

## Fortnightly Review

### Treating myopia with the excimer laser: the present position

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#### Background

It has been estimated that 8-10 million people in the United Kingdom suffer the inconvenience of myopia (short sightedness).<sup>1,2</sup> In this refractive error rays of light from a distant object entering the eye are brought to a focus in front of the retina. This may be due to a relatively long eyeball, a cornea that is too steeply curved, or a combination of these two factors. Even a relatively small amount of myopia results in distant objects being considerably blurred. For example, minus one dioptre (-1.00 D) of myopia would result in a Snellen unaided vision of between 6/12 (20/40) and 6/18 (20/60), which is below the accepted driving test standard of approximately 6/10 (20/33; equivalent to the recognition of number plate letters 79.4 mm high at a distance of 20.5 metres).<sup>3</sup> Spectacles or contact lenses form the mainstay of treatment but can be a hindrance in some occupations and sports. In addition, because of edge thickness, high minus lenses are unsightly, and image quality is reduced by minification and optical aberrations. Many myopic people would be grateful therefore to be free from such optical aids.

Because of the large difference in refractive index between air and the cornea, the cornea is the principal refracting element of the eye and accounts for about two thirds, or +43.00 D, of the total focusing power. A relatively small change in corneal curvature therefore causes a relatively large change in overall refractive status. Many surgical techniques have been devised to alter corneal curvature, the most common of which is radial keratotomy, first described by Sato in 1939,<sup>4</sup> popularised by Fyodorov in the 1970s,<sup>5</sup> and introduced to the United States in 1978.<sup>6,7</sup> The mechanism of action of this procedure is to weaken the midperipheral cornea by deep, radial diamond knife incisions, which cause a secondary flattening of the central (optical) zone of the cornea (fig 1). This results in a reduction of corneal refracting power and the image of a distant

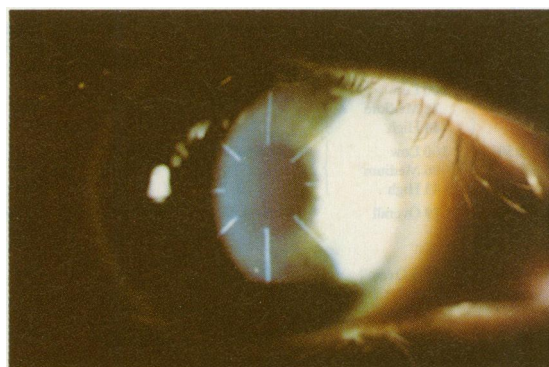


FIG 1—Appearance of cornea after eight cut radial keratotomy. The central (optical) zone is spared

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#### Summary points

- Excimer laser photorefractive keratectomy is the latest in a long line of surgical treatments for myopia (short sightedness)
- Around 50 centres (including three research centres) in the United Kingdom offer this treatment and tens of thousands of patients have been treated worldwide
- Considerable individual variation in corneal wound healing exists following photorefractive keratectomy, and this limits the predictability of the procedure
- Predictability of refractive outcome is much better for lower amounts of myopia (up to around -6.00 dioptres)
- Important side effects exist which are all more common in people with higher myopia (regression, corneal haze, loss of best corrected visual acuity)
- Overall patient satisfaction is high and around 85% of patients are pleased with the outcome even if this is a partial correction only
- Careful patient selection and counselling are vitally important, and all patients must be fully informed of possible side effects

object is shifted from the vitreous back towards the retina. Although this technique continues to be popular (particularly in the United States, where numerous refinements have been made), complications do occur.<sup>8-15</sup> Since myopia is not a disease and the eye is in other respects entirely normal, refractive surgery must be predictable, effective, and safe with a low incidence of complications. These considerations led to the recent development of excimer laser photorefractive keratectomy, which utilises an entirely different treatment rationale.

#### Excimer laser photorefractive keratectomy

Excimer lasers have been used in the printing and electronics industries to etch highly precise patterns in plastics for around 15 years. The term excimer is a conflation of "excited dimer," which describes the lasing medium within the laser cavity. Excited dimers are two atoms of an inert gas, in this case argon, bound in a highly unstable form with atoms of a halogen such as fluorine. On dissociation, highly energetic photons are emitted (at a wavelength of 193 nm); these are

capable of breaking molecular bonds at the surface of the target—a process termed photoablation. This removal of a thin layer of surface molecules over an area 5-6 mm in diameter with each successive laser pulse is essentially non-thermal and proceeds with virtually no damage to adjacent, unexposed areas. Investigation into the potential uses of the excimer laser in ophthalmic surgery began with the work of Srinivasan and Trokel in 1983<sup>16-19</sup>; they found that it was possible to remove layers of tissue from the corneal surface in rabbits with a high degree of precision. Detailed laboratory studies followed, and in February 1988 the first of a series of patients was treated at St Thomas's Hospital, London, to remove rough calcium deposits from the corneal surface.<sup>20</sup>

