

newsletter

Laser surgery on the eye

Next year more than 3.5 million people worldwide are expected to have laser surgery performed on their cornea to correct their focus and avoid permanent dependence on glasses or contact lenses. LASIK is one of the popular methods in use today.

Introduction

"For the knowledge of nature, human beings are pupils of the eye" (J F Fries, 1818). Nowadays, many people are choosing corneal surgery and intraocular lens operations as an alternative to wearing corrective glasses or contact lenses to correct short- or long-sightedness. In ophthalmology, the term refractive surgery is used to refer to any of a number of surgical procedures. The most common of these worldwide is an outpatient procedure known as LASIK (Laser Assisted in Situ Keratomileusis), which had been performed on nearly 22m patients by 2005 (Report on the Refractive Market, November 2005, Market Scope). The world's first refractive surgery procedure using the then innovative excimer laser (cold ultraviolet laser) was carried out in 1987 at the Charité clinic in Berlin. In Germany, LASIK was officially recognised by the Refractive Surgery Commission (KRC) in 1999.

Vision and the eye, optical defects

Visual perception is the result of interplay between sensory and motor functions of the eye and the central nervous system. The optical system of the eye consists of the cornea, the iris which forms the pupil, the lens (lens cristallina), the vitreous body (corpus vitreum) and the retina. The cornea and the lens bend the incoming light rays (refraction) so that they converge at the point on the retina where vision is sharpest (the focus). The various parts of the optical system contribute to the overall refractive power, which is measured in dioptres (dpt). The refraction of the eye is essentially determined by the surface curvature of the cornea, the refractive power of the lens and the length of the eyeball. Only precise interaction produces a sharp image on the retina. If the various components of the eye are not precisely in tune with each other (refraction errors/anomalies leading to inaccurate centering on the focus), the result is an optical defect: short-sightedness (myopia), long-sightedness (hyperopia) or astigmatism.

Correcting optical defects

An optical defect is not strictly speaking an eye disease, but for many people it is a nuisance that can most easily be relieved by temporarily interposing a correction factor (glasses, contact lenses). However, it has recently become more common to have refractive surgery procedures performed on the eye to achieve a permanent improvement in focus. The introduction of new technologies and ongoing improvements in existing systems such as excimer lasers, microkeratomes and eyetrackers has meant that more and more people are opting for surgery.

Besides lens surgery (implantation of intraocular lenses, replacement by artificial lenses), laser operations on the cornea are particularly popular. The spherical curvature of the cornea is an essential part of the optical system and has a major influence on the refractive power. Furthermore, the cornea's prominent location makes it readily accessible for surgical procedures, and the eye can be easily locally anaesthetised.

Corneal surgery, LASIK

The most commonly used procedures for surgically changing the shape of the cornea (to correct the refraction error) using laser are the following:

- lamellar procedures: LASIK, Femto-LASIK,
- surface treatments: PRK (photorefractive keratectomy), LASEK (Laser Epithelial Keratomileusis), Epi-LASIK.

These procedures are nowadays used to correct short-sightedness up to -8 dpt (at most -10), long-sightedness up to +4 dpt and astigmatism up to 3 dpt (at most 5 dpt).

The surgical procedure used will depend on the nature of the optical defect and the individual thickness of the cornea. Anatomically, the cornea consists of 5 layers of tissue, the outer 3 of which are altered to a greater or lesser extent during refractive surgery. The oldest method, PRK, involves ablating (burning off) a certain amount of the topmost layer (the epithelium). By contrast, in the more advanced LASEK procedure, the epithelium is preserved with alcohol, peeled off, and replaced when the laser ablation is complete. The disadvantage of both these methods is that manipulations are performed on the cover layer of the cornea, which is sensitive to pain, and leave behind large-area thermal wounds on the cornea. LASIK combines a microsurgical incision technique and tissue vaporisation. A microkeratome (cutting instrument) or femtosecond laser (Femto-LASIK) is used to remove a lamina (known as a flap) from the cornea under computer control, exposing the stroma, the middle layer of the cornea, for laser treatment. After the operation, the flap is put back in place and secured again. The advantage of this procedure is its relative painlessness and stabilisation of the patient's vision within just a few days. PRK and LASEK, by contrast, require a longer healing phase. Epi-LASIK (Epithelial Laser in Situ Keratomileusis) is the latest development in refractive laser surgery and is an automated version of LASEK. Again, it uses a microkeratome to remove the epithelium. However, its key feature is eyetracking, a control system integrated into the laser device that continuously monitors the setting of the laser and automatically compensates for involuntary motion of the eye during the operation, so that the laser beam is always precisely on target.

