The ROYAL COLLEGE of OPHTHALMOLOGISTS

Guidance

Professional Standards for Refractive Surgery

December 2021

Contents

1. Introduction

1.1 This document is targeted at surgeons and health care professionals involved in the care of patients undergoing refractive surgery. We emphasise throughout that surgeons are ultimately responsible for the safe delivery of patient care.

1.2 The General Medical Council (GMC) has indicated that refractive surgery is considered by them to be within the scope of their April 2016 'Guidance for Doctors who offer Cosmetic Interventions.[1, 2]

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)3, and the preceding 2013 Keogh Report[4]. Our additional recommendations here apply to surgeons treating patients where the primary purpose of surgery is to reduce dependence on spectacles or contact lenses and the patient has a normal cornea and a normal lens in both eyes.

1.4 We have adopted a format similar to the April 2016 CSIC guidance[3]. For ease of reference, the principles specific to refractive surgery are presented alongside relevant paragraphs from the April 2016 GMC guidance[2] with their original numbering and thematic subheadings. The April 2016 GMC guidance[2] should be read in its entirety alongside this document. For clarity, **'refractive surgical or refractive surgery'** is substituted for 'cosmetic' in paragraphs from the GMC guidance[2]. 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 guidance[3].

1.5 Our additional recommendations take two forms: direct advice to surgeons and advice that surgeons should ensure is upheld in relation to their practice. Direct advice to surgeons is prefaced by the heading *'In addition, surgeons who perform refractive surgery should.'* Advice that surgeons should ensure is upheld in relation to their practice is prefaced by the heading *'In addition, the following principles apply for refractive surgery.'*

1.6 Additional resources, including standardised patient information in refractive surgery, information on the CertLRS examination, and detailed advice on promotion (Standards in Advertising and Marketing) are available at rcophth.ac.uk

1.7 The original implementation date for these standards was 1st June 2017. The relevant GMC guidance[1] is has been in force since April 2016. These standards are regularly reviewed. The next scheduled review date is December 2024.

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, e.g. 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 If in refractive surgery practice prior to 1 August 2018, refractive surgeons should either hold the CertLRS **or** be on the GMC Specialist Register in Ophthalmology, and hold evidence in their last revalidation cycle of an established refractive surgery practice.

2.2 Refractive Surgeons who are not included in 2.1 (above), who are in, or have commenced, refractive surgery practice after 1 August 2018, should be on the GMC Specialist Register in Ophthalmology **and** hold the CertLRS entry level qualification.

2.3 They should 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 should be relevant to their refractive surgery practice and support their current skills, knowledge and career development. This is consistent with the CPD programme of The Royal College of Ophthalmologists which started in 1996.

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.
d. 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. 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 a *Refractive Surgery Data Set (RCOphth)** 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 Take part in professional networks, national and international meetings to allow discussion of complex cases with colleagues and help ensure that their practice is well aligned with contemporary clinical evidence.

3.3 Ensure that the clinic or organisation in which they practise has policies in place to maintain compliance with MHRA guidelines on the use of implants, medicines and medical devices; the use of custom made or non-CE marked devices†, and the off-label use of medical devices[5].

* The Refractive Surgery Data Set is a minimum set of common outcome measures in refractive surgery to be agreed by a multidisciplinary working group in accordance with the College's process for developing clinical data sets rcophth.ac.uk/standards-publications-research/clinical-data-sets/

† gov.uk/guidance/ce-marking

4. Commissioning of training for sustainable services

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) in England, or the equivalent regulator in Scotland, Wales and Northern Ireland.

4.2 Surgeons should be satisfied that the premises continue to meet the appropriate standards for undertaking refractive surgery procedures.

a. Laser refractive surgery should be perform-ed in a minimal access intervention[6] 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 must be in place for all refractive surgical lasers.

c. Intraocular refractive surgery should be performed within a standard ophthalmic operating theatre environment[5].

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 manufacturer's recommendations should be followed to check calibration and safety prior to use.

b. Separate instrumentation for each eye in bilateral corneal surgery and, in addition, separate manufacturing batches for fluids and devices, and separate sterilisation cycles for instruments used in each eye in bilateral intraocular surgery in accordance with contemporary guidelines for immediate sequential bilateral cataract surgery.[6]

c. Anaesthetic and other operating room staff.

d. Recovery nursing support.

