

The Royal College of Ophthalmologists



Cataract surgery guidelines

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1 Introduction

1.1 Background

The second College Guidelines for Cataract Surgery were published in 2001. Major developments have taken place in cataract surgery over the past 3 years with a large increase in surgical throughput together with an increase in the number of providers of cataract surgery.

The guidelines have therefore been updated and new chapters have been included on intraocular lenses, patient safety and commissioning cataract surgery.

The aims of modern cataract surgery include:

- Restoration of vision to meet the patient's needs
- Achievement of the desired refractive outcome
- Improvement in quality of life
- Ensuring patient safety and satisfaction

Whilst recent initiatives to reduce waiting times for cataract surgery and improve access are to be applauded it is imperative that quality and patient safety are maintained and training is safeguarded.

1.2 Aim of the guidelines

The aim of these guidelines is to identify good clinical practice, set standards of patient care and safety and provide a benchmark for outcomes within which high quality cataract surgery can be practised. They represent the current understanding of the guideline development group but will not necessarily all remain applicable until the next review in 2007.

1.3 Scope of the guidelines

These guidelines are for cataract surgery in adults. They cover the clinical aspects and management by the ophthalmic team of patients with cataract. They should also be used by commissioners for cataract surgery to ensure they commission to the highest standards and a chapter is included on commissioning cataract surgery.

There is some overlap with 'Action on Cataracts'¹ which provides invaluable guidance on streamlining the management of cataract services.

These guidelines cover the entire cataract care pathway and also address training, patient information and consent.

2 Methods

2.1 The guideline development group

This reflected the professional groups that are directly involved with the care and management of patients undergoing cataract surgery and with monitoring the quality and standards of care provided by the surgical service.

2.2 Gathering the evidence

The approach taken by the members of the guideline development group was as follows:

- a. A Medline literature search was conducted. The search was confined to English language reports on cataract surgery in adults.
- b. Studies taking place within the last 10 years were considered most important. Those most relevant to contemporary practice were included for further review.
- c. The following attributes were sought in all studies included in the review, that:
 - The design and approach taken to minimise bias should be reported
 - The intervention of interest should be addressed – namely cataract surgery
 - Systematic evaluation and consideration of possible confounding factors, with a description and discussion of the methods, should be used
 - The characteristics of the study population should be provided

All studies reviewed were assessed using a framework based on guidance from the Scottish Intercollegiate Guidelines Network (SIGN) and recommendations made were graded as follows:^{1,2}

2.3. Grades of recommendations

- | | |
|----------|---|
| A | Based on at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. |
| B | Based on the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation. |
| C | Based on evidence from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. |

2.4 Good practice points

- | | |
|-------------------------------------|--|
| <input checked="" type="checkbox"/> | Recommended best practice based on the clinical experience of the guideline development group and informed by feedback from consultant ophthalmologists in the UK during the pre-publication consultation process. |
|-------------------------------------|--|

2.5 Using this approach

- A significant limitation encountered when reviewing the existing epidemiological data on cataract (from both the aetiological and health care needs perspective), was the varying definitions of cataract that were used. In addition, much of the data was from countries with different health care settings to the UK. Consequently the data reported are predominantly UK based.
- The published literature included many studies reporting on cataract surgery that was performed more than 10 years ago. These and even some of those published within our specified time period of 1994 – 2004 related to surgical practice that is now considered outdated in terms of clinical management and surgical technique. These were excluded from the review and where relevant the most pertinent findings were used to provide a historical perspective rather than an evidence-base. However in some cases where no other reports were identified in the search, studies relating to earlier practice have been cited.
- In addition, findings of recent relevant studies, if unpublished at the time of writing, were included only if they were 'in press', indicating they had gone through the formal peer review process.
- There was a range of the desired study attributes defined above – some studies had all, others at least one.
- Finally, there are many aspects of this guideline that are based on clinical experience and clinical consensus of surgical practice.

2.6 Consultation process

A consultation process took place prior to publication and dissemination of this guideline. This involved all consultant ophthalmologists in the UK and members of The Royal College of Ophthalmologists Lay Advisory Group who were invited to send their opinions and comments to the guideline development group.

2.7 Methods references

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3 Epidemiology

3.1 Introduction

Cataract is a common and important cause of visual impairment world-wide. The term 'cataract' as used here includes those that are not congenital or secondary to other causes (e.g. chronic uveitis, prior intra-ocular surgery such as glaucoma filtration surgery or vitrectomy, and trauma). Cataract extraction accounts for a significant proportion of the surgical workload of most ophthalmologists and cataract surgery continues to be the commonest elective surgical procedure performed in the UK¹.

3.2 Prevalence and incidence

There are now a number of sources of population-based data for the prevalence of cataract in the UK.^{2,3,4,5,6} The North London Eye Study provides prevalence data specifically for visually impairing cataract (i.e. Snellen visual acuity less than 6/12 that is attributable to a lens opacity) in one or both eyes in a random sample of 1547 people of 65 years and over in an outer metropolitan district.² Overall, 30% of persons of 65 years and over in this population² were found to have visually impairing cataract in one or both eyes. A further 10% of persons in this age group had previous cataract surgery in one or both eyes. The prevalence of visually impairing cataract rose steadily with age:² 16% in the 65 to 69 year age group; 24% in persons of 70 to 74 years of age; 42% in those 75 to 79 years of age; 59% in 80 to 84 years; and 71% in persons of 85 years or more. The prevalence of cataract (after adjusting for age) was higher in women, the overall prevalence ratio (females : males) was 1.22 (95% confidence limits 1.07 to 1.40). Notably, the majority (88%) of people with treatable visual impairment from cataract were not in touch with eye health services², representing the level of potentially unmet need for eye health care for cataract in the population. It is estimated that 2.4 million people aged 65 and older in England and Wales have visually impairing cataract in one or both eyes.^{2,7} In addition it is estimated that a further 225,000 new cases of visually impairing cataract are expected each year. The 5-year cumulative incidence is estimated at 1.1 million new cases among the population aged 65 years and older.⁷

The Somerset and Avon Eye Study examined 1078 randomly sampled individuals aged 55 years and older.⁵ This study included a subjective refraction. Eligibility for cataract surgery was modelled in this population based upon a perception of a visual problem, vision related quality of life impairment, reduced best corrected visual acuity, cataract severity and presence or absence of visually significant ocular co-morbidity. Models for eligibility for surgery were constructed based upon various combinations of threshold levels for these variables. Intermediate criteria suggested that a backlog in the vicinity of 350,000 operations existed for England for people aged 55 years and older. This contrasts with the estimated 2.4 million in need of cataract surgery estimated from the North London Eye study data.⁷ The variation between the results of these two studies is probably explained by a combination of regional and methodological differences, the Somerset and Avon Eye study for example used best corrected acuity rather than habitual correction.

MRC Trial of Assessment and Management of Older People in the Community collected visual acuity data on a British population based sample of 14,600 people aged 75 years and older. Visual impairment (binocular acuity <6/18) was found in 1803 or 12.4% of individuals using their habitual correction.⁸ The cause of the visual impairment has recently been reported for 1742 of these people, cataract being responsible in 36% of individuals.⁶

- **In England and Wales rates of cataract surgery have increased from 153,000 in 1997-8 to 270,000 in 2002-3**
- **The majority of people (88%) with treatable visual impairment from cataract were not in touch with eye health services**
- **Although many advances have been made in the identification of risk factors for cataract there is, as yet, no proven primary or medical treatment for cataract**
- **With increasing life expectancy and the resulting expansion of the elderly population, both the prevalent cases of cataract and the demand for surgery will continue to rise**

3.3 Risk Factors

The cause(s) for cataract are multifactorial. Apart from age, aetiological epidemiological studies have identified a number of risk factors for cataract:^{9,10}

- gender
- diabetes mellitus
- sunlight
- steroids
- nutrition and socio-economic status
- life style- smoking and alcohol
- dehydration/diarrhoeal crises

More recently data emerging from genetic studies estimate that the heritability of age related cataract could be between 48% - 59%.^{11,12}

3.4 Prevention and Treatment

Although many advances have been made in the identification of risk factors for cataract, there is as yet, no proven primary or medical treatment for cataract. Surgical removal of the cataract remains the only effective treatment available to restore or maintain vision. Cataract surgery in this country is performed predominantly on elderly patients with about 80% being of 70 years of age or older.¹³ Serious co-existing eye conditions such as glaucoma, age related macular degeneration, diabetic retinopathy or amblyopia, are present in 30% of patients having cataract surgery.¹³ With the continuing advances in microsurgical techniques and intra-ocular lens technology the quality of post-operative optical rehabilitation has also continued to improve, inevitably influencing the indications for surgery. Increasingly other measures of visual functioning (e.g. glare, contrast sensitivity), and the degree of functional disability are being considered together with visual acuity in making recommendations for surgery and for evaluating the outcomes of surgery. All of these factors have undoubtedly contributed to the increasing demand for surgery. In addition, with increasing life expectancy and the resulting expansion of the elderly population, both the prevalent cases of cataract and the demand for surgery will continue to rise.

3.5 Access to services and surgical rates

Realisation of the levels of unmet need for surgery^{2,5,7} has resulted in dramatic increases in NHS cataract surgical throughput in recent years. In England and Wales rates of cataract surgery have increased from 153,000 in 1997-98¹⁴ to 270,000 in 2002-3¹, a rise of 75% in 5 years. Assuming a population of 52M with 15% aged over 65 years, the current surgical rate approximates to a crude rate of 5.2 extractions per 1000 population or 3460 per 100,000 people aged 65 years or older. Access is now good in many areas though not all, and further increases in throughput are planned with a view to reducing waiting times for cataract surgery to 3 months by the end of 2004.¹⁵ In the longer term the challenge for ophthalmologists and those funding health care will be to hold waiting times to these levels.

3.6 Assessment of the outcome of cataract surgery

Monocular visual acuity provides an incomplete assessment of surgical outcome and for this reason patient centred instruments have been developed.^{16,17,18} These developments represent a formalisation of the time honoured clinical approach where patients are asked about symptoms and difficulties with visual tasks. Obtaining self reported information relevant to a patient's every day visual experience in the context of their own environment should be seen as complimentary to standard visual function testing. Questionnaires with a predominantly functional emphasis may lack applicability to certain patient groups, particularly if applied across different cultures. Broad based quality of life in vision instruments aim to avoid this problem by tapping into generic psycho-social and emotional issues.¹⁹

3.7 Epidemiology references:

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4 Cataract Care Pathway

4.1 Clinical Responsibility

Cataract management is a multi-professional process involving ophthalmologists, optometrists, nurses and technicians. The ultimate responsibility for diagnosis and management of the patient lies with the ophthalmologist in charge. The decision on whether to proceed to surgery should be made by the patient in discussion with an ophthalmologist. Cataract surgery should be performed by an ophthalmic surgeon although much of the process may be undertaken by the non-medical members of the team provided that they are properly trained and supervised.

4.2 Referral

Referral for cataract surgery can be initiated either by the optometrist or GP. Action on Cataracts¹ suggested direct optometrist referral according to locally agreed protocols and there are now many such projects with audited outcomes and high conversion rates from referral to surgery. The Department of Health in the National Eye Care Plan proposes this as the preferred referral method.²

Whatever method of referral is used there are important underlying principles:

- the patient should have sufficient cataract to account for the visual symptoms
- the cataract should affect the patient's lifestyle
- the risks and benefits of surgery should be discussed with the patient and relevant written information supplied
- the patient should wish to undergo cataract surgery
- this information together with a report from a recent sight test should form the minimum data on the referral form.

Patients who do not meet all of the criteria should not be overlooked. Patients with co-morbidity who might appreciate only slight benefit from surgery may wish to consult with an ophthalmologist to discuss their case. Patients with lifestyle impairment due to cataract who do not complain should, if necessary, be encouraged to consider cataract surgery, particularly those who live alone or act as carers.

Other indications for cataract surgery include facilitating treatment and / or monitoring posterior segment disease e.g. diabetic retinopathy, correcting anisometropia or treating lens induced ocular disease.



Following referral the patient should be sent clear instructions on what they will be required to take to their out-patient visit and what to expect at the visit. If surgery is to take place the same day this should be made very clear in the appointment letter.

4.3 Only eye surgery

The indications for cataract surgery in one-eyed patients are the same as for two-eyed patients, but the ophthalmologist should explain the possibility of total blindness if severe complications should occur. A one-eyed patient's cataract operation should be performed by an experienced cataract surgeon.

4.4 Second eye cataract surgery

Over one third of all National Health Service cataract operations are performed on the second eye.¹ Second eye surgery confers significant additional gains in visual function in everyday activities and quality of life above and beyond those achieved after surgery to the first eye.² Functional improvement in visual symptoms after second eye surgery has been demonstrated.^{3,4} Surgery for cataract on the second eye also enables a greater proportion of patients to meet the DVLA driving standard.⁵ These benefits of surgery are recognised clinically and its value should not be overlooked in the management of cataract.^{2,3,4,6}

4.5 Out Patient Appointment and Pre-Operative Assessment



It is essential that the ophthalmologist performing the ophthalmic examination is appropriately trained if this is not performed by the surgeon.



In the interest of patient convenience the out-patient appointment should where possible be combined with the pre-operative assessment as waiting times for surgery reach 3 months.

The purpose of the out-patient appointment is to:

- confirm the diagnosis of visually significant cataract
- ensure the cataract is the cause of the visual symptoms
- determine if there is co-existing ocular pathology
- ensure the patient wishes to undergo surgery and understands the risks
- formulate a surgical care plan

The aims of the pre-operative assessment are to:

- ensure the patient is fit for surgery
- put a care plan in place (this can be helped by the use of an integrated care pathway).

4.6 Diagnosis and Evaluation of visual impairment

- A detailed visual history should be taken, in particular establishing near and distance vision and past history of eye disease, binocular function and amblyopia.
- The impact of cataract on the patient's lifestyle should be evaluated but it is important to realise that patients adapt to their visual impairment. (There is no single test to assess the effect of cataract on a patient nor is there a test to decide a threshold for surgery.) Questionnaires can be helpful in eliciting symptoms but should be used in conjunction with history taking and examination when deciding on surgery.

