Graefe's Arch Clin Exp Ophthalmol
(2002) 240:639–643

CLINICAL INVESTIGATION

DOI 10.1007/s00417-002-0499-2

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Long-term functional and topographic results seven years after epikeratophakia for keratoconus

Received: 21 December 2001
Revised: 26 April 2002
Accepted: 14 May 2002
Published online: 13 July 2002

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Abstract *Purpose:* To analyze the long-term effect of epikeratophakia (EKP) on corneal topography and visual acuity of eyes with keratoconus. *Methods:* Retrospective study of 36 eyes 7.2 years after EKP. Four eyes underwent penetrating keratoplasty (PKP) and were excluded from further evaluation. Best-corrected visual acuity (BCVA) values were obtained from 32 eyes, corneal refraction and astigmatism from 23 eyes, surface asymmetry index (SAI) and surface regularity index (SRI) from 17 consecutive eyes that were operated upon after 1991, when the Tomey Topographic Modeling System became available. *Results:* Only four eyes needed PKP. In addition to EKP six eyes had compression sutures and/or relaxing incisions, and one eye underwent photorefractive keratectomy. Mean refractive power of the cornea decreased from 51.8 to 45.8 and astigmatism from 7.2 to 3.8. SAI improved from 3.2 to 0.9 and SRI from 3.7 to 0.9. Mean BCVA was 0.3 preoperatively and 0.6 upon last follow-up. *Conclusions:* EKP was able to render PKP unnecessary in 32 of 36 eyes during the entire observation period. It was successful in permanently flattening the ectatic cornea and reducing astigmatism while restoring a symmetrical and smooth corneal surface. As a result, visual acuity improved considerably. In view of the young age of keratoconus patients needing surgery, and the fact that the lifetime of full-thickness corneal grafts is limited, EKP should be considered a valuable alternative to PKP in contact-lens-intolerant cases of keratoconus without central scarring.

Introduction

Epikeratophakia, a form of onlay lamellar keratoplasty, for the treatment of keratoconus was first introduced by Kaufmann and Werblin in 1982 [2]. The technique employs non-refractive, acellular, freeze-dried stromal lenticules prepared from donor corneas. After removing the corneal epithelium of the recipient, the lenticules are sutured under tension to a peripheral trephine groove in the patient's cornea with the aim of flattening the ectatic cornea and postponing or avoiding penetrating keratoplasty (PKP).We report on the functional and topographic results of this technique in the long term, 7 years after operation.

Materials and methods

Between 1987 and 1994 we performed EKP according to the technique described by McDonald and coworkers [4] on 38 eyes of 30 patients with different stages of keratoconus, causing various degrees of bulging, thinning and posterior wrinkling, but no central scarring. The study includes the eyes of eight patients who underwent surgery on two eyes. This fact may induce some bias, since observations on the two eyes of one person cannot be considered statistically independent. All eyes were contact-lens intolerant. The EKP tissue used was commercially prepared (Allergan Medical Optics, Irvine, Calif.).

The average age of the patients at the time of surgery was 31 (±9.9) years. Observation period was 7.2 (±1.8) years. During this period two patients died, reducing the number of eyes in this study to 36. In 13 eyes of patients who lived far away from the clinic we obtained the best-corrected visual acuity (BCVA) at the end of the

Table 1 Number of patients receiving epikeratophakia (*EKP*). *RI* Relaxing incisions, *CS* compression sutures, *PRK* photorefractive keratectomy, *PKP* penetrating keratoplasty

Procedure	No. of patients
EKP only	25
EKP + RI	5
EKP + RI + CS	1
EKP + PRK	1
EKP + PKP	4
Total	36

