (5.9%) by refraction (increase of myopic refractive error) and in 10 eyes (5.9%) by keratometry (corneal steepening).

Change in corneal thickness

Statistical analysis showed that there was no significant difference between the baseline central corneal thickness and those in either of the control visits (p>0.05) (Tab. V).

Reoperations

Enhancement operation was done when undercorrection had been demonstrated by manifest refraction, especially if accompanied by patient dissatisfaction. The initial RK procedure produced an inadequate reduction of the preoperative refractive error in 33 eyes (19.4 %) and yielded mean postoperative SE of manifest refraction of -4.9±3.6 D and mean cylindrical refraction of -3.2±1.8 D. In these eyes, re-deepening of the incisions was performed as a secondary procedure.

In 3 eyes (1.8 %), penetrating keratoplasty was performed 35.3±21.4 months following RK surgery, due to progression in 2 eyes (1.2%) and acute traumatic hydrops in 1 eye (0.6%). Previous RK did not create any problem during penetrating keratoplasty, compared to that in virgin cornea.

Complications

The following complications were observed:
- Microperforation (no sutures) in 4 eyes (2.2%).
- Macroperforation (sutures) in 2 eyes (1.2%).
- Acute traumatic hydrops in 1 eye (0.6%).
- Infectious keratitis in 1 eye (0.6%).
- Hyperopic shift in 1 eye (0.6%), which was corrected by Lasso suture.

DISCUSSION

In this study, we planned to investigate whether RK surgery would improve the visual acuity of eyes with early

TABLE IV - CHANGE IN CORNEAL CURVATURE

Follow-up (n/%)		Minimum	Maximum	Mean
Baseline	(170/100)	47.65±4.20	50.17±4.88	48.87±4.10
6th month	(121/71.2)	43.10±3.54*	44.90±4.21*	44.00±3.66*
12th month	(129/75.9)	42.90±3.63†	45.02±4.60	43.96±3.89
24th month	(93/54.7)	42.11±3.78	43.92±4.08	43.03±3.68
36th month	(67/39.4)	41.83±3.16	43.93±3.94	42.88±3.28†
48th month	(43/25.3)	43.32±5.43	44.95±5.13	44.14±4.97
60th month	(29/17.1)	41.23±3.48	43.92±3.92	42.57±3.61
Last visit	(163/95.9)	42.84±3.92	44.22±4.52	43.53±3.92

*p<0.05.
†p<0.0001

TABLE V - CHANGE IN CORNEAL THICKNESS

Follow-up (n/%)		Central (µm)	Thinnest (µm)
Baseline	(170/100)	489.7±48.6	472.7±51.2
6th month	(121/71.2)	491.4±43.6	468.9±47.3
12th month	(129/75.9)	495.4±49.6	467.1±36.6
24th month	(93/54.7)	467.2±49.8	446.3±51.1
36th month	(67/39.4)	438.6±20.9	420.1±26.8
48th month	(43/25.3)	471.4±20.7	447.0±13.0
60th month	(29/17.1)	489.9±50.9	468.3±52.5

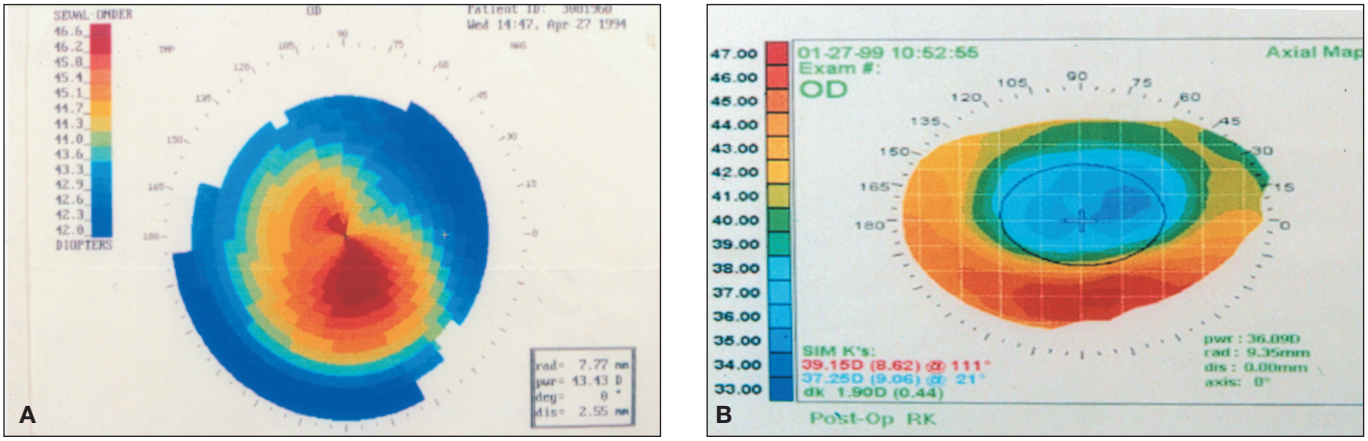

Fig. 2 - (A) *Preoperative corneal topography of a patient.* **(B)** *Postoperative fifth year corneal topography of the same patient.*

or moderate keratoconus. The RK procedure yielded significant gains in UCVA and BSCVA in the study patients. The improvement of UCVA was more pronounced than that of BSCVA. Postoperative mean UCVA improved to a level slightly better than the preoperative mean BSCVA. The gains in UCVA and BSCVA were stable and remained relatively unchanged throughout the follow-up. The visual acuity improvement following RK surgery was usually very rapid and occurred as early as the first postoperative day in most of the study patients.

