REFRACTIVE SURGERY – THE FUTURE IN SIGHT?

In Part 1 David Harris discusses recent techniques in refractive surgery

Refractive surgery development

Refractive surgery might be defined simply as any surgical method of alleviating ametropia. Attempts to do this, by one means or another, have been in existence for over 100 years. Indeed an eyecup with a spring-loaded mallet, used as an instrument to flatten the cornea, was invented during the 1850's! However this device failed to gain widespread acceptance and it is probably only in the last 20 years that significant numbers of patients have come forward for refractive error modification by surgery.

Recent techniques in refractive surgery have centred on alteration of the corneal curvature in order to change the dioptric power of the system. In the late 1960's, this was carried out manually for myopia by radial keratotomy (RK), pioneered in modern form by Svyatoslav Fyodorov in Russia. Here, deep incisions (around 90 per cent of the corneal depth) are made using a diamond blade micrometer scalpel, which allows localised weakening of the corneal structure in a controlled manner. These 'relaxing' incisions allow peripheral ectasia under the influence of the intra-ocular pressure, causing the central cornea to flatten, thus reducing or eliminating myopia **(Figure 1)**.

An experienced, skilled surgeon can achieve very satisfactory results with this technique, and in the United States, where laser based techniques were not available for a number of years, this became the technique of choice for suitable pre-operative prescriptions. Between 1978 and 1994 approximately 250,000 cases of RK were performed per year in the United States[1].

A major drawback of radial keratotomy is its limited effective prescription range and its inability to correct hypermetropia or astigmatism. A technique of using arcuate incisions (arcuate keratotomy or AK) has been developed to correct astigmatism and this has proved effective in a limited prescription range. Some surgeons, who principally use excimer lasers, use AK as a convenient means of treating residual astigmatic refractive error. Hypermetropic correction has been attempted using 'Hex K', which is a refined RK technique in which the incisions are made in an approximate hexagonal pattern, creating a centralised steepening of the cornea. This method had varied success and has now almost certainly been abandoned worldwide.

A big advantage of incision based refractive surgery is the relatively low cost of the specialised equipment and the speed of use. However clinical trials in the United Kingdom using excimer laser technology to change corneal curvature took place during the 1980's at St Thomas's hospital in London, led by physicist Professor John Marshall. After the initial clinical testing proved successful, excimer surgery began to develop as the surgery of first choice for myopia in the UK Excimer lasers took until 1996 to clear American Federal Drugs Administration investigation, but they were finally passed as 'safe and effective' at the end of that year.

Excimer Lasers

Excimer lasers, originally developed for industrial use during the 1960's and 70's, use high energy light in the UV portion of the spectrum (with a wavelength of 193 nm) to vaporise, or ablate, the exposed corneal tissue. The energy produced by the laser beam is of very high intensity, but of low temperature, and the molecular bonds of the tissue are broken, converting it into gas that is then dispersed. The ablation can produce precise corneal reshaping without 'collateral damage' to the surrounding tissue as all of the energy is absorbed in the superficial layers **(Figure 2)**.

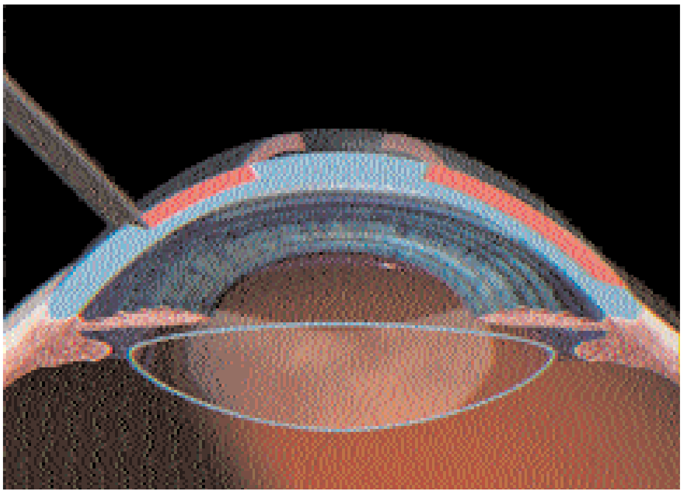
The term 'excimer' comes from the contraction of 'excited dimer', describing the gas molecules (typically argon fluoride) that are used in the laser.

The original ophthalmic clinical work used 'broad beam' lasers that extended to 4mm **(Figure 3)**. The size of the ablation was controlled by a diaphragm that would open during the treatment, rather like a camera iris. Thus, the centre of the ablation zone received laser exposure throughout the treatment and the peripheral areas only received exposure for a limited period, as the diaphragm opened. In this way a controlled bowl shape was created in the corneal tissue and myopic correction was possible.

