

Quality Standard

Correct IOL implantation in cataract surgery

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1 Summary

See also <http://nice.org.uk/guidance/ng77>

This standard incorporates the key requirements of NICE guidance for adult cataract surgery to prevent wrong intraocular lens (IOL) insertion and never events in cataract surgery, and expands on these with evidence based and expert consensus views on all aspects of IOL related safety in cataract surgery.

2 Key requirements

Primary care/secondary care interface referral

- When referring patients for surgery, information provision should include introducing the concept of planning post-operative refractive outcomes.

Decision to treat/thresholds and indications for treatment/surgery

N/A

Clinical assessment

- Clinical assessment for IOL selection should include:
 - Patient details: confirm name, date of birth, hospital number and ensure matches hospital records. Use active patient confirmation.
 - Ocular history (particularly prior eye trauma, amblyopia, squint, uveitis, previous ocular surgery, risks and requirements of contralateral eye) and full eye examination
 - Recent refractive data (objective or subjective refraction, or contact lenses or glasses prescription for both eyes) and details of current refractive correction use.
 - If anticipated postoperative anisometropia is significant or potentially intolerable, identify if a contact lens can be worn.
 - Details on previous refractive laser treatment or surgery if available.
 - Biometry for both eyes.
 - If monovision is requested, undertake a trial of tolerance with contact lenses.
- Consider macular OCT in selected cases (e.g. patients with diabetes, posterior segment disorder).
- Use optical biometry, or ultrasound if the results are inaccurate or unobtainable with optical biometry, to measure axial length:
 - Performed by appropriately trained staff if not the operating surgeon.
 - Sufficiently in advance of surgery to allow discussion of refractive aims and ensure correct IOL is present.
 - Contact lenses should be removed for a specified time prior to the biometry test agreed with the surgeon (e.g. soft lenses = 1 week; rigid gas permeable lenses = 2 to 4 weeks).
 - Biometry should be calibrated daily following manufacturer's instruction.
 - Biometry equipment should be serviced regularly in accordance with manufacturer's instructions.
 - Follow guidance for axial length formulae:

- If the axial length is < 22.00 mm, use Haigis or Hoffer Q.
 - If the axial length is between 22.00 and 26.00 mm, use SRK/T, or Barrett Universal II if it is installed on the biometry device and does not need the results to be transcribed by hand.
 - If the axial length is > 26.00 mm, use Haigis or SRK/T
 - Ensure correct A-constant used for desired lens and biometry method (optical or ultrasound).
 - Ensure appropriate setting for pseudophakic or silicone oil filled eyes.
 - Use a suitable formula such as Haigis-L for people with previous refractive surgery advised by a surgeon experienced in this practice.
 - Check correct transcription of data to formula where there is not automated transfer e.g. for keratometry and if B-scan or A-scan used for axial length.
 - Cross-check difficult/inconsistent reading with other experienced staff.
 - If axial length difference between eyes is >0.3 mm, ensure corresponds to preoperative history/refraction (anisometropia, amblyopia), consider consulting surgeon and/or repeating optical biometry or confirming with ultrasound.
- Use keratometry (minimum 3 measurements) recorded in dioptres to measure the curvature of the cornea. Calibrate regularly according to manufacturer's instructions.
 - Consider corneal topography for people who have abnormally flat, steep or irregular corneas, significant astigmatism or previous corneal surgery or if it is not possible to get an accurate keratometry measurement.
 - Repeat biometry if previous measurements are > 4 years old, IOL exchange is required, patient has had previous corneal surgery or a progressive corneal disease, a major eye operation since last biometry, axial length may have changed due to eye disease, or there is considerable change in measurement system/devices. Recalculate as necessary if there is a change in type or supplier of the IOL used routinely.
 - Consider using 50% of first-eye refractive outcome prediction error to guide second-eye power calculation.
 - Consider modifying a manufacturer's recommended IOL constant for individual surgeons and/or units based on feedback from previous deviations from predicted refractive outcomes.
 - Where, despite all efforts, measurements are not available or are incomplete, an informed choice based on the available information should be made and the patient advised of the limitations of this.

Shared decision-making

- Engage the patient in shared decision-making on IOL selection and refractive target, considering the patient's preferred refractive outcome, lifestyle and expectations.
- Advise the patient of the inherent limitations of accuracy for achieving refractive targets and inform and actively manage expectations if there is any increased uncertainty for their clinical situation such as small eyes, post refractive procedures.
- Document these discussions and the refractive target clearly in the records.

