



The ROYAL COLLEGE of
OPHTHALMOLOGISTS

Consultation Document

Professional Standards for Refractive Surgery

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1 Introduction

1.1 This document is targeted at surgeons and allied professionals involved in the care of patients undergoing refractive surgery.

1.2 Refractive surgery is primarily functional rather than cosmetic, but both refractive and cosmetic surgical procedures share key attributes setting them apart from other areas of routine medical intervention: they are entirely elective and predominantly self-funded. Accordingly, the General Medical Council (GMC) has advised that their April 2016 'Guidance for Doctors who offer Cosmetic Interventions'¹, should also apply to refractive surgery.

1.3 This document builds on the April 2016 guidance from the GMC, associated guidance, issued simultaneously, from the Royal College of Surgeons Cosmetic Surgery Interspecialty Committee (CSIC)², and the preceding 2013 Keogh Report³.

1.4 We have adopted a format similar to the April 2016 CSIC guidance². For ease of reference, the principles specific to refractive surgery are presented alongside relevant paragraphs from the April 2016 GMC guidance¹ with their original numbering and thematic subheadings. The April 2016 GMC guidance¹ should be read in its entirety alongside this document. For clarity, 'refractive surgical' is substituted for 'cosmetic' in paragraphs from the GMC guidance¹. Paragraphs 11 (relating to injectable cosmetic treatments) and 30-35 (relating to interventions in children and adults who lack capacity for consent) would not normally be relevant to refractive surgery practice and have been omitted. Where appropriate, our additional recommendations have been taken directly or adapted from the CSIC guidance².

1.5 Additional resources, including standardised patient information in refractive surgery, audit tools (Clinical Quality Indicators for Refractive Surgery), information on the CertLRS examination, and detailed advice on promotion (Standards in Advertising and Marketing) will be available at www.rcophth.ac.uk from the intended implementation date for these standards (April 2017). The April 2016 GMC guidance¹ is already in force.

2 Knowledge, skills and performance

The GMC says:

- 1 You must recognise and work within the limits of your competence and refer a patient to another practitioner where you cannot safely meet their needs.*
- 2 Before carrying out an intervention for the first time yourself, or supervising others performing it, you must make sure you can do so safely, eg by undergoing training or seeking opportunities for supervised practice.*
- 3 You must take part in activities to maintain and develop your competence and performance across the full range of your practice.*
- 4 You must keep up to date with the law and clinical and ethical guidelines that apply to your work. You must follow the law, our guidance and other regulations relevant to your work.*
- 5 You must seek and act on feedback from patients, including information on their satisfaction and physical and psychological outcomes. You must use this, and feedback from colleagues, to inform your practice and improve the quality of your work.*
- 6 You must make sure your annual appraisal covers the whole of your practice.*

In addition, surgeons who perform refractive surgery should:

- 2.1 Be on the GMC Specialist Register in Ophthalmology (or hold the CertLRS entry level qualification prior to 1 January 2018).
- 2.2 Hold the CertLRS entry-level qualification in refractive surgery.
- 2.3 Ensure that their skills and knowledge are up to date by undertaking a minimum of 50 hours of continuing professional development activity (CPD) per year across their whole practice, or 250 hours across the 5-year revalidation cycle. These activities must be relevant to their refractive surgery practice and support their current skills, knowledge and career development.
- 2.4 In each revalidation cycle, undertake at least one patient feedback exercise that includes patients' experience from their refractive surgery practice and present the results for discussion at appraisal, demonstrating the actions taken and the learning achieved.

3 Safety and quality

The GMC says:

- 7 To help keep patients safe you must follow the guidance on establishing and participating in systems and processes that support quality assurance and service improvement, as set out in Good Medical Practice and our related explanatory guidance. In particular, you must:*

- a. *comply with any statutory reporting duties in place.*
- b. *contribute to national programmes to monitor quality and outcomes, including those of any relevant device registries.*
- c. *routinely monitor patient outcomes, and audit your practice, reporting at least annual data report product safety concerns to the relevant regulator – in the UK this is the Medicines and Healthcare products Regulation Agency (MHRA).*

8 You should share insights and information about outcomes with other people who offer similar interventions, to improve outcomes and patient safety.

