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Executive Summary 2002

Over the last few years, laser refractive surgery techniques have continued to advance, making corrective surgery a viable alternative to spectacle or contact lens correction, particularly for short sight (myopic) individuals. Currently, between 200,000 and 300,000 patients undergo laser refractive surgery in the United Kingdom alone each year and more than two million have been treated worldwide. Regulatory and occupational bodies are encountering an ever, increasing proportion of applicants who have undergone some form of refractive surgery and need to ensure they have an up to date view of this rapidly progressing field.
Refractive surgery can be classified as corneal or intraocular. Currently, the most common forms of refractive surgery are LASIK (laser in situ keratomileusis) and PRK (photorefractive keratectomy), although other corneal techniques include RK (radial keratotomy) and ICRS (intracorneal ring segments) among others.

Intraocular surgery is associated with greater risk simply because the eye is being opened up but is often the best option for the treatment of higher refractive errors. Techniques include phakic intraocular lens implantation (phakic IOL) and refractive lens exchange. A number of other techniques are in development and are likely to be available in the near future. The choice of surgical technique for a particular patient depends on the nature of the refractive error requiring correction, their corneal thickness, pupil size, the views and experience of the operating surgeon and any special visual requirements of the individual patient.

Radial keratotomy (RK) was developed for the treatment of low and medium myopia and popularised, particularly in the United States during the 1970's. It involves making radial cuts in the peripheral cornea using a guarded micrometer blade. The cuts are made through approximately 95% of the corneal thickness, and the myopia is corrected by the relative flattening of the central cornea in relation to the bulging of the weakened peripheral cornea. This weakening of the eye is associated with various complications ranging from a significant variation in refractive error (and therefore vision) during the day in about 30% of patients (diurnal fluctuation) and a shift towards hypermetropia (long-sight) over time, to more serious issues such as an increased risk of globe rupture and wound infection years after surgery. RK is now virtually obsolete, having been replaced by excimer laser procedures.

Excimer laser treatment of myopia in the form of photorefractive keratectomy (PRK) was first introduced in the late 1980's. PRK involves the reshaping of the anterior surface of the eye by photoablation, allowing precision removal of corneal tissue. The corneal epithelium is removed prior to treatment and grows back over the treated zone within 4-6 days. Initially, very small areas of the cornea were treated leading to a high incidence of night vision problems. Much larger zones are now treated and night vision problems are uncommon. The healing of the corneal tissue that occurs post-PRK leads to the formation of haze during the first 2-3 months. In the early days of PRK, this haze could be quite severe, leading to reduced vision and glare problems in some individuals and regression of the refractive correction back towards the original pre-operative error. However, the restriction of PRK to the treatment of low myopia (<-4.00D) and improvements in the laser technology mean that significant haze and regression are rare, and the haze hardly ever persists beyond 6 months post-PRK. The integrity of the globe is unaffected by PRK and refractive stability is achieved within 3-6 months of surgery. No significant diurnal variations in refractive error or vision have been reported.

In order to avoid the corneal haze that develops post-PRK, laser in situ keratomileusis (LASIK) was developed in the early 1990's. By cutting a thin flap of corneal tissue and ablating the area beneath before replacing the flap, disruption of the epithelial layer is kept to a minimum, avoiding the aggressive healing response that leads to the formation of haze. Pain is also minimised and this is one of the reasons why LASIK has become the refractive surgery technique of choice for many patients. Another reason is the short post-operative recovery period with good vision retuning in a matter of hours and stability of the refractive correction within one month. LASIK requires more surgical skill than PRK because of the creation of a corneal flap, but in good hands, the outcome is very similar to PRK for low myopia and it provides a more predictable and safer method of correcting higher levels of myopia (>-4.00D) and low hypermetropia. The integrity of the globe is not affected by LASIK although the stability of the flap has been called in to question. The flap is held firmly in place by osmotic forces and the layer of epithelium that grows over the flap margins. Displacement of the flap during the first few days is possible but easily rectified. A small number of cases have been reported in which the flap has been displaced at a later date by a sharp object approaching from the side, such as a tree branch. Again, correct management leads to a good visual outcome in the majority of cases. To date, a small number of cases of keratectasia have been reported in the literature following LASIK. This condition is characterised by thinning of the cornea, leading to irregularity of the cornea, (similar to keratoconus) and associated distortion of the vision. It is thought to be caused by the ablation of too much corneal tissue beneath the LASIK flap due to miscalculation/accident. The condition is rare and only tends to occur in those treated for high myopia >-10.00D since more tissue is removed to achieve the desired correction. Fewer cases have occurred since LASIK treatment has been limited to the correction of <-12.00D.

