

# Peacock and Murphy

~ INDEPENDENT, PROFESSIONAL EYECARE ~

## Laser Surgery for Sight Correction

**Photorefractive surgery is performed using an excimer laser** in an attempt to correct refractive errors such as short-sightedness (myopia), astigmatism, and more recently long-sightedness (hypermetropia). These refractive errors are usually corrected by spectacles or contact lenses, however, over the years a number of surgical techniques have been used to correct refractive errors, mainly myopia, and these include 1.) radial keratotomy (RK), 2.) intracorneal rings, 3.) automated lamellar keratectomy (ALK), 4.) excimer laser surface based photorefractive surgery: photorefractive keratectomy (PRK), photo-astigmatic refractive keratectomy (PARK) and hyperopic photorefractive keratectomy (H-PRK), 5.) lamellar excimer laser techniques, specifically laser in situ keratomileusis (LASIK) 6.) clear lens extraction, and 7.) intraocular lenses.

This document deals only with the excimer laser techniques to correct refractive errors, i.e. the photorefractive techniques of PRK, PARK, H-PRK and LASIK. The following information should enable you to come to an informed decision about any prospective excimer laser surgery. However, should you have any further questions on the subject of refractive surgery these should be answered by the ophthalmic surgeon that you attend for assessment. It may be helpful to write down all your enquiries in a list form to take with you to your first assessment.

### **Development of excimer lasers in eye surgery**

Excimer lasers used in industry since 1975 were first considered for ophthalmic surgery in 1983. Since that time, experimental and clinical investigation of this new method of producing a permanent alteration in the optical status of the eye has emerged in the form of excimer laser photorefractive keratectomy (PRK) and excimer laser in situ keratomileusis (LASIK). Excimer lasers emit ultraviolet light (radiation) which is absorbed by the surface of the cornea, allowing removal of microscopic portions of tissue from the front of the cornea (approximately 0.25 microns or 1/4000th of a millimetre per laser pulse), thus altering its shape, to yield, theoretically, a very precise change in its focusing power.

Initial experimental application of excimer lasers confirmed the possibility of executing precise and smooth changes to the corneal surface allowing progress to large scale human clinical trials in the UK, the USA and elsewhere. The vast majority of excimer laser studies and clinical reports have been upon the treatment of myopia or myopic astigmatism. Approxi-

mately twenty percent of western nation populations suffer from myopia of some degree and clinical treatment of sighted eyes commenced in 1988.

Clinical excimer lasers are very complicated and sensitive instruments requiring careful calibration, monitoring of energy output and regular maintenance as is demanded by their meticulous application to surgery of the human cornea.

### **Important definitions in relation to refraction**

#### **i) Myopia (short-sightedness or near-sightedness)**

This is a very common condition in which the eye is too long for its own focusing power. Therefore, without spectacle correction, very near objects may appear sharply in focus but as objects become further away from the eye they are progressively blurred.

#### **ii) Hypermetropia/Hyperopia (long-sightedness or far-sightedness)**

Hypermetropia is a condition in which the eye is too short for its own focusing power. Without spectacles, persons with this condition often have blurred vision for both near and far, although in low degrees of hypermetropia subjects may see distant objects more clearly than near, hence the description as long-sightedness.

#### **iii) Astigmatism**

This is a condition in which the eye does not focus evenly and may be associated with long-sight, short-sight or both. It is usually related to the cornea demonstrating greater curvature in one direction than another, often likened to the oval shape of a rugby ball rather than the more even, spherical shape of a football.

#### **iv) Presbyopia**

This is a condition common to everyone with increasing age. Usually in persons about 40 years of age the eye begins to lose some of its ability to focus for near and most people need reading spectacles. However, at this age, those who have low myopia might be able to read close print simply by taking off their myopic spectacles when reading, but this will obviously render their distance vision uncorrected and therefore blurred.

#### **v) Measurement of refractive errors: Dioptres**

The size of refractive error is measured in dioptres (D) and expressed as a number prefixed by a (+) sign for hypermetropia (e.g. +4.50D) or a (-) sign for myopia (e.g. -6.00D). Astigmatism can be described with either a (+) or (⊥) sign. Most people have relatively low refractive errors between +4.00D and -4.00D with associated astigmatism of less than 1.00D. However, individuals may be much more hypermetropic or myopic and since this document largely deals with the correction of myopia and myopic astigmatism the classification of this will be enlarged. No single classification has

been agreed for myopia based on dioptres of refractive error but a reasonable and simple classification for the purposes of refractive surgery might be:

Low myopia -1.00D to -3.00D

Moderate myopia -3.25D to -6.00D

High myopia -6.25D to -10.0D

Extreme myopia -10.25D to -20.0D

vi) Measurement of vision: visual acuity

Visual acuity is usually measured by a letter chart for distance and reading text for near. In the UK distance visual acuity is most commonly assessed at 6 metres (The subject may actually be 6 metres from the chart or may read the reflection of the chart in a mirror 3 metres from the chart and patient i.e. a combined distance of 6 metres). Therefore visual acuity is usually written as two numbers, the first being 6/ (e.g. 6/12). The lower the second number the better is the individual's visual acuity e.g. 6/6 is normal vision and 6/60 (top letter on the vision chart) is very poor vision (Figure 1).

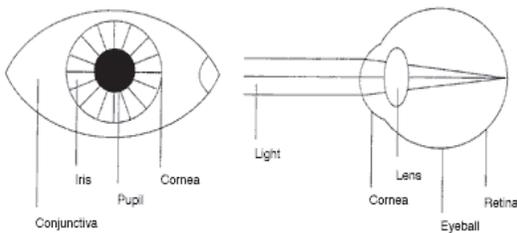


Figure 1. Diagrams of the main structures of the eye. The diagram on the left highlights the importance of the cornea and lens in focusing on the retina.