9 You must tell patients how to report complications and adverse reactions.

10 You must be open and honest with patients in your care, or those close to them, if something goes wrong and the patient suffers or may suffer harm or distress as a result.

11 N/A – refers to injectable cosmetic medications

12 You must seek and act on evidence about the effectiveness of the interventions you offer and use this to improve your performance.

13 You must provide interventions based on the best available up-to-date evidence about effectiveness, side effects and other risks.

In addition, surgeons who perform refractive surgery should:

3.1 Maintain an accurate portfolio of data regarding their clinical activity using outcome measures set out in *Clinical Quality Indicators for Refractive Surgery (RCOphth 2016)** and undertake regular audit to identify areas of improvement. They should discuss the results of their audit at their appraisal and form action plans where appropriate.

3.2 Contribute to national audits and registries where available.

3.3 Participate in case reviews in morbidity and mortality meetings. Where this is not possible, they should take part in professional networks to allow discussion of complex cases with colleagues.

3.4 Ensure that any implants, medicines and medical devices comply with guidelines of the MHRA.

* The quality indicators are still in development and will be available prior to the recommended implementation date for the standards. The purpose of the Indicators is to the development of a minimum set of agreed refraction and acuity measures together with web based patient reported outcome measures (PROMs) for refractive surgery with the aim of providing surgeons with data for revalidation, detecting problems with new refractive surgical procedures or implants at an early stage, and creating high quality evidence to support standardised patient information.

4 Safe environment

The GMC says:

13 You should be satisfied that the environment for practice is safe, suitably equipped and staffed and complies with any relevant regulatory requirements.

In addition, the following principles apply for refractive surgery:

4.1 Refractive surgery must be carried out in premises registered with the Care Quality Commission (CQC).

4.2 Registration with the CQC is a point in time activity and therefore surgeons should be satisfied that the premises continue to meet the appropriate standards for undertaking refractive surgery procedures.

- a. Laser refractive surgery should be performed in a minimal access intervention⁴ operating environment with a log of temperature and humidity conditions demonstrating that these are being maintained consistently within the range for safe operation of equipment specified by the manufacturers of the lasers being used.
- b. Uninterruptable power supplies should be in place for all refractive surgical lasers.
- c. Intraocular refractive surgery should be performed within a standard ophthalmic operating theatre environment⁴.

4.3 Surgeons must take responsibility for ensuring that staff, skill mix, and equipment are available and fit for purpose before proceeding. This includes:

- a. Operative equipment – standard operating procedures in accordance with manufacturers recommendations should be followed to check calibration and safety prior to use.
- b. Separate instrumentation for each eye in bilateral surgery cases
- c. Anaesthetic and other operating room staff
- d. Recovery nursing support

4.4 Surgeons must perform pre-surgical, verbal 'time-out' checks against medical records of:

1. patient identity
2. the operated eye
3. drug allergies
4. consent
5. (for implants) implant make, model and dioptric power
6. (for laser refractive surgery) the sphere, cylinder, axis and refractive target

5 Communication, partnership and teamwork

The GMC says:

14 You must communicate clearly and respectfully with patients, listening to their questions and concerns and considering any needs they may have for support to participate effectively in decision making.

Seeking patients' consent

15 You must be familiar with the guidance in Consent: patients and doctors making decisions together. In the following paragraphs we've highlighted key points from the guidance, which are important to protecting patients' interests in relation to cosmetic interventions.

Responsibility for seeking consent for refractive surgical interventions

16 If you are the doctor who will be carrying out the intervention, it is your responsibility to discuss it with the patient and seek their consent – you must not delegate this responsibility. It is essential to a shared understanding of expectations and limitations that consent to a refractive surgery intervention is sought by the doctor who will perform it, or supervise its performance by another practitioner.