4.7 Ophthalmic Examination

A complete ophthalmic examination should include:

- measurement of visual acuity (an up to date refraction should be available as part of the optometrist's report)
- pupil examination
- external eye examination including lids and lashes.
- measurement of intraocular pressure
- slit lamp examination
- dilated examination of the cataract and fundus
- biometry

Special investigations

If the view of the fundus is obscured, useful information may be gained from a careful examination of the pupil responses, the assessment of light perception or using entoptic tests (Purkinje effect). B-scan ultrasonography will establish that the retina is attached and identify any intraocular masses. Electrodiagnostic tests may sometimes be useful in the assessment of retinal or visual pathway dysfunction.

Tests for contrast sensitivity, glare, laser interferometry and specular photography are not of proven value.

No special tests of visual function, other than visual acuity with best spectacle correction, are required prior to referral for cataract surgery.

Following history taking and examination:

- discussion should take place with the patient about cataract surgery including preferred refractive aim and anaesthesia.
- if the patient wishes to proceed to surgery the patient should be given a date for surgery .
- Informed consent for the surgery should be obtained.

The surgeon should formulate a surgical plan including:

- type of anaesthesia
- IOL type and power (order special lenses if required)
- incision placement and astigmatism reduction procedures if appropriate
- complexity of surgery e.g. small pupil, pseudoexfoliation, previous eye surgery
- level of surgical experience required

The vast majority of patients are suitable for day surgery under local anaesthesia and this is the accepted model of care. Patients having surgery to their only seeing eye may need an overnight stay if the local anaesthetic reduces their vision post-operatively and they do not have a relative or carer to look after them.

4.8 Pre-operative assessment

This should include:

- general health evaluation including blood pressure check
- note of current medication
- record of allergies
- assessment of hearing and understanding of English.
- assessment of patients' ability to co-operate with the procedure and lie reasonably flat during surgery
- identification of social problems
- instruction on eyedrop instillation
- clear explanation of the procedure and effect on the patient
- opportunity for patient to ask questions

A Routine pre-operative medical testing (blood tests and ECGs) for patients having local anaesthesia have not been found to reduce the incidence of intraoperative or post-operative medical complications.⁹

C The patient should leave the combined out-patient appointment and pre-operative assessment with a good understanding of the procedure, a date for surgery and a contact number in case of need.

The patient should be encouraged to contact the hospital in the week prior to surgery to ensure there has been no change in the patient's ocular or general health.

4.9 Day of Surgery

In the interest of patient convenience, arrival times should be staggered where possible but patients should arrive for surgery in sufficient time to ensure adequate pupillary dilatation and routine nursing checks. (Patients can also be provided with dilating drops to self administer prior to leaving home).

The pre-operative checks (carried out as part of an integrated care pathway) should include identification of the patient and the eye for surgery together with external eye examination to ensure there is no ocular infection. Changes in general or ocular health since the patient was last examined must be noted and re-examination by an ophthalmologist should take place if indicated.

Adequate pupillary dilatation is essential for cataract surgery and is usually achieved by short acting mydriatics (g. Cyclopentolate, g. Tropicamide, g. Phenylephrine 2.5%). Care should be taken with g. Phenylephrine 10% due to its systemic side effects but it is useful in dark eyed patients. Routine pre-operative antibiotics have not been shown to be effective but surgery should be delayed if there is concurrent infection.

4.10 Surgery

Phacoemulsification is the preferred method of cataract surgery in the developed world but extracapsular surgery is still occasionally necessary.

Cataract surgery should include:

- minimal trauma to ocular tissues
- capsular fixation of the intraocular lens
- watertight incision closure with reduction of astigmatism where appropriate
- prevention of infection

B To date the only effective prophylactic measure in infection prevention has been Povidone iodine 5% aqueous solution irrigated into the conjunctival sac immediately pre-operatively¹⁰.

The use of intra-cameral or infusion fluid antibiotics remains controversial but a recent retrospective series has shown a reduced rate of post-operative endophthalmitis with intra-cameral cefuroxime¹¹ and a large European multi-centre randomized controlled trial is currently underway using intra-cameral and topical antibiotics.

Following surgery and return to the day-care unit the patient should be discharged by an appropriately trained member of staff who ensures that:

- the patient is comfortable and pain free
- the eye is examined and if there are any problems e.g. shallow AC or hyphaema an ophthalmologist is called to see the patient
- post-operative written instructions, medications, appointments and emergency contact details are all given to the patient

4.11 Post-operative visits

4.11.1 First day review

First day post-operative review is no longer in widespread use^{12,13} with many departments having replaced a patient visit with a telephone call by a trained nurse or a call by the patient to a trained nurse if necessary.

✓ Robust arrangements need to be in place to ensure that patients not reviewed next day have easy access to advice and assessment and that post-operative complications can be quickly identified and managed.

First day post-operative visits may be required:

- where surgery was complicated
- with co-existing eye disease e.g. glaucoma, uveitis
- patients with an only eye

4.11.2 Final review

For patients not seen on the first post-operative day a review appointment is necessary to:

- review progress and medication
- collect outcome data
- discuss second eye surgery where appropriate
- arrange follow-up for co-existing eye disease
- provide advice on spectacle prescription (which can be prescribed approximately 4 weeks following phacoemulsification)

This examination can be provided by ophthalmologists, nurses, optometrists or orthoptists working within the unit to agreed guidelines or by accredited optometrists working outside the unit. The ophthalmologist with responsibility for the patient should ensure that appropriate training and monitoring takes place when the post-operative care is delegated to others.

4.12 Cataract care pathway references

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5 Surgery in Special Circumstances

5.1 Introduction

There are numerous circumstances or conditions that conspire to make cataract surgery less than routine. These may be related to the context of surgery (e.g. cataract surgery in a patient who is diabetic or has undergone prior LASIK surgery), due to previous treatment (e.g. cataract surgery following glaucoma drainage surgery or vitrectomy) or in association with ocular co-morbidity (e.g. uveitis or corneal diseases such as Fuchs Endothelial dystrophy).



It is important to be aware of factors that make surgery more difficult, or that may affect the outcome. This awareness will inform the approach to surgical technique, grade and experience of the operating surgeon and to the pre- and post-operative care of these patients and will also influence the advice given to patients about their surgery.

Table 1 summarises the more common circumstances and conditions that may complicate cataract surgery, and suggests broad strategies for avoiding and treating any associated problems¹⁻¹⁵. This table is not exhaustive and is not intended to be prescriptive.

5.2 Simultaneous bilateral cataract surgery

Some ophthalmologists perform bilateral cataract surgery at one sitting and some patients may request it. This is termed Simultaneous Bilateral Cataract Extraction (SBCE). Although most of the published series of SBCE^{16,17,18} report no bilateral endophthalmitis, one case has been reported in a series of 448 cases.¹⁹ The precise risk of bilateral visual loss is unknown but surgeons who perform SBCE must advise their patients of the possibility and implications of bilateral endophthalmitis. Contamination of fluids, instruments or operating theatre air may result in serial cases of corneal oedema or endophthalmitis, therefore strict precautions should be undertaken.

Relative clinical indications

- When a general anaesthetic (GA) is necessary to perform the cataract surgery safely and repeated GAs are contra-indicated on general health grounds
- Bilateral cataract in a person who for reasons of disability cannot be fully assessed pre-operatively and who requires a general anaesthetic for the procedure

Precautions

- The operation on each eye must be treated as a completely separate procedure
- If complications occur with the first eye, careful consideration should be given before proceeding with surgery on the second eye
- Instructions should be given on using separate drop bottles for each eye post-operatively and washing hands before instilling eye drops into the second eye
- Every effort should be made to reduce the possibility of serial infection by using instruments, fluids and intra-ocular lenses prepared in different batches

The ophthalmologist should be prepared to justify a decision to perform bilateral cataract surgery on grounds other than convenience.

5.3 Surgery in special circumstances references

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6 Anaesthesia

To be read in conjunction with The Royal College of Ophthalmologists/Royal College of Anaesthetists guidelines 'Local anaesthesia for intraocular surgery'

6.1 Background

There has been a dramatic change of anaesthetic practice for ophthalmic surgery over the past decade. The use of local anaesthesia (LA) has risen from around 20% in 1991¹ to over 75% in 1996^{2a} and 86% in 1997³ and the use of sedation with LA has fallen from 45% in 1991 to around 6% in 1996.^{2a}

Successful day case cataract surgery has been reported using different GA techniques⁴ and LA techniques.^{5,6,7} Most patients presenting for cataract surgery are elderly and have pre-existing medical problems. A local anaesthetic is preferable, particularly for small incision surgery, as it will usually be associated with lower morbidity and it causes least disruption to daily routine.

The 1996 National Survey of Local Anaesthesia for Ocular Surgery confirmed that serious systemic adverse events may occur with all types of LA, but are rare (3.4 per 10,000), although a degree of under-reporting was suspected.^{2b} These events are not reduced by routine pre-operative investigations.^{8,9}

No LA technique is totally free of the risk of a serious systemic adverse event. This is not necessarily a consequence of a particular local anaesthetic technique. Other factors include pre-existing medical conditions, anxiety, pain or stress reaction to the operation.

6.2 Organisation of ophthalmic anaesthetic services

- Multi-professional teamwork is the key to day case cataract surgery and is essential at every stage of the process
- Every unit should identify an anaesthetist with overall responsibility for ophthalmic services
- Meticulous recording of important data is a necessary prerequisite for good communication, safe practice, clinical governance and audit

6.3 Recommending the type of anaesthesia

The surgical assessment should include recommendations on the type of anaesthetic indicated for the individual patient. This will depend on psychological aspects, the particular features of the globe and orbit, and the anticipated difficulty of the surgery.

6.3.1 Pre-operative investigations

A In a randomised survey of over 19,000 cataract operations, routine pre-operative medical investigations did not reduce the incidence of peri-and post-operative morbidity.⁸

A previous study in a large teaching hospital showed that even when routine investigations were performed, the results were rarely taken into account.⁹

To quote from the 'Local Anaesthesia for Intraocular Surgery Guidelines',

"Tests should only be considered when the history or a finding on physical examination would have indicated the need for an investigation even if surgery had not been planned.....Most abnormalities that would be detected on special testing (e.g. ECG, CXR, FBC, clotting studies, urea and electrolytes) can be predicted from taking a careful history and performing a physical examination. Special tests do not reduce morbidity in this context and are not required unless specifically indicated...For the patient with no history of significant systemic disease and no abnormal findings on examination at the nurse-led assessment, no special investigations are indicated. Any patient requiring special tests may need a medical opinion."

- Hypertension should be controlled well before the patient is scheduled for surgery and not lowered immediately prior to surgery.
- Angina should be controlled by a patient's usual angina medication which should be available in theatre. Every effort should be made to make the experience as stress-free as possible. Generally patients should not have surgery within three months of a myocardial infarct.
- Diabetic patients should have their blood sugar controlled. If surgery is planned under LA diabetic patients should have their usual medication and oral intake.
- Patients with chronic obstructive pulmonary disease may benefit from an open draping system or a simple venturi high flow oxygen enriched air system below the drapes.
- There is no need for antibiotic prophylaxis for intraocular surgery in patients with valvular heart disease.
- Those on Warfarin should have an INR (see below)

6.3.2 Warfarin and cataract surgery

A recent review of the available literature¹⁰ reported RCTs which conclude that:

- Warfarin is effective at reducing health and life-threatening thrombotic events
- To stop Warfarin risks stroke and death (events reported in questionnaires by those ophthalmologists who stop Warfarin). The risk of stroke increases to 1:100

They suggested that for those on Warfarin:

- The INR should be checked to ensure that a patient is within their desired therapeutic range (set by the treating physician)
- If needle local anaesthesia is performed, the risk of orbital haemorrhage is increased by 0.2 – 1.0%
- Consideration should be given to using either sub-Tenon's or topical anaesthesia.

6.3.3 Aspirin and cataract surgery

The same review of the literature suggested that aspirin was little better than placebo in prevention of thrombotic events in the two studies where these were compared with Warfarin.¹⁰ The inference, although this was not stated in the paper, is that aspirin could be discontinued without significant thrombotic risk .

6.4 General anaesthesia (GA)

A general anaesthetic is not an exclusion to day case surgery⁴ and may be appropriate for patients who:

- decline to have local anaesthesia even after careful counselling and an explanation of the risks involved
- are confused and unable to comply with instructions, or unable to communicate and whose safety might be compromised
- have a marked uncontrolled tremor
- have a medical condition severe enough to limit acceptable positioning
- are young - the age below which the clinician or patient prefers GA will be influenced by personal preference and the culture of both parties
- have previously experienced a severe reaction, allergy or other complication to local anaesthesia

Pre-operative fasting is necessary for general anaesthesia only and should follow set protocols established locally. Water can usually be taken until an hour before surgery. Patients should be instructed to take all their usual medication except for oral hypoglycaemic agents.

6.5 Local anaesthesia (LA)

With the advent of small incision techniques using phacoemulsification there is no longer a need for complete akinesia, ocular hypotony or absence of lid movement and many would regard the only goal of local anaesthesia to be pain-free surgery. This may be adequately achieved by most local anaesthetic techniques including topical anaesthesia in many patients. The main disadvantage of topical anaesthesia is the increased surgical difficulty in the absence of akinesia, and the possible need to augment the anaesthesia in the event of intra-operative complications.

The goal of LA for intraocular surgery is to:

- provide pain-free surgery
- minimise the risk of systemic complications
- facilitate the surgical procedure
- reduce the risk of surgical complications

6.5.1 Local anaesthetic techniques

Local anaesthesia for cataract surgery is administered either by injection or topical application to the conjunctiva. There are many techniques of local anaesthesia and practice varies widely throughout the world^{9,11} and within the U.K.²

The following techniques are used:

- Topical anaesthesia, alone, or in conjunction with preservative-free intracameral local anaesthetic
- Subconjunctival anaesthesia
- Sub-Tenon's anaesthesia

- Peribulbar (extracone) anaesthesia
- Retrobulbar (intracone) anaesthesia

All forms of cataract surgery with local anaesthesia demand significant patient co-operation throughout the procedure. Co-operation is most important when procedures are performed with topical anaesthesia.

Patients being operated upon by this technique should be able to tolerate instruments approaching the eye without anxiety or blepharospasm. This can be gauged pre-operatively. A separate VIIth nerve block is not generally recommended.

Patients undergoing all forms of anaesthesia require adequate counselling and explanation of the procedure. It is unnecessary to fast patients for local anaesthetic cataract surgery.

6.5.2 Minimising complications

There are two critical issues in the debate about minimising complications associated with LA injection: needle length and technique. Absolute distinction between peribulbar and retrobulbar injection cannot always be made, but complications of both are reduced by using a short (25-31 mm) needle.¹² It follows that longer needles are associated with a higher risk of complications.