A standard chart has 9 or 10 rows of letters with the largest type at the top (6/60) and smallest at the bottom (6/5 or 6/4). The majority of the population can read down to the seventh line (with appropriate spectacle correction where necessary) which is expressed as a visual acuity of 6/6 and this represents "normal" visual acuity (20/20 in the USA). However, a number of young individuals, including myopic subjects, can see one or two lines below this with spectacle or contact lens correction i.e. a visual acuity of 6/5 or 6/4. Results of refractive surgery studies are often expressed by highlighting the number of eyes able to see 6/12 unaided. This usually represents the fifth line from the top of a standard chart and is approximately the level at which many individuals can perform a number of social tasks without spectacles, however, when considering surgery prospective patients should be aware that this is obviously a little blurred when compared to the visual acuity of 6/6 or better that they might obtain with spectacles or contact lenses.

### **Excimer laser photorefractive surgical techniques**

Patients and eye surgeons have been exploring the prospect of the surgical correction of refractive errors of the eye for more than 100 years. However,

microsurgical techniques to perform refractive surgery have largely been developed in the last 30 years with laser techniques only coming to the fore over the last 10 years. As the cornea (the clear "window" in front of the pupil and iris) is the most important part of the focusing system of the eye and it is the most accessible eye structure, the majority of refractive surgical techniques attempt to correct refractive error by modifying the focusing power of the cornea (Figure 2).

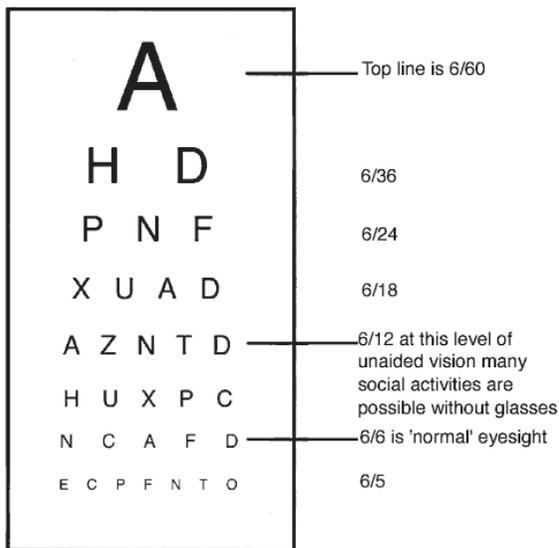


Figure 2. Diagram of a distance eye chart and explanation of recorded visual acuities.

The essential requirements of any surgical intervention are: safety, effectiveness and predictability. Excimer laser PRK/PARK for myopia and myopic astigmatism is well understood because it has been the subject of intense scrutiny and research since 1988. LASIK is a relatively newer technique, developed in 1991, which combines the surgical creation of a thin corneal flap with excimer laser treatment. Although surgical techniques to create thin corneal flaps have been available for more than 20 years, and excimer lasers have been utilised in treating refractive errors since 1988, the combination of both these techniques into the procedure of LASIK has been assessed in many fewer studies than PRK and continues to be the subject of ongoing investigations. The total UK experience of LASIK was between 500 and 1000 procedures in early 1997 compared to more than 30,000 PRK/PARK excimer laser treatments.

### Important definitions: Laser techniques

#### i) Excimer laser photorefractive keratectomy (PRK)

This is a technique in which the laser beam is applied directly to the surface of the cornea after the layer of surface cells (epithelium) has been removed. It is the most established of the excimer laser techniques and is widely used to correct myopia.

ii) Excimer laser photo-astigmatic refractive keratectomy (PARK)

This technique is essentially identical to PRK except the pattern of tissue removed from the cornea is altered to correct astigmatism in addition to myopia.

iii) Excimer laser hyperopic photorefractive keratectomy (H-PRK)

This technique corrects hypermetropia in a similar manner to PRK and PARK. It is the most recent form of surface based excimer laser techniques and very few studies have reported long term results such that at the present time this technique must still be considered investigational and only applicable to very low degrees of hypermetropia.

iv) Excimer laser in situ keratomileusis (LASIK)

This technique combines a surgical technique which creates a thin, hinged surface flap of cornea, which is gently moved aside before excimer laser treatment (similar to myopic PRK and PARK) of the exposed deeper layers of the cornea. The corneal flap is repositioned after the excimer ablation is completed. Studies have been reported since 1991 but few large long-term studies of outcome have yet been published. This is the technique referred to as "flap and zap" by the lay press.

### **Excimer laser photorefractive surgery: surgical techniques**

#### Excimer laser procedures

#### Surface based PRK, PARK, (H-PRK)

These techniques are generally used for low to moderate myopia and astigmatism, with best results achieved for myopia less than -6.00D. Although treatment up to -10.00D is possible, results are less successful as these higher corrections are attempted.

#### Lamella LASIK

This technique has generally been utilised for myopia greater than -8;00D with best results achieved for myopia less than -15.00D although treatment up to -20.00D is theoretically possible.

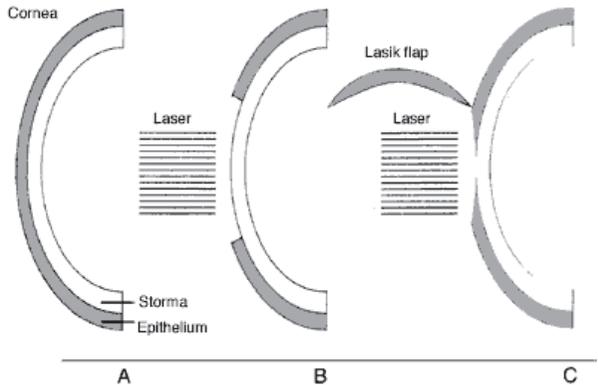
### **Description of surfaced based photorefractive surgical techniques: PRK, PARK and H-PRK**

The surface based excimer laser procedures are all performed in a similar manner, the only major difference being that the pattern created on the cornea by the laser differs depending upon whether myopic (PRK) myopic astigmatism (PARK) or hypermetropic (HPRK) corrections are being carried out.

