EXCIMER LASER PHOTOREFRACTIVE KERATECTOMY FOR MYOPIA: 12 MONTH FOLLOW-UP

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SUMMARY

A prospective study of excimer laser photorefractive keratectomy was performed with the aim of correcting a range of myopic errors between -1.00 and -10.00 dioptres. Corneal healing was monitored through the first post-operative year by serial assessments of refraction, contrast sensitivity, corneal haze, pachymetry and keratometry. Eighty-one patients were recruited for the study. At 12 months 81% were within ± 1.00 dioptre of desired emmetropia and with unaided vision of 6/12. Contrast sensitivity was found by Pelli-Robson assessment to be reduced throughout the 12 months and regression analysis predicted recovery by 2 years. At 12 months, however, only 15% of patients were found to have lost a single line of best corrected Snellen acuity. Predictability of results was found to be greatest for initial errors less than -4.00 dioptres. No serious complications were observed during the follow-up period, but refraction had not stabilised in all cases and patients remain under review.

Argon fluoride excimer laser ablation achieves precise corneal reprofiling, controlled by means of computer-generated algorithms.^{1,2} Although the laser can remove tissue with great precision, the healing response which follows appears to modify the reprofiled corneal curvature in the post-operative period.³⁻⁵ Healing is dynamic and complex and the unpredictability of clinical results must be attributable in part to this incompletely understood process.⁶⁻¹³ The aims of surgery are predictable results without loss of visual quality. Regression towards myopia has been identified by clinical trials and appears correlated with the magnitude of the attempted correction. We have extended the range of treatment to investigate the predictability for higher myopia.

Visual quality may be expressed in terms of symptoms

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and objective assessments. Glare has been reported, especially in conditions of low illumination, and appears to be a consequence of the diameter of the treatment zone compared with that of the pupil.⁵ By 1 year after surgery, however, the majority of patients are no longer seriously affected by such symptoms. Although very few patients have been reported to lose more than one line of Snellen acuity, this may not reflect subtleties detectable by contrast sensitivity assessment. We have monitored contrast sensitivity to determine the time course for loss and recovery.

PATIENTS AND METHODS

A clinical trial of excimer laser photorefractive keratectomy (PRK) was designed to establish the safety and predictability of this procedure for myopia up to -10.00 dioptres (D). Patients were recruited over a 6 month period from those referred to Moorfields Eye Hospital for refractive surgery. Patients were counselled about the experimental nature of the proposed treatment and gave their informed consent as approved by the Hospital Ethics Committee. The protocol limited the study to myopia ranging from -1.00 to -10.00 D and with astigmatism, measured in negative cylinders, not exceeding -2.00 D. Only 1 patient (with stable refraction) was under 21 years to exclude young patients with unstable myopia. All patients had otherwise normal general and ocular health and only one eye of each patient was treated in this study.

Investigations

The pre-operative work-up included routine clinical examination, documenting both uncorrected and best corrected visual acuities. Manifest refraction was performed using fogging techniques and was refined by the duochrome test. Cycloplegia was avoided as post-operative asphericity was anticipated in relation to the untreated paracentral cornea. Additional examinations included contrast sensitivity assessment (Pelli-Robson), video-keratotomy (Eyesys), corneal aesthesiometry, pachym-

etry, clinical assessment of corneal clarity and photography. Central corneal haze was scored on a scale 0–4 (0, none; 1, trace; 2, mild; 3, moderate; 4, severe). Each examination was usually performed by the same individual at sequential visits to ensure consistency.

Laser Delivery

The Summit Technology UV200 excimer laser system was used to deliver ablative therapy for correction of the spherical error or the spherical equivalent in patients with astigmatism. The wavelength of the argon fluoride laser was 193 nm, the fluence 180 mJ/cm² and the pulse repetition rate 10 Hz, producing a depth per pulse of 0.22 µm. At the beginning of each treatment session a homogeneity test was carried out to monitor beam quality.

Topical anaesthesia was administered to both eyes to avoid blinking through the procedure; usually this was amethocaine 1% but sometimes additional benoxinate 0.4% was required. The fellow eye was occluded and a lid speculum was used to expose the target eye. The pupil of the target eye was miotic with pilocarpine 4% to permit centration of treatment on the pupillary axis. The patient was positioned supine under the laser delivery system and a green light on the laser downtube provided fixation for the patient. The laser was aimed using two helium–neon aiming beams which intersected on the corneal surface and diverged to fall on the pupil margin. Continued centration was monitored and maintained by the surgeon (L.A.F. or A.D.McG.S.). Where myopia exceeded 6.00 D (the pre-set maximum for laser delivery), the treatment was delivered in two equal doses.