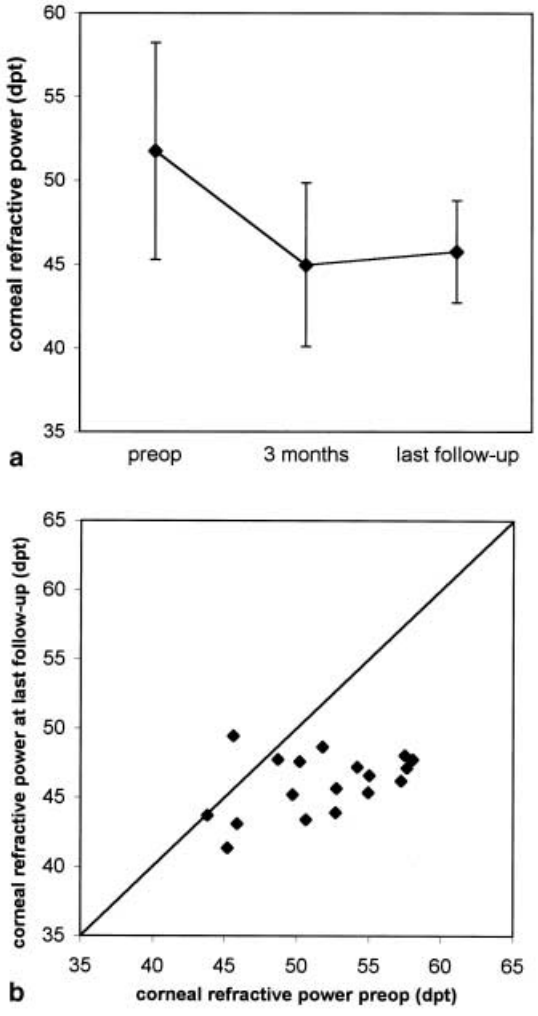

Fig. 1 **a** Mean refractive power of cornea before and after treatment. **b** Individual refractive power of cornea before and after treatment

observation period from the local ophthalmologists. In the remaining 23 eyes the late follow-up examination was carried out at our institution. In addition to BCVA these eyes were also examined for corneal refraction, astigmatism, and, after the technical prerequisites had become available to us in July of 1991, both surface asymmetry index (SAI) and surface regularity index (SRI) were obtained from all 17 consecutive eyes operated upon after this

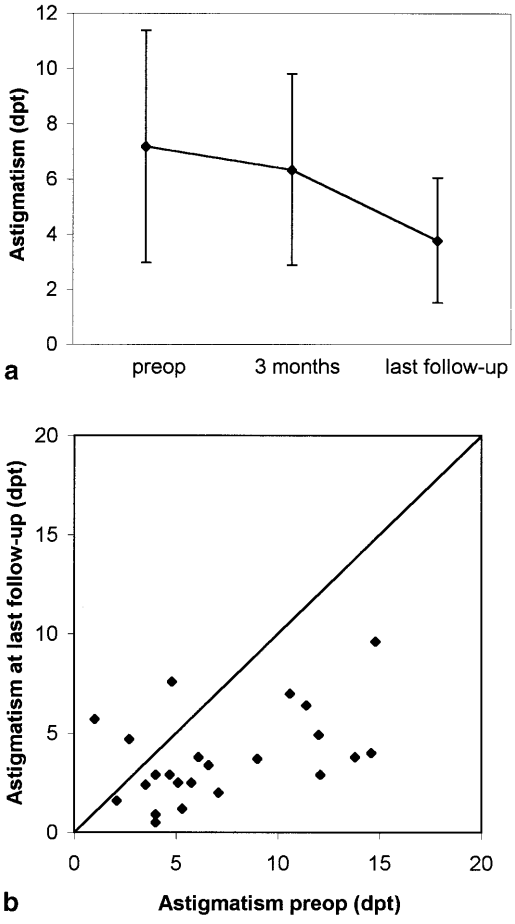

Fig. 2 **a** Mean keratometric astigmatism before and after treatment. **b** Individual keratometric astigmatism before and after treatment

date. These topographic measurements were taken with the Tomey Topographic Modeling System (TMS 1). Findings were compared to the values obtained preoperatively and 3 months postoperatively. Statistical analysis was performed using the signed rank test and Spearman rank correlation.

Results

Of the 36 eyes originally available for evaluation, 4 (3 checked by the local ophthalmologist and 1 by us) underwent PKP 7 months to 3 years after EKP and were excluded from further evaluation.

Of the remaining 32 eyes, 7 had further surgical interventions, namely relaxing incisions (5 eyes) at 7 to 74 months after EKP, relaxing incision + compression sutures (1 eye) 39 months after EKP, and PRK 19 months after EKP (1 eye) (Table 1). No complications occurred, and removal of the graft was not necessary in any of the cases.

Mean refractive power of the cornea (n=18) decreased from 51.8 dpt (±6.5) preoperatively to 45.0 dpt (±4.9) at