- A shared decision-making (SDM) sheet which includes refractive aims can be used to support the conversation between the patient and their clinical professionals about the decision to have cataract surgery, and to support consenting for surgery.
- Accessible written and verbal information (large print or audio where necessary) about the cataract surgery should be provided, and time allowed for consideration, and this should include information about IOLs and refractive choices.
- If simultaneous bilateral cataract surgery is indicated, when discussing the risks include the limitations on controlling refractive outcomes (cannot base second IOL choice on refractive outcome of first eye).
- Consent specifically for any enhanced refractive procedure (e.g. limbal relaxing incisions, toric IOL) in cataract surgery.

Record keeping

- The patient's medical notes, including the biometry, must be available in theatre on the day of surgery.
- Electronic records may prevent errors and support audit; if electronic and paper are both used, one should be primary and unnecessary duplication avoided.
- Immediately after preoperative biometry: print and secure results to the medical record, check they are marked with the patient's name, date of birth and hospital ID; use electronic transfer where possible.

Before surgery/general:

- Information to be documented in the patient record:
 - Right or left eye
 - Consent discussions and consent form
 - Details of the refractive outcomes discussion and decisions with refractive target clearly documented
 - Document if guarded visual or refractive prognosis if co-pathology or risks for greater uncertainty (e.g. previous refractive surgery, high preop refractive error) identified
 - Lens model and power in dioptres and refractive target
 - Incision planning
 - Other refractive interventions planned.
- Consider circling or highlighting the correct IOL model and power required on the source biometry print out page. This needs to be signed or initialled/dated and traceable.
- The use of IOL order or selection forms that require manual transcription from the biometry printout should be minimised. Where used, forms must be fully completed and all checks must also consult the source biometry printout.
- If transcription is necessary, handwriting must be large and digits must be very easily distinguishable.
- Consider writing out numbers in text.
- Errors or changes should be crossed out with a single line, signed and dated. Never write a new number on top of an old number.
- Avoid 'D' for dioptre, '-' for minus, non-standard or unclear abbreviations and jargon.

On the day of surgery:

- Minimise use of operating theatre 'white boards' and, if using theatre lists or white board transcription for recording IOL selection, all checks must also consult the source biometry printout.
- Complete and record the use of safety checklists including time out; organisations to decide level of documentation detail required for audits.
- Attach implant ID label to patient record and theatre lens record, and document on electronic patient record.

Preoperative assessment: IOL selection

- IOL selection should take place during the assessment clinic or in the preoperative ward-round.
- IOL selection performed during the assessment clinic should be checked at the preop ward round on the day of surgery
- IOL selection should be performed by the operating surgeon if possible, or by a suitably trained clinical professional to be confirmed by the operating surgeon.
- For IOL selection:
 - Ensure active confirmation by patient of patient identity details and eye to be operated and that this matches operating list, medical records, consent form and biometry data
 - Ensure the biometry is within date
 - Ensure any data has been transcribed correctly (e.g. ultrasound axial length, keratometry)
 - Ensure high quality scans
 - Ensure correct A-constant used for desired lens and biometry method (optical or ultrasound)
 - Ensure correct IOL formula used for axial length of eye
 - Check astigmatism and any requirements to manage it
 - Confirm refractive aims for patient. Undertake, or confirm, selection of IOL model and power, and record this in the notes
 - Be especially vigilant when patients change their mind regarding their refractive aim or which eye. Clearly cross out any non-current paperwork (or amend/delete any old electronic selections) and ensure the patient record only contains one correct and up-to-date IOL selection when the patient reaches theatre.

Toric IOLs

- Manual typing in of Ks, meridians and axial lengths into online toric IOL calculators can very easily be complicated by transcription errors. Always ensure all the figures match the biometry and corneal topography printouts, and that the flat and steep meridians are not inadvertently reversed.
- The checks for toric IOLs are mostly as for monofocal IOLs but also require:
 - marking of the meridian on the eye, done with patient sitting up, ideally at the slit lamp
 - the correct power IOL (both spherical *and cylindrical*)
 - the correct biometry *and correct toric IOL calculation* printouts for the patient
 - care to avoid inadvertent insertion of a non toric lens.

Treatment

- Posterior chamber monofocal IOL implantation in the capsular bag is the recommended option in NHS cataract surgery.
- Back-up IOLs should be available for non-capsular bag fixation, e.g. anterior chamber IOL or posterior chamber positioned in the ciliary sulcus.
- Current single-piece acrylic IOLs should not be implanted in the ciliary sulcus.
- If a more anterior location is anticipated, the sulcus IOL power for the average eye should be decreased by 0.5 D to 1.0 D (depending on IOL power) relative to that calculated for capsular-bag fixation (but less with capsulorrhexis capture of the optic).

Efficient theatre utilisation

- Theatre lists should be signed off by an assigned deadline, and changes avoided.
- A named team member should be responsible for stock check and ordering correct IOLs before procedures.
- Where possible ensure IOLs are available at least 24 hours before surgery.
- At least one alternative lens should be available before commencing surgery.