Two non-ablative pre-treatments were applied, firstly to methylcellulose on the ocular surface and secondly to the epithelium (each 25 pulses). This accustomed the patient to the sound and smell of the ablation. Epithelium was removed mechanically through an area of diameter 5 mm, defined by a radial keratotomomy marker. The treatment zone diameter was 5 mm for myopia not exceeding –8.00 D and 4.5 mm for myopia greater than –8.00 D, thus limiting the depth of ablation to a maximum of 50 µm. The laser aperture opened progressively through the procedure to the pre-set maximum diameter. No removal system was used to clear ablated tissue.

Post-operative Follow-Up

Post-operatively, patients were treated with chloramphenicol and betamethasone ointment and the eye was padded overnight. Analgesia (dihydrocodeine tartrate 60 mg) was prescribed and patients were warned the eye would be painful. Topical 0.5% chloramphenicol drops (q.d.s.) were administered for the first week to cover the period of re-epithelialisation. Dexamethasone 0.1% drops were tailed by one drop per week for 1 month in all cases. Steroids were recommenced at various intervals if regression towards myopia was identified, but no patient used steroids for longer than 6 months.

Follow-up examinations included a visit on post-operative day 1 (and day 2 if required) to ensure epithelial heal-

ing, and at months 1, 2, 3, 4, 6, 9 and 12 to repeat the special work-up and clinical examination performed pre-operatively. Additional visits were arranged if patients experienced any problems.

RESULTS

Eighty-one patients were recruited for refractive surgery and treated with excimer laser PRK. The motives for surgery included meeting refractive and optical standards for various professions, enabling participation in sports and as a consequence of contact lens intolerance. Eyesys videokeratoscopy ensured no abnormal corneal topographic features occurred in the study cohort, such as forme fruste of keratoconus. The 38 male and 43 female patients were aged 21–62 years (mean 33.4 years) and 61 of 81 were followed for 12 months (minimum follow-up 3 months).

Epithelial Healing

All corneas re-epithelialised during the first week and 78 by day 2. Pain was experienced by most patients, but subsided after 24 hours. Only one patient was found to have symptomatic microcysts during the first 3 months. Corneal sensation remained normal.

Stromal Healing

Corneal thickness decreased during the first week after treatment. The mean changes were more sustained in the lower myopes (<5.00 D), falling from 0.53 mm pre-operatively to 0.49 at 1 year, while for higher myopes (>5.00 D) the mean returned to the pre-operative value of 0.47 mm. The greatest increase occurred during the first post-operative month, with a wide confidence interval, but fluctuations were noted over the 12 months' follow-up (Fig. 1). Central corneal flattening was noted on post-operative topographic analysis and centration of ablations was verified.

All corneas were clear pre-operatively. Post-operative central corneal haze was noted in all patients, but was variable in both onset and duration. Mean values of haze are plotted against time (Fig. 2a) over the 12 month period of follow-up. The onset was usually within 6 weeks, the maximum score was less than 2 and the opacity began to resolve between 12 and 24 weeks. At 12 months the mean haze score was 1, signifying minimal subepithelial opacity. No statistical correlation was found between haze and initial refractive error, nor with age (Fig. 2b).

Refractive Outcome

All patients developed hypermetropia during the first week by an amount similar to the attempted correction. Subsequently refraction changed towards emmetropia over a 3 month period (Fig. 3a–f). The regression line for the overall results (Fig. 3a) indicates consistent observations. Refraction continued to change throughout the 12 month follow-up period (Fig. 3g). Sixteen patients remained hypermetropic (range +0.25 to +1.75 D) at the 12 month follow-up examination.

Fig. 1. Mean central corneal thickness (mm) with time. The 95% confidence intervals are also shown.

(a)

(b)

Fig. 2. (a) Mean corneal opacity with time. The dotted lines show the 95% confidence interval of the mean. (b) Development of opacity with respect to age of patients, taken at 12 weeks when mean opacity score was maximal. $R^2 = 0.02$.

(a)

(b)

Fig. 3. (a) Mean spherical equivalents after excimer laser PRK. The exponential regression line (continuous line) and 95% confidence intervals of the mean (dotted lines) are also shown. $R^2 = 0.95$. (b) Mean spherical equivalents (with 95% confidence intervals) of myopes up to 2 D ($n = 6$). (Continues.)