An extension of the ability to remove a thin surface layer from the cornea is the removal of more tissue from the central part of the circular photoablated zone than the edge. This is achieved by placing a computer controlled iris diaphragm in the path of the beam (fig 2) and results in a flattening of the central cornea and therefore treatment of myopia. The procedure has been termed photorefractive keratectomy and, since the cornea is reprofiled directly, it is quite distinct from radial keratotomies. Software algorithms relating depth of ablation to diameter of the ablated zone have been devised<sup>21</sup>—to achieve, for example, a -7.00 D correction within a 4 mm diameter treatment zone the axial corneal tissue is ablated to a depth of only 45 microns (less than 10% of the thickness of the central cornea). If a larger zone is used, however, this figure increases considerably. For example, when a diameter

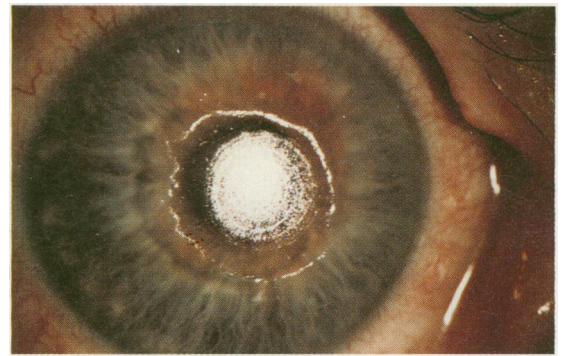


FIG 2—Appearance of cornea immediately after photorefractive keratectomy. The central concentric ring pattern represents the reprofiled cornea. The larger, irregular, outer reflection is the edge of the debrided corneal epithelium

of 6 mm is used for a -7.00 D correction the ablation depth increases to around 100 microns—about 20% of the corneal thickness.

The first series of "sighted eye" photorefractive keratectomy was undertaken at the Free University, Berlin, in August 1989.<sup>22,23</sup> The first British procedures started at St Thomas's Hospital in November 1989<sup>24,26</sup> at around the same time as those in the United States,<sup>27</sup> and at Moorfields Eye Hospital in December 1990.<sup>28</sup> Since then, tens of thousands of patients have been treated worldwide. Overall the results have been very encouraging. Gartry *et al*, however, reported considerable individual variation in response to this treatment