Responding to requests for refractive surgical interventions

17 If a patient requests an intervention, you must follow the guidance in Consent, including consideration of the patient's medical history. You must ask them why they would like to have the intervention and the outcome they hope for, before assessing whether the intervention is appropriate and likely to meet their needs.

18 If you believe the intervention is unlikely to deliver the desired outcome or to be of overall benefit to the patient, you must discuss this with the patient and explain your reasoning. If, after discussion, you still believe the intervention will not be of benefit to the patient, you must not provide it. You should discuss other options available to the patient and respect their right to seek a second opinion.

19 When you discuss interventions and options with a patient, you must consider their vulnerabilities and psychological needs. You must satisfy yourself that the patient's request for the cosmetic intervention is voluntary.

20 You must explain any monitoring or follow-up care requirement at the outset. You must tell patients if implanted medical devices may need to be removed or replaced and after how long.

21 You must tell prospective patients if alternative interventions are available that could meet their needs with less risk, including from other practitioners.

Discussing side effects, complications and other risks

22 You must give patients clear, accurate information about the risks of the proposed intervention and any associated procedures, including anaesthesia and sedation, following the guidance in Consent (paragraphs 28-36).

23 You must talk to the patient about any adverse outcomes that may result from the proposed intervention, paying particular attention to those the patient is most concerned about. You must talk about the potential adverse physical and psychological impact of the intervention going wrong or failing to meet the patient's expectations.

Giving patients time for reflection

24 You must give the patient the time and information they need to reach a voluntary and informed decision about whether to go ahead with an intervention.

25 The amount of time patients need for reflection and the amount and type of information they will need depend on several factors. These include invasiveness, complexity, permanence and risks of the intervention, how many intervention options the patient is considering and how much information they have already considered about a proposed intervention.

26 You must tell the patient they can change their mind at any point.

27 You must consider whether it is necessary to consult the patient's GP to inform the discussion about benefits and risks. If so, you must seek the patient's permission and, if they refuse, discuss the reasons for doing so and encourage them to allow you to contact their GP. If the patient is determined not to involve their GP, you must record this in their notes and consider how this affects the balance of risk and benefit and whether you should go ahead with the intervention.

Being clear about fees and charges

28 You must explain your charges clearly, so patients know the financial implications of any decision to proceed to the next stage or to withdraw.

29 You must be clear about what is included in quoted prices and what other charges might be payable, including possible charges for revision or routine follow-up.

30-35 Refractive surgery is normally performed in adults with capacity for consent. Where this is not the case, paragraphs 30-35 of the GMC advice apply.

In addition, the following principles apply for refractive surgery:

Standardised patient information

5.1 Up to date, independent, standardised, evidence-based patient information in plain English should be easily available for refractive surgery procedures (published on RCOphth; NHS Choices, Parliamentary Ombudsman website).

5.2 Standardised patient information should explain the procedure, suitability, benefits, risks and alternatives.

Information specific to the provider

5.3 Provider-specific promotional and advertising materials are part of the consent process, and should not conflict with patient information. Any claims for superior outcomes must be supported by independent audit or peer-reviewed clinical evidence.

5.4 Provider-specific information should include details of fees charged, possible additional costs, continuity of care, the extent of any aftercare provided, together with standardised information on alternative treatment choices not available at that provider.

The consent process

5.5 Written consent forms should not differ in tone or content from the patient information for procedures, and should take the form of an appropriate standard wording appended to the patient information which has been available to the patient throughout.

5.6 Responsibility for the consent process should not be delegated: the surgeon performing the procedure should be satisfied that the patient is happy to proceed with surgery, is aware of the risks, and has realistic expectations for the outcome. Although preparatory information may include written material, video material or advice from suitably trained non-medical staff, the consultation at which the procedure recommendation is made must be with the operating surgeon. This must be a face-to-face consultation (not conducted by telephone) and must not occur on the day of surgery. At every stage, patients should be clearly informed about which staff they will meet and who they are receiving care from.

