

Royal College of Ophthalmologists

STANDARDS FOR LASER REFRACTIVE SURGERY

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1 Purpose of these Standards

These Standards have been developed in the light of public concern about patient safety. They are not College regulations, but are intended to provide advice and assistance. Reference should be made to the publications mentioned on page 8 and elsewhere in the text.

a) Who the Standards are for:

These Standards are intended to assist medical, and other healthcare professionals involved in laser refractive surgery, as well as those involved in the administration of facilities where such surgery is performed.

b) What the Standards cover:

- The appropriate experience and qualifications of surgeons performing laser refractive surgery
- Requirements of the facilities at which it takes place
- Information that should be provided to patients
- The consent process
- Relevant issues of clinical governance
- Advertising and marketing of services
- Specific issues related to the post operative management of patients

c) Review of the Standards:

These standards will be reviewed at least annually by the Laser Refractive Surgery Guidelines Development Group (LRSGDG), a sub-committee of the Professional Standards Committee of the Royal College of Ophthalmologists (RCOphth) and updated accordingly on the RCOphth website (www.rcophth.ac.uk). The LRSGDG sub-committee may be contacted through the RCOphth for advice and further guidance.

2 Surgeons carrying out refractive procedures

- a) Surgeons must be registered with the GMC.
- b) A broadly based knowledge of ophthalmology is essential in order to appropriately assess patients and manage complications.
- c) The Royal College of Ophthalmologists recommend that laser refractive surgeons should hold the Certificate in Laser Refractive Surgery.
- d) Surgeons must always recognise and work within the limits of their professional competence.
- e) All surgeons undertaking refractive surgery must keep a folder for the purposes of revalidation. This will include documentation of on-going education in refractive surgery techniques and skills and audits of refractive surgery procedures.
- f) Surgeons performing refractive procedures must keep their knowledge and skills up to date and should regularly take part in educational activities. Surgeons where possible should belong to a relevant professional organisation which provides Continuing Professional Development and adheres to the principles of good medical practice, for example:
 - the Royal College of Ophthalmologists or
 - one of the Royal Colleges of Surgeons in the United Kingdom or Ireland

Surgeons should in addition consider becoming members of other relevant associations for the purposes of Continuing Professional Development (CPD). Examples include:

- British Society for Refractive Surgery (BSRS)
 - United Kingdom and Ireland Society of Cataract and Refractive Surgeons (UKISCRS)
 - International Society of Refractive Surgeons (ISRS)
 - European Society of Cataract and Refractive Surgeons (ESCRS)
 - Medical Contact Lens and Ocular Surface Association (MCLOSA)
 - American Society of Cataract and Refractive Surgery (ASCRS)
- g) Surgeons must be members of a medical defence organisation or maintain professional indemnity insurance.

3 Facilities

- a) The premises in which the surgery is undertaken must be registered under the Care Quality Commission.
- b) All equipment should be properly maintained and calibrated.
- c) There must be dated and documented procedures within the facility for the use of all clinical equipment. These must be reviewed annually.
- d) All staff using equipment must have completed training in the safe clinical use of the equipment and have demonstrated and documented competence to person(s) appointed by the Medical Advisory Committee, or an equivalent management group.
- e) There must be facilities available for patients to have confidential discussions with clinical staff in conditions of visual and auditory privacy.
- f) Staff identification badges must include both name and status.
- g) A backup power supply must be available in case of power failure during a procedure.

4 Information for patients

- a) An information document for patients is available on the Royal College of Ophthalmologists web site (www.rcophth.ac.uk).
- b) Information for patients should be in concise, plain non-technical language.
- c) Information for patients, ideally in written format, should include:
 - the range of refractive surgery procedures stating which ones are available at the facility
 - eligibility criteria for patients
 - treatment options including relative advantages and disadvantages
 - general and procedure-specific risks and complications associated with surgery, their frequency, management course and possible outcome
 - statistical information regarding the probability of achieving the desired goal or probability of needing more than one procedure

- d) Information for patients should include the following details about the operating surgeon:
- qualifications
 - all substantive posts held within the previous 10 years including status, location and dates
- e) Patients should be informed of the risks and benefits of bilateral simultaneous surgery compared with treating the two eyes on separate occasions.
- f) Information for patients should include a price list of procedures and should be explicit about what is and is not included in the quoted fees. It should also give details about payments of deposits, their refund, and any penalty which may be incurred by cancellation.
- g) Written post-operative instructions should be given to patients to take home after the procedure/operation. They should include a contact number for the hospital/clinic and a 24 hour emergency number.
- h) Information should be displayed in patient areas outlining how to complain or make comments and suggestions about the organisation's services.
- i) The following information should be given to the patient and recorded in the notes:
- Pre-operative keratometry
 - Pre-operative pachymetry
 - Pre- and post-operative best corrected acuity
 - Pre- and post-operative intraocular pressure
 - Pre-operative and stabilised post-operative refraction