TABLE 1—Results of excimer laser photorefractive keratectomy for myopia

| Study  | Laser type (beam diameter) | No of patients                 | Follow up                    | Mean treatment range (mean) (dioptries)            | Refractive outcome (% of patients) |                                | No of lines of best corrected visual acuity lost (% of Snellen chart) |               |              | Comment  |
|--|----------------------------|--------------------------------|------------------------------|--|------------------------------------|--------------------------------|---|---------------|--------------|--|
|  |                            |                                |                              |  | Within ±1D of intended             | Unaided vision >6/12           | 1   | 2             | >2           |  |
| Seiler <i>et al</i> , 1991 <sup>25</sup>                             | Summit (3.5 mm)            | 26                             | 1 Year                       | -1.40 to -9.25                                     | 92 Overall                         | 96                             | 7.7   | Nil           | Nil          | 1 Corneal graft needed—slow healing in SLE     |
| Gartry <i>et al</i> , 1991* and 1992 <sup>22</sup>                   | Summit (4.0 mm)            | 120                            | 1 Year to 22 months          | -2.00 to -3.00<br>-4.00 to -5.00<br>-6.00 to -7.00 | 83 Low*<br>45 Medium<br>30 High    | 56 Low<br>49 Medium<br>13 High | 15  | 3             | Nil          | Regression proportional to degree of myopia    |
| Gartry <i>et al</i> , 1992* and 1993 <sup>22</sup>                   | Summit (4.0 mm)            | 113                            | 1 Year minimum               | -3.00 group<br>-6.00 group                         | 56<br>20                           | Not reported                   | 9   | 6             | Nil          | Steroids of no significant benefit             |
| Salz <i>et al</i> , 1993 <sup>26</sup>                               | Visx (5.0 and 5.5 mm)      | 12<br>71<br>77                 | 2 Years<br>1 Year<br><1 Year | -1.25 to -7.50                                     | 88 Low<br>73 High                  | 93<br>79 at 1 year             | 17  | 1.4           | Nil          |  |
| Piebenga <i>et al</i> , 1993 <sup>27</sup>                           | Visx (5.0 mm)              | 133                            | 2 Years (mean)               | -1.25 to -8.37                                     | 75 Overall                         | 75 Overall                     | 8   | Nil           | Nil          | Role of steroids questioned                    |
| Ficker <i>et al</i> , 1993 <sup>28</sup>                             | Summit (4.5 and 5.0 mm)    | 61 (81 total)                  | 1 Year                       | -1.00 to -10                                       | 81 Overall                         | Not reported                   | 15  | Nil           | Nil          | Regression proportional to degree of myopia    |
| Taylor <i>et al</i> 1993 <sup>29</sup>                               | Visx (6 mm)                | 32                             | 6 Months                     | Up to -6.00  | 88 Overall                         | 88 Overall                     | 25  | 19            | Nil          |  |
| Seiler <i>et al</i> 1994 <sup>30</sup>                               | Summit (4.5 and 5.0 mm)    | 126<br>176                     | 2 Years<br>1 Year            | -1.25 to 7.10                                      | 98 Low<br>92 Medium<br>34 High     | Not reported                   | 6   | 1             | Nil          | Complications intolerable above -6.00 D        |
| Les Jardins <i>et al</i> , 1994*                                     | Meditec (5 mm)             | 63                             | 6 Months or more             | -1.25 to -9.00                                     | 91 Low<br>62 Medium<br>41 High     | Not reported                   | 8   | 14            | Not reported |  |
| Kim <i>et al</i> , 1994 <sup>31</sup>                                | Summit (5.0 mm)            | 45                             | 2 Years                      | -2.00 to -6.00                                     | 91.1 Overall                       | Not reported                   | 4   | Not reported  | Not reported | "Quality" of acuity reduced in 22% of patients |
| Rogers <i>et al</i> , 1994*†   | Summit (3.6 to 5.0 mm)     | 14                             | 1 Year                       | -10.25 to -20.50                                   | 71 Overall                         | Not reported                   | 50% lost a "variable" amount of acuity and were treated               |               |              | Significant scarring in 50% of patients        |
| Shimizu <i>et al</i> , 1994,*†                                       | Summit (4.5 mm)            | 11 Low<br>45 Medium<br>41 High | 1 Year                       | 2.00 to -7.50                                      | 100 Low<br>76 Medium<br>44 High    | Not reported                   | Nil   | Nil           | Nil          | Predictability better in low myopia            |
| Orsaud <i>et al</i> , 1994*†   | Summit (5.00 mm)           | 176                            | 6 Months (mean)              | -1.00 to -8.50                                     | 100 Low<br>86 Medium<br>43 High    | Not reported                   | 8<br>18<br>73   | 9<br>38       | Not recorded | Not recorded                                   |
| Maguen <i>et al</i> , 1994*  | Visx (? 6.0 mm)            | 240                            | 1 Year (mean)                | -1.00 to -7.75                                     | 79 Overall                         | 89 Overall                     | Not reported  | 4-7 At 1 year | Not recorded | One potentially serious corneal infection      |
| Epstein <i>et al</i> 1994* update (see also Tengroth <i>et al</i> *) | Summit (4.3 to 4.5 mm)     | 495                            | 2 Years minimum              | -1.25 to -7.50                                     | 87.5 Overall                       | 91 Overall                     | 0.4   | Nil           | Nil          | Stabilisation between 18 months and two years  |
| Dutt <i>et al</i> , 1994 <sup>32</sup>                               | Summit (5 mm)              | 35                             | 1 Year                       | -1.50 to -6.10                                     | 80 Overall                         | 94 Overall                     | Nil at 1 year   | Nil           | Nil          | Loss of acuity in first 4 months only          |

\*For comparison between series, low myopia is defined as up to -3.00 D, medium from -3.10 to -6.00 D and high greater than -6.10 D. SLE=Systemic lupus erythematosus.

†Proceedings papers (no peer review process).

### Box 1—Complications of photorefractive keratectomy

| Complication  | Percentage of patients affected |
|---|---------------------------------|
| Significant regression (> 1.00 D undercorrected)      |                                 |
| Low myopia (up to -3.00 D)                            | 12                              |
| Medium myopia (-3.10 to -6.00 D)                      | 28                              |
| High myopia (greater than -6.00 D)                    | 60                              |
| Reduced BCVA* (at one year)                           |                                 |
| 1 Line loss   | 12                              |
| 2 Line loss   | 8                               |
| Slight tenderness to the touch**                      | 25                              |
| Slight foreign body sensation**                       | 15                              |
| Reduced night vision                                  | 15                              |
| Night halo sufficient to interfere with night driving | 12                              |
| Epithelial instability (recurrent erosion)            | 3                               |
| Slight ptosis   | 1                               |
| Acuity reduced in bright light                        | 1                               |

\*Most patients in this category have medium or high myopia. Three lines of reduced Snellen best corrected visual acuity (BCVA) have been reported at the six month stage, improving to a maximum two line loss at one year.

