Epikeratophakia for Keratoconus

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Summary

Results of the author's first 15 cases of epikeratophakia for keratoconus are presented. All patients were intolerant of contact lens correction and could not achieve satisfactory acuity with spectacle correction due to corneal ectasia and irregular astigmatism. The average follow-up was 13 months. Seventy-three per cent of eyes treated had a pre-operative spectacle acuity of 6/60 or worse. One eye had a pre-existing amblyopia that limited final acuity, but every other eye achieved a post-operative spectacle acuity of 6/12 or better and 50% achieved 6/6. One eye had 11 dioptres of post-operative astigmatism and required penetrating keratoplasty; the remaining eyes had an average astigmatism of 1.9 dioptres. Epikeratophakia appears to be a safe alternative to penetrating keratoplasty in selected cases.

Although most cases of keratoconus can be successfully managed with spectacle or contact lens correction, a small proportion of patients require surgery to improve visual acuity.¹

Penetrating keratoplasty is the most common surgical procedure and usually results in a clear graft and good visual acuity.^{2,3} Important common complications of penetrating keratoplasty include allograft rejection and high residual astigmatism. More rarely, serious complications such as primary graft failure, endophthalmitis and glaucoma may occur.

Epikeratophakia is an alternative technique that can be used in selected cases of keratoconus.⁴⁻⁷ The aim of surgery is to flatten the ectatic cornea and to eliminate irregular astigmatism. Compared to penetrating keratoplasty, epikeratophakia is less invasive, being essentially extraocular, and may therefore be safer. Epikeratophakia has additional potential advantages; rejection of the cryolathed lenses does not occur and, as the host cornea remains intact, astigmatism may be less of a post-operative problem. Potential disadvantages of epikeratophakia include

slow post-operative recovery of visual acuity and a slightly sub-optimal final visual acuity due to the fact that the host cornea remains *in situ*.

This paper presents the results from the first 15 cases of epikeratophakia for keratoconus performed by the author.

Patients and Methods

Patient selection

Patients were referred to the Corneal Clinic at Moorfields Eye Hospital where they were assessed as potential candidates for surgery. Epikeratophakia was only considered when simpler alternatives were considered inappropriate. In every case spectacle correction was impossible due to irregular astigmatism and all patients were intolerant of hard contact lenses. Every eye treated had marked corneal ectasia, but in no case was there any great degree of central corneal scarring.

Lens manufacture

Lenses were manufactured by the author using donor corneas supplied from Moorfields Eye Hospital Eye Bank. Only corneas that

had been stored either in K-Sol or in McCarey-Kaufman storage media were used. In general these corneas had been rejected as suitable for penetrating keratoplasty by virtue of the age of donor, poor endothelial appearance or prolonged time in storage. A 9 mm disposable trephine was used to punch out, from the endothelial side, a corneal disc from the donor cornea.

A specially developed cryolathe (City-crown Sales, 14 Kempston Close, Gatehouse Way, Aylesbury, Buckinghamshire) was used to manufacture the lenses. The lathe has a concave, 8 mm radius, aluminium base for the corneal disc which is cooled using carbon dioxide to approximately -40° Celsius. At this temperature the cornea is frozen hard and lathing becomes possible. The 9 mm corneal disc was mounted on the lathe, frozen, and then machined with a diamond tipped cutting tool from the endothelial side. An 8 mm radius of cut was used to give a parallel sided lens of thickness 0.5 mm. A 'wing' of thickness 0.3 mm was then lathed on the peripheral part of the corneal disc to facilitate tucking of the lens into the corresponding pocket in the host cornea.

Surgical Technique

An almost identical technique was used on all the patients. Surgery was performed under general anaesthesia. Superior and inferior rectus sutures were used only if the eye was not pointing vertically.

Corneal epithelium was removed using a D15 scalpel blade. A caliper, set to 7.5 mm, was used to guide the area of epithelial removal; peripheral corneal epithelium was left intact to facilitate subsequent post-operative epithelial regeneration over the sutured epikeratophakia lens. Care was taken to ensure that the scalpel blade did not pause as it swept across the cornea as this can result in linear marks on Bowman's layer.

