

Laser eye surgery

- taking a closer look

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Introduction

First there were glasses. Then in the 1950s came contact lenses, a step forward that was both convenient and yet still inconvenient. Use of soft lenses later emerged as a big improvement. But neither glasses nor lenses were a cure. Laser surgery represents a breakthrough in that, if successful, the patient's vision will be permanently improved – or so its protagonists believe.

Any operative treatment on the eye entails precision. Modern science has delivered that fundamental – or at least has delivered the capability of delivering precision when properly maintained equipment is used correctly in skilled hands. The days of an ophthalmic doctor using a scalpel and steady hand are over. Clinical trials of laser surgery started in Europe in 1988 and in the USA in 1991. The first operations were carried out only around ten years ago and no unknown long-term side effects have yet emerged. However, many experts are reserving judgment on laser surgery, believing that more time is needed to be sure that there are no adverse reactions or hidden problems.

Laser surgery (or more properly refractive vision surgery) is widely misunderstood: it does not prevent change due to ageing, a condition known as presbyopia. Thus someone aged below forty who has surgery must still expect to wear glasses or contact lenses sometime after that age. Someone already wearing reading glasses for this reason will still need them. Laser surgery can be concluded in about fifteen minutes with the patient's vision usually disturbed only until the following day. Specialist surgical clinics have flourished, enabling those doctors able to use the hi-tech equipment to undertake large numbers of operations daily. The public, however, has confused brevity with simplicity and has underestimated the significant risks of what remains a highly skilled process.

Introduction (continued)

Headlines and adverts about the low costs and amazing results in effective (but not always ethical) marketing have created this booming business. Around 100,000 operations take place in the UK each year. In the USA, there are around one million operations each year. However, the blessing of restoring impaired vision quickly and cheaply has led to the downside of many examples of failed treatments, sometimes with dreadful consequences. The immediate issues that arise from a legal liability aspect concern the quality of the medical treatment and the proper use of the equipment. Laser machine failure has also created problems.

The framework of this Aspen Opinion is as follows:

Part one - The development of today's surgical procedure

Part two - The known risks

Part three - Informed consent

Part four - The equipment

Part five - Liability beyond surgery

Part six - Lawsuits

Part one - The development of today's surgical procedure

The forerunner to today's laser surgery was called Radial Keratotomy (RK). The surgeon would alter the shape of the cornea by a series of cuts around the cornea like spokes of a wheel. The cornea is the clear dome at the front of the eye. The more domed the cornea, the greater the myopic problem for the patient. The cuts were made by scalpel penetrating up to 90% and caused the cornea to flatten and thus to improve nearsighted (myopic) vision.

The next progression after RK enabled scalpels to be replaced by lasers for this procedure. The results were no great improvement and limitations associated with RK continued. Limitations included:

- an inability to help patients with more serious problems of myopia
- an inability to help patients with far-sightedness (hyperopia / hypermetropia)
- a risk of the patient's cornea flattening further over time causing increased hyperopia.

Doctors sought to overcome these problems by reducing the depth of cut (Mini-RKs) and this treatment is still carried out. However, it was the next generation of laser treatment that has created the High Street boom in eye surgery.

Part one (continued)

Photorefractive Radial Keratotomy (PRK)

The concept of changing the shape of the cornea remains but instead of a series of up to eight cuts around the cornea, a small area on the front of the dome is completely cut away. This flattens it and avoids the previous consequence of a weakness of the cornea. That weakness had caused far-sightedness.

In a severe case of myopia, up to a third of the thickness of the cornea is removed. That may sound a large amount of tissue but this is not the case. The laser is operating at micro-precision levels. Reshaping the cornea in this way has led to surgery capable of curing myopia, hyperopia and astigmatism, the latter being a condition that can cause blurred vision and headaches.

Not every patient is suitable for laser treatment – this gateway having narrowed in the light of experience on earlier patients – see below. Despite the precision of laser equipment, a human element remains. The role of the doctor remains critical. A patient visiting two different clinics might obtain two different opinions on what can or should be done. This might be because of a difference of approach or because of the capability of the laser machine.

Lasik laser eye treatment

Lasik (Laser Assisted In Situ Keratomileusis) is the procedure best known for treating near or far-sightedness and astigmatism. It has built on the success of PRK and in skilled hands is effective for all but the most severe vision problems. The top of the cornea is lifted like a flap and the tissue is removed from underneath by use of a microkeratome. The flap is then replaced.

Zyoptix

This latest procedure is marketed as an improvement on Lasik. Less of the cornea is removed and the process has been effective for more seriously impaired patients.