Although ocular perforation has been reported with an intended sub-Tenon's anaesthetic (STLA) (the perforation occurred during the preparatory dissection in a patient with previous retinal detachment surgery¹³), it is generally accepted that the risk of true perforation is much lower in blunt-cannula STLA than in needle local techniques. Needle anaesthesia should be avoided where possible in the high myopes.

B Systemic adverse events have been reported in all forms of local anaesthesia including topical.^{2b}

6.5.3 Choice of local anaesthetic technique

In deciding which type of anaesthesia to use, the following factors should be considered.

PATIENT FACTORS

All forms of cataract surgery with local anaesthesia require significant patient co-operation throughout the procedure. Thus, patient preference, anxiety and ability to co-operate should all be taken into account.

- LA is the procedure of choice for the majority of patients, provided co-operation can be assured.
- The patient's ability to tolerate manipulation around the eye without blepharospasm should have been gauged at the pre-operative assessment
- The experience of the anaesthetist (an inexperienced practitioner is likely to do less damage with a blunt cannula than with a sharp needle)

SURGICAL FACTORS

- The type and size of incision
- Axial length
- The risk of complications

- Duration of the operation
- The experience of the surgeon

6.5.4 Who Should Administer LA?

Local anaesthetic injections should only be performed by anaesthetists or ophthalmologists who have been trained appropriately. Nurses, technicians and others may be trained to administer topical, or subconjunctival or sub-Tenon's anaesthesia. In some centres, nurses have been trained to administer sub-Tenon's blocks, but the administration by these professionals of peribulbar or retrobulbar injections is not recommended.

6.6 Sedation for ocular anaesthesia

Ideally, the patient undergoing cataract surgery under local anaesthesia should be fully conscious, responsive, and free from anxiety, discomfort and pain. For most this can be achieved by sensitive and personalised assessment and counselling, with support throughout the operation and verbal reassurance. This is greatly facilitated by continuity of staff care at all pre-operative stages. However a few patients require sedation (6% in 1996).^{2a}

Intravenous sedation should only be administered under the supervision of an anaesthetist, whose sole responsibility is to that list

- Good rapport, counselling, support and the use of relatively painless techniques all reduce the need for sedation
- Sedation should only be used to allay anxiety and not to cover inadequate blocks, which must be corrected by the administration of more local anaesthesia

6.7 Monitoring

Severe systemic complications are a well known, albeit rare complication of cataract surgery and have been associated with all LA techniques. The patient should be assured that they will be carefully monitored.

6.7.1 Methods of Monitoring

Continuous monitoring of ventilation and circulation is essential, both by clinical observations, and by pulse oximetry. Monitoring should commence just prior to the administration of local anaesthesia and continue until the surgical procedure is ended. The level of monitoring required during local anaesthesia will depend upon the anaesthetic technique and the medical condition of the patient.

Monitoring should be the role of a member of the staff who remains with the patient throughout the monitoring period and whose sole responsibility is to the patient. This person is trained to detect and act on any adverse events, and may be an anaesthetist, nurse, operating Department Practitioner (ODP), Assistant (ODA) or anaesthetic nurse as long as they are trained in basic life support (BLS)

- All theatre personnel should participate in regular Basic Life Support (BLS) training, and there should always be at least one person present who has Intermediate (ILS) or Advanced Life Support (ALS) Training or an equivalent qualification.

6.7.2 Level of monitoring required during cataract surgery under LA

- Communication with attendant

Probably the single most important monitor - an individual whose sole responsibility is to remain in contact with the patient and who is trained to detect and act (or alert someone more senior) on any adverse event

- Clinical observations

Monitor the patient's colour, responses to surgical stimulus, ventilatory movements and palpation of the pulse

- Pulse oximetry

To detect cardiac and respiratory problems promptly

- IV access

Essential if peribulbar or retrobulbar techniques are employed or intravenous sedation is used

6.7.3 Level of staffing required during cataract surgery under LA

- The method of anaesthesia and local staffing availability will dictate whether an anaesthetist can be provided for all ophthalmic lists. An anaesthetist is not essential when topical, subconjunctival or blunt-cannula sub-Tenon's techniques without sedation are used
- An anaesthetist should be present if retrobulbar, peribulbar and sharp-needle sub-Tenon's techniques are used
- In the absence of an anaesthetist, the hospital, trust or treatment centre is responsible for ensuring that someone in the operating theatre is trained to perform cardiopulmonary resuscitation
- Intravenous sedation should only be administered under the supervision of an anaesthetist, whose sole responsibility is to that list

6.8 Facilities

All intraocular surgery performed under LA should be carried out in a facility which is appropriately equipped and staffed for resuscitation. Oxygen and suction must be available. Patients should be on a tipping trolley or equivalent chair.

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7 Biometry

7.1 The aim of biometry

- Biometry is an essential step before cataract surgery
- The purpose of biometry is to enable the selection of the correct lens implant to meet the refractive needs of an individual patient.



The refractive aims of cataract surgery should be discussed with the patient in terms of their requirements, expectations, what is achievable and what is available.

7.2 Biometric components

The basic parameters of biometry are:

- axial length of the eye (AL) measured by ultrasound or optical biometry
- central corneal curvature measurements (K1 and K2)
- corneal topography

7.3 Logistical issues

- i) who should perform biometry ?
- ii) where should it be done ?
- iii) when should it be done ?
- iv) with what equipment ?
- v) with which formulae ?

7.4 Who should do biometry ?

Biometry is a highly skilled process, the results of which are crucial to the success of the operation. The service may be provided by a number of suitably trained professionals (ophthalmologists, ophthalmic technicians, nurses and optometrists) according to local arrangements. It is essential that these investigations are carried out in a consistent manner to allow for predictable results.

Ophthalmologists in training should learn to perform and be familiar with biometry, but it is not appropriate for them to provide a routine biometry service.

7.5 Where should it be done ?

To maintain consistency and predictability, the equipment used should be standardised as much as possible. Therefore a relatively small number of technicians and equipment should be used on as few sites as possible.

7.6 When should it be done ?

Sufficiently in advance of surgery to allow for adequate discussion between patient and surgeon of the refractive aims. This would also allow time to order appropriate intraocular lenses (IOLs).

7.7 With what equipment ?

There are two components to this investigation: axial length measurement by A-scan ultrasound or laser interferometry and corneal curvature measurement by keratometer or corneal topography. It is the responsibility of each unit to ensure that these instruments are regularly serviced and calibrated and operated in accordance with the manufacturers' instruction manual.

Both eyes should be measured even if unilateral surgery is planned to allow for cross-checking. Similarly focimetry should be carried out or the latest copy of the patient's refraction cross referenced with the biometry results, taking into account the effect of cataract on refraction.

The biometry printout should be kept in the patient's notes and be clearly marked with the patient's name, hospital number, and date of birth in full.

a) Axial Length

i) Optical: This method has been shown to be as accurate as acoustic methods and has the advantage of being non-contact. It cannot be used for dense cataracts.

ii) Acoustic: This method can be used for all types of cataracts but is more user dependant for accuracy. Immersion techniques (with a Praeger shell) are said to offer greater accuracy.

The measurement parameters are different for these methods and therefore there may be different A constants for the same lens for each of these systems.

b) Keratometry

i) Manual using a Javal-Schiotz keratometer.

ii) Automated

iii) Hand-held automated

Whichever method is used, an average of 3 readings should be taken including the axes. Corneal topography is a desirable, but not essential component, of the pre-assessment unless it is intended to carry out limbal relaxing incisions.

7.8 Biometric data

- 96% of axial lengths fall within the range 21.0 to 25.5 mm and for 60% this is between 22.5 and 24.5 mm^{1,2}
- 98% K-readings fall within the range 40 to 48D and for 68% this is between 42 and 45D²
- In the absence of pathology that might affect eye size (e.g. unilateral refractive error, coloboma or staphyloma), most individuals have similar axial lengths in each eye
- Most corneas are relatively regularly curved and similar between the two eyes of one individual
- An interocular difference in axial length of more than 0.3mm or K readings which vary by more than one dioptre requires confirmation. These results should only be accepted when repeated measurements show consistent results
- When there are large differences between the K readings and/or axial lengths, consider the possibility of amblyopia or vitreous opacities such as asteroid hyalosis. An amblyopic eye may have been forgotten by the patient and may not be corrected in the current spectacle prescription.
- For highly myopic eyes (axial > 28mm) a B-scan should be carried out to determine the presence or otherwise of staphylomata.

7.9 Formulae

There are a number of options:

- In a review of 900 eyes comparing SRK I, SRK II, SRK/T, Holladay, Hoffer and Binkhorst II formulae, the SRK/T and Holladay formulae worked best overall³
- In a further study of 450 eyes, comparing regression and theoretical formulae in 1993, SRK I and II were found to be least accurate. They are regarded as obsolete and should not be in use⁴
- In the same study, no statistical difference was found between SRK/T, Hoffer Q and the Holladay formulae.



The SRK T is regarded as a very good general formula. If Hoffer Q is used the appropriate constants should be checked and used.

Axial length (mm)	Formula
< 22 mm	Hoffer Q or SRK/T
22 – 24.5 mm	SRK/T or Holladay, Haigis
> 24.6 mm	SRK/T

7.10 Audit considerations



The accuracy of the biometry should be continuously audited by comparing the expected spherical equivalent with the achieved spherical equivalent.

Each surgeon should attempt to personalise the A-constant, however it may be more appropriate to do this on a departmental basis. This requires standardisation of the techniques used in a department, with a minimum number of technicians. The technician and equipment set used should be identifiable and recorded on the printout.

7.11 Inability to obtain reliable biometric data

Sometimes ocular pathology precludes obtaining accurate biometric data. At this juncture:

- Ask about previous refractive surgical procedures
- Perform a full ophthalmic examination including objective and subjective refraction of each eye
- Compare ultrasound or keratometric data from each eye
- Obtain and review the patient's refractive history backed up by reports from his / her optometrist

Where measurements are not available or are incomplete, an informed choice based on the available information should be made. The fellow eye's biometry can be helpful.

7.12 Unexpected post-operative results

If a patient has an unexpected refractive result after a cataract operation, firstly check the spherical equivalent, which may be closer to the intended spherical equivalent than is at first apparent. Then, check the pre-operative prediction, the lens type and its A-constant and the pre and post-operative AC depth to establish where the lens is positioned.

If the power of the implant is incorrect, the following options can be considered:

- Leave the lens in situ if the patient can tolerate this refraction
- Contact lens over-correction
- Intraocular lens implant exchange based on refraction (the ophthalmologist should be aware of possible labelling errors of the original IOL packaging which could confound this option)
- Insertion of a corrective additional intra-ocular lens
- Corneal refractive surgery

If the other eye requires cataract surgery, consideration should then be given to the power of lens to be inserted into the second eye, recognising the importance of avoiding symptomatic aniseikonia. Any further surgery needs to be discussed in detail with the patient.

7.14 Post Laser Refractive Surgery Lens Power calculations

Corneal refractive surgery alters the relationship between anterior and posterior corneal curvature and therefore renders inappropriate the assumptions made in keratometry. As a result there is an unpredictable undercorrection of the corneal power resulting in a hyperopic surprise after cataract surgery.

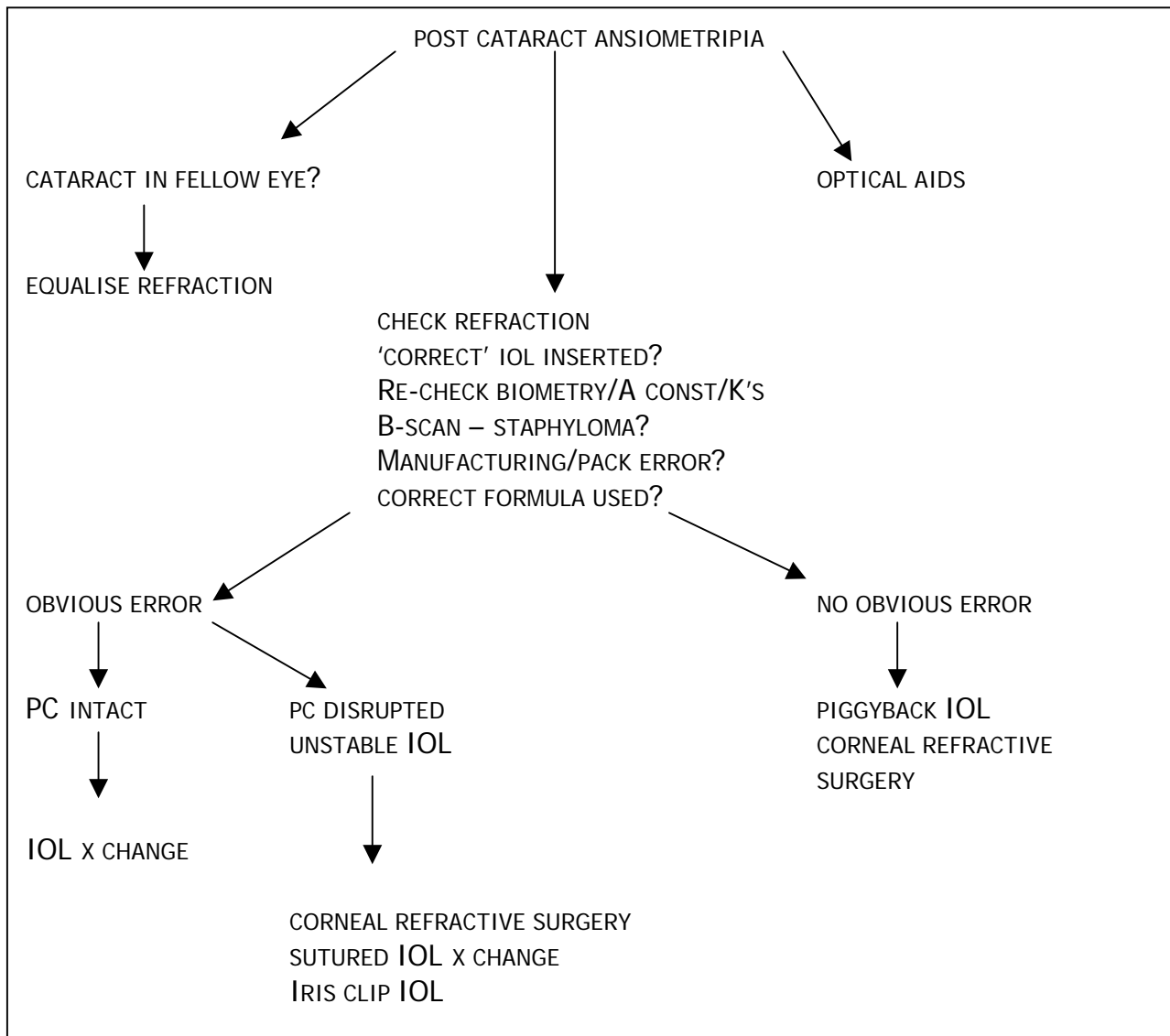
The patient needs to be advised of these problems both prior to refractive and cataract surgery.

