



Irish College of Ophthalmologists

GUIDELINES FOR REFRACTIVE SURGERY IN IRELAND

The Irish College of Ophthalmologists recommends that the following guidelines be adhered to by surgeons carrying out refractive procedures in Ireland

- (A) Surgeons must be registered with the Medical Council (Ireland) on the specialist register, Division of Ophthalmic Surgery and abide by the "Guide to Professional Conduct and Ethics for Registered Medical Practitioners."
- (B) Surgeons must have undergone sub specialist training for refractive surgery.
- This may take the form of:
- (1) A Fellowship with an Ophthalmic Surgeon with a recognised sub-specialty interest in refractive surgery.
 - (2) Completion of an approved training course in refractive surgery.
- (C) Surgeons must always recognise and work within the limits of their professional competence.
- (D) All surgeons undertaking refractive surgery must keep a record for purposes of clinical audit. This will include documentation of on-going education in refractive surgery techniques and skills, and audits of refractive surgical procedures performed.
- (E) Communication; accurate, fair and balanced communication with the patient and the general public is essential. Communication through statements, testimonials, photographs, graphics or other means must not convey false, untrue, deceptive, or misleading information. They must not omit material information without which the communications would be deceptive. Communications must not appeal to an individual's anxiety in an excessive or unfair way; and they must not create unjustified expectations of results. If communications refer to benefits or other attributes of ophthalmic procedures that involve significant risks, realistic assessments of their safety and efficacy must also be included, as well as the availability of alternatives and, where necessary to avoid deception, descriptions and/or assessments of the benefits or other attributes of those alternatives. Communications must not misrepresent an ophthalmologist's credentials, training, experience or ability, and must not contain material claims of superiority that cannot be substantiated. If a form of communication is paid for by an ophthalmologist, this must be disclosed unless the nature, format or medium makes it apparent.
- (F) Media Presentation: Information on procedures must not trivialise the seriousness of surgery or minimise the potential risks. Due to increased direct-to-patient advertising, advances in treatment (such as a day case surgery and topical rather than full anaesthesia) should not be presented in such a way as to lead to the misconception that surgical procedures are without risk. When in contact with the media, surgeons must exercise caution to avoid trivialisation of these procedures. Surgeons are obliged to give a balanced, considered opinion, including the contraindications, limitations and possible complications of each procedure. They should exclude any personal bias towards their own hospital/clinic i.e. an ophthalmologist's clinical judgment and practice must not be affected by economic interest in, commitment to, or benefit from professionally related commercial enterprises.
- (G) Surgeons performing refractive procedures must keep their knowledge and skills up to date and must regularly take part in educational activities.
- (H) Surgeons should be members of a relevant professional organisation which provides continuing professional development and adheres to the principals of good medical practice.
- Relevant professional organisations include:
- Irish College of Ophthalmologists
 - Royal College of Ophthalmologists
 - Royal College of Surgeons in the UK and Ireland

Surgeons should in addition be members of at least one of the relevant sub-specialist associations

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).

- (I) Surgeons must be members of a medical defence organisation or maintain professional indemnity insurance.
- (J) Competence of the Ophthalmologist: An ophthalmologist must maintain competence. Competence can never be totally comprehensive, and therefore must be supplemented by other colleagues when indicated. Competence involves technical ability, cognitive knowledge, and ethical concerns for the patient. Competence includes having adequate and proper knowledge to make a professionally appropriate and acceptable decision regarding the patient's management.

FACILITIES

- (a) There must be strict adherence to protocols provided by manufacturers of equipment (maintenance and calibration).
- (b) There must be dated recording of the service history of all the technical equipment in use.
- (c) All staff using equipment must have completed training in the safe clinical use of this equipment and demonstrated documented competence to persons appointed by the Medical Advisory Committee or an equivalent clinical management group.
- (d) Facilities must be made available for patients who wish to have confidential discussions with clinical staff.
- (e) The consultants name must be visible on a name badge or on the door to the consulting room. Staff identification badges must include both name and status.
- (f) A back-up power supply must be available in case of power failure during a procedure.

CLINICAL GOVERNANCE

- (a) Surgeons must be personally responsible for patient care.
- (b) Surgeons must maintain an out-patient service; either at the clinic/hospital where refractive surgery is undertaken or elsewhere such that the practitioner can assess the patients' suitability 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) Incentives should not be offered in return for the referral of patients for refractive surgery.
- (e) Clinical staff must have documented ongoing education in refractive surgery techniques and skills.
- (f) Surgical results must be reviewed at regular intervals as part of the hospital/clinic audit programme.
- (g) All clinical incidents and errors must be recorded and investigated.
- (h) Reports on clinical incidents should be discussed regularly at the Medical Advisory Committee, or equivalent Clinic Management Group. This may be part of a wider quality/clinical audit report.
- (i) There should be documented integrated care pathways/clinical guidelines in use.
- (j) Clinical guidelines and care pathways should be agreed with staff and be made known to all staff, working in the service area.
- (k) The clinical guidelines/care pathways should cover the range of common variances from the care pathway.
- (l) All persons making entries into the care pathway notes should sign and date each entry. An entry should be made on each occasion that the patient is seen or contacted (including telephone conversations).
- (m) Clinical support staff (AHP / Allied Health Professionals) should be fully trained and subject to clinical audit. This would apply to hospital based units and privately run clinics.
- (n) All surgeons and other clinical staff should have up-to-date immunisation against Hepatitis B.