At present, LASIK accounts for about 90% of all refractive surgery procedures performed in Europe and the US (Germany: on average up to 20 procedures per surgeon per month, totalling around 120 000 in 2005), followed by PRK, LASEK and Epi-LASIK. At 77%, laser use is more widespread in private practices (opticians, laser centres) (www.dgii.org/members/DGII_Current_01-2005.pdf). The number of procedures performed worldwide has nearly doubled since 2000. As the market is thought to be approaching saturation in Europe and the US, growth rates are expected to slow down going forward. However, other markets (eg Asia, the Middle East) still harbour high growth potential, so that quantum increases are still possible.

Risks

As with any surgical procedure, laser treatment of the cornea involves some risk. A thorough examination of the eye and specifically of the cornea (precise measurement of the thickness of the cornea and the refractive power) is essential to choosing the appropriate operation method, as an accurate diagnosis accounts for around 80% of the success of the operation. Use of an inappropriate procedure can have serious consequences. As a general rule applicable to all surgical procedures, the number of complications rises in line with the extent of the corrections to be performed; however, permanent sight impairments up to blindness are very rare. The risk of complications in the LASIK

context is currently estimated at 2 to 2.5%, although the complications rate can vary widely from one surgeon to another. In rare cases there have been reports of infections, detachment of the flap and incision errors. Complaints of dry eyes are common (40%).

About 10 to 12% of patients have to be operated on again as a result of over- or under-correction (www.augeninfo.de/crc/qualit.pdf). In principle, the correction to the refraction anomaly lasts a lifetime; however, natural deterioration of vision with age (presbyopia) can detract from the correction. Around 5% of patients still have a residual defect 2 years after the operation, so that they still have to wear glasses. All in all, there is not yet enough long-term experience available, for example about the long-term effects of thinning of the cornea due to tissue ablation.

Information for the underwriter

LASIK, particularly, is enjoying an ongoing boom. The technology for laser treatment of the eye is by now considered mature, even though there is still not enough data available from long-term experience to support a reliable evaluation of the method's safety and efficacy.

Experience to date indicates that product liability claims are likely to be very much less of a problem than in the case of other medical products. It is important to remember that corrective laser surgery on the eye is classified as a cosmetic operation and, if anything goes wrong, can have serious consequences which (unlike medically essential eye operations) can impair a previously intact eye. Experience, dexterity and quality assurance on the part of the surgeon and the quality of the equipment and technology (state of the art, hygiene) are thus cornerstones for success, in addition to careful choice of the procedure to be used. Complications can result in patients being unable to work or even having to change jobs (eg computer users, drivers). Most liability claims to date have been brought against the operating surgeons for errors committed during treatment. For example, one patient in Germany was awarded EUR 40 000 for pain and suffering (2006) and a claimant in the US was given USD 7.25m for pain and suffering and loss of earnings (2005) as a result of the use of incorrect operating methods. Claims resulting from deficiencies in informed-consent procedures are also possible in the context of medical malpractice liability. There is some evidence of patients needing reading glasses about 2 to 5 years earlier after laser treatment, although at present it is not possible to predict what effect thinning of the cornea due to tissue ablation may have on the patient's vision at some time in the future. Identifying the nature and number of adverse long-term consequences is made even more complicated by the possible presence of unconnected health-related factors.

A further aspect to be considered is that advertising campaigns stressing the simplicity of the surgical procedures are raising patients' expectations in terms of success and freedom from complications.

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