Safety

- Identify a robust and written local process for ordering, storing, selecting, retrieving, and verifying IOLs.
- Adhere to operative protocols and surgical safety checklists, adapted to be cataract surgery specific, which should include:
 - Team brief (including all team members introduced by name and role) and debrief
 - 2+ person checks at key steps of the procedure (e.g. sign in = entry into theatre, time -out = before anaesthesia or immediately pre-procedure, immediately before implantation)
 - 2+ person confirm choice of lens model and power
 - Verbal active patient identity and surgical side verification at all checks
 - Procedure site is marked with permanent marker and visible after prep and if possible after drape
 - Verbal and documented lens verification with cross checks to side/eye marked, source biometry sheet, record of IOL selected (in history sheets/biometry/IOL selection sheet/EPR/whiteboard), consent form and theatre list
 - The final “surgical plan” for the implant is confirmed by the operating surgeon at time out clearly and loudly stating to the rest of the team the IOL power and model which should also be recorded in the notes or biometry
 - Any error up to this point resulting in wrong implant is a serious incident
 - Any error after that point results in a wrong implant is a never event
 - Check lens and backup are available and only one lens is in theatre prior to anaesthetic. There should only be one lens out in theatre at any one time
 - Be particularly careful where staff other than the surgeon obtain the IOL from the lens bank and ensure the IOL is shown to and positively confirmed by the surgeon as correct.
- It is of utmost importance that staff make a conscious effort to concentrate while checking patient identity, IOL selection and side for which IOL has been chosen, instead of just going through the motions of the checking process. The WHO

surgical time-out is an appropriate time to perform these checks, during which no other activities or distractions should be tolerated. Staff of all disciplines and ranks should feel empowered to speak up if they have any doubts at any time.

- Avoid disruption or interruption during surgery and last-minute changes to the list.
- If a new IOL is selected during the procedure, remove the original IOL from theatre and repeat full IOL checks as an intra-operative complication and change in IOL selection during the procedure is a vulnerable stage of the procedure, particularly if using a different IOL model, A-constant and IOL power.
- If staff change during a list, repeat the team brief.
- Surgeons in training should be closely supervised, including for IOL selection and insertion.
- Train staff in non-technical skills (teamwork, leadership, situation awareness, decision making, communication, challenging uncertainties regarding procedure and IOL selection). Multidisciplinary simulation team training is recommended, particularly to develop non-technical skills and to have training on vulnerable stages of procedure/process for wrong IOL including intra-operative complications, change in staff or change in list order.
- Educate non-medical theatre staff in understanding biometry data, IOL types and selection principles.
- Adapt local processes according to staff feedback, experience and learning from previous incidents (local and national).

Postoperative review

- Postoperative review may be conducted by an ophthalmologist, or appropriately trained nurse, optometrist or orthoptist and may be undertaken in community settings working with the operating unit. Those conducting postoperative reviews must be able to spot and action poor refractive outcomes.
- There should be a final refractive visit to provide accurate prescription glasses.
- Postoperative refractive outcomes should be returned and used to audit refractive outcomes, identify refractive surprise, and to assist in modification of A constants for units/surgeons.
- In the event of unacceptable or intolerable refractive error following IOL implantation, weigh risks of additional surgery with alternatives (glasses/contact lenses/refractive surgery) and decide course of action in shared decision making with patient.

Appraisal/audit/governance

- There should be a standardised process for documenting adverse incidents, near misses and unexpected outcomes including refractive surprise and wrong IOL insertion.
- Continually assess and improve systems to be proactive to emerging risks, and reactive to reported never events and near misses.
- Processes to audit include:
 - Relevant quality and completion of health records
 - Completion/documentation of safety checklists
 - Never events and lens related incidents and near misses
 - IOL exchange procedures
 - Refractive outcome (85% +/- 1.0D is achievable)

- Adherence to safety reporting procedures
- Methods of audit include:
 - Random clinical record review
 - Undercover live monitoring
 - Electronic medical record analytics
 - Never event records
 - Performance monitoring
 - Organisations should implement local safety standards for invasive procedures (LocSSIPs) which are compliant with National safety standards for invasive procedures (NatSSIPs); and ensure that there is sufficient time and human resource to support their implementation and audit
 - Ophthalmology staff should be engaged with developing, and adhere to, their organisation's LocSSIPs
 - Report never events and IOL related serious incidents and conduct a root cause analysis with the multidisciplinary team
 - Declare and record intraoperative and postoperative complications related to IOLs
 - Encourage a culture of openness and safety in staff of all levels where all staff are responsible for voicing possible error and can do so without criticism
 - In the event of an error causing implantation of a wrong IOL, duty of candour guidance should be followed with the patient and their family

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