\*\*These symptoms improve throughout the first year but may not disappear completely.

because of differences in wound healing from patient to patient, and in particular they found that it was much more difficult to treat moderate to high myopia (greater than around -6.00 D).<sup>24-26</sup> Over the past two years these findings have been confirmed by other centres using different laser systems (table I).<sup>28 30 33 39-45</sup> Most myopic people have less than -6.00 dioptres of myopia, and in these patients predictability and stability of refractive outcome are relatively good.<sup>24-28 30 33 39-45</sup> In addition, while photorefractive keratectomy has side effects (box 1), few sight threatening complications have been encountered.<sup>23 34</sup> It should be emphasised that maximum follow up at present is around only five years. Mean follow up is considerably less than five years, and the procedure therefore should be regarded as experimental and investigational. However, the available data suggest that serious longer term side effects (such as late onset sight threatening infection, corneal decompensation, or serious permanent scarring) are unlikely, though not impossible.<sup>24-28 30 33 39-45</sup> To date, because of potential long term problems, the American Food and Drug Administration has taken a cautious approach, and the procedure has yet to gain its approval.

#### Criteria for selecting patients

The following guidelines (box 2) have been derived from peer reviewed publications from current research trials.<sup>24-33 39-49</sup> It is important that prospective patients are counselled by a surgeon experienced in the technique so that a fair representation of the treatment and its limitations is given and all questions raised can be answered. Detailed written background information should be given and this, in addition to counselling by the surgeon, should provide adequate information to allow an informed consent form to be signed.

It is most important that prospective patients have realistic expectations in relation to the procedure. This may mean excluding patients on psychological grounds—those who are by nature perfectionists or those who would be most unhappy with anything other than perfect unaided vision. In keeping with the guidelines issued by the Royal College of Ophthalmologists and endorsed by the British College of Optometrists, all prospective patients must be referred through their general practitioner.

#### SEX

There is no exclusion criterion relating to the sex of the patient, with the exception of caution in relation to pregnancy. Since some authorities advocate the use of high dose topical corticosteroids for several months after treatment (see below), most would exclude pregnant patients. In addition, wound healing characteristics of the cornea may be altered in pregnancy.

#### AGE

The minimum age should be 21 years to ensure stabilisation of myopia, which should be confirmed by scrutiny of optometric records. Exceptions, however, might include patients with an appreciable difference in refraction between the two eyes (anisometropia), in whom the more myopic of the eyes is treated to eliminate this difference. However, the social and work circumstances of the prospective patient must be considered carefully and, because of the relatively prolonged visual rehabilitation after treatment, it might not be appropriate to treat a 21 year old who is studying for important examinations.

Presbyopic or borderline presbyopic patients must be counselled carefully with regard to their almost certain need for reading spectacles if their myopia were to be eliminated completely. This is particularly important for those patients with low to moderate degrees of myopia who may have become accustomed to reading comfortably unaided.

#### OCULAR OR SYSTEMIC DISEASE

All patients should undergo complete ophthalmological examination, and any patient with a history of

### Box 2—Patient selection criteria for photorefractive keratectomy

- Age—≥ 21 Years. This may depend on other factors such as nature of employment or studies. Important commitments such as examinations etc should not be disrupted. Presbyopic or pre-presbyopic patients should be warned that reading spectacles will be required after treatment. There is also a weak correlation with overcorrection and increasing age.
- Sex—No exclusion based on gender (with the exception of pregnancy).
- Ophthalmic history—Patients with a history of ocular disease or surgery should be excluded.
- Refraction—Stable refraction up to around -6.00 D; those with more than -6.00 D have a significant chance of "regressing" a considerable way back towards their original refraction. Relative success in high myopia, defined as a significant reduction (partial correction) of myopia, has been reported, but complications are also commoner in these patients.
- Astigmatism—Less than 1.00 dioptres of astigmatism is a relative guideline only and depends on degree of simultaneous myopic treatment (results of astigmatic treatments are, at present, variable).
- Visual acuity—Best corrected visual acuity 6/9 or better in both eyes; an "only eye," where the other eye is "lazy" or of limited visual potential, should not be treated.
- Contact lens history—Contact lens wearers preferred due to likelihood of significant induced anisometropia (difference between eyes after treatment). Patients with evidence of fluctuating refraction due to corneal distortion should be excluded.
- Occupation—Those with exacting vocational visual requirements should be excluded (pilots, professional or night drivers).
- Motivation—Prospective patients should be asked to state their reasons for wishing to undergo treatment. Only those with realistic aims and expectations should be included.

eye disease or in whom an ocular abnormality is discovered on examination (for example, dry eye, keratoconus, glaucoma, herpes simplex keratitis, amblyopia) should be excluded. It is now accepted as best clinical practice that corneal topography should be assessed with videokeratography to exclude patients with undiagnosed corneal disease. Patients with systemic disorders, such as diabetes, and in particular autoimmune or collagen vascular disorders such as rheumatoid arthritis, systemic lupus erythematosus, or polyarteritis nodosa, should be excluded because of potentially serious problems of wound healing.<sup>23</sup>

#### AMOUNT OF MYOPIA

As discussed above, the individual variability in corneal wound healing and incidence of complications after treatment increases with greater amounts of myopia.<sup>24-28 30 33 39-45</sup> Predictability of refractive outcome varies inversely with degree of myopia and is relatively good up to  $-4.00$  D and poor beyond  $-10.00$  D. There is no absolute divide between success and failure, but at  $-6.00$  D or  $-7.00$  D there is a "watershed zone" below which predictability is acceptable but above which predictability becomes progressively worse. Successful results above  $-9.00$  D or  $-10.00$  D are often quoted in support of photorefractive keratectomy for high myopia, but as predictability is poor such results are the exception rather than the rule.