A 7 or 7.5 mm Hessburg-Baron suction trephine was then used to make a circular cut in the host cornea to a depth of approximately 190 microns (turning the capstan by three one-quarter turns).

A 23 gauge hypodermic needle, mounted with its tip bent to an angle of 90° , 1.5 mm from the end, was then used to dissect a

pocket into the peripheral cornea from the base of the trephine cut.

To minimise the possibility of residual epithelial cells causing interface opacities, a cellulose swab, barely moistened with absolute alcohol, was then used to wipe the cornea within the area of the trephine cut. The cornea was then washed thoroughly with a stream of irrigating fluid.

The epikeratophakia lens was then sutured in place with interrupted 9/0 nylon. Full thickness bites were taken through the wing of the lens and the needle was then passed into the depth of pocket at the base of the trephination. The suture was tied very tightly to flatten the ectatic cornea. For mild to moderate amounts of keratoconus this suture tightening alone was sufficient to flatten the cornea. For more marked keratoconus an assistant helped to flatten the cornea as the suture was tied by pressing on the cornea with a disposable irrigating vectis (Steriseal 1619 25G). In every case sufficient flattening of the cornea was achieved without the need to perform a paracentesis.

After the first eight sutures were in place, a cyclodialysis spatula was used to tuck the wing of the lens into the peripheral pocket. The resulting corneal contour was then subjectively assessed using an operative keratoscope. Additional sutures were then added or over-tight sutures removed, as required, in an attempt to minimise any suture induced astigmatism.

The procedure was completed with a subconjunctival injection of antibiotic and the eye was padded until the first dressing.

Patients were generally discharged on the first post-operative day using chloramphenicol 0.5% and prednisolone 0.3% eye drops three times a day. Eyes were left unpadded and bandage contact lenses were not used. Sutures were left in place unless they become loose or they appeared to be contributing to high or irregular astigmatism.

Results

One eye was treated in each of 15 patients whose average age was 25 years (range 16 to 42). Pre-operative spectacle acuities were generally very poor with 11 eyes (73%) having an acuity of 6/60 or worse. Further details are

given in Table I. The average length of follow-up was 12.8 months.

The majority of patients had an uneventful post-operative course with rapid re-epithelialisation of the epikeratophakia lens and with steadily improving lens clarity paralleled by an improvement in corrected visual acuity. The topical steroid and antibiotic drops were gradually tailed off and in no case were they continued beyond six weeks.

There were few complications in the post-operative period. In three cases it was necessary to temporarily increase the dose of topical steroids (up to six times a day) to control post-operative inflammation.

At most clinic visits a Placido disc was used to verify the corneal regularity and where possible this was checked with refraction. Individual sutures were removed if they become loose, or if it was felt, on the basis of the Placido reflex or the refraction, that they were contributing to a high astigmatism. It was not always possible to predict the effect of individual suture removal. For example in one case (patient number 11) an astigmatism of three dioptres was initially recorded. A suture was removed in an attempt to reduce this. The result was that the unopposed action of the remaining sutures induced astigmatism, in the axis orthogonal to the initial astigmatism, of 24 dioptres. To correct this the missing suture was first replaced, then individual sutures were successively removed and finally two additional sutures were inserted, leaving

the patient with just 0.5 dioptres of astigmatism. Patient number three had two dioptres of astigmatism at three months after surgery and all the sutures were removed. The astigmatism increased to five dioptres by five months and to 11 dioptres by seven months. At this stage the lens was removed and subsequently penetrating keratoplasty was performed.

Table I shows the final refractions and visual acuities. For patient number three the figures given are for the refraction obtained just before the epikeratophakia lens was removed. Patient eight was assumed to be amblyopic; she had strabismus surgery at the age of 18 months and had no recollection of good acuity in the operated eye. Unfortunately these facts were not appreciated prior to epikeratophakia surgery. Of the remaining 14 patients, all achieved a post-operative spectacle acuity of at least 6/12, with 11 (78%) reaching 6/9 and seven (50%) managing 6/6. Excluding patient number three, the average astigmatism was 1.9 dioptres.