Methods of correcting Keratometry:

- a) Clinical History Method
Pre-laser K - Refractive error change at 6 months = Corrected K
- b) Contact Lens Method
HCL base curve 40D
Refraction with CL X
Refraction without CL Y
Corrected K = 40 + (X-Y)

The corrected Ks should be entered into the SRK-T, Haigis, Hoffer Q and Holladay 2 formulae and the highest IOL power used.

7.13 Algorithm for the management of pseudophakic ametropia



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8. Factors affecting the Choice of Intraocular Lens (IOLs)

8.1 General

All intraocular lenses have their individual 'pros and cons' and there is no 'best buy'. Quality, track record, the supplier's ability to service a lens bank and provide the required range of dioptric powers and cost must all be considered. Recent problems due to opacification of IOLs are well documented by the Medicines and Healthcare Regulatory Agency (MHRA) www.mhra.gov.uk

Surgeons should have available suitable IOL models and powers not only for routine 'in the bag' surgery but also to cover unexpected situations such as the need for sulcus or anterior chamber fixation. Special powers or models of IOL may be required for particular patients or situations and these need to be ordered in advance.

IOL technology is a continually developing field and some of the factors to be considered in the choice of IOL include:

8.2 Incision size

Many of the advantages of phacoemulsification surgery lie in the reduced incision size and routine phaco surgery requires a foldable IOL.

8.3 Method of insertion

The method of folding is a matter of choice for the individual surgeon. There is a trend to injectable IOLs which have advantages of predictable incision size, speed and ease of insertion, less damage to the IOL and possible reduced risk of bacterial endophthalmitis.¹ Unfolding of the IOL from any delivery system should be controlled so that the bag is not damaged in the process and the incision should be sufficiently large to prevent tissue damage.

8.4 Optic size

Lens optics vary in diameter.

B At present there is a trend to larger optics (6mm+) as these are less centration dependent, have fewer dysphotopic symptoms in patients with large pupils or under mydriatic conditions and lower rates of posterior capsule opacification (PCO).²

Conversely these factors need to be weighed against the possible requirement of a larger incision size with some IOLs.

8.5 IOL materials

IOLs are at present manufactured from either silicone or acrylic polymers. All IOL materials can be classified by their hydrophilic or hydrophobic nature. These terms are relative. IOL biocompatibility can be divided into uveal (inflammatory cell attachment) or capsular (anterior capsular fibrosis, PCO). Each polymer appears to have its own biocompatibility profile. Hydrophilic materials are generally considered to have a better uveal biocompatibility profile (lower inflammatory cell attachment) in comparison to hydrophobic materials but the latter with present IOL designs, may have a better performance in preventing PCO.^{3,4} Newer hydrophilic IOL designs are available and it remains to be seen whether these have a comparable PCO performance.

Pseudophakic patients have an increased risk of AMD.⁵ A recent development has been the introduction of IOLs which filter out short wavelength blue light and there is some early experimental evidence that these could retard age related macular changes. Their effect on scotopic vision remains controversial.⁶

B

Square edge optic profile has been shown to be an important factor in preventing PCO⁷ but this can be at the expense of increased dysphotopic symptoms: most manufacturers now engineer the edge profile to minimise such symptoms.

8.6 Haptics

Haptic size needs to be appropriate for bag fixation without causing posterior capsular folds as these can cause symptoms from scattering of light or PCO.⁸ An appropriate IOL with a larger haptic is required for sulcus fixation.

8.7 Other Design Considerations

There is much new development in IOL design such as multifocality, pseudophakic accommodative lenses, toric IOLs for correction of pre existing astigmatism and correction of spherical aberration. The precise role of these in routine clinical practice remains to be defined.

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9 Posterior Capsule Opacification (PCO)

9.1 Introduction

In spite of advances in IOL design PCO remains the commonest complication of cataract surgery. It is caused by residual lens epithelial cells (LECs) which are inevitably left behind after surgery and is essentially a wound healing response of the lens to surgery. With time the residual LECs proliferate to form Elschnig's pearls or undergo metaplasia to myofibroblasts. These can migrate to obscure the visual axis or cause fibrosis of the capsule potentially causing IOL decentration.

9.2 Pathogenesis

PCO is a multi-factorial problem and is related to patient factors (e.g. age, concurrent ocular disease such as uveitis, retinitis pigmentosa), surgical factors and IOL design features. The latter have received most attention in recent years.

B It has been shown that IOLs with a square edge profile inhibit LEC migration on to the posterior capsule.

Other design features such as large optic diameter, posterior flexion of the haptics, prevention of posterior capsular folds by flexible haptics and possibly IOL material are all additional important features.^{1,2,3}

B Many clinical studies have shown that PCO is reduced if the anterior capsulorhexis lies completely on the anterior IOL surface

This compresses the IOL against the posterior capsule producing a mechanical barrier to LEC migration, no matter what type of IOL is used.^{4,5} Polishing the anterior or posterior capsule to remove LECS at surgery has not been shown to prevent future PCO.

B With improvement in IOL design and surgical technique laser capsulotomy rates have fallen from 30-50% to less than 10% at 2 years post-operatively⁶.

✓ Because patients are discharged soon after surgery it is essential to warn them that posterior capsular opacification can occur and to seek advice if their vision deteriorates.

PCO is a particular problem in paediatric cataract surgery which has implications for surgical technique and follow up.

9.3 Indications for Treatment of PCO.

The indication for treatment is the presence of visual symptoms in the presence of PCO on slit lamp examination. Most adult patients present with PCO within 2 years of their operation but a few can present many years later. Symptoms are more important than tests of visual function: severity of PCO correlates poorly with high contrast visual acuity.⁷ Blurred vision, glare, dysphotopsia and reduced contrast in the presence of PCO on slit lamp examination are common symptoms. Symptoms may be more noticeable in bright light or conversely at night with driving or other mydriatic circumstances.

9.4 Treatment

PCO is most commonly treated by Yag laser capsulotomy. In rare circumstances surgical removal may be required.

The posterior capsule should be opened sufficiently to clear the visual axis to the patient's largest physiological mydriatic pupil diameter. Minimum laser energy should be used and care should be taken to avoid pitting the IOL. In some units treatment is performed by appropriately trained paramedical staff. Laser capsulotomy may be followed by an IOP pressure spike within the first few hours. This may not be clinically important in healthy eyes but can potentially damage the optic disc in eyes with glaucoma. Many surgeons prefer to routinely give all patients a hypotensive agent immediately after treatment.

9.5 Complications of Treatment

Laser capsulotomy can be occasionally followed by raised IOP, cystoid macular oedema, subluxation or dislocation of the IOL, intraocular inflammation or endophthalmitis from release of loculated bacteria in the capsule or retinal detachment.^{8,9,10,11} For these reasons, and to check resolution of symptoms, some surgeons like their patient to be checked 1-2 weeks after treatment. This can be delegated to appropriately trained paramedical staff. If the patient is not seen post treatment an advice sheet should be provided. The incidence of cystoid macula oedema is thought to be reduced if capsulotomy is postponed to 3 months after surgery but this may depend on the clinical circumstances.

Retinal detachment (RD) is of particular concern in high myopes.¹² Consideration should be given to these patients having an IOL implanted at surgery with a proven low PCO rate. Prophylactic treatment of pre-existing retinal pathology has not been proven to reduce the risk of RD. It is therefore important to warn these patients of the symptoms of RD and encourage them to report urgently should they develop.

9.6 Posterior capsular opacification (PCO) references

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10 Patient information and consent

10.1 Introduction

'Consent' is a patient's agreement for a health professional to provide care. Patients may indicate consent non-verbally, orally, or in writing. For the consent to be valid, the patient must be competent to take the particular decision, have received sufficient information to take it and not be acting under duress. The NHS Plan has led to recent changes in the way patients are asked to give their consent to treatment, so protecting the fundamental legal and ethical right for patients to determine their own healthcare.

Consent can take many different forms depending on context. In some cases, the health professional will suggest a particular form of treatment (such as cataract surgery to improve vision) and after discussion the patient may agree to accept it. In others there may be a number of ways of treating a condition (for example cataract extraction or drops to help intraocular pressure control), and the health professional will help the patient to decide between them. Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, no-one else can give consent on their behalf. However, treatment may be given if it is in their best interests, as long as it has not been refused in advance in a valid and applicable advance directive. In this case Consent Form 4 should be completed (see below).

10.2 Written consent

Consent is often wrongly equated with a patient's signature on a consent form. If a patient is rushed into signing a form agreeing to cataract surgery on the basis of too little information, the consent may not be valid, despite the signature. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. Patients may also withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract.

It is rarely a legal requirement to seek written consent but it is good practice to do so, especially if the cataract operation is complex or involves significant risks; the term 'risk' properly refers to any adverse outcome, including those which some health professionals would describe as 'side-effects' or 'complications'. There is no statistical 'threshold' for complications, below which it is not necessary to discuss the possibility of their occurrence with the patient; case law determines whether consent was truly informed.

10.3 Consent forms

Both consent forms and consent policy should be consistent and recognisable across the NHS. There are four standard model forms for consent to treatment that have recently been developed by the Department of Health:

- Consent Form 1: for patients able to consent for themselves
- Consent Form 2: for those with parental responsibility, consenting on behalf of a child or young person
- Consent Form 3: both for patients able to consent for themselves and for those with parental responsibility consenting on behalf of a child/young person, where the procedure does not involve any impairment of consciousness. The use of this form is optional.
- Consent Form 4: for use where the patient is an adult unable to consent to investigation or treatment.

Consent form 1 is designed in the form of a 4-page booklet with the crucial information for patients on the facing inside pages. This may, however, be reduced to 2 sides of a single sheet by making the guidance notes on the back available to health professionals in another way, clearly referenced and readily accessible.

An example of such an amended form 1 in use in one trust, is available as Appendix A. An amended form 1 based on national and local audits might be of use in some trusts.

The standard consent form text should not be amended, nor any section removed. However, it may be appropriate to customise the documentation by adding material relevant to local circumstances, as long as this does not result in forms becoming too unwieldy or in the font size being reduced inappropriately.



Relevant sections of the forms such as those dealing with benefits and risks may be pre-printed; this is particularly relevant and feasible for high throughput cataract surgery.

Whatever the format used, a copy of the page documenting the details of the treatment should be offered to the patient, for example through the use of 'no carbon required' (NCR) copies. Furthermore, the text for patients 'About the consent form' as well as details of the procedure and its associated benefits and risks, should be made available to patients in advance of their being asked to sign a consent form.

The consent form is available online in portable document format at www.dh.gov.uk

10.4 Patient information

The provision of information understandable to patients is central to the consent process.



All patients should be provided with information on cataract surgery, counselled on their expected treatment, and allowed time to consider the need for an operation.

A suggested draft of 'Information for Patients - Consent for cataract surgery' may be found in Appendix B.

Before patients can come to an informed decision about treatment, they also need comprehensible information about the associated risks and benefits of cataract surgery (including the consequences of not having surgery) put into context using accurate evidence-based data. This information is readily available for cataract surgery and it is a simple matter to provide a list of the most common complications with the approximate probability of their occurrence. A working example of such a list is incorporated into a pre-printed consent form in Appendix A.

Other information that patients should be given includes:

- The name of the doctor who will have overall responsibility for the treatment and, where appropriate, names and grades of other members of the team
- Whether doctors in training will be involved in the surgery
- Whether additional procedures are likely to be necessary as part of the procedure
- A reminder that patients can change their minds about a decision at any time, or ask for a second opinion

Once a decision to have a particular treatment has been made, patients need further information about what will happen: where to go, how long they will be in hospital, what drops to put in the eye and for how long, how they will feel afterwards and so on. Patients vary in how much information they want, but the presumption must be that the patient wishes to be well informed about the risks and benefits of cataract extraction. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

Other considerations for consent include:

- Language and communication needs, for example through translations, interpreters (link workers), signers, or the patient's representative
- Involvement of nursing and other healthcare staff in discussions with the patient, where appropriate

- Allowing sufficient time for patients to reflect, before and after making a decision about surgery, especially where the information is complex or the severity of risk is high. Patients should have time to consider the options and ask questions. The timing of the process of taking consent varies considerably, and is a matter of personal preference having taken into account the above considerations.
- The patient must be aware that there is a chance of the vision being worse after a cataract operation and indeed that there is a very small chance of blindness
- The patient should be given a realistic idea of the expected visual result and a careful explanation of the relevance of co-existing pathology and the limitations of biometry, especially in extreme refractive situations
- After dilating drops have been instilled the vision will be blurred, so the patient may not be able to read the patient information literature, nor the consent form. This can be addressed by giving them the information before their appointment, on the day of their appointment before pupillary dilatation, or by having the information read to them.

10.5 Taking Consent

GMC guidelines make it clear that the person taking consent does not have to be the person who will carry out the surgery, nor does it have to be someone who is capable of undertaking the procedure. The person must, however, be someone who is familiar with cataracts and cataract surgery who has been trained to communicate effectively and to take patient's consent, and whose professional practice is audited. It is the surgeon's responsibility to ensure that before any treatment is started, the patient has been given appropriate information, and that valid informed consent to surgery has been obtained and documented.

10.6 Patient information and consent references

Department of Health

<http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Consent/fs/en>

British Medical Association

<http://www.bma.org.uk/ap.nsf/Content/consenttk2?OpenDocument&Highlight=2,consent>

11 Outcomes and complications

11.1 Introduction

Cataract surgery is widely perceived to be a safe and successful procedure. This is so in the large majority of cases, but complications can occur at every stage and visual results may not reach patient expectations.