(c)

(d)

(e)

(f)

(g)

Fig. 3 (continued). (c)–(f) Mean spherical equivalents (with 95% confidence intervals) of myopes: (c) from 2 to 4 D ($n = 29$), (d) from 4 to 6 D ($n = 27$), (e) from 6 to 8 D ($n = 12$), (f) from 8 to 10 D ($n = 7$). (g) Changes in refraction between 6 and 12 months (stippled columns) and between 9 and 12 months (dark columns) after PRK.

Fig. 4. Discrepancy in refraction at 12 months with respect to emmetropia (in spherical equivalents). Black columns, up to 0.5 D; grey columns, up to 1 D; stippled columns > 1 D. Ninety per cent range is from -2.25 to +1.75 D.

Fig. 5. Magnitude of induced cylinder after PRK with respect to pre-operative cylinder, as determined by vector analysis. All cylinders were refracted in negative cylinders. Only the magnitude of the induced cylinder is shown, not the sign. Where several points coincide only one is shown.

Fig. 6. Unaided visual acuity at 12 months after PRK. Stippled columns, 6/6 or better; dark columns, 6/12 or better.

Fig. 7. Loss of visual acuity at 12 months after PRK. Those not losing vision are shown as horizontal bars.

Fig. 8. Change in contrast sensitivity with time. Time 0 = immediately before treatment. The exponential regression line is also shown. R^2 (exponential) = 0.94.

Fig. 9. Loss of contrast sensitivity at 12 months with respect to the correction applied. R^2 (exponential) = 0.14.

Regression to myopia was more commonly seen among moderate and high myopes (greater than -4.00 D). The results have been analysed separately for each 2.00 dioptre group included in the trial (Fig. 3b–f). The 95% confidence limit of the means were narrowest for low myopia and widest for high myopia. Steroids were recommenced in 37 patients at post-operative intervals ranging from 6 to 29 weeks (mean 13.5 weeks) for regression ranging from -0.25 to -3.50 D (spherical equivalent) and were continued for a mean of 12.7 weeks. Regression was reversed in 82% for the duration of steroid therapy, but reverted to myopic values ranging between -0.25 and -8.75 D over the following 12–24 weeks. A transient rise in intraocular pressure was observed in 11% of patients (up to 36 mmHg) and in each case reverted to normal after steroid withdrawal.

Overall, 90% of patients fell within the range -2.25 to $+1.75$ D. Sixty-one per cent of patients were within ± 0.5 D of emmetropia and 81% within ± 1.00 D at 12 months (Fig. 4). Residual errors greater than 1.00 D occurred in 19% and changes in refraction up to 0.5 D were observed in 51% (between 0.5 D and 1.00 D in 26%) during the period from 6 to 12 months post-operatively (Fig. 3g), these being more marked for high myopia. Induced astigmatism was analysed by vector analysis (Fig. 5) but was not a clinically significant problem.

Visual Acuity

More than 60% of patients achieved unaided visual acuity of 6/12 or more by 4 weeks after laser therapy. Significantly more patients achieved 6/6 vision unaided for attempted corrections less than 4.00 D (Fig. 6). A maximum of 26% of patients lost at least one Snellen line of best corrected acuity (Fig. 7). Only 1 patient lost more than one Snellen line, but this improved with time. At 12 months 15% were found to have persistent loss of one Snellen line, but none had lost more than one line at 12 months. Glare was an early symptom among 19% of patients with onset 2–6 months post-operatively (mean 3.7 months), but was not a significant symptom by 12 months and was not quantified by formal psychophysical testing.

Contrast Sensitivity

Contrast sensitivity dropped immediately from a mean value of 1.8 to a trough value of 1.51 at the first week. Thereafter there was gradual recovery over 12 months to a mean value of 1.6 (Fig. 8). There was no correlation between loss of contrast sensitivity and intended correction (Fig. 9). Regression analysis predicts the 95% confidence interval for recovery to be 80–110 weeks.