5.7 Information on the consent conversation should be tailored to fit the patient, aiming to help them make balanced choices, and highlighting any areas of particular risk or benefit for them as individuals.

5.8 Surgeons should consider their patients' wellbeing and seek expert advice from colleagues if they are concerned that a patient may not cope well with either the surgery itself or the recovery period.

5.9 Consent for refractive surgical interventions should include a two-stage process in which consent forms are taken away from the consultation at which the procedure recommendation is made by the operating surgeon, and patients are given an open line of communication with their surgeon (email, telephone, or optional repeat consultation) for follow-up questions during a cooling off period.

5.10 Surgery must not take place on the day on which the procedure recommendation is made. A minimum cooling off period of one week is recommended between the procedure recommendation and surgery.

5.11 There should be no pressure to proceed **with surgery. Specifically, patients should not be offered time limited discounts, or a refund of the initial consultation fee if they choose to proceed. Any deposit for surgery must be fully refundable within 3 working days if patients choose not to proceed.** Rates of conversion to surgery should not be used as a performance measure for surgeons, optometrists or other staff.

6 Providing continuity of care

The GMS says:

36 You should consider whether you or a colleague will need to review the patient's response to the intervention and make sure the patient understands whether you recommend a follow-up appointment.

37 You must make sure the patient has the medicines or equipment they need to care for themselves after an intervention.

38 You must make sure that your patients know how to contact you or another suitably-qualified person if they experience complications outside your normal working hours.

39 You should give patients written information that explains the intervention they have received in enough detail to enable another doctor to take over the patient's care. This should include relevant information about medicines or devices used. You should also send this information, with the patient's consent, to their GP, and any other doctors treating them, if it is likely to affect their future healthcare. If the patient objects to the information being sent to their doctor, you must record this in their notes and you will be responsible for providing the patient's follow-up care.

In addition, the following principles apply for refractive surgery:

Before the day of surgery

6.1 Pre-treatment instructions should include a clear explanation of what to expect during the surgery, with instructions about how the patient can help the procedure to go smoothly and reassurance about discomfort or disconcerting lights, sounds or smells which are normal during the surgery.

On the day of surgery

6.2 Surgery under local anaesthetic should not be performed in silence. It is helpful to keep up a reassuring dialogue, talking to patients through the surgery and explaining when they are likely to experience sensations such as pressure in the eye, temporary loss of vision, a bright light, a burning smell, or fluid running over the eye.

6.3 The operating surgeon should explain the course of the operation. Where relevant, any complications that have occurred and their possible solutions should be explained.

6.4 The operating surgeon should ensure that the patient has additional written discharge information detailing what to expect after surgery, aftercare instructions and an open line of communication (mobile or 24-hour telephone number) with the operating surgeon or experience refractive surgeon on-call. Although calls may be triaged through non-medical staff; immediate onward communication to the surgeon on-call should be available.

6.5 The operating surgeon should ensure that the patient is clear about the timing of routine review appointments and whether they should expect to see the operating surgeon or another member of the team at each visit.

6.6 Review appointments are always required after refractive surgery. These are early stage – designed to intercept problems that could affect the outcome; and later stage – when the refractive outcome is stable. Later stage review helps in tracking outcomes, allows patients the opportunity to feedback any residual concerns about the visual outcome, and to consider whether any further treatment might be beneficial.

6.7 Review of complex cases or cases experiencing intraoperative complications should not be delegated. There should be clear arrangements for transfer to another provider where appropriate in the case of an emergency.