Many studies have reported the complications and results of cataract surgery. Powe et al¹ summarised the literature of 90 studies between 1979 and 1991. The UK National Cataract Survey collated information on 19,000 cataracts in 1997/8.² The Swedish National Cataract Register continues to provide useful information³ as will other national databases such as the National Eyecare Outcomes Network (NEON)⁴ in the USA and the International Cataract Surgery Outcomes Study⁵. A more recent survey of cataract has been completed in eight Eye Units in the UK⁶.

11.2 Outcomes

The visual performance of the eye is characterised in five major areas – high contrast acuity (e.g. Snellen), contrast sensitivity, glare disability, visual field and colour vision.⁷ Most reports on the outcome of cataract surgery assess high contrast acuity only. This measure remains important in the assessment of eligibility to drive, enter many uniformed services and for vision impairment certification. Increasingly, results of patient experience are being reported. Patients may find no benefit from surgery despite an improvement in visual acuity, mostly as a result of anisometropia or disturbance from the fellow eye.³

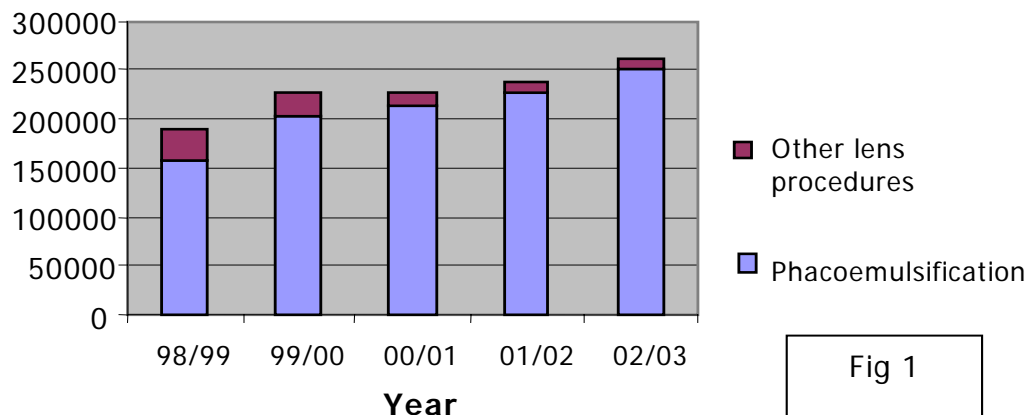
11.3 Visual acuity

The indications for cataract surgery have changed progressively, particularly over the last decade. Only 27% of eyes saw 6/12 or better pre-operatively in the 1997/8 study² compared with 45% in the recent survey.⁶ This loosening of the indications for surgery has correlated with the rise in small incision phacoemulsification as the operation of choice. During the 2002-2003 year 97% of all cataract surgery in England was done this way.⁸

The potential for visual acuity benefit is therefore now less than before. There is now more emphasis on improving unaided visual acuity by correcting associated astigmatism, and reducing the dependence on glasses.⁹

✓ Standard high contrast Snellen acuity is insufficient to gauge patient satisfaction – standardised questionnaires give valuable extra information.

Number of cataract operations in England 1998-2003



The average age at surgery has not risen significantly over the last 5 year⁶ but the rise in overall numbers means that many more patients of advanced age are being done. The presence of more ocular co-morbidity, particularly age-related macular degeneration does limit visual prognosis in this group.¹⁰

Second eyes surgery is now the norm and the subjective visual benefit from this is well established.^{11,12}

Table 1 – Results of cataract surgery

		UK NCS	ICSOS	NEON	S NCR	UK EPR AUDIT
Number		15 787	1073	7626	400 000	16 541
Age (mean)		76.5	72	72.9	76.1	76.1
Male:female		35:65	36:64	38:62	34:66	37:63
% phaco		77	51	92.3	98	99.9
Pre-operative BCVA		27% 6/12 or better	Mean acuity 6/36	Mean acuity 6/18	31% 6/60 or worse	45% 6/12 or better
Post – operative BCVA *	All patients	86% 6/12 or better at final refraction	86% 6/12 or better (mean 6/9)	Mean acuity 6/7.5	84% 6/12 or better	92% 6/12 or better
	With ocular co-morbidities	77% 6/12 or better		Mean acuity 6/7.5	72% 6/12 or better	78% 6/12 or better
	Without ocular co-morbidities	92% 6/12 or better		Mean acuity 6/6	95% 6/12 or better	96% 6/12 or better
Ocular co-morbidity	ARMD	17.7	2	17		5.8*
	Glaucoma	11.6		11		3.3*
	Diabetic retinopathy	3.2		5		1.2*
	Amblyopia	1.4				0.9*
	Total	41.3	21	44		15*

UK NCS UK National cataract survey (Desai 99)

ICSOS International Cataract Surgery Outcomes Study

NEON National Eyecare Outcomes Network

S NCR Swedish National Cataract Register

UK EPR AUDIT UK 8 Centre Electronic Audit 2002-2003 (Personal communication RL Johnston)

* Co-pathology (but only when considered a reason for a guarded visual prognosis)

11.4 Astigmatism

Surgically induced astigmatism can be minimised by small incisions and careful wound design and placement. Induced astigmatism averaged 0.55 dioptres in the Swedish Cataract Register.³

11.5 Refractive error

Accurate biometry, correct use of lens power formulas and an understanding of patient requirements are central to choosing the correct lens (chapter 7). A recent survey showed that only 4% of UK eye departments were implementing the Royal College of Ophthalmologists biometry guidelines in full and few surgeons were regularly customising A constants.¹³ The percentage of patients with a post-operative refraction of predicted \pm 1.00 dioptre improves from 72%¹⁴ to 97%¹⁵ when these two steps are taken.

11.6 Self reported outcomes

A variety of self reported outcomes have been used to judge the morbidity and treatment benefits of cataract surgery.^{4,11,16} Self reported improvements in function have confirmed that cataract surgery is generally well received and provides the intended benefits. Subgroup analysis of 10,675 patients using 'Catquest' within the Swedish National Register show that 84% of patients perceived a benefit from surgery, 7% perceived no change and 9% reported increased difficulty in performing daily life activities 6 months after surgery. Pre-operative visually significant ocular co-morbidity was the most important predictor of a poor subjective outcome. Older age was not in itself a predictor of poor outcome unless associated with ocular co-morbidity. Second eye surgery in younger people was associated with the greatest benefit.³ Initial reports from the American Academy of Ophthalmology National Eye care Outcomes Network (NEON) Cataract Surgery Database indicated broadly similar results on a subgroup of 2,600 patients. In this study 95% were satisfied with the results of their surgery with large average improvements in self reported VF-14 and Cataract Symptom Scores.⁴

11.7 Complications

Complications and errors may manifest at any stage of the patient's journey. Some are detailed in Table 2.

Table 2 Possible complications and errors in cataract surgery

	Pre-operative	Operative	Post-operative
Incision	Wrong site	Perforation	Wound leak
		Descemet's detachment	Wound dehiscence
		Thermal burns	
Cornea	Missed endothelial pathology		Astigmatism
			Oedema / bullous keratopathy
Anterior segment		Haemorrhage	Pressure rise
			Endophthalmitis
Capsule		Radial tears of anterior capsule	Capsule block syndrome
		Rhexis too small	Late tear with IOL posterior dislocation
		Rupture with hydrodissection	Posterior capsule opacification
		Rupture during phaco	
Zonules	Missed phacodonesis	Subluxation	IOL / bag decentration
	Missed lens subluxation	Dislocation	Sunset syndrome
Nucleus		Trapped nucleus (non-rotating)	
		Subluxation	
		Dropped nucleus	
Iris		Prolapse	Pupil capture
		Phaco damage	Epithelial ingrowth
IOL	Wrong power calculation	Damage during insertion	Opacification
		Incorrect positioning	Inflammation
Retina / vitreous		Incarceration in the section	Cystoid macular oedema
		Retinal tear	Retinal detachment
		Choroidal Haemorrhage	

Table 3 – Per and post operative adverse affects in percentages

	UK NCS	AAO PPP		UK EPR AUDIT
	77% Phako	All surgery	Phaco only	99.9% Phaco
Endophthalmitis	0.03	0.13	0.74	0.06
Bullous keratopathy		0.3	0.3	
Clinical CME		1.4	2.3	0.6
Retinal detachment		0.7	0.93	0.02
Wound gape / iris prolapse	0.25	0.6	0.2	0.06
Anterior chamber haemorrhage	0.5	0.5	0.4	0.09
Hypopyon	0.02	0.2	2.0	0.06
Iris trauma	0.7	1.3	0.7	0.68
Zonular / posterior capsule rupture	4.4	3.1	1.8	2.68
Vitreous loss		0.8	0.24	1.35
Vitreous haemorrhage		0.3		0.00
Choroidal haemorrhage	0.1	0.3		0.10
Uveitis	5.6	1.8	3.1	2.40
Raised IOP (angle closure)	7.9	0.2	1.0	
Raised IOP (open angle)		1.2	1.0	0.28

UK NCS UK National Cataract Survey (Desai 99)

AAO PPP American Academy of Ophthalmology Preferred Practice Pattern (AAO 01)

UK EPR AUDIT UK 8 Centre Electronic Audit 2002-2003 (Personal communication RL Johnston)

11.7 Capsule tear

Tearing of the posterior lens capsule remains one of the most common adverse surgical events. The incidence during phacoemulsification varies from 0.7% to 16%¹⁸, being higher with less experienced surgeons. Senior surgeons converting to phacoemulsification had rates from 4.8% to 11%. The visual results after capsule tear are not as good as uncomplicated surgery – in one study 87% achieved 6/12 or better. Poor vision in the rest was mostly because of cystoid macular oedema.¹⁹

11.8 Cystoid Macular oedema

The overall incidence of cystoid macular oedema remains around 1-2%. The rate is increased with many complications or pre-existing conditions including posterior capsule rupture, vitreous loss, iris incarceration, active uveitis, and diabetes.²⁰ After YAG laser capsulotomy it has been reported in 0.7% to 4.9% of eyes.²¹

11.9 Endophthalmitis

The 1998 Swedish national prospective survey reported on 58 cases in 54 666 cataract operations (0.1%).²² This equates with other series reported using modern microsurgical techniques. The incidence of presumed infectious ophthalmitis in the UK was recently estimated using the British Ophthalmological Surveillance Unit

reporting card system. Here 213 baseline cases in one year were reported giving a corrected estimated incidence of 0.14%.²³

11.10 Retinal detachment

The incidence of retinal detachment after phacoemulsification cataract surgery ranges from 0% to 3.6% and averages 0.7% in the literature.²⁴ The calculated excess risk of developing a retinal detachment after cataract surgery in the first 10 years over eyes without surgery is 5.5.²⁴ It is estimated that 94% of retinal detachments occurring in the first year after surgery are the result of the surgery.²⁵ The risk is increased by surgical complications – the excess risk of detachment after posterior capsule rupture over uncomplicated cataract surgery is estimated at 13 and after vitreous loss at 4.5 (5% at 4 years with anterior vitrectomy vs. 1.1% without).²⁴

Nd: YAG laser capsulotomy also increases the risk of retinal tears and detachment.^{21,24} The reported incidence of retinal detachment up to four years after treatment varies from 0% to 4.1% with an excess risk of detachment following YAG capsulotomy vs. no capsulotomy estimated at 3.9.

Outcomes and complications need to be judged with reference to comparators. The Royal College of Ophthalmologists is promoting the development of a Cataract National Dataset (see Appendix C for the current draft standard). There is too much information in this dataset for it to be collected by a paper-based system. The NHS National Program for Information Technology will ensure that most Eye Units will be using electronic Care Records within five years. The data needed for the CND may be abstracted from such electronic records. As more Eye Units contribute to the CND, benchmarking should improve.

11.11 Outcomes and complications references

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12 Training for cataract surgery

12.1 Introduction

It has been recognised in recent years that structured supervised training for all surgical specialities, and for ophthalmology in particular, is essential. The Royal College of Ophthalmologists has a microsurgical skills faculty, which delivers courses in microsurgical skills over a two day course. All trainees are required to attend the course within the first 4 months of their first substantive SHO post in the UK. Evidence of participation in the whole course is required to apply for the CEEHST. Exemption for experienced Surgeons from abroad can be sought from the chairman of the Surgical Skills Faculty.

Courses for Higher Surgical Trainees are being introduced in 2004 in line with the HST curriculum.

12.2 The need for training

There have been major changes in the way cataract surgery is delivered which have lead to unprecedented pressure to produce better results more quickly. These include:

- phacoemulsification being the preferred method of lens extraction
- earlier intervention
- increasing service pressure
- greater patient expectation
- an ageing population
- targets for maximum waiting lists
- Proposals to shorten the total training time

All these factors have increased demands on the service and highlighted the importance of training in order to prevent the exposure of patients to any additional risk.

12.3 Use of the wet lab

Modern cataract surgery not only involves delicate micro-manipulation under a microscope but also requires knowledge of the phacoemulsification machine. Surgeons should be fully cognisant of the surgical techniques and the phaco-dynamics of the machine. Frequent use of a wet lab is probably the best way to get this experience. Various practice eyes are available and it is recommended that beginners should attend one of the many courses held nationally. The Royal College of Ophthalmologists runs regular courses on basic phacoemulsification in its new skills centre. Time taken to learn how to use the phacoemulsifier in the wet lab will be repaid by faster and safer progress in the operating theatre.

Live surgery should not be attempted until the surgeon is completely familiar with the machinery. Instruction and supervision by an experienced phaco-surgeon is essential and invaluable when transferring these skills to the operating theatre. In the early stages the component steps of the operation may be learnt separately before the surgeon completes the whole procedure.

It is likely that in the future most hospitals will demand evidence of such structured training for any new surgical technique especially involving new apparatus. This should be seen as part of post-graduate development and evidence of such training or re-training kept in a personal revalidation folder.

12.4 Delivering the training

Not every consultant wishes to be involved with training nor is every consultant a good trainer and regular structured training of junior doctors and even senior colleagues can be stressful.

12.5 Training 'contract'

It is vital, therefore, to enter into a 'training contract' with the trainee before entering the operating theatre. This can be in the form of a verbal agreement about what is expected, what the trainee should undertake, when the trainer will take over and how much time is allowed for training in a particular circumstance.