No injections are required for these procedures, the eye is numbed (anaesthetised) by the application of a few drops of topical anaesthetic in the 10 minutes before the surgery. The patient will then be taken to the laser room and will usually lie down on a couch which slides under the laser.

A small device (speculum) is placed between the eyelids to prevent them from blinking or closing during treatment. In order to create a lasting refractive effect the laser has to remove tissue from the surface of the corneal stroma which lies immediately under a thin layer of surface cells (epithelium). This layer of surface cells can be removed manually by rubbing with either a sharp or blunt instrument and the procedure is usually completely painless. Normally this layer is removed in 60-120 seconds (recently some surgeons have begun to use the excimer laser to remove this layer) (Figure 3).

Figure 3. Diagrams of the cornea (not drawn to scale) showing A) normal cornea with layer of surface (epithelial) cells B) mechanical removal of the epithelial cells to allow excimer laser PRK to the cornea C) a LASIK flap, with intact epithelial cell attached, lifted aside to allow excimer laser to the deeper cornea before the flap is carefully put back into place.



Once the epithelium is removed, the patient will usually be asked to concentrate on a light or target within the laser and the PRK procedure commences with a series of clicking or clapping noises as the excimer laser painlessly removes corneal tissue to a pattern pre-determined by the particular patient's own refraction. Patients may be aware of a gentle tapping sensation and a faint smell similar to singed hair. However, subjects should not be concerned if they detect this smoke-like smell, the excimer laser is not a thermal (heat) laser and no tissue is being burned during the procedure. The smell is probably related to carbon molecules liberated from the corneal surface by the laser ablation. The laser component of the treatment will usually take 15 to 90 seconds depending upon the laser used and the refractive error being treated. Following treatment topical drops and ointment are applied to the eye and a pad will usually be placed over the eye for 6-24 hours.

### **Description of lamellar excimer laser procedures (LASIK)**

Lamellar excimer laser procedures, such as laser in situ keratomileusis (LASIK), are fundamentally different from the surface based procedures already described. In LASIK a thin hinged flap or cornea is created and lifted to one side in order to allow direct laser treatment to the deeper part of the cornea (stroma). Preparation is similar to that for PRK with only topical anaesthetic drops being required to anaesthetise the eye. LASIK is a more extensive surgical procedure than PRK and the skin around the eye will be cleaned with antiseptic solution and a sterile drape placed over the eye and

forehead before the lid speculum is positioned. The epithelia (corneal surface) cells are not removed in this procedure.

The corneal flap is created by an automated microkeratome which is a complicated and sophisticated piece of surgical equipment which contains a very fine surgical blade. The microkeratome should only be used by surgeons who have undergone thorough training in its use. Usually the patient will be asked to look at a target directly above them within the laser, and a suction ring (which stabilises the eye and guides the microkeratome) is placed on the eye. The application of the suction ring is usually painless but the patient may be aware of slight movement of the eye and a sensation of fullness or mild pressure. Vision usually become very grey and blurred or disappears entirely whilst the suction ring is in place (60-120 seconds). Once the suction ring is properly positioned the microkeratome is fitted to the guide in the ring and passes over the eye to create a thin flap of cornea complete with the overlying epithelium. The creation of this flap, which is approximately 25-30% of the corneal thickness, takes less than 20 seconds. The suction ring is released and the patient's vision returns. The hinged corneal flap is then elevated and turned to one side (Figure 3) and the excimer laser treatment of the deeper cornea commences in a similar manner to that outlined for PRK. During the excimer treatment the patient will be required to look at a target within the laser and will hear a clapping sound, may notice a mild sensation of tapping on the eye and may be aware of the aforementioned smoke-like smell.

Once the excimer laser ablation is complete (30-120 seconds) the corneal flap is placed gently back into its original position. The space between the flap and the underlying corneal stroma is usually washed out with fluid to remove any particles which may have landed on the exposed surface during treatment and the flap is then allowed to dry into place. No stitches are required and the flap usually settles firmly into position within 3-5 minutes. Topical drops are applied to the eye and a pad or shield may be placed over the eye. Many surgeons will inspect the flap within 60 minutes of the procedure to confirm it has settled into the correct position.

## **The post-operative period following photorefractive surgery**

### **PRK/PARK: the first few days after the operation**

Following PRK or PARK the eye has a large epithelial defect, in a basic sense similar to a large abrasion of the corneal surface. Topical eye-drops and pain-killers should be provided by your ophthalmic surgeon to relieve the pain related to this epithelial defect. A pad may be placed on the eye for the first 24 hours. Generally post-operative pain occurs within the first two to four hours after the procedure, is worst in the first 12-16 hours, and improves significantly by 24 hours. By using eyedrops and oral painkillers the majority of patients find the post-operative pain mild to moderate and quite bearable, however, approximately one in ten subjects find the pain to

be severe. Usually the pain has resolved by the second day though the eye may feel gritty, sensitive to light, and a little uncomfortable for 3-4 days in total. Once the surface epithelial cells have healed over, generally by day 3-4 post surgery, the eye is much more comfortable and the severely blurred vision created by the epithelial defect improves dramatically. Individuals undergoing PRK/PARK should anticipate being unable to work properly for 2-4 days after surgery and may not be able to drive for 4-7 days. In addition to eye drops to ease pain, patients might expect to apply topical antibiotic drops four times per day for one week following surgery. The patient might reasonably anticipate being reviewed within the first 3 days following treatment. Depending upon the surgeon's preference and the degree of attempted myopic correction, a short course of topical steroid drops might also be prescribed for 2-12 weeks. Steroid eyedrops should not, however, be used long-term.