4.4 Surgeons should perform pre-surgical, verbal 'time-out' checks[7] against medical records of:

1. Patient identity
2. The eye to be operated on
3. Drug allergies
4. Consent
5. (For implants) implant make, model, sphere, cylinder, target axis and spherical equivalent refractive target.
6. (For laser refractive surgery) the programmed treatment sphere, cylinder, axis, the spherical equivalent refractive target, the treatment modality and any adjustable parameters.

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 [7]. In the following paragraphs, we've highlighted key points from the guidance, which are important to protecting patients' interests in relation to **refractive surgical 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 **refractive surgical** 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 websites).

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 standardised patient information. Any claims for superior outcomes should be supported by independently verifiable 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[9]

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 should be with the operating surgeon. This should be a face-to-face consultation (not conducted by telephone) and should 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[10].

5.7 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 Operating surgeons may use video remote consultation technology as an alternative to a conventional face-to-face pre-operative consultation provided all the following elements are in place:

a. The patient or the surgeon has the option of choosing a conventional face-to-face consultation in advance of the day of surgery if this is the pathway they would prefer.

b. The surgeon has access to the following minimum eye examination and test information recorded within one week of the video consultation: visual acuity and refraction information specified (2.01 – 2.16) in the National Clinical Dataset for Refractive Surgery; intraocular pressures; widefield fundus images; corneal tomography (including contemporary keratoconus screening indices); internal anterior chamber depth; mesopic pupil diameter.

c. Medical indemnity cover includes remote consultations for both the operating surgeon and the healthcare professional providing eye examination and test information.

d. The video remote consultation takes place at least 1 week before the day of surgery.

e. The operating surgeon personally examines the patient's eyes preoperatively on the day of surgery.

f. The patient is aware of the limitations of a video consultation and, in particular, the possibility that surgery may be postponed or cancelled if examination on the day of surgery reveals new information indicating an alternate procedure recommendation.

g. If information revealed at examination on the day of surgery indicates an alternate procedure recommendation, the patient and the operating surgeon may opt to proceed only if the prior consent discussion and information provided covers both the original intended procedure and the alternate procedure choice. In practice this restricts procedure switches on the day of surgery to those falling within the same category of standard patient information: laser vision correction, phakic intraocular lens implantation, or refractive lens exchange.

h. If the procedure recommendation is altered on the day of surgery, the patient is under no pressure to proceed, and may opt for a further period of reflection with no financial penalty in the event that they decide not to proceed with the alternate treatment.

5.9 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.

5.10 Consent for refractive surgical interventions should include a two-stage process in which consent forms are available to the patient from the time of 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.

5.11 Surgery should not take place on the day on which the procedure recommendation is made and the initial consent discussion with the operating surgeon takes place. A minimum cooling off period of one week is recommended between the procedure recommendation and surgery. In exceptional circumstances, where a one-week cooling off period is impractical, the reasons for this should be agreed with the patient and documented in the medical record.

5.12 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 should be fully refundable within a reasonable time period 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 GMC 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 named 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 information 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 an experienced 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:

a. Early-stage review appointments are designed to intercept problems that could affect the outcome.

b. Later stage review appointments take place when the refractive outcome is stable. These help in tracking outcomes, allow 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 should not be delegated until the treatment for any complications is complete, the risk of further complications has returned to baseline levels for the procedure, and routine care pathways can be resumed safely.

6.8 Complex cases are cases with preoperative risk factors for complications after surgery or cases that, as a result of a complication during or after surgery, may require any addition to previously scheduled routine review or treatment. There should be clear arrangements for transfer to another provider where appropriate in the case of an emergency or where additional specialist treatment is required for the treatment of complications.

6.9 If early or later routine review appointments are delegated[10] 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 in relation to the procedure performed until discharge from the provider after later stage review.

b. The operating surgeon should ensure that the ophthalmologist or optometrist reviewing the patient is appropriately trained in refractive surgery care.

c. The operating surgeon should ensure that the ophthalmologist or optometrist is working from clear guidelines when defining whether he/she should 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 should have adequate medical indemnity cover.

f. The operating surgeon or an experienced refractive surgeon on-call should be available to deal with any additional interventions required or concerns raised.

g. If the operating surgeon is unavailable post-operatively, he/she should transfer the patient's care to a named surgeon[10].