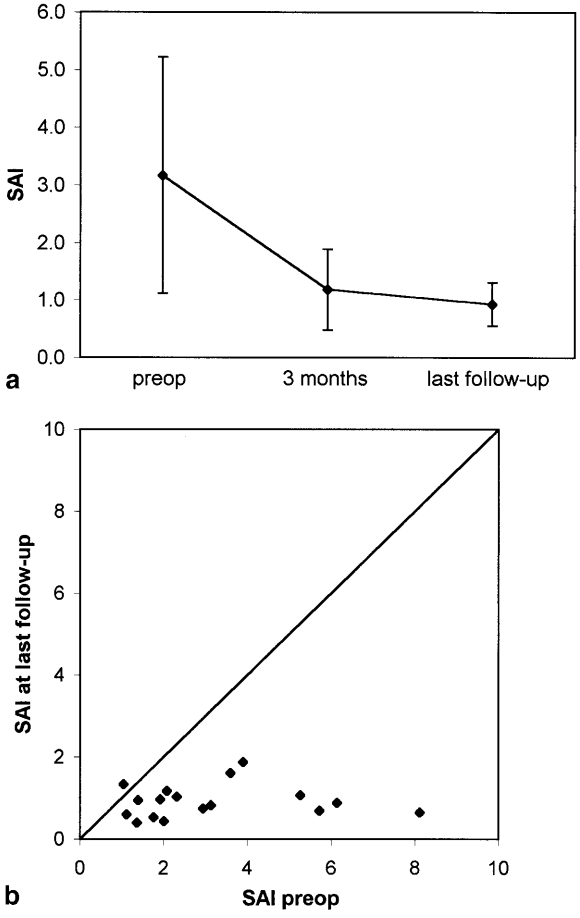

Fig. 3 **a** Mean surface asymmetry index (*SAI*) before and after treatment. **b** Individual surface asymmetry index before and after treatment

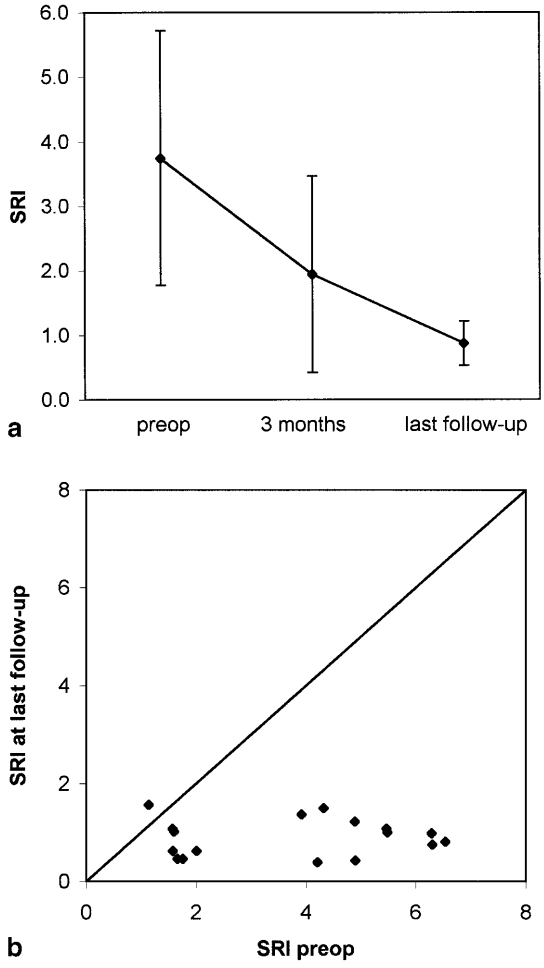

Fig. 4 **a** Mean surface regularity index (*SRI*) before and after treatment. **b** Individual surface regularity index before and after treatment

3 months postoperatively and was 45.8 dpt (±3.1) upon late follow-up (Fig. 1). The changes were statistically significant ($P<0.001$).

Mean astigmatism in diopters in the 23 eyes checked at our institution was 7.2 (±4.1) preoperatively, 6.3 (±3.4) 3 months postoperatively, and 3.8 (±2.2) upon late follow-up (Fig. 2). Whereas the 3-month results did not differ significantly compared to baseline, the late follow-up did ($P<0.001$).

Mean SAI ($n=17$) improved from 3.2 (±2.0) preoperatively to 1.2 (±0.7) 3 months postoperatively and further to 0.9 (±0.4) upon late follow-up (Fig. 3). The changes were statistically significant ($P<0.05$; $P<0.001$).

Mean SRI ($n=17$) was 3.7(±1.9) preoperatively. It improved to 1.9 (±1.5) 3 months postoperatively and further to 0.9 (±0.3) upon late follow-up (Fig. 4). The changes were statistically significant ($P<0.05$; $P<0.001$).

Mean BCVA ($n=32$) was 0.3 (±0.2) preoperatively. After 3 months it had improved to 0.4 (±0.2) and further to 0.6 (±0.2) upon late follow-up (Fig. 5). Whereas the 3-month results did not differ significantly compared to baseline, the late follow-up values did ($P<0.001$).

Discussion

McDonald et al. [4] reported favorable short-term results after EKP for keratoconus. However, it was not clear at that time whether and how long the effect was going to last. In our material we were able to confirm that EKP did in fact flatten and reinforce the ectatic cornea. This becomes evident when comparing the preoperative refractive power of the cornea (51.5 dpt) with an average corneal refraction of 45.2 dpt measured 3 months postoperatively. The effect was long-lasting and remained stable over the entire observation period.