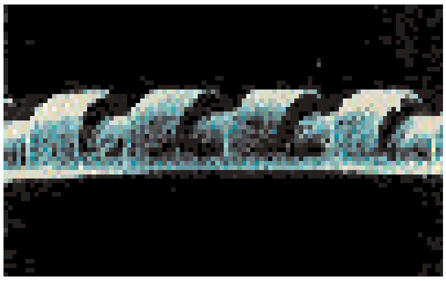
This technique could not be applied to the corneal epithelium because regeneration of the cells would occur that would remove the bowl shaped depression from the corneal surface. Thus it was necessary to apply the ablation to deeper layers of tissue so that re-epithelialisation of the area did not adversely affect the refractive outcome.

PRK

The first procedure to successfully correct myopia in this way was photo-therapeutic keratectomy (PRK). This involved the manual removal of the epithelium followed by excimer laser

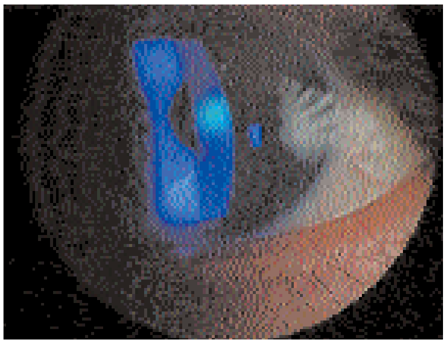


▶ **Figure 1: RK – schematic illustration of radial keratotomy incisions.** *Photograph by Visx*



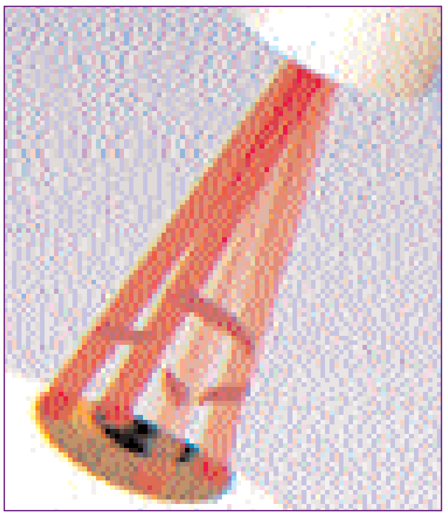
▲ **Figure 2: Classic photograph of a human hair having undergone excimer laser ablation. Note the precision of the ablation and the lack of surrounding damage to the tissue.**

▲ **Figure 3: Illustration of a broad beam laser, prior to the development of flying spots.** *Photograph by Bausch & Lomb*



▲ **Figure 4: PRK healing abrasion – five days post-op.**

▼ **Figure 5: Illustration of multiple laser beams in flying spot ablation.** *Photograph by Bausch & Lomb*



ablation. The ablation vaporised Bowman's membrane and produced re-shaping of the stroma, after which the epithelium grew over the wound.

PRK suffers from a number of limitations:

● Until the area re-epithelialises there can expected to be significant post-operative pain and photophobia **(Figure 4)**

● Very poor vision. This is variable as the epithelium progresses but initially this may only be finger counting at best.

● Unilateral treatment. It is usual to perform PRK on one eye at a time, with an interval between eyes of four to six weeks. Although simultaneous bilateral PRK is sometimes attempted the patient is likely to have extremely poor vision and significant post-operative pain. They may well find this very alarming until the vision improves and the pain subsides.

● Anisometropia. If unilateral treatment is carried out there will be a period where one eye will have undergone correction and the other will have not. Spectacles will produce unequal image sizes between the eyes (aniseikonia), which may lead to visual discomfort, and possibly diplopia. An obvious solution is a contact lens in the un-operated eye but as contact lenses are required to be removed for a period prior to surgery, this is not ideal.

● Limited treatment range. Although very high prescription corrections have been attempted in the past (-11.00D or higher) the unpredictable healing responses between patients, particularly in these higher ranges, have largely limited the procedure to pre-operative prescriptions below −6.00D. Many clinics now confine PRK procedures to pre-operative prescriptions of −3.00D or lower.

The PRK procedure, despite its disadvantages, continued to grow in the United Kingdom from the establishment of the first private clinic in 1991. As the procedure is not normally available as one that is paid for by the National Health Service, it was necessary for private facilities to provide the treatment. Usually this is carried out entirely by private clinics, but occasionally NHS hospitals would incorporate a facility into their infrastructure and provide private patient treatments.