INFORMATION FOR PATIENTS

- (a) Information for patients should be written in concise, plain, non-technical language.
- (b) Information for patient should include:
 1. The range of refractive surgery procedures and stating which ones are available at the facility.
 2. Eligible criteria for patients.
 3. Treatment options, including advantages and disadvantages.
 4. General and procedure specific risks and complications associated with surgery, their frequency, management, course and outcome.
 5. Statistical information regarding the achievements of the desired goal or of needing more than one procedure.
- (c) Information for patients should include details regarding the experience and qualifications of the operating surgeon and his or her relevant training.
- (d) Patients should be informed of all details related to unilateral or bilateral same day surgery. Once the advantages and disadvantages of each method have been explained to the patient, the choice remains with the patient. It is important that the patient feels fully informed and comfortable with the decision that they make.

Bilateral simultaneous surgery must be practiced using the most stringent criteria (e.g. separate instrument set for each eye, one blade per procedure, strict aseptic techniques, etc).
- (e) 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.
- (f) 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.
- (g) Details should be given to the patients of:
 1. Pre-operative keratometry and pachymetry.
 2. Pre and post-operative refraction.
 3. Pre-operative IOP.

THE CONSENT PROCESS¹

- (a) The consent process should follow the Medical Council (Ireland) guidelines² and Department of Health guidelines³.
- (b) The information document must be given to the patient at least 24 hours before the procedure is undertaken. It is essential that time be allowed for the patient to take in the information and discuss the risks and benefits of the procedure before it is undertaken.
- (c) The surgeon performing the pre-operative assessment must ascertain from the patient if there are any questions arising from the information given re:
 - The treatment expectations
 - Potential risks
 - Alternative treatments
- (d) All patients must have an appointment with the operating surgeon prior to the procedure. This consultation should exclude unsuitable patients at an early stage.
- (e) It is recommended that no patient should have the procedure carried out sooner than 24 hours after the initial consultation with the surgeon, to allow the patient and relatives to study the consent document.
- (f) The consent document must be signed in the presence of the operating surgeon.
- (g) The consent form must itemise the risks, possible complications, all of which should have been discussed with the patient at the initial consultation/examination.
- (h) The consent form should contain a section for the surgeon to certify that in his/her professional opinion, the patient has fully understood all material risks pertaining to the individual patient in question.

¹National Policy and Procedure for Safe Surgery (2013), (HSE, RCSI, CAI.)

²Guide to Professional Conduct and Ethics for Registered Medical Practitioners, Irish Medical Council 7th Ed, 2009.

³Department of Health/HSE: Guidelines for Consent to Clinical Examination and/or Treatment, HSE Mid-West Area Acute Hospitals, May, 2009

POST-OPERATIVE EVALUATION

- (a) The post-operative check is critical to the appropriate aftercare of a patient. Precise instructions should be given to the patient on discharge and the post-operative visit arranged for a date considered appropriate by the surgeon.
- (b) The surgeon should evaluate the patient on the first post-operative visit or if necessary delegate this duty to a suitably qualified medical practitioner.
- (c) It is the responsibility of the surgeon to ensure that the post-operative management is carried out appropriately. The patient should be given a contact number, either for the operating surgeon, an appropriate deputy or the hospital, to use in the event of a query or unexpected developments.
- (d) Surgeons must be fully trained and well versed in the management of the complications of refractive surgery.
- (e) Surgeons operating in clinics lacking microbiological or other specialised services should have pre-arranged established links to providers offering these services.
- (f) A surgeon without in-patient admitting rights should have a pre-arranged agreement with an appropriate consultant ophthalmologist to provide this service should the need arise.
- (g) Information on all medical/surgical procedures should be communicated to the patients' general practitioner.

ADVERTISING AND MARKETING

- (a) All material advertising must adhere to the relevant Advertising Standards Authority of Ireland (ASAI) Standards⁴ and the Medical Council (Ireland) Guidelines⁵. It must be legal, factual and not misleading.
- (b) Marketing materials must be drafted and designed to safeguard patients from unrealistic expectations.
- (c) Advertisements should not offer discount linked to a deadline date for booking appointments for surgery, or other date linked incentives.
- (d) Advertisements should not offer surgery as a competition prize or trivialise surgery by way of offering it as a package deal (e.g. refer a friend, reduced price for two people).
- (e) Promotional events such as open evenings should not include financial incentives for potential patients to book a consultation appointment, at the event.
- (f) All staff and speakers at promotional events should be clearly identified with regard to their profession and role within the organisation.

Guidelines for Refractive Surgery in Ireland
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⁴A.S.A.I.: *Manual of Advertising Self-Regulation, with Code of Standards for Advertising, Promotional and Direct Marketing in Ireland* (6th Edition Jan, 2007, Chapter 1, Para 8.1).

⁵Section E PARA 54, *Guide to Professional Conduct and Ethics for Registered Medical Practitioners, Irish Medical Council, 2009.*