The improvement of visual acuity was the result of corneal flattening and reduction of spherical and astigmatic refractive errors by the RK procedure. These effects could be easily demonstrated by the changes observed in corneal curvature, topography, and refraction. In order to reduce preoperative astigmatism, we employed a special RK nomogram developed by ourselves for keratoconus in which oblique optic zone shapes were used instead of circular ones. However, in our study eyes we found that the spherical component of refractive error rather than the astigmatism was more susceptible to the RK procedure. In other words, we could induce only a small (not more than a diopter) and relatively transient reduction in astigmatism despite the use of that nomogram. On the other hand, we were able to eliminate more than 4 diopters of myopic refractive error by the RK procedure. Also in contrast to astigmatism, the change induced in the spherical component of refraction by the RK surgery seemed to be stable – even a small and insignificant amount of myopia reduction in the magnitude of less than half a diopter in the long term – throughout the follow-up.

The reduction induced in the myopic refractive error was roughly proportional to the amount of corneal flattening induced by the RK surgery. However, there were small but statistically significant differences present between them. In the sixth month control, approximately 4 diopters of corneal flattening effect from the preoperative baseline was detected by analyzing the keratometry data. However, this effect progressively increased and it was found that an additional flattening of more than 1 diopter was induced at the last control visit.

The progressive corneal flattening was a well-known side effect of traditional RK surgery. In the prospective evaluation of RK study, it was shown that more than 2 diopters of late hypermetropia on the average was developed 10 years after surgery (19). In another study, the presence of subclinical keratoconus was questioned as a possible underlying mechanism for the pathogenesis of that progressive flattening effect following RK (20). We believed that additional flattening of about 1 diopter 5 years following surgery would not cause a big problem in eyes with keratoconus, because most of our study eyes were left with a myopic refractive error following the RK procedure.

The optimal rehabilitation of contact lens intolerant patients with mild or moderate stages of keratoconus still remained a controversial issue. Some authors recommended the use of corneal laser refractive surgery (PRK or LASIK) in some selected patients, but the results were usually disappointing (21-23). Penetrating or lamellar keratoplasty procedures, on the other hand, were generally reserved for the advanced stages because of postoperative astigmatism, graft rejection, progressive endothelial cell loss, and other problems (24). The most encouraging

results appeared with the use of intracorneal ring segments. Both Intacs and Ferrara rings were reported to yield satisfactory improvements of visual acuity and reduction of myopia and/or astigmatism in some selected eyes with keratoconus (6, 25, 26). However, those improvements were usually limited and unpredictable; also some problems such as implant extrusion and infectious keratitis were reported with the use of those implants (27). We recently initiated a controlled study comparing the results of RK and Ferrara rings in the fellow eyes of same patients with keratoconus and early data showed that visual rehabilitation was more rapid in eyes with RK and implant related problems were more common in the ring group (unpublished results).

All of the above procedures also including RK were mainly palliative and used mainly for optical rehabilitation. Keratoconus is a progressive disease and currently we do not have any established therapeutic option for eliminating, stopping, or delaying the progression of that disease. Recently, Wollensak et al reported good results with the use of UVA irradiation following epithelial debridement and photosensitizing with topical riboflavin application (28, 29). They demonstrated that treatment induced collagen cross-linking and thus improved the mechanical stability of keratoconic cornea. Their results were encouraging but it was too early to reach a final conclusion. Also the issue of probable UV toxicity on the corneal endothelium must be addressed (30).

Patient selection is very important in order to achieve satisfactory results with RK surgery in keratoconus. RK should not be considered as a procedure of choice for every patient with keratoconus. In advanced stages with very thin corneas, the procedure would indeed yield very unpredictable results. Therefore, we limited our patient selection criteria and included only those eyes with at least 400 µm stromal thickness at the central cornea. We selected that limit for two reasons. First we had some unpredictable results in eyes with CCT below 400 µm (on some patients operated between 1990 and 1995; unpublished results) and 400 µm (250 µm stromal bed plus flap thickness of 150 µm) has been also recommended by many refractive surgeons as an important surgical limit for routine LASIK applications in order to prevent iatrogenic keratectasia (31, 32).

Our study had some limitations. First, it did not include a control group. The selection of an appropriate control group is difficult when studying diseases like keratoconus, because the rates of progression vary considerably between different subjects and presently we do not have enough natural history data in order to identify those keratoconic eyes with higher predisposition for progression. The progression of keratoconus usually stops at some stage. It has been reported that only a minority (less than one third) of eyes with keratoconus would progress to the advanced stage and undergo penetrating keratoplasty (33, 34). The selection of fellow eyes as controls will not completely eliminate the problem because the disease can be quite asymmetric and progression rates of fellow eyes may be markedly different from each other (35). The second limitation of our study is relatively large number of drop-outs. Only half of our study population could be followed more than 3 years following RK procedure. This would cause bias when extending our results in the long term.

In conclusion, our study, which included a large number of patients with fairly long follow-up, demonstrated that RK surgery produced a reasonable option for the rehabilitation of contact lens intolerant keratoconus patients in the early or moderate stages. In most of our study patients, the slope of the disease progression curve has remained as a flat line even after 5 years or longer following RK procedure.

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