12.6 Operating lists

It is possible to organise operating lists into training lists and service lists or, as in some units, to allow a specific time (perhaps 40 minutes) during an operating list which is dedicated to structured training of junior doctors. This may be at the beginning of the list, or after a specified number of cases and everyone should be in agreement that the consultant or supervisor of the list will take over after the set time so that the list finishes on time; all the cases are done but everybody gets adequate exposure to surgery. It is the regular and frequent exposure to supervised training that will increase surgical speed, competence and confidence more than anything.

12.7 Local anaesthesia

Although general anaesthesia is probably the ideal type of anaesthetic for training, local anaesthetic is now much more commonly administered for cataract surgery and techniques should be developed for allowing training to go on without alarming the patient or the trainee during the procedure.



Agreement about specific phraseology used during surgery and understanding of the patient's perception of what is said and heard should be discussed before surgery starts. The patient should be made aware that junior Surgeons will be appropriately supervised so that they are only doing what they are capable of.

12.8 Training the trainers

All trainers who regularly have responsibility for delivering training should consider attending a course on how to train, such as 'Training the Trainers' held under the auspices of The Royal College of Surgeons of England, which imparts training methodology and information on how trainees learn. This is an invaluable way of making the best use of limited time for training.

12.9 Auditing the training

A continuous audit of cataract outcomes is important.



Complication rates should be monitored for each individual surgeon. A good way of performing continuous audit is to video every case especially for the trainees so that specific points can be reviewed and discussed. Time needs to be set aside for this to be done in a structured way.

12.10 Summary

Regular, frequent supervised training for cataract surgery involves teamwork and discussion before the operating theatre is even entered. Outlining what the trainee can expect before the surgery starts is a good way of relieving the pressure on the trainer whilst the list is proceeding and, with the additional use of a wet lab out of the theatre environment, training time should be shortened considerably.

12.11 Summary points

- There should be a commitment to both the culture and practice of training
- Regular use of a 'wet lab' is beneficial
- Trainees must be supervised by an experienced surgeon
- Training should be structured (i.e. modular) and planned
- Patients should be aware that a trainee may be operating upon them but also be reassured that a trainee will not be allowed to operate unless they are safe.
- Complications may still occur but will be less likely as trainees will have a basic set of skills and knowledge and will be supervised as appropriate.

13 Patient safety in cataract surgery

13.1 Safety in healthcare

Risk management has traditionally been the domain of reducing litigation for the defence of healthcare and other organisations. An emerging enlightened view is that a focus on patient safety as an organisational priority will enhance the quality of clinical care while reducing harm. The National Patient Safety Agency (NPSA) has been initiated in response to a growing awareness about errors in healthcare and this intensifying focus on patient safety. A patient safety incident is defined by the NPSA as any 'unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded healthcare'. This is also referred to as an adverse event/incident or clinical error, and includes near misses. Patient safety has been further defined as 'the process by which an organisation makes patient care safer. This should involve: risk assessment; the identification and management of patient-related risks; the reporting and analysis of incidents; and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring' All clinical interventions carry some risk. While there may be occasional poorly performing staff, most surgical errors are performed by well-trained, well-motivated individuals.¹ Improving the safety of surgical care systems is a multi-faceted task and requires multi-disciplinary and organisational commitment. Weak systems create the conditions for and the inevitability of error. Some national and international resources of relevance to patient safety are at Table 1.

Table 1 Patient safety resources.

National Patient Safety Agency	www.npsa.nhs.uk
Patient Safety Research Programme	www.publichealth.bham.ac.uk/psrp
Medicines and Healthcare products Regulatory Agency	www.mhra.gov.uk
Agency for Healthcare Quality and Research	www.ahcpr.gov
Institute for Healthcare Improvement	www.ihl.org
Australian Patient Safety Foundation	www.apsf.net.au

13.2 Think about risk

Consideration should be given to underlying causes leading to un-safe care. Efforts should be made to overcome or minimise these risks. Examples in cataract surgery might include:

- Clinical staff not relying on evidence-based medicine (e.g. not using povidone iodine pre-operative prophylaxis despite the evidence base)
- Lack of risk assessment which may be at an individual patient level, e.g. elective cataract surgery in the presence of active infection, or at organisational level such as lack of risk assessment for consequences of novel commissioning plans.
- Failure to collect patient outcomes. Lack of patient involvement and insufficient attention to patient complaints.
- Insufficient continuous professional development of cataract surgeons and healthcare personnel. Lack of team working and team training of the cataract surgical team.
- Staffing issues. Inappropriate staffing levels and lack of effective clinical leadership.² Lack of familiarity of staff with equipment. Poor staff orientation in unfamiliar environments. Lack of continuity of clinical care.
- Poor infrastructure and under-investment in ophthalmic facilities.

- Failure of timely and appropriate management of complications, including early referral to tertiary centres.
- Lack of integrated patient care pathways.
- Service pressures. Rushing, focus on targets and performance rather than on quality and safety. Interruptions and distractions during surgery. Last minute changes such as late changes to operating lists or un-expected admissions.
- Inappropriate case selection including unnecessary surgery. Inappropriate training and inadequate supervision of trainees. Stratification of surgical risk has been proposed to assist in patient selection for surgery for trainees.³
- Failure or non-availability of equipment including additional equipment that might be required for intra-operative complications e.g. ensure anterior vitrectomy equipment and alternative IOL types are available in advance.
- Poor written and verbal communication. This might include poor handwriting in case notes. Verbal communication issues may occur when the patient's or staff's first language is other than English or in patients with learning difficulties or with hearing impairments. Inadequate communication is also a risk if the surgeon has not met the patient prior to surgery.

13.3 Incidents in cataract surgery

13.3.1 Adverse drug events or medication issues

- Errors with intra ocular infusions; mix-up of concentrations and dilutions of infusion additives.
- Medications injected intraocularly that should not be.
- Retinal or endothelial toxicity from incorrect dose of correct drug injected into wrong compartment of eye.
- Wrong drops prescribed or dispensed or instilled.
- Allergy; patient known allergy ignored or not requested.

13.3.2 Healthcare acquired infections; in particular post-operative endophthalmitis.

Timely and vigorous treatment of the patient with endophthalmitis is needed. An outbreak of such cases requires detailed investigation to establish causation.

13.3.3 Wrong site surgery

The surgeon is ultimately responsible for performing the correct operation on the correct patient's correct eye. The Royal College of Surgeons advises that the surgical site be clearly marked with the patient's agreement while they are awake and prior to pre-medication.⁴ Providers of cataract surgery who do not routinely mark the eye should ensure that they have robust alternate systems in place to prevent wrong site surgery. Guidance on marking and on preventing wrong site surgery will be available from the NPSA in late 2004.

13.3.4 Incorrect IOL placement

Incorrect dioptré power, or size or type of IOL inserted. The surgeon is responsible for assuring that the correct implant is placed at the time of surgery.⁵

13.3.5 Failure of IOLs

- IOL opacification;
- IOL dislocation;
- Poor IOL quality (leading to uveitis–glaucoma–hyphema syndrome);
- Unwanted optical images, perhaps requiring IOL explantation;

13.3.6 Anaesthesia

Anaesthesia issues include hazards of ocular perforation and patient collapse. Swift access to resuscitation facilities and arrangements for rapid transfer to high dependency or intensive care facilities are precautions that should be available and considered in advance by both providers and commissioners of cataract care.

13.4 Reducing risk; safeguards that can be deployed

13.4.1 Governance

B

- Regular multi-disciplinary ophthalmic clinical governance meetings where patient safety incidents are discussed and potential root causes analysed.
- Referral of concerns and/or solutions identified to higher levels for action.
- Staff should be proactive and not just reactive about patient safety.

13.4.2 Audit

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- Participation in national and regional audit
- Use of computerised audit systems to track patient outcomes
- Development of regional clinical networks.

13.4.3 Incident Reporting

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Where incidents occur NHS Trust local risk management reporting procedures must be used. This includes documentation of the incident in the case notes and on local reporting forms. Patients should be informed about any incidents that affected them. The NPSA will collect reports from local risk management systems via the National Reporting and Learning System with the ultimate aim of improving patient safety. Multi-professional reporting is encouraged. 'Near misses' have the potential to provide learning where patients have not been harmed. Patient safety incidents that lead to (or might have lead to) significant harm such as unexpected death or lasting disability, including loss of sight, may be regarded as 'critical incidents'. They might be preventable by a change of practice and are worthy of further investigation of causation. The NPSA provides training in root cause analysis of patient safety incidents. Suggested critical incidents in cataract surgery are at Table 2. The 'Open category' includes issues that are a cause of concern for staff, or patients. Examples in cataract care might include wrong IOL power implanted; dropped nuclear fragments; requirement for IOL explantation; inadequate staffing levels, etc. Medication and device events including IOL related problems should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA).

13.5 Conclusion

Attention to both individual clinical detail and organisational systems enhances patient safety. Unexpected events will however happen. Such events provide learning opportunities to potentially reduce the risk of similar events recurring. Investment in appropriate staffing and equipment; team working and team training; and a culture that puts patient safety to the fore are key elements in making cataract surgery safer. The Royal College of Ophthalmologists supports steps that improve the safety of cataract care at both patient and organisational levels.

TABLE 2 Suggested critical incidents; cataract surgical care.

Incident	Comment
Wrong eye	Cataract operation on the incorrect eye
Wrong operation performed	E.g. Cataract surgery instead of glaucoma surgery on correct eye
Missing case notes at surgery	Elective surgery should be cancelled
Globe perforation	From peri-operative injection
Expulsive haemorrhage	Extensive intra-operative haemorrhage
Surgical site infection	Post –operative endophthalmitis
Peri-operative patient collapse	On the day of cataract surgery
Death	Within 28 days of cataract surgery
Unplanned re-admission	Return to theatre within 28 days of cataract surgery for non-elective treatment of the same eye
'Open category'	Includes incidents causing concern amongst staff or patients for whatever reason

13.6 References

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4. The Royal College of Surgeons. Good Surgical Practice. London 2002.
5. American Academy of Ophthalmology. Minimizing Wrong IOL Placement, Patient Safety Bulletin Number 2. 2001

13.7 Recommended further reading

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2. National Patient Safety Agency, Seven steps to patient safety: A guide for NHS staff. National Patient Safety Agency. London. 2003
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14 Commissioning Cataract Surgery – an Outline of Good Practice

14.1 Introduction

The primary purpose of this chapter is to provide guidance on the standards which commissioning agencies should expect of any provider of ophthalmic care, whether in the NHS, in independent sector treatment centres (ISTCs) in UK private healthcare or abroad, with whom they plan to place contracts for cataract surgery.

14.2 Recommendations

14.2.1 Communication

The provider should inform the patient's general practitioner at the points when the patient is listed for surgery, when the surgery occurs and when the patient is discharged. Where a patient is under the ongoing care of another ophthalmologist, he/she should also be copied into the correspondence.

- The provider is responsible for arranging handover of care to another ophthalmologist where this is necessary (e.g. for management of a complication or where ongoing monitoring of another eye condition is required). Where a commissioning agency arranges transfer of patients already on the waiting list of a consultant ophthalmologist to an alternative provider, the agency is responsible for obtaining the consent of the patient, and should inform the consultant from whose list the patient is being removed, and the patient's general practitioner (L Donaldson, personal communication, 14 November 2001).

14.2.2 Case selection and pre-operative preparation

- The provider must perform a detailed pre-operative assessment to ensure that case selection is appropriate to the level of expertise of the operating team and the clinical facilities.

In particular, it is vital to take adequate account of ocular or systemic co-morbidity which might increase the technical difficulty of the procedure, or increase the risk of complications. Where appropriate, advice should be sought pre-operatively from other doctors who are supervising these aspects of the patient's care. Where appropriate, advice should be sought pre-operatively from other doctors who are supervising these aspects of the patient's care. The provider should also ensure that adequate account is taken of the patient's social circumstances (availability of transport, help at home etc) when planning the episode of care.

14.2.3 Patient information and consent

The provider is responsible for providing adequate verbal and / or written information about cataract and cataract surgery to allow the patient to give informed consent to the procedure. Informed consent must be taken by someone who has the knowledge and competence to explain the benefits and risks of the procedure and to provide accurate answers to questions. Although NHS patients do not have a right to choose their surgeon, they have a right to expect that their surgeon has the experience and skill to perform their operation. It is reasonable that the patient should have the opportunity to know the identity and qualifications of the operating surgeon and to meet him / her prior to entering the operating theatre.

- It is the final responsibility of the operating surgeon (or the supervising surgeon where the operating surgeon is a trainee) to ensure that the patient has been adequately assessed, prepared and consented prior to the start of the operation.

14.2.4 Hotel Facilities

The commissioning agency and the provider have a joint responsibility for ensuring that the adequate facilities are available for the patient to be accommodated for the duration of the episode of care. This is particularly important where the provider unit is too distant from the patient's home to allow a return journey in the same day.

14.2.5 Clinical facilities

The commissioning agency and the provider have a joint responsibility to ensure that the premises and equipment in the provider unit is adequate for performing modern small incision cataract surgery safely, and that the unit complies with relevant legislation.

14.2.6 Anaesthesia and perioperative care

Most cataract surgery is carried out under local anaesthesia, and has a very low mortality and systemic morbidity, especially considering that a high proportion of patients are elderly and would be graded as 2 or worse on the American Society of Anaesthetists (ASA) scoring system.

- The provider has a responsibility to ensure that resuscitation facilities are readily available, and that an appropriately qualified person is readily available to undertake resuscitation should the need arise.

Contingency plans should be in place for emergency transfer of patients who suffer a life-threatening complication. The National Confidential Enquiry into Perioperative Deaths (NCEPOD) has criticized the practice of undertaking ophthalmic surgical procedures on very unfit patients in isolated units. Provider units which are geographically isolated from accident and emergency or intensive care facilities should give particular consideration to contingency planning for life-threatening emergencies and to case selection.

14.2.7 Post-operative care and contingency planning for complications

- The provider is responsible for arranging routine post-operative care following cataract surgery, in order to monitor for post-operative complications and for the collection of information on outcomes.

The patient must be provided with any necessary post-operative medication and instructions, and a discharge summary. The provider unit must have adequate arrangements for handling urgent enquiries from patients who have had surgery. It is not acceptable for patients merely to be told to go to their local accident and emergency department or to contact their GP if they have a problem. If operative or post-operative complications occur, the provider unit should either manage them, or arrange direct referral to another specialist, keeping the general practitioner informed. The commissioning agency should ensure that there is a funded agreement in place with a suitably equipped NHS facility with adequate capacity for dealing with any early or late post-operative complications which cannot be managed by the provider.