At discharge from the provider

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

6.11 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 supervised[9].

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 Key stages of the patient journey in refractive surgery comprise:

1. Initial advice from clinic staff
2. Procedure choice and discussion with the operating surgeon
3. Surgery
4. Early and later stage review consultations

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 tests, screening consultations and routine postoperative review may be delegated to appropriately trained staff, the operating surgeon remains responsible for the entire patient journey until discharge from the provider after late-stage review or transfer of care to another provider for emergency or additional specialist treatment.

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 Practice[10].

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, if 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 should be available for independent verification.

9.4 All advertisements for surgical procedures where possible should 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 should 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 discouraged. In the event that the price of surgery is advertised, all material information should be given which patients need in order to make an informed decision about the advertised price, such as eligibility criteria, specific details of the treatment being provided and, if there is a range of prices, patients should be made aware that actual pricing could vary significantly from the advertised price. Information should be given in a clear, unambiguous and intelligible manner.

9.7 The content of marketing information should 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:

Honesty

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 refractive surgical intervention, or an organisation providing refractive surgical 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 To help avoid any financial conflict where referral recommendations are made, surgeons should ensure that they or their employing refractive surgery provider only accept referrals where:

a. Any fee for services provided in relation to making a referral to a refractive surgery provider has been 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, has been made clear to patients prior to referral.

10.2 Surgeons performing refractive surgery should:

a. Disclose any personal affiliation or other financial or commercial interest relating to their practice including: other private healthcare companies, laser manufacturers, implant manufacturers, pharmaceutical companies or instrument manufacturers.

b. Obtain adequate professional indemnity insurance that covers the procedures they undertake.

11. References

1. 'Does the guidance cover laser or refractive eye surgery?' www.gmc-uk.org/guidance/ethical_guidance/29160.asp

2. 'Guidance for doctors who offer cosmetic interventions' (GMC 2016). www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/cosmetic-interventions

3. 'Professional standards for cosmetic practice' (The Royal College of Surgeons 2016). www.rcseng.ac.uk/standards-and-research/standards-and-guidance/service-standards/cosmetic-surgery/professional-standards-for-cosmetic-surgery/

4. 'Review of the Regulation of Cosmetic Surgery Interventions (Department of Health 2013) www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions

5. Regulatory guidance for medical devices (MHRA December 2014) www.gov.uk/government/publications/report-a-non-compliant-medical-device-enforcement-process

6. Immediate Sequential Bilateral Cataract Surgery (ISBCS) during COVID recovery: RCOphth/UKISCRS rapid advice document, (The Royal College of Ophthalmologists, 2020) www.rcophth.ac.uk/standards-and-guidance/

7. 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. www.journalofhospitalinfection.com/article/S0195-6701(11)00444-0/fulltext

8. WHO surgical safety checklist and implementation manual (WHO 2008) www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.pdf

9. 'Consent: patients and doctors making decisions together' (GMC 2008). www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

10. Guidance for doctors acting as responsible consultants or clinicians (GMC 2014) www.gmc-uk.org/guidance/ethical_guidance/25335.asp

11. 'Delegation and referral' (GMC 2013) www.gmc- uk.org/guidance/ethical_guidance/21187.asp

12. 'Marketing of cosmetic interventions' (The Committee of Advertising Practice 2013) www.asa.org.uk/resource/cosmetic-interventions.html

Additional reference documents (not cited in the text)

13. Plain English guidance on consent at NHS Choices nhs.uk/conditions/consent-to-treatment/pages/introduction.aspx

14. American Academy of Ophthalmology guidance on consent in refractive surgery www.aao.org/Assets/9d4edb52-14e0-48d2-9e6c-7d5197c37958/636102302610070000/practice-guidelines-for-informed-consent-dec-2011-pdf

15. American Academy of Ophthalmology guidance on marketing in refractive surgery www.aao.org/ethics-detail/policy-statement--guidelines-refractive-surgery-ad

12. Refractive Surgery Standards Working Group

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- Mr James Ball FRCOphth
- Mr Don Williams, Clinical Adviser, College of Optometrists
- Mr Bernard Chang FRCOphth, President and
- Dr Kieren Darcy, FRCOphth
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