One excimer laser procedure that is commonly paid for by the NHS is photo-therapeutic keratectomy (PTK). This is a therapeutic application of the laser and is not designed to produce changes in refraction. Here irregularities to the corneal surface that are affecting vision are removed with the laser, resulting in a smooth, even surface that can significantly improve vision. One example of the application of the laser in this way is where a patient suffers from band keratopathy. Here a grey opacity (calcium in origin) progresses across the superficial cornea and threatens sight when it reaches the pupil. Removal may be undertaken manually, but lasers are becoming increasingly popular by including the affected area in a central, round, superficial non-refractive ablation. Where elevations or depressions of the cornea are present that require removal, the whole central cornea is smoothed with methyl cellulose (Hypromellose), through which the laser energy does not penetrate and is used as an ablative mask. Following this the excimer laser ablation is carried out, transferring the new smooth surface on to the cornea.

Early ophthalmic excimer lasers used ablation zones of around 4mm and were only able to correct spherical prescriptions. With patients having pupil sizes that were larger than this in photopic conditions it was not ideal and with larger pupils in mesopic conditions it could cause significant distress. Follow-up of early patients in the UK having 4mm treatment zones showed promising results, although 78 per cent reported night-time haloes in the early post-operative period. This had reduced to 12 per cent within six years[2].

Occasionally, patients undergoing PRK elect not to have their second eye treated. This may be to achieve monovision, because of the pain that they experienced with the first eye or dissatisfaction with the visual outcome of the first eye. In one study[3], almost 15 per cent of patients had not undergone treatment on their second eye within one year. 75 per cent had expected post-operative unaided vision to be equal to their pre-operative best corrected vision, but only 23 per cent had achieved this. Hyperopia, glare and haloes were found to be significant causes of dissatisfaction.

Corneal haze, which is a product of the strong healing response initiated by PRK in which protein production manifests itself as a cloudy appearance to the tissue, was shown to reduce over time[2,3], being maximal at around six months. Many patients are not aware of significant corneal haze as it is often more easily seen at the slit-lamp than from 'behind' by the patient, with a consequently reduced number of reported symptoms in comparison to the recorded incidence.

Laser development

Progression in the technology led to increased zone sizes, and by the early 1990's this was most commonly 5mm, expanding within a relatively short period to 6mm. Astigmatic treatments were also carried out using ablatable masking systems that enabled the laser to differentially treat the corneal meridians. This method proved to be variable in its results and, despite developments that has led to the system still being available, it is no longer widely performed in favour of improvements to the laser delivery system itself.

Improvements in the laser application led to 'Flying Spot' lasers appearing from the mid-1990's. These delivered the laser pulse in a small diameter beam (typically about 1-2mm) which is controlled by the laser computer to create multiple ablation points on the cornea that coalesce to form a single ablated area **(Figure 5)**. The main advantage of this technique is that the shock-wave that is produced by a broad beam laser striking the cornea is considerably reduced. The excimer laser pulse and shock wave causes fluid to form on the interface bed and this, as well as the plume of ablated tissue thrown up by from the shock wave, may interfere with the next laser pulse and produce 'central islands' of insufficiently ablated tissue. With non-adjacent ablation through flying spot delivery, the smaller plume is avoided by the following pulse and the difficulties with central islands have been virtually eliminated.

Expansion of treatment range

Thus, as the technology improved, so prescriptions that were previously untreatable became possible. Perhaps the most major step in excimer lasers was hyperopic correction. Until that point the procedure offered most often was Laser Thermo Keratoplasty (LTK) with an holmium laser. Here the heat produced by eight or sixteen spots of holmium laser applied symmetrically in the mid-peripheral cornea causes collagen fibre contraction and spherical steepening of the central cornea, correcting low levels (up to around +4.00D) of hyperopia.

LTK suffered from difficulties including stability of refraction, with regression back in to hyperopia being common. The American Federal Drugs Administration (FDA) ruled that the lasers are labelled 'For the non-permanent or temporary correction of hyperopia' in the United States. However, LTK has enjoyed renewed interest in recent years with a new generation of holmium and pulsed diode lasers that the manufacturers claim produces significantly less regression. Reports indicate greater stability with low levels of hyperopia (up to +4.00D) expected to stabilise between six and 18 months after treatment[4,5].

With the development of laser technology and the subsequent improvements in results, laser surgery began to grow in popularity both in the UK and abroad. By the mid 1990's it was clear that the ideal procedure would produce a safe, predictable set of results on a wider range of prescriptions with fast visual recovery and little or no post-operative discomfort. Laser assisted in-situ keratomileusis (LASIK) was just around the corner . . .

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David Harris, FBDO (Hons) CL, has worked in the field of refractive surgery since 1995 and is head of refractive co-management with Maxivision. He firmly believes in the concept of involving opticians and optometrists in their patients' care following surgery and that education is a key factor. Working with Maxivision, he plans to encourage the optical and medical professions involved in refractive surgery to work together in partnership. ■