DISCUSSION

Epithelial Healing

The clinical response to excimer laser ablation is complex and appears to reflect phases of corneal wound healing. It is known that the first phase of the healing response is epithelial repair.^{6,7} Laboratory models have demonstrated

that epithelial anchoring fibrils are re-established during the first 12 weeks⁸ which account for the rarity of epithelial instability. Mechanical rather than laser removal of the epithelium was used in this study as there was reported to be a trend towards greater accuracy of final refraction.⁹

In common with other studies using the Summit laser, we observed overcorrection by about 100% at the first post-operative week when corneal thickness was at its minimum.⁵ Pachymetry demonstrated rapid recovery of corneal thickness after the laser ablation, which supports the concept that this is due to epithelial hyperplasia, as cellular proliferation is the most likely mechanism for such rapid change. In experimental models such hyperplasia has been observed soon after ablation.^{6,7} The depth of ablation may determine the amplitude of epithelial healing. Abrupt transition between normal and treated cornea may induce greater epithelial hyperplasia.⁷ This would account for the greater tendency for recovery of initial corneal thickness in higher myopes and regression towards myopia for larger attempted corrections.

Stromal Healing

Corneal haze was observed in all patients, but did not correlate with intended correction. In contrast Gartry *et al.*¹⁴ found a difference in haze between patients treated for 3 D and for 6 D. The mechanism for variations in haze is not understood, hence it is difficult to explain these different observations. Animal models, based on relatively few observations, have suggested that deeper ablations may result in increased stromal remodelling and associated haze.^{10–13} Studies of a possible molecular basis for haze have been undertaken which identified the presence of fibrinogen, fibronectin, laminin and type III collagen at the time of clinically observed haze.¹⁵ Haze may, however, reflect differences between individuals with respect to healing which may in part be determined by techniques of epithelial removal and stromal dehydration during the procedure.¹⁶ Induced irregularities may promote less organised stromal remodelling. The quantification of haze is, however, subject to inter-observer variation as there is uneven distribution of haze within the treatment zone and scatter measurements have been used in other studies to overcome this problem.¹⁷ Assessment of haze is as yet subjective and lack of observational consistency must also be considered for each observer.

Refractive Outcome

The refractive outcome is measured by manifest refraction and may be qualified by contrast sensitivity testing. Corneal topography and keratometry represent further analyses which permit correlation between changes in corneal curvature and manifest refraction. Corneal topography, for the purpose of this study, was used to verify that treatments were centred and that central flattening was induced.

Predictability of refractive outcome among our patients was best for patients with initial errors less than -4.00 D. It has been the experience of other clinicians also, using different laser systems, that predictability of excimer PRK is

best for low myopia.³⁻⁵ Stability of refraction compares with the PERK study results for radial keratotomy.¹⁸ Between 6 and 12 months after PRK the overall refractive change was less than 0.5 D in 51% of PRK patients and less than 0.25 D in 56% of RK patients. The stability of refraction being greater for lower myopia, the groups are not strictly comparable as 57% of PRK patients had initial myopia between 4 D and 10 D while 48% of RK patients were between 4 D and 8 D. Unaided vision at 12 months was 6/12 or better for 77% of PRK patients and 78% of RK patients.

The concept of persistent epithelial hyperplasia has been invoked to explain regression in high myopia where the transition between treated and untreated cornea is initially abrupt and may act to trigger epithelial proliferation. This can be modulated by controlling the depth of ablation, which is dependent on treatment diameter. The refractive outcomes for different treatment diameters may then be compared.

Seiler and Wollensak⁴ reported that 92% of patients were corrected to within 1.00 D of intended corrections ranging from -1.40 to -7.25 D (mean 4.4 D), for a small treatment diameter of 3.5 mm (maximum ablation depth 50 μ m), and that from 6 months 58% of these refractions were stable within 0.25 D. This group was small ($n = 26$) and was not therefore analysed separately for low and higher myopes. Gartry *et al.*⁵ reported predictability of results at 12 months to be within 1.00 D of intended correction for 90% of treatments of -2.00 D, but only for 20% of treatments of -7.00 D (maximum ablation depth 44 μ m). There were 20 patients in each subgroup.

A problem with small treatment zones, however, is night-time glare which results from the discrepancy between refractive powers in the central and paracentral cornea.⁵ Glare was not a significant symptom among our patients and this may be attributable to the use of a 5 mm treatment diameter which reduced the aspheric effect at times of pupillary dilatation. Gartry reported that symptomatic haloes were experienced by 78% patients with a 4 mm treatment diameter; indeed, 10% of these patients declined PRK to the fellow eye as night-time glare persisted. Seiler reported an incidence of 23%, but only 4% (1 patient) found it a problem. In our study, by comparison, 19% of patients perceived glare at a mean post-operative interval of 3.7 months, but at 12 months it was not perceived as a problem.