### **LASIK: the first few days post-operation**

Although PRK and LASIK techniques both utilise the excimer laser to create the refractive correction, because LASIK involves the creation of a thin corneal flap (with intact overlying epithelium) which is put back into its original position following the excimer laser ablation, there is no significant defect of the surface cells after LASIK treatment. The absence of an epithelial defect means that LASIK is relatively pain free in the post-operative period and most patients experience only minor discomfort for 6-12 hours. Antibiotic eye drops will usually be required four times per day for seven days and, depending on surgeon preference, topical steroid drops may be used four times per day for two weeks or less. Vision usually begins to improve within the first 12 hours and should be adequate for work purposes within 2-4 days. The patient might reasonably anticipate being reviewed within the first 3 days following treatment. Although a pad is not usually applied to the eye following treatment, patients must be very careful not to rub their eyes for the first several weeks. To minimise the risk of eye rubbing, which might displace the LASIK flap as it heals down, some surgeons may recommend a clear shield be worn over the eye for the first week when the patient is sleeping at night.

### **The first few months after excimer laser refractive surgery**

Vision may be blurred for the first few days or weeks as the healing process proceeds. This may be associated with a temporary over correction (towards long sight) following which "normal" sight usually develops. The degree of over-correction varies considerably from laser to laser. It also tends to be greater with higher attempted refractive corrections.

Stabilisation of the refraction following excimer laser photorefractive surgery may take a few weeks to several months and depends upon three major factors: a) the magnitude of attempted correction, with higher corrections generally taking longer to stabilise than lower ones, b) whether PRK or

LASIK has been performed, with refraction tending to stabilise more rapidly following the correction of high myopia by LASIK compared to PRK and c) individual healing characteristics. These factors cannot be accurately quantified pre-operatively. Although some individuals will stabilise their post-operative refraction within a few weeks, and the majority within three to six months, a minority of eyes (especially those with higher corrections) may take 12 months or more to fully stabilise.

### **Anisometropia in the post-operative period**

A difference in focus between the two eyes (anisometropia) will result from the treatment of the first eye, but its effects may be minimised by contact lens wear in the unoperated eye. If patients are unable to wear a contact lens in the untreated eye and have myopia of approximately  $-4.00D$  or greater prior to treatment then this difference in focus might be quite marked and may impair perception of depth of field and compromise the ability to drive. This interim period of potential imbalance, between the treatment of the first and second eyes, should be carefully considered by those with moderate myopia who cannot tolerate contact lenses. In general terms a difference of more than  $5.00D$  in refractive power between eyes cannot be tolerated comfortably in spectacles (e.g. a treated eye with a post-operative refraction of  $-0.50D$  and the opposite untreated eye with a refraction of  $-6.00D$  produces a difference in refractive correction of  $-5.50D$  until the second eye is treated).

### **Clinical results of photorefractive surgery**

#### **Surface based photorefractive surgery: PRK, PARK and H-PRK**

Theoretically, excimer lasers are capable of treating myopia of up to 20 dioptres and in some cases lasers are able to treat patients with up to 3.0 to 4.0 dioptres of associated astigmatism. The results from this wide spectrum of refractive error, however, are by no means uniform. It is now clear that for low to moderate degrees of myopia ( $-1.0D$  to  $-6.0D$  dioptres) the majority of patients may enjoy a very satisfactory result following PRK.

However, with high myopia, the proportion of successful outcomes gradually declines. Subjects with high myopia between  $-6.25D$  and  $-10.00D$  are much less likely to achieve 6/6 vision unaided following excimer laser PRK, although the majority should obtain a very significant reduction in myopia and unaided vision in the region of 6/12.

The treatment of greater than  $-10.00D$  of myopia by surface based excimer laser is not recommended.

Where photo-astigmatic refractive keratectomy (PARK) is performed the best results are achieved for those myopic eyes with associated astigmatism that does not exceed 1.5 dioptres. For those whose myopia and astigmatism exceeds these lower limits, a proportion of patients will continue to get a pleasingly satisfactory result. Patients should ask their oph-

thalmic surgeon to provide a breakdown of the results for the particular laser and clinic before treatment.

Six representative studies of excimer laser PRK are highlighted in Table 1. In each of these studies the patients were followed up for a minimum of a year and the maximum level of attempted myopic correction was -10.00D. In the later studies, using wider ablation zones and more contemporary excimer lasers (1994-1996), it can be readily seen that approximately half of those treated for less than -7.75D of myopia obtained 6/6 vision unaided post-treatment and approximately 90% achieved an unaided vision of 6/12. Those subjects presenting with lower levels of myopia for PRK were more likely to obtain 6/6 or 6/12 unaided vision post-treatment than those with greater than -6.00D.

It should always be remembered that many patients will still require spectacle wear for some tasks such as driving, visiting the cinema, and reading, even if they achieve sufficiently good unaided vision for many other tasks.

**TABLE 1**

<i>Authors and year published</i>	<i>No. eyes treated</i>	<i>Attempted myopic correction</i>	<i>Within +/- 1.00 of plano</i>	<i>6/6 unaided vision</i>	<i>6-12 unaided vision</i>
1. Garty et al. (92)	66	< - 7.00D	62%	45%	70%
2. Maguen et al. (94)	137	< - 7.75D	79%	37%	89%
3. Dutt et al. (94)	47	< - 6.10D	80%	74%	94%
4. Talley et al. (94)	60	< - 5.00D	95&	52%	98%
5. Snibson et al. (95)	80	< - 5.50D	96%	46%	88%
6. Schallhorn et al. (96)	30	< - 5.50D	87%	100%	100%
7. Talley et al. (94)	25	5.1 to 7.5D	88%	24%	96%
8. Snibson et al. (95)	62	-5.1 to 10D	68%	34%	68%
9. Carson et al. (96)*	194	-5.1 to 10D	67%	28%	71%

Table 1. Nine representative clinical studies of surface based excimer laser PRK highlighting unaided vision twelve months after attempted corrections of up to -10.00 Dioptres of myopia. In studies treating myopia up to -6.00D (studies 3,4,5,6) 46% to 100% of eyes obtained 6/6 or better unaided vision and 88% to 100% obtained 6/12 or better unaided vision. However, with higher attempted corrections between -5.00D and -10.00D (studies 7,8,9) fewer eyes obtain a final refraction within 1.00D of plano (zero refractive error) (column 4) and the number of eyes that achieve 6/6 unaided vision reduces dramatically (column 5) as does the number of eyes achieving 6/12 unaided (column 6) (\*six months follow up).