14.2.8 Clinical Governance

- The commissioning agency should ensure that the provider unit follows the requirements of clinical governance, whether the provider is within the NHS or the private sector.

In particular, medical staff should undergo annual peer appraisal, there should be evidence of ongoing audit of outcomes and complications in relation to national comparators, there should be a robust mechanism for recording and acting on complaints and clinical incidents, and there should be facilities for monitoring the progress of staff in training.

14.2.9 Accreditation of private healthcare providers

From 31st March 2002, it is a requirement that doctors and establishments engaged entirely in private practice must register with the National Care Standards Commission. The commissioning agency has a responsibility to ensure that a private healthcare provider with whom they contract is registered, or can demonstrate exemption.

14.3 Commissioning cataract surgery references

1. The NHS Plan, a plan for investment, a plan for reform. Department of Health, July 2000
2. Growing capacity: a new role for external healthcare providers in England. Department of Health, June 2002
3. Code of Practice and Guidance for NHS employers commissioning and using overseas teams. Department of Health, February 2004

14.4 Further sources of information

Department of Health website: www.doh.gov.uk

Seeking patients' consent: the ethical considerations. General Medical Council November 1998

Good Medical Practice. General Medical Council. May 2001.

15 Working Party Members

Chair:

Ms. Helen Seward, Consultant Ophthalmic Surgeon, Mayday University Hospital, Croydon, Surrey

Members:

Mr. Larry Benjamin, Consultant Ophthalmic Surgeon, Stoke Mandeville Hospital, Aylesbury, Buckinghamshire

Mr. Philip Bloom, Consultant Ophthalmic Surgeon, Western Eye and Hillingdon Hospitals, London

Mr. Chris Canning, Consultant Ophthalmic Surgeon, Southampton Eye Unit, Southampton, Hampshire

Ms. Parul Desai, Consultant Ophthalmic Surgeon, Moorfields Eye Hospital, London

Mrs. Betty Fisher, Chair of the Lay Advisory Group, The Royal College of Ophthalmologists

Mr. Simon Kelly, Consultant Ophthalmic Surgeon, Bolton Hospitals NHS Trust, Farnworth, Bolton

Mr. Paul Rosen, Consultant Ophthalmic Surgeon, Oxford Eye Hospital, Oxford

Mr. David Smerdon, Consultant Ophthalmic Surgeon, North Riding Infirmary, Middlesbrough

Mr. Richard Smith, Consultant Ophthalmic Surgeon, Stoke Mandeville Hospital, Aylesbury, Buckinghamshire

Mr. David Spalton, Consultant Ophthalmic Surgeon, St. Thomas' Hospital, London

Mr. John Sparrow, Consultant Ophthalmic Surgeon, Bristol Eye Hospital, Bristol

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17 Review of these guidelines

The review of these guidelines will take place in 2007

Request / consent for left / right cataract extraction with lens implant under

- local anaesthetic
- general anaesthetic

Appendix A
Insert Addressograph here

Statement of health professional (only complete if you have appropriate knowledge of this procedure as specified in consent policy). I have explained the procedure to the patient. In particular I have explained:

The intended benefits of the operation

The main aim of the cataract operation is to improve the quality of your vision; it may also be of benefit to improve the doctors' view of the back of the eye. We will try to reduce your dependence on spectacles as much as possible, but you may require distance glasses for best vision and you will probably need reading glasses; in any case your glasses prescription will change after the operation.

Serious or frequently occurring risks during the operation

It is possible for a cataract operation to leave you worse off than you are now. One person in every 1000 will go blind in that eye as a direct result of the operation. One in 10,000 will lose the eye. There is virtually no risk to the other eye. Details on the most common specific complications are given below.

Ecchymosis - Bruising of eye or eyelids (quite common).

Posterior capsule rupture and / or vitreous loss - a split in the thin back wall of the cataract which can allow communication between front and back compartments of the eye.

Post operative glaucoma - raised pressure in the eye for the first day or so (common). This may require temporary treatment.

Posterior capsular opacification - clouding of the membrane behind the implant causing blurred vision.

Cystoid macular oedema - inflammatory fluid in the centre of the retina. This is commonly mild and needs no treatment. It can be severe and require prolonged treatment.

Refractive surprise - unexpectedly large (or different from expected) need for glasses.

Allergy - to drops given after the operation, causing an itchy swollen eye until the drops are stopped or changed.

Dropped nucleus - part or all of the cataract falls through a posterior capsule rupture into the back part of the eye, needing another operation to remove it.

Suprachoroidal haemorrhage - bleeding inside the eye which may require the operation to be completed on another day.

Corneal decompensation - clouding of the normally clear front window of the eye.

Detached retina - peeling off of the seeing layer of cells within the eye.

Endophthalmitis - severe (usually painful) infection inside the eye.

Dislocation of the implant - movement out of position of the lens implant.

Complications are rare and in most cases can be treated effectively. In a small proportion of cases, a further operation may be required. If you decide against a cataract operation, your vision will probably slowly worsen. If you need to discuss your options further, or at a later date, please contact (preferably in writing) the person whose details are

Signature of Health professional.....

Job Title

Printed Name.....

Date

Statement of interpreter (where appropriate). I have interpreted the information above to the best of my ability and in a way in which the patient can understand.

Interpreter's signature

Print Name

Date

Statement of the patient

Please read this form carefully. You should already have been offered a copy of page 1 which describes the risks and benefits of cataract surgery, but if you don't have one please ask for one now. If you have any further questions, please ask - we are here to help you. You have the right to change your mind at any time, even after you have signed the form.

- I agree to and request to have the procedure described on this form
- I agree that any tissue that is normally removed in this procedure can be stored and used for medical research rather than being discarded. Please tick here if you agree .

I understand that:

- It has not been guaranteed that a particular individual will perform the procedure. The surgeon will, however, have the appropriate experience.
- I will have the opportunity to discuss the details of my anaesthetic with an anaesthetist before the procedure, unless the urgency of my situation prevents this (applies to general anaesthetic only).
- Any procedure in addition to those described on this form will only be carried out if it is necessary to save my life, or to prevent serious harm to my health or to my sight.

I have been told about additional procedures which may become necessary during my operation. I have listed below any procedures which I do not wish to be carried out without further discussion.

Signature Name (print)
 Date

A witness should sign below if the patient is unable to sign but has indicated consent. Young people / children may also like a parent to sign here (see DOH guidelines).

Witness's signature Name (print)
 Date

Confirmation of consent
 (to be completed by a health professional when the patient comes in for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that he or she has no further questions and wishes the procedure to go ahead.

Signature of Health Professional Name (print)
 Job Title Date

Important notes: (tick if applicable)

- See also advance directive / living will (e.g. Jehovah's Witness form)
- Patient has withdrawn consent (ask patient to sign / date here

APPENDIX B

Consent for cataract surgery INFORMATION FOR PATIENTS

This leaflet gives you information that will help you decide whether to have cataract surgery. You might want to discuss it with a relative or carer. Before you have the operation, you will be asked to sign a consent form and so it is important that you understand the leaflet before you decide to have surgery.

If you have any questions, you may wish to write them down so that you can ask one of the hospital staff.

The cataract

Your eye surgeon has recommended cataract surgery because the lens in your eye has become cloudy making it difficult for you to see well enough to carry out your usual daily activities. If the cataract is not removed, your vision may stay the same, but it will probably gradually get worse. Waiting for a longer period of time is unlikely to make the operation more difficult, unless your eyesight becomes so poor that all you can see is light and dark.

The operation

The purpose of the operation is to replace the cloudy lens (cataract) with a plastic lens (implant) inside your eye.

An experienced eye surgeon will carry out the operation or may supervise a doctor in training who also performs some operations.

With a local anaesthetic you will be awake during the operation. You will not be able to see what is happening, but you will be aware of a bright light. Just before the operation, you will be given eye drops to enlarge the pupil. After this, you will be given an anaesthetic to numb the eye. This may consist simply of eye drops or injecting local anaesthetic solution into the tissue surrounding the eye.

During the operation you will be asked to keep your head still, and lie as flat as possible. The operation normally takes 15-20 minutes, but may take up to 45 minutes. A member of the nursing staff is usually available to hold your hand during the operation, should

you want them to. Most cataracts are removed by a technique called phacoemulsification, in which the surgeon makes a very small cut in the eye, softens the lens with sound waves and removes the cataract through a small tube. The back layer of the lens is left behind. An artificial lens (implant) is then inserted to replace the cataract. Sometimes a small stitch is put in the eye. At the end of the operation, a pad or shield may be put over your eye to protect it.

After the operation

If you have discomfort, we suggest that you take a pain reliever such as paracetamol every 4-6 hours (but not aspirin - this can cause bleeding). It is normal to feel itching, sticky eyelids and mild discomfort for a while after cataract surgery. Some fluid discharge is common. After a few days even mild discomfort should disappear. In most cases, healing will take about two to six weeks, after which new glasses can be prescribed by your optician. You will be given eye drops to reduce inflammation. The hospital staff will explain how and when to use them. Please don't rub your eye. Certain symptoms could mean that you need prompt treatment, including:

- Excessive pain
- Loss of vision
- Increasing redness of the eye

You will be given an emergency telephone number to ring in case you develop any of the above, or should you need urgent advice about your eye.

This number is: _____

Likelihood of better vision

After the operation you may read or watch TV almost straight away, but your vision may be blurred. The healing eye needs time to adjust so that it can focus properly with the other eye, especially if the other eye has a cataract.

The vast majority of patients have improved eyesight following
cataract surgery

Please note that if you have another condition such as diabetes, glaucoma or age-related macular degeneration your quality of vision may still be limited even after successful surgery.

Benefits and risks of cataract surgery

The most obvious benefits are greater clarity of vision and improved colour vision. Because lens implants are selected to compensate for existing focusing problems, most people find that their eyesight improves considerably after surgery but will need to replace their glasses. Reading glasses are usually needed after cataract surgery.

However, you should be aware that there is a small risk of complications, either during or after the operation.

Some possible complications during the operation

- Tearing of the back part of the lens capsule with disturbance of the gel inside the eye that may sometimes result in reduced vision
- Loss of all or part of the cataract into the back of the eye requiring a further operation which may require a general anaesthetic
- Bleeding inside the eye

Some possible complications after the operation

- Bruising of the eye or eyelids
- High pressure inside the eye
- Clouding of the cornea
- Incorrect strength or dislocation of the implant
- Swelling of the retina - macular oedema
- Detached retina which can lead to loss of sight
- Infection in the eye - endophthalmitis - which can lead to loss of sight or even loss of the eye
- Allergy to the medication used

Complications are rare and in most cases can be treated effectively. In a small proportion of cases, further surgery may be needed. Very rarely some complications can result in blindness.

The most common complication is called 'posterior capsular opacification'. It may come on gradually after months or years. When this happens, the back part of the lens capsule, which was left in the eye to support the implant, becomes cloudy. This prevents light from reaching the retina. To treat this, the eye specialist uses a laser beam to make a small opening in the cloudy membrane in order to improve the eyesight. This is a painless outpatient procedure which normally takes only a few minutes.

We hope this information is sufficient to help you decide whether to go ahead with surgery.

Please use the space below to write down any further questions to ask the doctor or nurse when you come to the hospital for your appointment. Don't worry about asking questions. Our staff will be happy to answer them.

Table 1 Surgery under special circumstances

<u>Circumstances or Co-Morbidity</u>	<u>Considerations</u>	<u>Prevention or Treatment Strategies</u>
Difficult Access (Deep set eye, narrow lid fissure, big brow)	Reduced visibility Poor access to the superior limbus Pooling of irrigation fluid	Corneal methylcellulose, lateral cantholysis Temporal approach Drainage wick, head tilt
Dense (brunescant) nuclear cataract	Concomitant zonular laxity and intraoperative miosis Increased phaco time and risk of post-operative cornea oedema Greater risk of thermal injury to the cornea with phaco Increased risk of posterior capsule rupture Little cortex to protect capsule during phacoemulsification	Iris hooks, endocapsular tension ring Phaco chop, viscoprotection Insulated irrigation sleeve Low flow phaco
Diabetes (1,2)	Worsening of retinopathy Cataract may limit retinal view for diagnosis and treatment Pre-existing clinically significant macular oedema identified post-op Post-operative cystoid macular oedema (CMO) Good retinal view needed post-op Increased risk of post-op uveitis Increased risk of posterior capsular opacification (PCO) Co-existing advanced diabetic eye disease Poorly dilating post-operative pupil	Adequate pre-operative laser treatment Close post-operative observation Per-op indirect laser Post-operative laser treatment Prompt laser treatment Post-op topical non-steroidal anti-inflammatory medications Large diameter optic intra-ocular lens (IOL) Adjust post-operative regime of topical steroids Avoid lens implants with high PCO rates Combined phaco-vitreotomy
Fuchs' corneal endothelial dystrophy (3)	Reduced visualization during surgery Prolonged post-operative corneal oedema Pseudophakic bullous keratopathy	Viscoprotection Topical hyperosmotic agents Corneal graft combined with, or after, cataract surgery
Glaucoma (4,5)	Shallow anterior chamber in narrow angle glaucoma Higher IOP during the first post-operative week Reduced function of prior filtering surgery	Tight entry sites, viscoprotection; later IOP often reduced Ocular hypotensive agents Per- and post-operative anti-fibrotics and topical steroids
High hyperopia (6)	Shallow anterior chamber with increased risk of endothelial trauma Increased risk of iris trauma and prolapse Difficulty calculating lens implant power Intraoperative suprachoroidal effusion (esp. nanophthalmic eyes)	Tight entry sites, viscoprotection Use appropriate biometry formula Prophylactic posterior sclerostomy
High myopia (7)	Anterior chamber depth fluctuation Difficulty calculating lens implant power with posterior staphyloma Increased risk of retinal detachment	Low flow phaco Use appropriate biometry formula Warn patients re. symptoms
High risk for vitreoretinal surgery	Silicone IOLs may compromise subsequent surgical visibility	Use acrylic IOLs