5 The Consent Process

- a) The consent process should follow General Medical Council and Department of Health guidelines (Good Medical Practice, GMC 2008).
- b) Information documents should be given to the patient at least 24 hours before the procedure is undertaken. It is essential that adequate time is allowed for the patient to take in the information and discuss the risks and benefits of the procedure before it is undertaken.
- c) The person performing the preoperative assessment must ascertain from the patient if there are any questions arising from information given and recap the treatment expectations, potential risks and alternative treatments before confirming that the patient fully understands the written and discussion material.

- d) All patients should have an appointment with a refractive surgeon prior to the day of surgery.
- e) The consent form must reference the Information given to the patient and state:
 - the elective nature of the procedures
 - that glasses or contact lenses may still be required after surgery
 - that pain or discomfort may occur
 - all material risks pertaining to the individual patient in question
- h) The consent form should contain a section for the surgeon to certify that in his/her professional opinion the patient has fully understood the risks, benefits, alternative treatments and potential complications of the procedure.

6 Clinical Governance

- a) Surgeons must be personally responsible for patient care.
- b) Surgeons must maintain an outpatient service, either at the clinic / hospital where refractive surgery is undertaken, or elsewhere, such that the practitioner can assess the patient's appropriateness for refractive surgery and provide appropriate follow-up care.
- c) Surgeons must ensure their availability for emergencies or pre-arrange appropriate cover if on leave.
- d) Clinical staff must have documented on-going education in refractive surgery techniques and skills.
- e) Surgeons' quality indicators, from all types of refractive procedures undertaken, must be reviewed at regular intervals as part of the hospital's /clinic's clinical audit programme. Adverse variances should be reported to the Medical Advisory Committee or equivalent.
- f) All clinical incidents, errors and near misses must be recorded, investigated and collated.
- g) Reports on clinical incidents should be discussed regularly at the Medical Advisory Committee, or an equivalent clinical management group for the hospital/clinic. This may be part of a wider clinical quality/clinical audit report. Information relating to individual surgeons should be passed to them so that it can be included in their revalidation folders.

- h) There should be documented integrated care pathways/clinical guidelines in use for common refractive surgery procedures.
- i) Clinical guidelines, care pathways should be agreed with staff and be made known to all staff working in the service area.
- j) The clinical guidelines /care pathways should cover the range of common variances from the care pathway.
- k) All persons making entries into the care pathway notes should sign, date and add their printed name, designation and initials in at least one place on the pathway documentation for each patient and initial their entries in all other places. An entry should be made on each occasion that the patient is seen or contacted.
- l) Clinical support staff (e.g. Optometrists, Registered Nurses) delegated to carry out procedures on behalf of a doctor should be trained and competent in the techniques.
- m) All surgeons and other clinical staff engaged in exposure-prone work must have up to date immunisation against Hepatitis B.

7 Advertising and marketing

- a) All advertising must adhere to ASA standards, and where appropriate the BMA and GMC guidelines on advertising.
- b) It must be legal, factual and not misleading.
- c) Marketing materials must be drafted and designed to safeguard patients from unrealistic expectations of refractive surgery procedures.
- d) All staff and speakers at promotional events should be clearly identified with regard to their profession and role within the organisation.

8 Post-operative evaluation

- a) A refractive surgeon should examine, or be available to examine, the patient at the first post-operative visit.
- b) It is the responsibility of the surgeon to ensure that the postoperative management is carried out appropriately (in accordance with the General Medical Council document 'Good Medical Practice', May 2006)
- c) Surgeons are expected to be fully trained and well versed in the management of the complications of refractive surgery.

- d) Surgeons operating in clinics lacking microbiological or other specialised testing should have prearranged established links to providers offering these services should the need arise.
- e) A surgeon without inpatient admitting rights should have an arrangement with an appropriate Consultant Ophthalmologist to provide this service should the need arise.
- f) The patient's General Practitioner should be informed of procedures performed unless the patient requests otherwise, in which case this should be recorded in the notes.

Bibliography

GMC (General Medical Council) Good Medical Practice 2006
GMC Patient and Doctors Making Decisions Together 2008
UKCC (United Kingdom Central Council – Nursing) Guidelines for Professional Practice, 1996
IHA (Independent Hospitals Association) Working Papers on Practising Privileges, January 2002

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