In addition to these variations in results associated with the degree of presenting myopia, the higher degrees of attempted correction are associated with a higher incidence of post treatment complications, particularly myopic regression (return of myopia), increased irregular astigmatism and loss of best spectacle corrected visual acuity (BSCVA).

Claims for correction of hypermetropia, currently under investigation with the excimer laser, are yet to be fully substantiated by large clinical trials. However, initial results for the correction of hypermetropia with the excimer laser suggest reasonable correction up to +4.00D of hypermetropia.

Presbyopia, the development of which is related to changes in the focusing power of the lens of the eye, is NOT amenable to laser surgery.

### **Clinical results of lamellar photorefractive surgery: LASIK**

Although LASIK, as an excimer laser technique, has been around since 1991 it has only been regularly practised in the UK since 1995 and fewer than 1000 procedures had been performed by January 1997. Generally LASIK has been used to correct high to extreme myopia with many surgeons reserving this treatment for myopia greater than -8.00D to -10.00D and less than -20.00D. However, in some established centres in Europe and Canada this technique is now being used for myopia of -4.00D and above. There have been very few published scientific studies on the clinical results of LASIK and several of these are highlighted in Table 2. Unlike treatment of low to moderate myopia (up to -6.00D) treatment of high and extreme myopia is unlikely to eliminate the patient's need for spectacles. Published data suggest that for high and extreme myopia few subjects will obtain 6/6 unaided vision post LASIK, but a large number (depending on magnitude of pre-operative myopia) will have their myopia reduced to -1.00D or less (approx. 50-70%) and obtain 6/12 unaided vision (50-80%). LASIK retreatment or enhancement to refine the final visual outcome appears to be more successful than retreatment by PRK but very limited data is presently available on this topic.

**TABLE 2**

<i>Authors</i>	<i>Year</i>	<i>Follow-up months</i>	<i>No. eyes studied</i>	<i>Mean myopia treated</i>	<i>Within +/- 1.00D intended</i>	<i>Loss of 2 lines of BSCVA</i>
Pallikaris et al.	1994	12	9	16.61	67%	0%
Fiander et al.	1995	3	124	-7.65	70%	0%
Kremer et al.	1995	3	31	-6.25	74%	0%
Bas et al.	1995	3	88	-10.75	47%	13%
Salah et al.	1995	5.2	88	-8.24	73%	4%
Marinho et al.	1996	6	34	-14.18	68%	9%
Helmy et al.	1996	12	40	-6 to -10	60%	-
Kim et al.	1996	6	18	-16.40	47%	0%
Guell et al.	1996	6	43	-7 to -18	63%	0%

Table 2. Results of nine representative clinical studies of LASIK for high to extreme myopia. The authors and year of publication are shown in the first two columns. Follow up in months post LASIK and the number of eyes reviewed in each study are shown in columns three and four. The mean myopia of patients is highlighted in the fifth column and the following column

demonstrates the percentage of eyes that achieved a final correction within 1.00 dioptre of the intended final result, notably in studies with a lower mean myopia to be corrected (Fiander et al., Kremer et al. and Salah et al.) the majority of eyes (70-74%) were within 1.00D of intended but this was less common in studies attempting to correct a greater mean myopia. Some patients had worse vision after LASIK (last column). Loss of 2 lines of best spectacle corrected visual acuity (BSCVA) is a significant complication of any photorefractive procedure and although five of the eight studies documenting this complication recorded no cases (0%), two recorded high levels (9-13% of patients).

## **Complications of surface based PRK/PARK**

### **Short term side effects (which should not permanently affect vision)**

#### **A) Pain**

The actual laser treatment itself is usually painless; however, two to three hours after treatment most patients will develop mild to moderately severe eye pain which will last 24 to 36 hours (see Section 5.1).

#### **B) Corneal haze**

All patients will develop at least a mild degree of haze in the central cornea following laser; this can cause a reduction of vision and haloes around lights. This haze is worst during the first 2-3 months and generally disappears within 6 months.

#### **C) Difference in refractive error between eyes (anisometropia)**

Since only one eye is treated at a time it does mean that for 2-6 months (depending on the timing of the treatment of the second eye), the untreated eye will be short sighted and the treated eye may be normally sighted (see Section 5.4).

### **Persistent side effects which should not affect corrected visual acuity (i.e. best eyesight obtained with glasses or contact lenses)**

#### **D) Minor overcorrection or undercorrection of myopia**

Since all patients' eyes differ in the rate and manner of healing, the computer predicted result may not achieve the expected correction, and although 90% of patients with lower levels of myopia might achieve 6/12 without glasses or spectacles, invariably some patients will be a little over or under corrected and will require spectacles or contact lenses to obtain their best vision (see Table 1).

#### **E) Significant regression of PRK correction**

Reduction of the original laser correction can occur with time and the patient once more becomes a little short-sighted or astigmatic; however, with newer excimer lasers utilising 6.0mm diameter treatment zones this appears to affect less than 10% of eyes with low to moderate levels of myopia (-1.00D to -6.00D).