Several surgeons who have pioneered the technique of photorefractive keratectomy have recommended that, at present, the maximum level of correction attempted should be up to around  $-6.00$  or  $-7.00$  dioptres. For example, a recent update paper that addressed the complications of the technique concluded that "most of the complications such as reduction of glare vision, overcorrection, scarring, and continued regression are strongly dependent on the attempted refractive change. When refractions exceed  $-6.00$  D, the incidence of these complications reach ... intolerable levels."<sup>33</sup>

Although the most predictable results are in the treatment groups up to  $-4.00$  D, all patients should be warned that they may achieve only partial correction of their myopia. Although unusual, it is by no means impossible for patients with low myopia (up to around  $-3.00$  D) to regress back to their original refractive state.<sup>24,26</sup> This problem is encountered much more commonly in people with high myopia.

#### ASTIGMATISM

In astigmatism, a variation of power exists in the different meridians of the cornea. Two discrete spectacle lens powers are required for these meridians which, in the case of regular astigmatism, are at  $90^\circ$  to each other. The standard illustration used is that of a rugby football compared to a spherical soccer football. At present astigmatism can be treated only with certain of the commercially available excimer lasers and results are more variable than for simple myopia. One study recently reported an average of about 55% reduction in astigmatism.<sup>46</sup> Another concluded that excimer laser photoastigmatic keratectomy "offers an effective option in the treatment of myopic astigmatism,"<sup>32</sup> although most patients treated had relatively small amounts (less than 1.50 dioptres) of astigmatism, and the change in most cases was variable and subtle, as highlighted in recent published correspondence.<sup>47</sup>

To avoid disappointment, patients should have less than 1.00 dioptres of astigmatism before photorefractive keratectomy. This is a relative guideline; an exception might be a patient with 5-6 dioptres of myopia in whom a large overall improvement in myopia can be expected and in whom 1.5 or 2 dioptres of astigmatism represents proportionately less of their total refractive error. In preoperative counselling it

should be explained that it is difficult to treat astigmatism predictably at present. The best possible unaided vision without correction of the astigmatic component can be demonstrated to the patient before treatment.

#### TREATMENT OF THE SECOND EYE

Generally, a minimum of around three months between treatment of the two eyes in low myopia (up to  $-3.00$  D) and six months in the higher degrees of myopia (up to around  $-7.00$  D) is advised. This allows for stabilisation of refraction and manifestation of complications in the first eye. Original research protocols, subject to approval of an ethics committee, required a minimum period of one year,<sup>24,26</sup> but most authorities feel that this can be revised in the light of an increasing database worldwide.

#### CONTACT LENS WEAR

In the interval after treatment of the first eye, during which an imbalance exists between the eyes (anisometropia), patients able to wear one contact lens in the untreated eye will achieve the most comfortable binocular vision. This is particularly important in the case of high myopia since anisometropia can be considerable.

#### OCCUPATION

Great caution should be exercised when considering the treatment of people with particularly demanding occupations requiring high visual standards—for example, pilots or professional drivers. Early research protocols excluded patients in this category<sup>24,26</sup> and, in view of possible complications (box 1), it could still be argued that these individuals should not be treated. Those wishing to join the armed forces, police, or fire service should verify that their prospective employer will not reject their application because they have had photorefractive keratectomy surgery. Because visual performance at night may be reduced, night driving—in the course of police work, for example—might be hazardous. In addition, exposure to bright sunlight soon after treatment may cause loss of the effect of the surgery (regression), but this is yet to be proved statistically.

#### PUPIL SIZE

Patients with large pupils are likely to experience a "halo effect" around lights at night.<sup>24,26</sup> This is due to a contribution of the retinal image from untreated peripheral cornea—an extreme form of positive spherical aberration. This halo effect depends also on the amount of correction attempted since the greater the attempted correction—and in particular the greater the change in refraction—the larger the effect. Patients undergoing corrections above  $-4.00$  D with pupil diameters larger than 6 mm in subdued lighting should be counselled very carefully with regard to this complication.

It is important also to consider driving habits. A younger patient with relatively large pupils who drives frequently at night could be expected to encounter significant halo problems. The newer generation of lasers has been designed to provide ablation zone diameters of around 6 mm, which should help to minimise the problem.