Excluded patients

The main obstacle to any laser operation is that the patient must have had stable vision for two years. Interestingly, some police forces and the military may preclude personnel from treatment. Patients must not suffer from a dry eye condition, corneal abnormalities or any family history of eye disease. Patients taking certain medications or suffering vascular conditions may be unable to be treated. Some types of medication for migraine or antihistamines may be problematic. Pregnant women are excluded.

Part two – The known risks

Improvement from successful surgery should be obvious in as little as two hours (though there is discomfort). Full recovery usually takes about two days and ongoing checks may last up to three months. Patients must not drive for a period of time dictated by the surgeon. That may be for a few days and nights.

If the procedure goes wrong whether from a known risk or not, the consequences can include:

- total loss of sight
- over-correction
- under-correction
- halos around light
- glare
- hazy vision
- blurred vision
- sensitivity to light
- astigmatism
- delayed healing
- ptosis (drooping eyelid)
- dry eyes or
- double vision.

Infection

Probably the greatest danger comes from infection causing total loss of vision, though use of antibiotics keeps this risk low. Infection during the operation ought not to occur. If it does, it becomes evident within 48 hours. If proven, then it would be hard to resist the issue of liability in litigation. However, infections are also caused by patients' lifestyle issues such as use of eye makeup, swimming or using jacuzzis or hot tubs within seven days of the operation. Fortunately, even total loss of vision following infection can sometimes be treated by corneal transplant. A controversial aspect of best practice relating to infection is discussed later.

Under or over-correction

There may be under or over-correction. Under-correction is less serious than the latter as fine-tuning may be carried out to increase the initial adjustment. Though over-correction of myopia may be resolved by further enhancement surgery, this is not always possible so that the patient is then left with a serious problem such as blurred vision. This may be helped by glasses or contact lenses.

Diffuse Lamellar Keratitis (DLK)

Diffuse Lamellar Keratitis is disturbing because surgeons do not yet know for sure why this condition arises. Though a rare problem, when a patient does suffer it, haziness in vision may result from white deposits beneath the corneal flap. Their existence may be due to an inflammatory reaction unique to the patient's own bodily secretions. Alternatively, it may be due to adverse reactions to medication or antigens from bacteria.

Occurrence may be linked to a lack of cleanliness between the corneal flap (created during surgery) and the corneal stroma. Sterile tape is used to keep eyelashes away from the cornea during the treatment. The cornea is also rinsed to ensure removal of created debris which might include metal fragments from the laser blade. Once all debris of any kind has been removed and the surface has been dried, the corneal flap is then folded back into position. It is arguable that a proven failure to clean out and dry the area would be negligence but the difficulty may be proof of this when a defence could be made out that sometimes this condition occurs for no clear reason.

Part two (continued)

Central Lamellar Keratitis (CLK)

This is a variation on DLK and exists when a larger amount of debris gathers centrally between the cornea and the corneal stroma beneath. Curing this problem is somewhat harder than DLK.

Subsequent surgery

Further surgery may be needed to improve the first treatment in up to 10% of patients – under or over-correction being possible reasons. In percentage terms, the number of patients who end up with worse problems than before is unclear. Estimates that between 20 and 30% of patients have problems after surgery have been made but reliable statistics are not available.

The FDA suggests a figure of 5% but other reports show that over 40% of patients have increased difficulties with driving at night. The doctors undertaking the operations portray the risks as low. Nevertheless, interference with such vital senses means that in rare cases, the consequences may ruin or change someone's entire life. Usually though, most poor results (after any possible perhaps extensive corrective treatment) will only mean that patients end up having to wear glasses or hard contact lenses.

'Experimental' surgery?

Proponents of laser surgery contend that as operations go, it is now as safe a procedure as exists. Nevertheless, to protect themselves against liability for negligence, doctors warn patients before operative treatment of what may go wrong. This is discussed below.

Whether the failure rate is as low as the doctors proclaim or not, the high volume of operations means that for a substantial number of patients the surgery is either unsuccessful or a disappointment. But that does not mean that any legal claim can be made. At issue is whether the surgery fell below an acceptable standard of care in treatment still regarded by some ophthalmologists as experimental.

A true incident this year involved an American doctor that went for a consultation at a laser clinic to have his myopia treated. He was told he was suitable and encouraged to go ahead. At that point, the doctor noticed that the surgeon himself wore glasses. So he asked the obvious question and got the unexpected reply that the surgeon would not have the operation himself as he remained concerned about the long-term effects!

Part three – Informed consent

Signature by the patient consenting to the risks compared to the benefits is a corner-stone of laser surgery, just as for any operation. Chains of clinics sometimes give the patient a video explaining the procedures and problems which supplements the written form of consent. There may be as many as nine pages or more of explanations and caveats, designed to protect the doctor and warn the patient.