#### F) Presbyopic (reading) spectacles

Most people require reading glasses when they reach their early to mid forties; however, short-sighted people (by removing their distance glasses and reading without spectacles) often do not require glasses for reading when they reach this age. However, if a myopic patient is treated by excimer laser photo-refractive keratectomy, he or she will effectively become "normal sighted" in this regard and whilst glasses may not be required for everyday tasks, once the treated person reached 40-45, like most of the population, reading glasses will be required for near work.

#### G) Stability of the cornea following laser

Generally with less than 10-20% of the corneal thickness removed by excimer laser photorefractive keratectomy, the eye is not significantly weakened and is therefore unlikely to be at risk from trauma.

### **Vision threatening complications**

Many of the complications listed below are related to abnormal healing of the cornea with the development of haze or an irregular surface. For low to moderate myopia the overall risk of significant complications which will permanently affect vision is probably in the region of 1-3%.

#### H) Severe haze and scarring

Occasionally this is severe enough to cause a reduction of the best corrected visual acuity (i.e. the best vision obtained with spectacles or contact lenses) and may affect 1-3% of eyes treated for mild to moderate myopia (up to -6.00D). This reduction is usually mild (e.g. reducing vision by one line from 6/6 to 6/9) although some patients may lose 2 lines of vision (e.g. reduced from 6/6 to 6/12) in which case the best unaided and spectacle correction may be limited to 6/12.

#### I) Persistent epithelial defect

Very rarely the surface (epithelial) cells on the cornea do not adhere properly to the laser treated surface (less than 1% of treatments). This is called a persistent epithelial defect and can cause pain and watering of the eye in addition to predisposing the eye to infection. If this persists a reduction in vision may occur.

#### J) Infection

Although this has only been recorded in a few cases world-wide (two reported cases in the UK), since the surface of the cornea is removed during treatment, it is possible that the eye may develop infection in the immediate post operative period (first week) following excimer laser treatment. Severe infection might result in permanent corneal scarring and reduced vision.

#### K) Halo and distorted vision

Due to irregular healing, severe haze, decentration of the treatment, or induced astigmatism, patients may note subjective visual symptoms such

as halo or starburst around lights; this is more common when the pupil is dilated at night under low light conditions. These symptoms were more common when small diameter treatment zones were utilised but may still affect 1-2% of treated eyes.

### **Miscellaneous side effects**

#### **L) Contact lens wear**

Due to the changed shape of the cornea it may be more difficult to properly fit and wear contact lenses post PRK or LASIK.

#### **M) Ptosis (drooping of the upper lid)**

Mild ptosis is relatively common in the first few weeks after PRK but rarely persists.

#### **N) Recurrent corneal erosion syndrome**

Occasionally the healing epithelial cells do not heal down and adhere properly to the corneal surface as strongly as before PRK. This may be associated with the recurrent loss of a small number of cells from the corneal surface intermittently. Symptoms may include a stinging sensation in the eye, watering of the eye, sensitivity to light and pain which may last a few hours. Minor symptoms are relatively common in the first few months but severe symptoms are rare. These problems are usually self limiting and persist in less than 1% of cases.

### **Specific complications of LASIK**

Since both PRK techniques and LASIK utilise an excimer laser to produce the refractive correction many of the complications are similar; however, due to the lamellar flap technique used in LASIK, some complications are less than in PRK and some are unique to LASIK.

#### **A) Pain**

Since during LASIK the surface epithelium remains intact and is repositioned, along with the flap, unlike PRK, there is usually minimal or no pain after LASIK.

#### **B) Corneal haze**

Due to the lamellar technique there appears to be less healing after LASIK and a greatly reduced likelihood of haze. Although mild haze may occur in some eyes severe haze has not been reported.

#### **C) Difference in refractive error between eyes (anisometropia)**

This is similar for LASIK and PRK, although because higher levels of myopia may be corrected by LASIK the symptoms of anisometropia may be greater between the treatment of first and second eyes.

D) Minor overcorrection or undercorrection of myopia

This is similar for PRK and LASIK since both depend upon individual healing response to obtain the final refractive result.

E) Significant regression of myopic correction

Although a degree of myopia will return in a percentage of patients undergoing PRK or LASIK, the magnitude of this is less in LASIK due to the lesser healing response noted in LASIK compared to PRK.

F) Presbyopic (reading) spectacles

The likelihood that a subject will require reading spectacles is similar after PRK and LASIK.

G) Stability of the cornea following laser

Although up to 30% of corneal thickness may be removed centrally following LASIK, studies to date suggest that the eye is stable within 6 months, and thereafter is unlikely to be at increased risk from trauma.

H) Severe haze or scarring

This is very rare following LASIK.

I) Persistent epithelial defect

Since the surface epithelium is minimally disturbed by LASIK persistent epithelial defects are extremely rare.

J) Infection

Like PRK there is a small risk of infection, as is the case after any surgical procedure to the eye.

K) Halo and distorted vision

The risk of these problems following LASIK are likely to be similar to, or slightly less than after surface based PRK but there is insufficient data to draw firm conclusions.

L) Permanent reduction in best corrected visual acuity

Whilst a number of LASIK studies have recorded a very low percentage of eyes with loss of best corrected visual acuity, this technique is less well established than PRK, and it is likely that a small percentage of eyes treated by this procedure will have permanent reduction in vision.

M) Permanent difference between the refractive power of both eyes (anisometropia)

The risk of significant visual problems created by different spectacle power between eyes if the patient elects to have only one eye treated is likely to be higher than after PRK due to the higher levels of myopia corrected by LASIK.

## **Problems related specifically to the LASIK surgical procedure**

These problems are all related to the creation of the hinged corneal flap and are more likely to occur if proper attention is not paid to the stringent maintenance of the microkeratome and the exacting surgical execution of the LASIK procedure. It is difficult to establish the exact risk of these complications but they have been reported as infrequently as 1% to as much as 4%. All these complications may be associated with permanent loss of best corrected vision.