Macular degeneration (8)	Subretinal neovascularization	Patient information re. symptoms, relevant investigations
Miotic pupil	Poor visualization Increased risk of capsule tear / vitreous prolapse Increased risk of iris damage and prolapse	Iris hooks, pupil stretch, sphincterotomies, pupil expanders
Posterior polar cataract	Defective posterior capsule	Low flow phaco
Posterior synechiae	Intraoperative miosis Prolonged post-operative inflammation Iris bleeding Inflammatory deposits on IOLs	Iris hooks, pupil stretch, sphincterotomies, pupil expanders Intensive post-operative topical steroids Viscotamponade Topical steroid drops, YAG 'polishing'
Pseudoexfoliation syndrome (9)	Intraoperative miosis Zonular laxity or instability Floppy iris and tendency for iris prolapse into cataract section Accelerated posterior capsule opacification Anterior capsulorhexis contraction Vitreous loss IOL tilt and decentration Late (decades) dislocation of IOL possible	Iris hooks, pupil stretch, sphincterotomies, pupil expanders Endo-capsular tension ring, capsule hooks Iris hooks Aspiration of lens epithelial cells Adequate sized capsulorhexis
Prior glaucoma filtration surgery (10)	Increased filtration through the bleb during surgery Decreased filtration through the bleb following surgery Post-operative hypotony Zonular laxity	Per- and post-operative anti-fibrotics and topical steroids Capsule hooks, endocapsular tension ring
Prior keratorefractive surgery (11)	Difficulty calculating IOL power Dehiscence of refractive keratotomy incision Thin pliable cornea post LASIK, AC depth fluctuation	Knowledge of prior Ks, contact lens method Low flow phaco
Prior pars plana vitrectomy (12)	Anterior chamber depth fluctuation Intraoperative miosis Sub-conjunctival scarring Increased frequency of posterior capsule plaques Weakened lens capsule and zonules Increased nuclear sclerosis, lens hardness	AC maintainer Iris hooks, pupil stretch, sphincterotomies, pupil expanders Corneal phaco section Posterior capsulorhexis Capsule hooks, endocapsular tension ring Phaco chop, viscoprotection
Prior penetrating keratoplasty	Poor visualization Graft rejection or failure IOL power calculation inaccuracy	Pre-and post-operative topical +/- systemic steroids Use appropriate biometry formula
Prior scleral buckling surgery	Increased axial myopia Sub-conjunctival scarring	Aim for myopia Corneal phaco section

Retinopathy of prematurity (13)	Intraoperative miosis Traction retinal detachment Loose zonules	Iris hooks, pupil stretch, sphincterotomies, pupil expanders Endo-capsular tension ring
Uveitis (14,15)	Pre-operative posterior synechiae Post-operative posterior synechiae Intraocular inflammation Protein and cellular deposits on the lens implant Fibrinous uveitis Cystoid macular oedema Secondary glaucoma Increased incidence of posterior capsular opacification	Viscodissection Large anterior capsulorrhexis Pre-and post-operative topical +/- systemic steroids Biocompatible IOL Minimise iris manipulation, intracameral rtPA Post-op topical non-steroidal anti-inflammatory medications Ocular hypotensive agents Aspiration of lens epithelial cells; YAG may precipitate CMO
White cataract (mature cortical cataract)	Difficulty performing the capsulorrhexis Lens intumescence	Capsular staining, capsulorrhexis under air Viscotamponade, needle decompression
Zonular laxity or dehiscence	Phacodonesis Vitreous prolapse around the lens equator Post-operative lens implant decentration Loss of cataract into vitreous Increased difficulty in capsulorrhexis and cortical clean-up	Capsule tension ring, capsule hooks Viscotamponade Capsule tension ring (may be sutured)

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Appendix C Cataract National Dataset V1.2 – Royal College of Ophthalmologists

Field	Field values	Notes
Patient		
Unique identifier for the Acute Trust	Pseudonymised number	Lookup table held centrally
Unique identifier for the Patient	NHS number or Hospital number	Each Trust may want to pseudonymise patients with a lookup table held on the cataract EPR software
Date of birth	dd/mm/yyyy	
Sex	Male Female Not known or specified	Specified in NHS Data Dictionary and Manual.
Ethnic category	White A British B Irish C Any other White Mixed D White and Black Caribbean E White and Black African F White and Asian G Any other mixed Asian or Asian British H Indian J Pakistani K Bangladeshi L Any other Asian Black or Black British M Caribbean N African P Any other Black Other Ethnic Groups R Chinese S Any other ethnic group Z Not stated	Specified in NHS Data Dictionary and Manual. The ethnicity of a person as specified by the PERSON. Note: ETHNIC CATEGORY is the classification used for the 2001 census, replacing ETHNIC GROUP in the flows through the NHS-wide Clearing Service
Route of referral	Direct from optometrist Optometrist via GP GP Other hospital specialist Other	
Pre-op assessment		
Date of preassessment	dd/mm/yyyy	
V/A Operated eye - Best corrected when listed	6/3, 6/4, 6/5, 6/6, 6/7.5, 6/9, 6/12, 6/15, 6/18, 6/24, 6/30, 6/36, 6/48, 6/60, 5/60, 4/60, 3/60, 2.5/60, 1/60, CF, HM, PL, NPL	Allowable values Snellen - Convert to LogMar for analysis Need VA in both eyes if the visual impairment prior to cataract surgery is to be defined as in the National Cataract Audits
V/A Fellow eye - Best corrected VA when listed	6/3, 6/4, 6/5, 6/6, 6/7.5, 6/9, 6/12, 6/15, 6/18, 6/24, 6/30, 6/36, 6/48, 6/60, 5/60, 4/60, 3/60, 2.5/60, 1/60, CF, HM, PL, NPL	Probably best to make only best-corrected VA obligatory to force clinicians to make an assessment of whether the PH value is a true reflection of what the patient can best achieve. This then only gives one value for later comparison
V/A Operated eye – Best corrected at pre-assessment	6/3, 6/4, 6/5, 6/6, 6/7.5, 6/9, 6/12, 6/15, 6/18, 6/24, 6/30, 6/36, 6/48, 6/60, 5/60, 4/60, 3/60, 2.5/60, 1/60, CF, HM, PL, NPL	
V/A Fellow eye – Best corrected at preassessment	6/3, 6/4, 6/5, 6/6, 6/7.5, 6/9, 6/12, 6/15, 6/18, 6/24, 6/30, 6/36, 6/48, 6/60, 5/60, 4/60, 3/60, 2.5/60, 1/60, CF, HM, PL, NPL	
Refraction - Operated eye sphere	+20 to -40 dioptres	As assessed by focimetry, autorefractometry or subjective refraction (specify) Glasses worn by patient, ignoring prism Dioptres to two decimal places
Cylinder	+10 to -10 dioptres	
Axis	0 – 180 degrees	
Reading add	0 to +6 dioptres	
Refraction – Fellow eye sphere	+20 to -40 dioptres	
Cylinder	+10 to -10 dioptres	

Axis	0 – 180 degrees	
Reading add	0 to +6 dioptres	
Cataract morphology	Nuclear sclerosis Cortical Posterior subcapsular Other Clear crystalline lens Mature Hyper mature Morgagnian Polar Lamellar Subluxed	Grade +, ++, +++ (optional) Grade +, ++, +++ (optional) Grade +, ++, +++ (optional)
Aetiology	Age-related Diabetic Uveitic Drug induced Congenital Metabolic Atopic Familial Traumatic Post vitrectomy Unknown	
Pre-operative medical conditions predictive of outcome	Diabetes – type 1 Diabetes – type 2 Diabetes – type unknown / other Anticoagulation Inability to lie flat for cardiopulmonary or orthopaedic reasons	
Pre-operative eye conditions predictive of a poor visual outcome	Corneal pathology	Best to keep the category general but then allow detailed data collection if desired H17.1 (central NEC) H17.8 (specified NEC) H17.9 (unspecified) Q13.3 (congenital) H18.4 (degenerative) H18.5 (hereditary) corneal ectasias
	Glaucoma	H40.0Z94.2 – H40.9 Q15.0 (congenital)
	Uveitis	
	Pseudoexfoliation	
	Vitreous opacification	H43.3 - Sufficient to predict reduced post-operative vision
	Diabetic retinopathy	E10.3, E11.3, E12.3, E13.3, E14.3 +H36.0
	Age related macular degeneration Geographic atrophy / dry Neovascular / wet	H35.3 Sufficient to predict reduced post-operative vision
	Other retinal vascular disorders	Central or branch retinal vein occlusion or other vasculopathy sufficient to predict reduced post-operative vision
	Previous vitreoretinal procedures	Sufficient to predict reduced post-operative vision
	No view of fundus	
	Optic nerve / CNS disease	
	Amblyopia	In operated eye
Other		
K1 – pre-operative	30 – 50 (dioptres) or 6.5 – 9.0 (mm)	Convert to a single format automatically
K2 – pre-operative	30 – 50 (dioptres) or 6.5 – 9.0 (mm)	
Axis K1	0 – 180 degrees	
Axial length	10 - 35 mm	Two decimal places
Biometry machine for axial length	Ultrasound PCI (partial coherence interferometry, so far only the IOL Master)	Vital. There are large differences between the A constants needed for the 2 methods – up to 1D
Formula used	Hoffer Q Holladay SRK/T SRK II Haigis Other	Encourage usage in accordance with the college guidelines: <22 mm Hoffer Q 22 – 24.5 mm Average of Hoffer Q, Holladay and SRK/T 24.6 0 26 mm Holladay >26mm SRK/T
IOL model		Use the manufacturers code as defined in the annual register Reference: Special report: International Intraocular Lens & Implant Registry 2003, Holladay JT, International intraocular lens &

		implant registry 2003. J Cataract Refract Surg 2003 Jan;29(1):176-97
IOL power	-10 to +35 dioptres	
A constant used	100 - 140	
Predicted post-operative refraction	+20 to-40 dioptres	Calculated refraction that should result from the lens implant used, sphere to two decimal places
Anaesthetic		
Grade of staff administering anaesthetic	Consultant Specialist registrar Fellow Associate specialist Senior house officer Clinical assistant Trust doctor Trained nurse Other	
Type of anaesthetic	General Retrolbulbar Peribulbar Subtenons Subconjunctival Topical Intracameral None Other	More than one may be selected
Anaesthetic medications	NHS Drug Dictionary	May include type of local, adrenalin, hyalase, buffers, anxiolytics, analgesics or other medicines administered locally or systemically
Antiseptic conjunctival preparation	NHS Drug Dictionary None	Most likely iodine or chlorhexidine
Complications of LA	Eyelid haemorrhage / bruising Conjunctival chemosis Retrolbulbar / peribulbar haemorrhage Globe / optic nerve perforation Inadequate anaesthesia Systemic problems including bradycardia, hypotension and apnoea Operation cancelled due to complication None	More than one may be selected
Operation		
Hospital	Arbitrary number (if different to originating Trust)	Lookup table held centrally (as before)
Type of admission	Day case / ambulatory Inpatient	
Date of surgery	dd/mm/yyyy	
Time spent on waiting list	Days	Allowing for suspensions during waiting time
Surgeon	Pseudonymised number	Lookup table held locally
Surgeon grade	Consultant Specialist registrar Fellow Associate specialist Senior house officer Clinical assistant Trust doctor Other	
Assistant	Consultant Specialist registrar Fellow Associate specialist Senior house officer Clinical assistant Trust doctor Other None	
1 st / 2 nd eye	1, 2	
Side of eye operation	Left	Bilateral surgery is better handled with two CND entries – the

	Right	rest of the dataset does not allow values for right and left eyes
Type of cataract Operation	Phaco + IOL ECCE + IOL Phaco converted to ECCE Aspiration of lens ICCE Lensectomy	OPCS4 code C712 C718 C718 C713 C728 C743
Site	Clear corneal Scleral tunnel Limbal Pars plana	
Meridian	0-360 degrees	
Incision length	1 – 12	One decimal place (mm)
Per-operative factors increasing the difficulty of surgery	Uncooperative patient Uncontrolled eye movement Deep-set eye Shallow anterior chamber Small pupil Atonic iris Phacodonesis Other	
IOL position	In the bag Partly in the bag In the sulcus Anterior chamber Sutured posterior chamber Iris fixated Aphakic	
Additional planned surgical procedures	None Eyelid surgery Refractive procedure Penetrating keratoplasty Glaucoma filtering procedure Mechanical pupil dilation Iridectomy Capsule tension ring Posterior capsule capsulorrhexis / capsulotomy Posterior segment vitreoretinal procedure Other	Includes stretch, hooks, rings Peripheral or broad
Operative incidental events / complications	None Phaco wound burn Corneal oedema Iris damage Hyphaema Zonule dialysis PC rupture no vitreous loss PC rupture with vitreous loss Dropped lens Decentred IOL Choroidal / expulsive haemorrhage	All or part of the cortex or nucleus
Per and post-operative eye related medication	NHS Drug Dictionary	Includes all per and post op medicines administered on, in or around the eye or systemically
Follow up		
Date of last follow up	dd/mm/yyyy	
V/A Operated eye - unaided	6/3, 6/4, 6/5, 6/6, 6/7.5, 6/9, 6/12, 6/15, 6/18, 6/24, 6/30, 6/36, 6/48, 6/60, 5/60, 4/60, 3/60, 2.5/60, 1/60, CF, HM, PL, NPL	
V/A Operated eye – best corrected	6/3, 6/4, 6/5, 6/6, 6/7.5, 6/9, 6/12, 6/15, 6/18, 6/24, 6/30, 6/36, 6/48, 6/60, 5/60, 4/60, 3/60, 2.5/60, 1/60, CF, HM, PL, NPL	
Refraction - Operated eye sphere	+20 to -40 dioptres	As assessed by focimetry, autorefractometry or subjective refraction (specify) Dioptres to two decimal places
Cylinder	+10 to -10 dioptres	
Axis	0 – 180 degrees	
Reading add	0 to +6 dioptres	

K1	30 – 50 (dioptres) or 6.5 – 9.0 (mm)	Rarely performed but essential if outputs regarding surgically induced refractive change are to be generated
K2	30 – 50 (dioptres) or 6.5 – 9.0 (mm)	
Post-op complication	None Ptosis External eye infection Hypotony Raised intraocular pressure Corneal oedema / striae Wound leak / dehiscence Shallow anterior chamber Uveitis Hypopyon / endophthalmitis Hyphaema Vitreous to section Iris prolapse Pupil block IOL decentered / subluxed IOL dislocated into vitreous Anterior capsulophimosia Posterior capsule opacity – capsulotomy indicated Retained soft lens matter Cystoid macular oedema Retinal tear Retinal detachment Choroidal haemorrhage Globe perforation identified Other	
Outcome	Discharged Listed for other eye Follow up for pre-existing pathology Follow up for pathology identified during this event	