Recovery of visual acuity after epikeratophakia is believed to be slow. The average time to achieve 6/12 acuity was 3.6 months and for the patients that reached 6/6 acuity, this was achieved by an average of 5.1 months. Survival (Kaplan-Meier type) analysis gives a graphical description of the recovery of acuity and takes account of patients who have been followed up for different lengths of time. Figure 1 plots the probability of achiev-

Table I Patient data

Patient number	Age (years)	Pre-operative spectacle acuity	Follow-up (months)	Post-operative refraction	Post-operative spectacle acuity
1	20	CF	28	+ 1.00/- 2.00 × 142	6/6
2	20	6/60	25	+ 0.50/- 1.50 × 20	6/9
3	42	6/18	8	- 1.50/- 11.00 × 115	6/12
4	28	6/60	22	- 0.50/- 2.00 × 90	6/6
5	34	6/24	18	- 8.00/- 2.25 × 70	6/6
6	19	6/60	14	- 11.00/- 1.50 × 70	6/6
7	34	6/60	14	+ 0.75/- 4.75 × 95	6/9
8	32	6/36	12	+ 4.00/- 3.50 × 15	6/36
9	22	CF	11	- 4.50/- 2.00 × 40	6/9
10	16	CF	8	- 3.50/	6/6
11	28	6/36	7	+ 1.00/- 0.50 × 160	6/6
12	26	CF	7	+ 3.25/- 2.50 × 160	6/12
13	18	6/60	7	- 3.00/- 2.50 × 150	6/9
14	18	CF	7	- 6.25/- 0.25 × 85	6/6
15	17	6/60	4	+ 0.50/- 2.00 × 80	6/12

CF = counting fingers.

Fig. 1. Kaplan-Meier type plot showing the cumulative probability of achieving a given visual acuity against time after surgery. Dotted line—6/6; Dashed line—6/9; Solid line—6/12.

ing visual acuities of 6/12, 6/9 and 6/6 against the time from surgery. All the patients are included in this plot.

Discussion

The length of follow-up in this series (average 13 months) is relatively short when compared to the natural history of keratoconus. While these results appear to be encouraging, it remains to be seen whether the improvement in spectacle corrected acuity persists in the long term.

One patient required penetrating keratoplasty after epikeratophakia. The epikeratophakia lens was removed at the slit lamp using topical anaesthesia. Penetrating keratoplasty was performed two months later when the pre-existing partial thickness trephination was extended to full depth then a donor cornea sutured in place. It has been suggested that prior epikeratophakia may increase the risk of rejection episodes in a subsequent penetrating graft,⁸ but no rejection has been seen in this patient who is now 14 months from surgery.

All of the patients treated had relatively clear corneas without discrete corneal scars. Where a diagnostic contact lens was tried pre-operatively this usually gave good acuity, although two patients (numbers 6 and 11), when fitted with a hard contact lens, only managed to achieve 6/18 acuity. Both of these

patients improved to 6/6 after epikeratophakia.

In the absence of irregular astigmatism a small discrete corneal scar may only slightly impair visual acuity. It is therefore possible that patients with such scars may benefit from epikeratophakia. It is intended to widen the inclusion criteria for epikeratophakia to include patients with corneal scars where there is a relative contra-indication to penetrating keratoplasty such as susceptibility to trauma and previous complicated penetrating keratoplasty in the fellow eye.

This study has confirmed that epikeratophakia can improve spectacle corrected acuity in selected keratoconus patients. There was no undue delay in the recovery of acuity, the majority of patients achieved 6/12 or better and complications were confined to suture problems and astigmatism. If these results are confirmed over the long term then epikeratophakia may become the treatment of choice for contact lens intolerant patients who have relatively clear corneas.

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