- L1. Incomplete resection (creation) of the corneal flap
- L2. Loss of or extensive damage to the corneal flap
- L3. A completely free corneal flap - which might require sutures (stitches)
- L4. Debris or fibres under the corneal flap
- L5. Epithelial ingrowth under the corneal flap
- L6. Wrinkling of the corneal flap
- L7. Penetration of the eye by the microkeratome.

In view of these surgical risks the Royal College of Ophthalmologists recommends that only surgeons who are fully trained in ocular microsurgical techniques, who are registered as specialists with the General Medical Council (GMC), and have undergone additional training specifically in the technique of LASIK should undertake this procedure.

## **How to establish your own refractive error**

Myopia is a very common defect affecting approximately one in five adults. It often commences in early teenagehood and stabilises around 20 years of age. Without their spectacles, short-sighted individuals are able to see near objects clearly if held at the appropriate distance, but usually objects become blurred when farther away. Normally, myopia is corrected by spectacles or contact lenses and such spectacles are usually thicker at the edge of the lens, where it meets the spectacle frame, than in the centre of the lens.

If you wear myopic spectacles, then by holding them a few inches away from a printed page, you will note that they make everything seem smaller. Alternatively, if you have a spectacle correction from your optometrist (optician) your degree of myopia will be indicated in the "sph" box of the prescription with a minus sign - either above or in front of that number.

In contrast, if you are hypermetropic/hyperopic (long-sighted) then your glasses will magnify if held a few inches away from a printed page and a plus sign (+) will be noted above or in front of the number in the "sph" box of your prescription. At present, studies using excimer laser PRK or LASIK techniques for the correction of hypermetropia are promising, but these studies are small in number and treatment of hypermetropia must still be considered investigational.

Both myopic and hypermetropic eyes may also exhibit astigmatism and this will usually be written in a box labelled "cyl" which comes after the myopic or hypermetropic correction indicated in the "sph" box previously discussed. A few examples might be helpful: example a) - 5.50/-0.75D indicates that this eye is myopic (-) with 5.50 dioptres of myopia and 0.75 dioptres of astigmatism; example b) +3.00/+\_1.00D indicates that this eye is hypermetropic (+) with 3.00 dioptres of hypermetropia and 1.00 dioptre of astigmatism; example c) -4.00/+0.75D represents a more complex way of writing the prescription with this eye showing 4.00 dioptres of myopia and 0.75 dioptres of hypermetropic astigmatism (+); however, remember that astigmatism can be expressed as either a (+) or (-) and it is the sign in front of the first number ("sph" box) which tells you whether you are myopic or hypermetropic.

### **Contraindications to photorefractive surgery**

Relative ocular contraindications to laser refractive surgery are:

#### **Unstable spectacle refraction**

Refraction does not stabilise in humans until the late teens or early twenties. Preferably patients should therefore be over 21 years of age and have demonstrated less than 0.5D change in refraction over the 2-3 years preceding excimer laser treatment. Subjects with a refraction that has not yet stabilised or continues to change should not undergo treatment.

#### **Patients with low myopia who have, or are approaching, presbyopia**

The need for reading glasses, prevalent over 40 years of age, has previously been discussed. All patients should understand that laser surgery will not affect this age related process, and those with low levels of myopia, who are in this age group but presently can read by removing their myopic spectacles, should be aware that they will need reading glasses if their myopia is fully corrected by excimer laser surgery.

#### **Inappropriate motivation or unreasonable expectation**

Although results of photorefractive surgery generally produce improved unaided vision and a reduced reliance upon spectacles or contact lenses, the final outcome largely depended upon patients' healing responses and therefore cannot be guaranteed. Patients who desire an absolutely perfect result and wish to be completely free from spectacles or contact lenses may be dissatisfied with the outcome following excimer surgery.

### **Contraindications**

The following conditions are generally reasons not to undergo any form of excimer laser surgery, or only to do so in exceptional circumstances following extensive informed discussion of the increased risks of the procedure in these conditions.

### **Monocularity or severe amblyopia**

This is in the case of patients with only one useful eye due to the opposite eye being diseased or amblyopic ("lazy").

### **Severe dry eye disease**

Patients who require frequent topical eyedrops or ointment for dry eye symptoms may be at greater risk of complication due to poor healing post excimer laser treatment.

### **Severe local infective or allergic conditions**

These include significant blepharitis, a past history of infection of the eye by the Herpes Simplex virus, and allergic eye disease, which is problematic enough to require regular treatment.

### **Abnormalities of the cornea**

These include: decreased sensation in the cornea due to previous disease or injury, keratoconus (a disease causing thinning, scarring and forward bowing of the cornea), irregular astigmatism, and diseases of the cornea which upset the corneal surface such as an extensive ingrowth of blood vessels into the cornea.

### **Cataract or Glaucoma**

A significant percentage of subjects over 60 years of age develop cataracts. Excimer laser surgery should not be performed in the presence of significant cataract. Glaucoma management usually involves the monitoring of intraocular pressure. Excimer laser techniques produce a relative flattening of the cornea and may make accurate measurement of the intraocular pressure more difficult, therefore glaucoma is a relative contraindication to excimer laser surgery.

**Systemic conditions** that might affect healing and outcome of refractive surgery. These include: pregnancy, diabetes mellitus, diseases or drugs that compromise the immune system, severe rheumatoid arthritis, systemic lupus erythematosus and other collagen diseases, and systemic medication which affects healing, e.g. systemic steroids.

### **Assessment for excimer laser refractive surgery**

Patients for PRK, PARK, H-PRK or LASIK must be well motivated and well informed as to the rationale for treatment, its predictability and the time course of events which may include an interim period when the two eyes may not work together due to differences in refractive error.