6.8 If early or later routine review appointments are delegated⁶ to another member of the care team (ophthalmologist or optometrist) by the operating surgeon:

- a) The operating surgeon remains responsible for the care of the patient until discharge from the provider after late stage review.
- b) The operating surgeon must ensure that the optometrist or ophthalmologist reviewing the patient is appropriately trained in refractive surgery care.
- c) The operating surgeon must ensure that the optometrist or ophthalmologist is working from clear guidelines when defining whether he/she must refer back to the operating surgeon for guidance or additional review.
- d) Where possible, the ophthalmologist or optometrist caring for the patient after surgery should also have been involved in their pre-operative care.
- e) The ophthalmologist or optometrist caring for the patient after surgery must have adequate medical indemnity cover.
- f) The operating surgeon or an experienced refractive surgeon on-call must be available to deal with any additional interventions required or concerns raised.
- g) If the operating surgeon is unavailable post-operatively, he/she must transfer the patient's care to a named surgeon.

At discharge from the provider

6.9 Patients should not be discharged from follow-up care with the provider until they have a stable outcome.

6.10 After the final review appointment, further written discharge information should explain the need for any ongoing eye health care and any problems to look out for after follow-up is complete.

7 Record keeping

The GMC says:

40 You should organise your care records in a way that allows the identification of patients who have been treated with a particular device or medicine in the event of product safety concerns or regulatory enquiries.

41 You must keep records that contain personal information about patients securely and in line with:

- a. Any data protection requirements*
- b. Our Confidentiality guidance*

- c. *Guidance published by the UK health departments, even when the interventions are provided outside the National Health Service.*

In addition, the following principles apply for refractive surgery:

7.1 At every stage in the refractive surgery patient journey, all members of the care team should have full access to well organised medical records from the provider.

7.2 Wherever possible, electronic patient record systems should record standard audit outcomes, readable by and contributing to a national database of refractive surgery outcomes.

8 Working with colleagues

The GMC says:

42 You must make sure that anyone you delegate care to has the necessary knowledge, skills and training and is appropriately supervised⁵.

43 You must work effectively with healthcare professionals and others involved in providing care. You must respect the skills of colleagues within multidisciplinary teams and support them to deliver good patient care.

44 You must ask for advice from colleagues if the patient has a health condition that lies outside your field of expertise and that may be relevant to the intervention or the patient's request.

45 You must make sure you build a support network of experienced professional colleagues who can support and advise you. You should ask for advice when you treat patients who may need psychological or other expert assessment or support.

In addition, the following principles apply for refractive surgery:

8.1 The patient journey in refractive surgery comprises:

- Referral
- The initial consultation with the operating surgeon
- Surgery
- Early and late stage reviews
- Ongoing eye health care

A cohesive team based approach with clear lines of responsibility and each member of the team playing to their strengths is essential at every stage.

8.2 Although the performance of test, screening consultations and routine postoperative review may be delegated to appropriate trained staff, the operating surgeon remains responsible for the entire patient journey.

8.3 Patients should be told at the outset whether it is the operating surgeon or another member of the team who will be providing their care at each of the main stages in their refractive surgery journey. The patient can then make an informed choice between refractive surgery providers.

9 Maintaining trust

The GMC says:

Honesty

46 You must always be honest and never misleading about your skills, experience, qualifications, professional status and current role.

Communicating information about your services

47 When advertising your services, you must follow the regulatory codes and guidelines set by the Committee of Advertising Practice⁷.

48 You must make sure the information you publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge.

49 Your marketing must be responsible. It must not minimise or trivialise the risks of interventions and must not exploit patient's vulnerability. You must not claim that interventions are risk free.

50 If patients will need to have a medical assessment before you can carry out an intervention, your marketing must make this clear.

51 You must not mislead about the results you are likely to achieve. You must not falsely claim or imply that certain results are guaranteed from an intervention.

52 You must not use promotional tactics in ways that could encourage people to make an ill-considered decision.

53 You must not provide your services as a prize.

54 You must not knowingly allow others to misrepresent you or offer your services in ways that would conflict with this guidance.

In addition, the following principles apply for refractive surgery:

9.1 Patients' rights to privacy and confidentiality must be respected at all times, particularly when communicating publicly, including in the media or social media.