#### The procedure and early postoperative period

Photorefractive keratectomy is an outpatient procedure which usually requires only topical amethocaine hydrochloride 1% and is painless. It takes about 10 minutes (which includes manual debridement of the corneal epithelium), with the actual laser beam exposure lasting on average 30 seconds, depending on the amount of myopia to be treated. Immediately after

the treatment most surgeons instil a mydriatic (such as homatropine hydrobromide 2%) and an antibiotic ointment (chloramphenicol 1%) and recommend using a firm eye pad for 24 hours. Prospective controlled trials have shown that topical diclofenac (Voltarol, Geigy) instilled immediately after the surgery has a significant analgesic effect.<sup>30</sup> Although the procedure itself is painless, the eye is usually sore one to two hours later and may be very painful during the first 8-12 hours. Oral analgesics are prescribed and most patients manage to sleep through the first night. The following day the pain improves considerably, and 48 hours later, by which time the cornea will have re-epithelialised in most patients, the eye feels essentially normal. After the pad is removed a topical corticosteroid and antibiotic regimen is followed; at present this varies from centre to centre. However, in view of their potentially serious complications and minimal effect on refractive outcome, as shown in a randomised controlled trial,<sup>26,29</sup> the need for routine topical corticosteroids after treatment has been questioned.<sup>24-26,29,31,48</sup> Vision is usually considerably improved within three or four days, and most patients become slightly overcorrected (long sighted) for a few weeks before settling to the final level of correction (fig 3). Stabilisation takes 3-6 months for low myopia and 6-18 months for higher myopia.<sup>40,45</sup> Regular follow up visits are necessary in the first year, and patients must be told to contact their surgeon immediately if new symptoms arise.

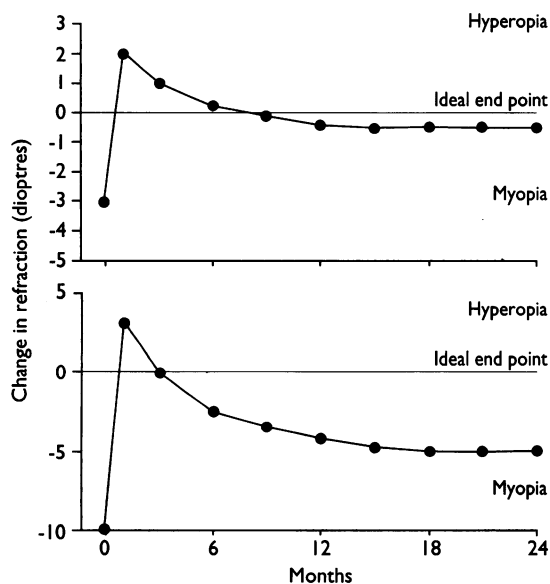


FIG 3—Average change in refraction after photorefractive keratectomy. Top: Low myopia ( $-3.00$  D). Initial overcorrection to long sightedness (hyperopia) is followed by regression to a slightly undercorrected plateau. Bottom: High myopia ( $-10.00$  D). Greater overcorrection is followed by rapid regression to a considerably undercorrected position. Since these are average changes, some patients with higher myopia have regressed back to their preoperative levels of myopia

#### Side effects and complications

Box 1 summarises the side effects and complications of photorefractive keratectomy. There are five areas to consider.

##### REGRESSION

The treated eye tends to lose some of the effect of the surgery (regress) within the first few months. This is due to wound healing characteristics and is greater in high myopia. The increasing individual variation and regression in high myopia is best shown when the refraction results are displayed as a scattergram (fig 4). A questionnaire survey of 182 patients from two early cohorts found that regression was the major cause

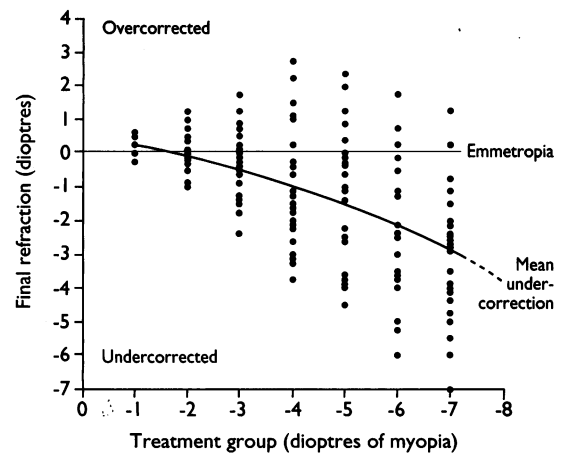


FIG 4—Individual variation in refractive outcome and regression for patients with myopia of  $-2.00$  D to  $-7.00$  D (adapted from Gartry et al).<sup>25</sup> The increasing scatter in the data and trend towards greater undercorrection in high myopia is apparent

of dissatisfaction after photorefractive keratectomy (fig 4).<sup>24-26</sup> A successful outcome in the first eye is not always followed by the same result for the second eye, and patients should be made aware that there are no guarantees that both eyes will heal in the same way.