More recently, laser epithelial keratomileusis (LASEK) has developed from PRK and looks set to increase in popularity. This technique involves creating a thin flap of epithelium using a 20% alcohol solution. The underlying tissue is ablated and the flap replaced, acting as a bandage lens. The visual outcome is very similar to PRK and LASIK but it minimises the pain and haze associated with removal of the corneal epithelium during PRK and avoids the potential complications associated with creation of a LASIK flap. There is evidence to suggest that visual quality (best corrected visual acuity) is better following LASEK than PRK, probably due to minimization of corneal haze and intraocular light scatter. In a recent study, 98% of eyes were found to achieve a level of unaided vision of 6/12 or better at two weeks post-LASEK with no loss of best-corrected visual acuity. All eyes showed an unaided vision of 6/7.5 or better at 12 months post-surgery.

The accuracy and safety of current excimer laser techniques is excellent. Close to 90% of eyes treated for less than –3D and around 75% of eyes treated for between –3 and –6D of myopia, achieve a post-operative refractive error within ± 0.50D of emmetropia (no refractive error) and it is rare for any eyes to lose two or more lines of best-corrected high contrast visual acuity (close to 0%). However, all techniques have the potential to cause a reduction in the quality of vision. They do this by causing an increase in intraocular light scatter and/or ocular aberrations (poor optics), resulting in a reduction in the contrast of the retinal image in a minority of patients. Although high contrast objects such as the letters on the Snellen chart are unaffected by a reduction in retinal image contrast, low contrast objects may become invisible. These problems are exacerbated at night when the pupil dilates and the scatter and aberrations increase as the peripheral cornea begins to influence the retinal image. Customised ablations are now being developed in an attempt to minimise the extra aberrations induced by the surgery and it is hoped that the proportion of patients who suffer from reduced visual quality will reduce significantly over the next few years.

It is important that individuals being considered for visually demanding professions following refractive surgery undergo an assessment that includes a measure of visual performance that is sensitive to scatter and aberrations, such as low contrast visual acuity or contrast sensitivity, in order to detect the minority of people who suffer from a reduction in visual performance. This is the approach taken by the United Kingdom Civil Aviation Authority who now accept any form of refractive surgery for the correction of up to ± 5.00D for commercial pilots, and +5.00D and -8.00D for private pilots. Mesopic contrast sensitivity must be normal and the CAA is in the process of introducing a new, computer-based test of visual performance as part of the entry criteria (the Contrast Acuity Assessment test). The armed forces in the United States now allow PRK and LASIK refractive surgery under a series of waiver schemes, and both aviators and front-line troops have been successfully operated on (Schallhorn, 1994; Schallhorn *et al.*, 1996). Army personal undergoing extreme combat training have reported no problems following surgery and have highlighted the benefits of avoiding spectacle fogging and contact lens loss under such conditions.

For highly myopic (short-sighted) refractive errors where the corneal thickness is generally insufficient to allow a pure corneal correction of the refractive error, intraocular surgery is an option. Phakic intraocular lens procedures involve the insertion of an additional lens in to the eye, placed either in the anterior chamber of the eye, attached to the iris or between the iris and the crystalline lens. Visual outcomes are good and highly predictable but there is a low risk of cataract and glaucoma due to the proximity of the additional lens to the iris and natural lens of the eye. Using an excimer laser to steepen the cornea to treat long-sighted (hypermetropic) individuals is more difficult and therefore less predictable than treating myopic individuals but phakic intraocular lenses have been successful. Clear lens extraction is identical to cataract surgery only the crystalline lens is removed and replaced despite being clear and non-cataractous. Removal of the lens in a young person results in the premature need for reading glasses, although multifocal lens inserts, allowing clear vision at all working distances are increasing in popularity. The procedure is well established but as with all refractive surgery techniques there is an element of risk.

In conclusion, radial keratotomy has been superceded by other procedures due to the risk of unstable vision, the increased risk of eyeball rupture and the risk of infection. As with all corneal refractive surgery techniques, RK can lead to reduced visual performance due to a reduction in the optical quality of the eye but unlike excimer laser techniques, advances in technology to minimise the risk of reduced visual performance are not foreseen in the field of RK. PRK is considered a safe and predictable technique as long as it is restricted to the treatment of low refractive errors. LASEK looks promising as a technique to minimise the post-operative pain and corneal haze levels compared to PRK. LASIK remains the most popular technique in the United Kingdom and in good hands, it is highly predictable and accurate when used to correct myopia up to around –12D.

Due to the rapidly increased popularity of refractive surgery as an alternative to spectacle or contact lens correction, regulatory and occupational bodies are likely to encounter an ever, increasing proportion of applicants who have undergone such a procedure. Currently, between 200,000 and 300,000 patients undergo laser refractive surgery in the United Kingdom alone each year and more than two million have been treated worldwide. In mind of the recruitment issues faced by some public services and the Disability Discrimination Act, it is important that policies on refractive surgery for visually demanding occupations are evidence-based.

Occupations that are particularly visually demanding, such as rapid response driving and flying could not consider candidates with a significant reduction in visual performance. However, developments in the field of refractive surgery of the last few years have greatly increase the potential for treated individuals to achieve excellent visual performance and avoid some of the pitfalls of conventional vision correction.

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