A full ophthalmic examination should be carried out by an ophthalmic surgeon trained in the practice of refractive surgery and the diagnosis of corneal disorders. This examination should include computerised corneal topography which can reveal corneal irregularities not otherwise demon-

strable, measurement of intraocular pressure and retinal examination after pupil dilation.

All contact lens wearers need to be advised to remove their contact lenses for a period before treatment. Current advice is that for patients wearing soft contact lenses this period should be not less than one week. For patients wearing hard or gas permeable lenses, the period should be not less than two weeks to one month. Re-examination after this period with computerised topography is usually advised in order to detect any remaining corneal warpage (corneal distortion) resulting from previous contact lens wear.

### **Excimer laser treatment**

The various treatment options have already been outlined. These vary considerably in procedure when comparing LASIK and surface based laser techniques such as PRK or PARK; however, in general the following statements apply to these procedures: a) excimer laser surgery is an outpatient procedure performed under topical anaesthesia (anaesthetic eye drops) by an ophthalmic surgeon, b) usually no injections are required, c) although the laser component of the treatment may only take 30-60 seconds on average, the total procedure may take 10-25 minutes.

### **Ophthalmic follow-up after excimer laser photorefractive surgery**

The responsibility for patient care following excimer laser photorefractive surgery remains with the ophthalmic surgeon who carried out the procedure. Regular post-operative examination by an ophthalmologist is necessary to monitor progress, detect any untoward complications, and alter treatment when required. These examinations should continue for at least one year after treatment.

### **Treatment of the second eye**

Early PRK on the second eye depends on the speed of recovery of the first eye. In order to identify abnormal healing or refractive complications following the treatment of the first eye, it is seldom advisable for the second eye to be treated within a period of less than one to three months after the treatment for the first. Following the attempted correction of higher levels of myopia (6.00D or more) by PRK, the second eye should not be treated until the post-operative refraction in the first appears stable, generally three to six months. Following LASIK refractive stability appears to occur earlier than after PRK for high to extreme myopia and the second eye may be treated in 6 to 12 weeks if the post operative refraction appears stable.

Treatment of both eyes at the same time by PRK/PARK or LASIK is specifically not recommended.

*Remember PRK/PARK and LASIK are not reversible.*

### **Retreatment by excimer laser photorefractive surgery**

Due to the natural variation in healing in the normal population not all patients will obtain the refractive result that they desire and may be considered for retreatment. Retreatment by surface based excimer PRK/PARK is quite different from retreatment by LASIK and these will be dealt with separately. Available data suggest that retreatment is required in approximately 5-10% of subjects with a preoperative myopia less than -10.00D. However, in some cases retreatment will be contraindicated which does mean that a small number of individuals (1-2%) will ultimately end up with only one eye treated and may experience the previously outlined symptoms of anisometropia due to the difference in refraction between the eyes.

### **Retreatment of PRK utilising surface based PRK techniques**

Following surface based PRK/PARK a number of patients will heal in a fashion which leaves the treated eye a little hyperopic, or more commonly a little myopic. The tendency to return to a degree of myopia is often associated with variable degrees of corneal haze. Eyes which regress by more than 50% of the original attempted correction, or eyes which regress with significant haze development are generally not good candidates for retreatment.

However, if there is minimal haze and only mild to moderate myopic regression retreatment may be considered. A period between primary treatment and retreatment of 6-12 months is recommended in order to allow the eye to stabilise fully after the first procedure. Since, by default, those eyes which are retreated have healed unpredictably after the first procedure, retreatment is also likely to be unpredictable with a final outcome that cannot be guaranteed. Published studies suggest that in eyes with mild myopic regression after the initial treatment, that approximately 80% will obtain 6/12 or better unaided vision following retreatment. All patients should be carefully counselled in relation to the risks and benefits of retreatment in respect to their individual requirements and the refractive of their opposite eye prior to undergoing repeat excimer laser PRK/PARK.

### **Retreatment of LASIK utilising LASIK techniques**

Due to the use of a lamellar corneal flap severe haze or marked myopic regression of effect is not a common feature of LASIK procedures. Nonetheless under and over corrections do occur due to individual responses to the excimer laser treatment. Stabilisation of refraction occurs earlier than after PRK and therefore retreatment following a LASIK procedure may be considered 4-12 weeks after the primary LASIK treatment. The original flap is re-elevated and additional excimer laser ablation is applied to correct the residual refractive error. Very few studies have been published in respect to retreatment by LASIK, but from available data it is anticipated that retreatment results following LASIK are likely to be similar to or better than retreatment results following PRK.

## **Alternative Treatments**

Lower degrees of myopia and some forms of astigmatism, especially in older patients, may yield more readily to radial and astigmatic keratectomy. Another alternative procedure for the correction of low myopia is the intracorneal ring (ICR) although this technique is still under investigation.

## **The future of photorefractive surgery**

PRK (especially H-PRK) and LASIK remain the subject of multiple clinical trials and other investigations. The medical profession is constantly pooling its knowledge and sharing its resources to ensure that patient care is based on the sound knowledge of accumulated experience.

## **Which questions should one ask in respect to prospective excimer laser treatment?**

i) Will the ophthalmic surgeon who assesses and counsels you in respect to treatment be the same one who performs the excimer procedure and sees you in the follow up clinics?

ii) Based upon their treatment data, can the clinic or surgeon provide results and accurate information in respect to your likely refractive outcome following treatment (always remembering the exact outcome cannot be guaranteed)?

iii) Are all necessary drugs, drops and clinic reviews included in the cost of treatment, and if retreatment is advised, is this covered by the initial treatment fee?

iv) If you are seeking LASIK treatment:

Is the ophthalmic surgeon a registered ophthalmic specialist with the General Medical Council (GMC)?

Does (s)he regularly perform intraocular microsurgical procedures?

Has (s)he undertaken a specific training course in LASIK surgery and the management of complications?