##### NIGHT HALO EFFECTS

If the surgery is particularly effective a "halo" effect around lights at night may be noted, particularly by patients with large pupils.<sup>24,25</sup> As regression proceeds this effect decreases during the first few months, and it should be reduced considerably by the use of larger diameter ablation zones where appropriate.<sup>31,49</sup>

##### CORNEAL HAZE OR SCARRING

A variable amount of anterior corneal haze, detected on slit lamp examination, occurs in most patients at around one month after treatment (fig 5). This increases up to the five or six month stage and then fades over the first year (although it may not disappear completely).<sup>24-26</sup> As with other complications, the incidence and severity of this haze increase as higher degrees of myopia are treated.<sup>25,26,29</sup>

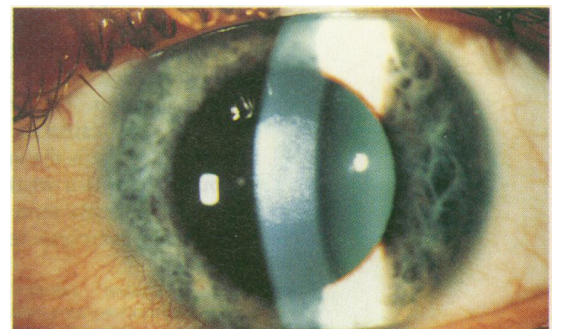


FIG 5—An extreme example of corneal haze seen at around six months after surgery. An almost confluent corneal opacity delineates the treated zone. This degree of opacity fades with time but it is not known whether it disappears completely in every case. In spite of the appearance of the cornea this patient had an unaided vision of 6/6 (20/20) and was keen to have the other eye treated

##### LOSS OF BEST CORRECTED VISUAL ACUITY

In some patients the period of maximal haze coincides with a significant loss of best corrected visual acuity (up to three or four lines in rare instances where higher degrees of myopia have been treated or retreated). This haze or irregular astigmatism, or both, may cause some permanent deterioration in best corrected visual acuity in 15% or so of the higher myopia treated. When data in the table are combined, about 13% of patients lose one line of Snellen acuity at

one year and around 8% lose two lines. Longer term (two year) studies have shown that best corrected visual acuity improves with time in these patients, particularly between the sixth and 12th months.<sup>29</sup>

#### WOUND INFECTION AND DELAYED HEALING

It is of considerable concern that one case of presumed bacterial keratitis has been reported, which occurred the day after surgery and responded, fortunately, to intensive topical antibiotics.<sup>39</sup> Though it is often stated that excimer laser radiation at 193 nm (far ultraviolet) acts as a sterilising source, it is evident that infection can occur in the early postoperative period while an epithelial defect exists, in spite of instillation of a broad spectrum antibiotic. It is also of concern that a 62 year old patient with systemic lupus erythematosus required a penetrating keratoplasty (full thickness corneal graft) after delayed epithelial healing which resulted in a non-infectious, perforating corneal ulcer.<sup>23</sup>

#### Results overall

After early laboratory and clinical studies the lay press and commercial excimer laser clinics were almost universally enthusiastic about photorefractive keratectomy and numerous claims were made in relation to the success of the procedure. The laser is capable of removing tissue with great precision, but because of the vagaries of corneal wound healing the stage has not yet been reached when a guarantee can be given that a prospective patient will not need spectacles or contact lenses after treatment. Careful prospective studies have highlighted considerable individual variation, especially when high degrees of myopia are treated.<sup>22-26 28-31 33 39-45 48 49 51</sup> By definition, this limits predictability.

Complications must also be taken into account. For example, around 15% of patients lose one or two lines of Snellen acuity, a significant loss, and a further 10% experience halos around lights at night, which may make night driving difficult.<sup>24 25</sup> Other less troublesome complications include an intermittent sensation of a foreign body in the eye on waking and tenderness when rubbing the eye.<sup>25</sup>

Nevertheless, patient satisfaction has been high, and around 85% of patients say they are pleased that they underwent photorefractive keratectomy (table II). This percentage could be increased further with careful patient selection. The only useful predictor of regression (the chief cause of dissatisfaction) that has been identified to date is the amount of pre-existing myopia, although there is a weak correlation also with age in that older patients tend to regress less and therefore may remain overcorrected—a situation that should be