Besides warning of the inherent risk in any surgery, a warning that Lasik is a relatively new procedure which may have long-term unknown results is usual. Some clinics point out that the risk of serious infection with laser treatment is about one in five thousand compared to one in one thousand using PRK. The patient is warned to expect problems with night glare and blurriness. This is common initially but usually improves quickly but may be prolonged. The tennis star, Jennifer Capriati, had successful treatment by a top doctor but has been quoted as alleging that subsequently she has had problems playing under floodlights. Adverse consequences and legal liability are not the same thing.

One clinic warns in these terms:

“The overwhelming majority of Lasik complications are related to the creation of the corneal flap.” That interesting observation does not explain whether such a complication arises from lack of skill or is an inherent and inevitable risk that the patient must take.

Six months after surgery, about 2% of patients apparently suffer from night glare problems. The risk may turn on the size of the patient’s pupils or the degree of myopia to be treated. Indeed, for many of the listed known risks, the percentages are about 1-2%. Adding up 1-2% for each known risk to the unknown ones explains why the web is littered with so many bitter and angry patients who now try to warn potential patients away from undertaking the process.

Part four – The equipment

There are many manufacturers of laser machines and within this generic term, there are also differing types of machine. Manufacturers include VISX, Bausch & Lomb and Alcon.

Litigation has often involved a patient suing both doctor and manufacturer. Doctors also seek to pass on or divert blame to manufacturers. The attraction for a patient to sue a manufacturer is that in the USA, and to differing extents in Europe, there is strict liability without proof of blame. There may also be improved potential for a punitive damage award too.

If a manufacturer is involved, the doctor may make common cause with the patient to escape blame. Manufacturers may deny liability and blame doctor usage error or failure to maintain the equipment in accordance with their instructions. Laser machines have given rise to serious malfunction problems – and indeed to recalls. Alcon Autonomous Radar Vision recalled their product after 136 defective units were discovered which had produced ‘unanticipated laser pulses’ that could create centred corneal defects.

Part four (continued)

Novartis Ophthalmics GenTeal produced eye drops to help prevent dry-eyes but the product had become contaminated and was recalled.

Perhaps the most serious recall involved Alcom SKBM & Lasitome Microkeratome in 2003 in which a problem with their model led to the possibility of an uncontrolled depth of cut. The Informed Consent form envisages a known risk of equipment malfunction - perhaps forcing a commenced procedure to be aborted and postponed for around three months.

While the equipment has to be approved for use by the appropriate national body such as the Food & Drug Administration in the USA, there is evidence that some doctors may contravene regulations. They save money by using the same blade on several patients, thus increasing the risk of infections. The penalties against guilty doctors have been modest and certainly not sufficient to make the risk of discovery not being worth taking.

Part five – Liability beyond surgery

Critics of laser surgery point to a malaise involving unprofessional conduct in the fight to win business. This has given rise to lawsuits.

Just as any patient consenting to surgery should perform due diligence on the known competence or otherwise of the doctor, so should insurers who may be asked to provide cover for professional negligence. Websites list names of some doctors who are alleged to have a poor or unacceptable track record but such a list is not exhaustive. Checks too should be made against the names of the clinics for any warning signs.

Unfortunately, certification by the American Academy of Ophthalmology is not necessarily a sufficient assurance that the doctor performs at the highest levels of skill and best practice. For example, the Academy does not condemn the reuse of microkeratome blades without sterilisation, even though such reuse may increase the risk of infections and has founded the basis of damages awards. The California Department of Health forced one clinic to notify 2,700 patients that their surgery had involved reused and unsterilised blades.

In the UK, the best guidance based on qualification may be that the doctor is a Fellow or Member of the Royal College of Ophthalmologists or a Fellow of the Royal College of Surgeons. The doctor should also be on the GMC Register. Advertisements in the UK tacitly admit that quality varies between clinics. Wording adopted by one leading clinic is cautious too: "In expert hands, laser eye surgery can be an extremely safe life changing experience." The word can provides the cautionary note.

Part five (continued)

One indication that may filter out some bad risks is to know whether the doctor is linked with a reputable academic medical centre such as a teaching hospital. The pace of change in technology and procedures means that those involved in such institutions are more likely to be up to speed. Doctors who are Fellows of the American College of Surgeons may also be less likely to be involved in the worst examples of unprofessional trends.

Besides obviously needing to know that the doctor has never had insurance cover denied, it is especially important to establish whether the doctor has ever been rebuked for unprofessional misconduct – perhaps leading to revocation or suspension of licence to operate.

One notable feature from reading horror stories is how the first unsuccessful attempt at refractive surgery is too often followed by further lack of success on one or two further corrective attempts – perhaps leading to a downward spiral to transplant surgery.