At the same time, preoperative keratometric astigmatism improved from 7.2 to 3.8. This improvement was not yet very pronounced 3 months postoperatively (6.3),

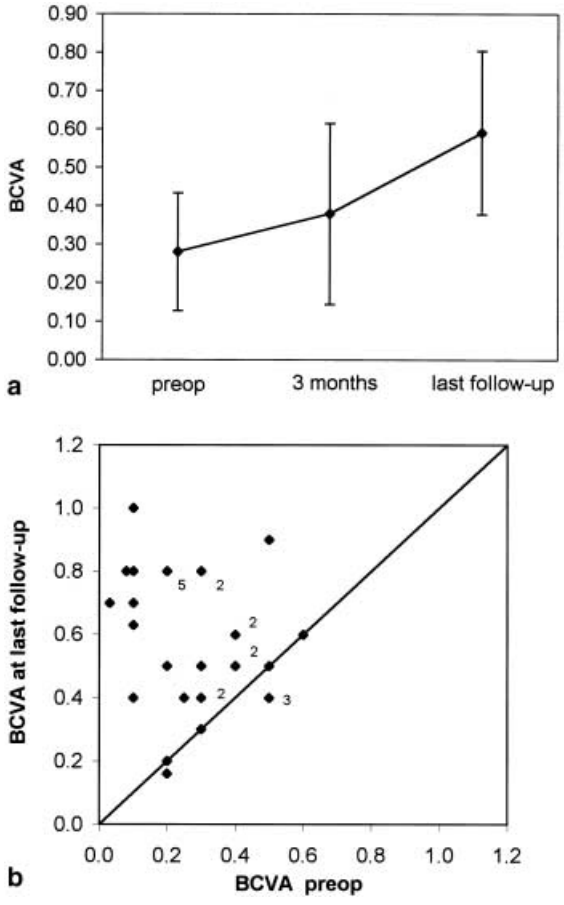

Fig. 5 **a** Mean best-corrected visual acuity (*BCVA*) before and after treatment. **b** Individual best-corrected visual acuity before and after treatment

but the rate of change was gradual with a maximum during the first postoperative year followed by a slow decrease (unpublished personal observation). An identical observation was made by Waller et al. [7], and these findings may indicate a slow progression of the conic process.

Normally, power distribution across a corneal surface is highly symmetrical. In keratoconus this is not the case. The asymmetry can be measured and expressed as the surface asymmetry index (SAI), which is defined as the centrally weighted sum of the differences in corneal power between corresponding points on theTMS-1 mires 180° apart. Normal corneas generally have SAI values less than 0.5, whereas the highly asymmetrical corneas in keratoconus may reach values above 5.0. In our 17 consecutive patients operated upon after the TMS had become available in 1991, the SAI improved from 3.2 preoperatively to 0.9 upon last follow-up, indicating that EKP had been successful in permanently restoring the highly asymmetrical cornea of the patients to almost normal values.

Another quantitative descriptor of the optical quality of the corneal surface is the surface regularity index (SRI), which is calculated from the local regularity of the surface over the area of the cornea enclosed by an approximate average virtual pupil of 4.5 mm. Like the SAI, the SRI of normal corneal surfaces is relatively low, and higher values indicate surfaces of lesser optical quality. In our patients the SRI improved from 3.7 to 0.9, showing that the corneal surface had not only become symmetrical, but smooth as well.

Best-corrected visual acuity, averaging 0.3 preoperatively and 0.6 at long term, obtained after EKP alone in 25 eyes and after additional minor surgery in 7 eyes, was very satisfactory. These values confirm the findings of Waller et al. [7] on ten patients 5 years after EKP.

Seven years after EKP only 11% of the eyes in our study had needed PKP. In view of the lasting visual rehabilitation after EKP and the fact that the life span of transplanted corneas is limited [5], this is an excellent result. This is especially true when considering that the average age of the patients at the time of surgery was only 31 years. Our positive findings are confirmed by the recent report by Haugen et al. [1], who described good results of EKP in mentally retarded patients with keratoconus. However, in contrast to us, Haugen and coworkers prefer to perform PKP in patients under the age of 40.

In conclusion, epikeratophakia should be considered a valuable alternative to penetrating keratoplasty in contact-lens-intolerant cases of keratoconus without central scarring. So far, long-term results on a large series of eyes are available only for commercially prepared, lyophilized lenticules. Such lenticules are still commercially available and can be purchased from Cryo-Optics (Houston, Texas, USA). Recently, Vajpayee and Sharma [6] followed 11 eyes for 4 years and Krumeich et al. [3] 8 eyes for 2 years in which the donor lenticules had been manually prepared by the surgeon from living eye-bank tissue, employing a manual lamellar dissection technique or cutting with a specially designed instrument. If further follow-up of a larger series produces equally favorable results, such fresh lenticules might be as useful as the commercially available tissue.

Acknowledgements We are grateful to Dr. R. Fimmers from the Institute of Medical Biometrics, Computer Science and Epidemiology for his help with statistical analysis. This study was supported in part by Aktion Kampf der Erblindung.

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