TABLE II—Patient satisfaction with excimer laser photorefractive keratectomy after minimum of 18 months

| Criterion                                 | No (%) of patients (n=182) |
|---|----------------------------|
| Satisfaction with outcome:                |                            |
| Pleased                                   | 154 (85)                   |
| Indifferent                               | 14 (8)                     |
| Unhappy                                   | 14 (8)                     |
| Reasons for dissatisfaction:              |                            |
| Regression                                | 24 (13)                    |
| Haze (reduced visual acuity)              | 1 (1)                      |
| Long rehabilitation time                  | 1 (1)                      |
| Pain of procedure                         | 1 (1)                      |
| Overcorrection                            | 1 (1)                      |
| Should the treatment be freely available? |                            |
| Yes                                       | 127 (70)                   |
| No  | 41 (23)                    |
| Undecided                                 | 14 (8)                     |
| Second eye to be treated?                 |                            |
| Yes                                       | 114 (63)                   |
| No  | 37 (20)                    |
| Undecided                                 | 31 (17)                    |

avoided.<sup>25 52</sup> Results from published studies (table I) show that about 88% of patients up to -3.00 D can expect to be within one dioptre of emmetropia, and about 72% of those between -3.10 D and -6.00 D, and 41% of those between -6.10 D and -9.00 D will be within these limits. In addition, around 70% of those with higher myopia benefit by having their myopia reduced by at least half, albeit with the greater risk of complications.<sup>25 26</sup> These patients with partial correction are usually pleased, as they benefit from considerable improvement in their unaided vision and less absolute dependence on spectacles or contact lenses. In addition they are able to use thinner spectacle lenses.

Such has been the interest in excimer laser refractive surgery over the past five years that continued efforts to improve the results can be expected to produce better (or perhaps entirely different) lasers and greater knowledge of mechanical or pharmacological manipulation of the corneal wound healing response. Photorefractive keratectomy would seem to be relatively predictable and safe for lower degrees of myopia, but it is vitally important that patients are made aware of the limitations of photorefractive keratectomy so that they can make a fully informed decision. To quote George Waring, a leading American ophthalmic surgeon,<sup>8</sup> "Critical caution, not unrestrained enthusiasm, should characterise the assessment of refractive surgical techniques. If a particular technique emerges as clearly superior there will be plenty of time for exultation, as well as fame and profit."<sup>53</sup>

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## The rhetoric of research

Richard Horton

*Richard Horton criticises authors and editors for their increasing use of rhetoric in scientific papers. We invited Trisha Greenhalgh to take up his challenge to readers to decipher the encoded intentions in his article.*

A naturalist's life would be a happy one if he had only to observe and never to write.

(Charles Darwin)

Be careful while reading this article. My purpose is to persuade. To achieve this goal I must not only appeal to your intellect and seek your sympathy for my point of view but also diminish your natural reticence to believe all that you read. If I am successful you should remain unaware of my intention to penetrate your critical guard.

Medical journals—and grant awarding bodies for that matter—proudly adhere to the rigours of peer review despite the striking lack of research about either its efficacy or its reliability. But this system of collegiate accountability frequently ignores a factor that, to the doctor or scientist, may be thought too trivial to devote much attention to: the manipulation of language to convince the reader of the likely truth of a result.

The task of removing hyperbole from a paper is normally left to an editor. But just as qualitative review of research demands knowledge about the subject of that research, and just as statistical review requires mathematical skill, so the analysis of argument demands an understanding of the tools of persuasion available to the author. To interpret a result correctly reviewers, statisticians, editors, and readers should know the conscious and unconscious tricks of authorial rhetoric.

Although applied widely, peer review is by no means a secure discipline. For instance, Altman is critical of the entire notion of peer review, a term that he believes is jargon with no agreed meaning.<sup>1</sup> He has described good peer review as the equivalent of good technical editing.

This view is unreasonable. Qualitative and statistical analyses of a research paper frequently raise important issues that, when resolved, improve the manuscript substantially.<sup>2</sup> If peer review is simply good editing then journals, according to Altman, should return to a long past age of unaccountable decision making and attention to stylistic matters alone, which made them the idiosyncratic but elegant communicators that they were 50 or more years ago.

However, in one sense Altman's attempt to locate peer review within the sphere of language study is correct. A critical linguistic analysis of a research report, as a complementary process to other forms of peer review, offers a way of investigating the reasoning that underpins an author's point of view. Such a systematic analysis is an essential, but currently missing, part of the review procedure.

### Rules of discourse

A scientific article is carefully crafted by its authors.<sup>3,4</sup> A maxim taught to many editors is that, because a paper belongs to these authors, they alone should make the final decision about their article's content. The question I wish to pose is, should authors own their own words? Given that, for the time being, they do, does their freedom benefit or hinder medical research?

The format of research papers published in this and other journals conforms to classical ideas of rhetorical presentation. Aristotle distinguished four elements that make up successful oratory: introduction, narration, proof, and epilogue.<sup>5</sup> The historical link to the familiar "IMRAD" format of a scientific paper—introduction, methods, results, and discussion—is self evident.

To the extent that science is a search for the reason

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Richard Horton, North American editor

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