It is evident that the quality of doctors involved in this virtual conveyor-belt process is very variable – and so are the procedural safeguards they adopt. The market is highly competitive. Prices are often quoted at about US\$299 per eye in the USA. In reality, after the patient has entered the clinic, too often the prices escalate for all manner of reasons, allegedly peculiar to the patient. Often the price is well over US\$1,000 per eye and one survey suggested that the average cost in 2005 was around US\$1,750 per eye. In the UK, the cost tends to be rather higher.

The adverts and marketing methods adopted have been criticised by some doctors as going far beyond proper professional boundaries – whether by promising results that are over-ambitious, quoting prices that are rarely available or discounting the risks of the procedures. Thus it is no surprise that there have been class actions taken against doctors regarding issues going beyond the failure of the surgery.

One such Californian action alleged fraud and deceit; concealment; material misrepresentation; unlawful, fraudulent and unfair business practices; violations of the Consumer Legal Remedies Act; breach of warranties and professional negligence. The action was against a group of about fifty doctors who allegedly represented that Lasik treatment was safe. The doctors allegedly used the same blades more than once and failed to sterilise the equipment so as to be able to treat more patients per hour. The risk of HIV and similar infectious diseases was thus needlessly raised.

One doctor operating in this field has been named in at least fifty different complaints. In 2000, his insurers had refused to provide cover – but he continues to treat patients. The stack-'em high, sell-'em cheap philosophy and the marketing methods adopted are blamed for many failed operations. Too many unsuccessful procedures have also resulted from doctors failing to advise that a particular patient was unsuitable for the treatment (contra-indications) due to existing vision problems or other physical problems already present. Inadequate screening and a rush to encourage patients to proceed is too evident from some doctors and clinics.

In consequence, insurers prepared to underwrite this business have to be alert to the quasi-cowboys elements that adopt unprofessional practices. These will be exposed under scrutiny of litigation.

Part six – Lawsuits

There have been many lawsuits, mostly settled but enough judgments exist to provide an indication of the expensive consequences for insurers. Eye damage is evidently an emotive area for jurors and this is reflected in the awards.

Schiffer v Speaker & Others (2005)

Allegedly, contra-indications to surgery were not spotted and the patient ended up with serious problems in both eyes. The jury awarded US\$7.5 million. An appeal or review is pending.

Johnson v LCA Vision Inc & Others (2000)

Incorrect assembly of the equipment was alleged. The patient suffered from laceration through the cornea. The plaintiff was awarded US\$1,258,000.

Oliver v Abell (2001)

The plaintiff had corrective surgery for astigmatism in 1998 but ended up with other visual problems for which the award was US\$1,700,000.

Ware v Boop (2006)

The plaintiff had to undergo corrective surgery after the first operations failed but in the end two corneal transplants were needed. The award was US\$944,200.

Wells v Northern Refractory Surgery Center (2006)

Allegedly, the defendant failed to screen the patient adequately. There were alleged contra-indications including that the patient's pupils were too large. The plaintiff also contended that the risks were inadequately explained and that after the surgery, there was permanent vision disturbance, especially at night. The award was US\$3 million.

Who may be liable?

As appears from the background above, the main liability exposures are for:

- doctors
- clinics
- hospitals
- equipment manufacturers
- importers / distributors / wholesalers / retailers
- equipment maintenance / servicing companies or agents.

Part six (continued)

Liability theories, whether in the USA, Europe or Australia will include negligence of doctors and clinics. Hospitals may have some vicarious liability for the neglect of servants or agents or as suppliers of equipment. Additional exposure for doctors and clinics may occur through misleading advertising or false / sharp business practices - areas that could lead to allegations of fraud and unfair business practices and thus to class actions and, in the USA, perhaps to punitive awards.

Servicing / maintenance companies will be exposed to claims arising from alleged breaches of contract and / or negligence.

As to manufacturers, subject to defences which vary by jurisdiction, their potential exposure is to actions based on product liability and theories of strict liability (though strict is not an absolute in all jurisdictions). The other risk for manufacturers is of a failure in the production process creating the need for a costly product recall and perhaps a class action too.

Those involved in the importation or distribution chain may also be sued, a complex area that can also give rise to jurisdictional issues, especially when European Union countries are involved. For insurance carriers, exposure will usually arise under medical malpractice and products liability policies. However, claims could also arise under public liability cover for importers and distributors.

Conclusions

In this relatively young field of developing knowledge, provision of cover needs careful attention. Though it is fair to emphasise the sharp and, some say, recklessly gung-ho approach of some clinics and doctors, it is prudent also to warn that even with the best doctors performing at the highest level of skill, there are probably still unknown and inherent dangers in laser treatment.

Use of fair and balanced Informed Consent forms may assist in reducing exposure to liability but when emotive issues like total loss of sight are involved, jurors may ignore that consent and still manage to find for the plaintiff.

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