McDonald *et al.*⁹ varied the treatment diameter as a

Table I. Relationship between back vertex distance (BVD) and spectacle plane and corneal plane refractions

BVD	Spectacle plane (D)	Corneal plane (D)
8	-2.00	-1.97
	-5.00	-4.81
	-10.00	-9.26
12	-2.00	-1.95
	-5.00	-4.72
	-10.00	-8.93
16	-2.00	-1.94
	-5.00	-4.63
	-10.00	-8.62

function of intended correction, to limit ablation depth: 5 mm up to 6.0 D, 4.5 mm between 6.0 and 7.0 D, and 4.25 mm between 7.0 and 8.0 D. At 12 months 57% of patients with myopia less than -5.00 D were corrected to within 1.00 D of emmetropia ($n = 17$), as compared with 18% patients corrected for 5.00 to 8.00 D. These results compare with our study in which the treatment diameter was 5 mm for corrections up to 8 D and reduced to 4.5 mm up to 10 D; 81% of these patients were corrected to within 0.5 D at 12 months, 41% of refractions fluctuating within limits of ± 0.5 D (maximum ablation depth 50 μ m). Detailed analysis of haze and regression in relation to ablation depth is not possible from published data, but there are unexplained differences between studies.

The role of steroids cannot be determined from this study, which was not designed for the purpose. Steroids were recommenced in an uncontrolled fashion in patients found to have regression, on the basis of previous reported experience.⁴ Although regression was countered during the period of steroid treatment, the modified refraction was not maintained after steroids were withdrawn. It appears, therefore, that topical steroids do not influence the refractive outcome. Gartry¹⁴ has reported a randomised trial of topical steroid compared with placebo which confirms the lack of long-term effect, although a difference (reduced regression towards myopia) was observed during the period of high-dose steroid therapy.

The less predictable results observed for higher myopia are in part attributable to the assumption of average values in the treatment algorithm which does not allow for variables such as the back vertex distance (BVD) of the spectacle correction. For low degrees of myopia, the average BVD value does not significantly affect the computed corrective ablation (Table I), but for higher myopia these can become significant. For corrections of -2.00 D the power at the corneal plane ranges between -1.97 (BVD = 8 mm) and -1.94 (BVD = 16 mm), while for -10.00 D it ranges between -9.26 D and -8.62 D. The impact of keratometry (K) on ablation depth is less significant (Table II), but errors may be cumulative in individual cases.

The differences between reported series include laser delivery systems and treatment algorithms, details of which are not generally known to the clinical investigators. The algorithms may not achieve expected ablation depths uniformly through the range of treatments and different systems may have different errors.

Table II. Relationship between keratometry, spherical myopia and ablation depth

Keratometry	Sphere	Ablation depth (μ m)
40	-2.00	26
	-5.00	65
	-10.00	130
44	-2.00	27
	-5.00	67
	-10.00	132
48	-2.00	28
	-5.00	68
	-10.00	135

Visual Acuity

Unaided vision of 6/12 was achieved more frequently among low and moderate myopes, as a function of refractive outcome. Loss of one line of best corrected Snellen acuity was the maximum loss among our patients at 1 year. This compares with McDonald³ who reported losses up to three lines in 3 of 17 patients and Gartry⁵ who reported loss of up to two lines in 12 of 120 patients. The loss of best corrected acuity and maximum haze both peaked at about 12 weeks among our patients, but statistical correlation could not be established. Induced astigmatism did not account for visual loss in our patients, but decentration has been reported as a cause of loss of up to two lines of best corrected acuity.¹⁹

Contrast Sensitivity

Contrast sensitivity dropped immediately after ablation and prior to development of haze. This was tested under a constant level of illumination. Pupillary diameter was not measured under these conditions, but would be expected to be mid-dilated rather than constricted. Paracentral aberration may therefore have contributed to this phenomenon, which was most marked during the phase of hypermetropia when the differences between refractive powers of treated and untreated cornea were greatest.

Other investigators have established correlation between haze and low contrast visual acuity⁵ based on objective measurements of light scatter due to the haze. It would seem that contrast sensitivity changes may be multi-factorial and need further analysis.

The study has shown that excimer laser PRK is safe for treatment of myopia up to -10.00 D. Unaided acuity is improved although best corrected acuity has been compromised in a few cases. Contrast sensitivity can be shown to be impaired at 12 months, but 2 year follow-up will be needed to confirm it has been restored as predicted. Longer follow-up will also be required to establish when refractive outcome can be expected to stabilise and whether there are late consequences of ablations which destroy Bowman's membrane and produce corneal thinning.

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