9.2 Celebrity endorsements are discouraged and, in the event these are used, a written declaration clarifying any financial relationship, including reduced cost treatment, between the clinic and the celebrity should appear alongside the endorsement.

9.3 Data supporting all claims and statements must be available for independent verification.

9.4 All advertisements for surgical procedures where possible must state the following: *“All eye surgical procedures carry a level of risk including not obtaining the desired outcome through to varying levels of visual loss. Your eye surgeon will discuss the risks, benefits and alternatives of sight correction surgery, including those specific to your own circumstances, at the time of your preoperative consultation.”*

9.5 The following are considered socially irresponsible and must not be used:

- a. Time-limited deals
- b. Financial inducements
- c. Package deals, such as ‘buy one get one free’ or reduced prices for previous patients’ friends and family.

9.6 Advertising price is highly discouraged. In the event that the price of surgery is advertised, the majority of recipients (>50%) should in reality be receiving surgery at that price.

9.7 The content of marketing information must be consistent with other patient information documents and should not differ substantially from the content of consent forms provided to the patient.

10 Honesty in financial dealings

The GMC says:

55 You must be open and honest with your patients about any financial or commercial interests that could be seen to affect the way you prescribe for, advise, treat, refer or commission services for them.

56 You must not allow your financial or commercial interests in a cosmetic intervention, or an organisation providing cosmetic interventions, to affect your recommendations to patients or your adherence to expected good standards of care.

In addition, the following principles apply for refractive surgery:

10.1 GMC advice on honesty in financial dealings should extend to doctors, community optometrists, other eye care professionals, and comparison websites directing referrals to refractive surgery providers or providing post-discharge eye care. To ensure that there is no financial conflict in making a referral recommendation.

- a. Any fee for services provided in relation to making a referral to a refractive surgery provider must be charged directly to the patient.
- b. Any contractual relationship with a refractive surgery provider, including fees paid by the provider for co-management or continuing care after discharge, must be made clear to patients prior to referral.

10.2 Surgeons performing refractive surgery must:

- a. Inform patients if any part of the fee goes to another healthcare professional.

- b. Disclose any personal affiliation or other financial or commercial interest relating to practise, including other private healthcare companies, laser manufacturers, implant manufacturers, pharmaceutical companies or instrument manufacturers.
- c. Obtain adequate professional indemnity insurance that covers the procedures they undertake.

11 References

1. 'Guidance for doctors who offer cosmetic interventions' (GMC 2016). http://www.gmc-uk.org/guidance/news_consultation/27171.asp
2. 'Professional standards for cosmetic practice' (The Royal College of Surgeons 2016). <https://www.rcseng.ac.uk/publications/docs/professional-standards-for-cosmetic-practice/>
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4. Humphreys H Et al. Guidelines on the facilities required for minor surgical procedures and minimal access interventions. Journal of Hospital Infection 2012: 80: 103-109. https://www.his.org.uk/files/8813/7389/0782/Guidelines_on_the_facilities_required_for_minor_surgical_procedures_and_minimal_access_interventions.pdf
5. 'Consent: patients and doctors making decisions together' (GMC 2008). http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp
6. 'Delegation and referral' (GMC 2013) http://www.gmc-uk.org/guidance/ethical_guidance/21187.asp
7. 'Marketing of cosmetic interventions' (The Committee of Advertising Practice 2013) <https://www.cap.org.uk/~media/Files/CAP/Help%20notes%20new/CosmeticSurgeryMarketingHelpNote.ashx>

Additional reference documents (not cited in the text)

8. Plain English guidance on consent at NHS Choices <http://www.nhs.uk/conditions/consent-to-treatment/pages/introduction.aspx>
9. American Academy of Ophthalmology guidance on consent in refractive surgery <http://www.aao.org/patient-safety-statement/informed-consent-guidelines-2>
10. American Academy of Ophthalmology guidance on marketing in refractive surgery <http://www.aao.org/ethics-detail/policy-statement--guidelines-refractive-surgery-ad>