NICE National Institute for Health and Care Excellence

May 2025 surveillance of cataracts in adults: management (NICE guideline NG77)

Surveillance report

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Surveillance proposal

We propose to update NICE's guideline on cataracts in adults: management. The update will focus on intraocular lens selection, as the new evidence and intelligence for this topic appears sufficient to update recommendations for lens design and material (recommendations 1.4.1 and 1.4.4). We propose not to update recommendations around biometry formulas, surgical timing and technique, bilateral simultaneous cataract surgery and toric lenses as the new evidence and intelligence was not deemed sufficient.

Context

NICE was tracking a UK audit by the Royal College of Ophthalmologists (RCOphth), which subsequently published and was assessed for potential impact on the section on intraocular lens selection, which triggered a surveillance review of this topic. Part way through the surveillance review NICE were subsequently contacted by the RCOphth directly who submitted further evidence and feedback in relation to this area and 4 additional topic areas: biometry formulas (recommendations 1.3.5 to 1.3.8); surgical timing and technique (recommendation 1.6.1); bilateral simultaneous cataract surgery (recommendations 1.6.2 to 1.6.4); and toric lenses (recommendation for research 1).

Methods

This surveillance review process consisted of:

- Considering the UK audit by the RCOphth for its impact on the guideline.
- A search for systematic review and randomised controlled trial (RCT) evidence related to different intraocular lens (IOL) designs and materials for preventing posterior capsule opacification (PCO) in cataract surgery.
- Considering the additional evidence and intelligence submitted by the RCOphth across 5 topic areas.
- Considering the guideline evidence base related to the 5 topic areas.
- Examining related NICE guidance and quality standards.
- Examining the NICE event tracker for relevant ongoing and published events.
- Assessing all of the new evidence and intelligence against current recommendations across each of the 5 topic areas to determine whether or not to update sections of the guideline.
- Contacting topic experts about bilateral simultaneous cataract surgery.
- Consulting with stakeholders about bilateral simultaneous cataract surgery.

For further details about the process and the possible update decisions that are available,

see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Search and selection strategy

We searched for new RCT and systematic review evidence related to different lens designs and materials for preventing PCO in cataract surgery. We included systematic reviews published from the date of the last search (January 2017) and RCTs which had published from the systematic review cut-off dates (January 2020). We did not do additional searches across other topic areas as the evidence submitted was sufficient.

Related NICE guidance

We searched the NICE guidance database and identified the following:

- NICE's quality standard on serious eye disorders
- NICE's interventional procedures guidance on implantation of accommodating intraocular lenses for cataract
- NICE's interventional procedures guidance on implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery

Other related guidance

We identified the following UK guidance:

- High flow cataract surgery (RCOphth and GRIFT, February 2022)
- Quality Standards for cataract services (RCOphth, December 2021)
- Correct IOL implantation in cataract surgery (RCOphth, December 2021)

Evidence and intelligence considered in this review

The following content is a summary of the evidence and intelligence considered when developing the original guideline, previous surveillance (where relevant), and the new evidence considered in this surveillance review, spit across the 5 topic areas: biometry formulas (recommendations 1.3.5 to 1.3.8); intraocular lens selection (recommendations 1.4.1 and 1.4.4); toric lenses (recommendation for research 1); surgical timing and technique (recommendation 1.6.1) and bilateral simultaneous cataract surgery (recommendations 1.6.2 to 1.6.4).

Biometry formulas

Evidence considered when developing the guideline

Recommendations 1.3.5 to 1.3.8 relating to biometry formulas were underpinned by the review question: What are the most appropriate formulas to optimise intraocular lens biometry calculation?

The review found 18 relevant observational studies that compared the predictive accuracy of different IOL formulas in a range of axial lengths of virgin eyes undergoing phacoemulsification cataract surgery. Six observational studies in eyes with a history of corneal refractive surgery were also included. No RCTs were identified and no economic evidence.

The committee noted the general high levels of statistical imprecision observed across all the formulas and outcomes. For eyes without a history of corneal refractive surgery, the main results of the evidence synthesis were that the SRK/T formula performs poorly in eyes with short axial lengths (those less than 22.00 mm) in contrast to eyes with very long axial lengths (those greater than 26.00 mm), and the Hoffer Q performs poorly in eyes with very long axial length (greater than 26.00 mm). The Haigis formula was among the best options for 3 of the 4 axial length subgroups. For eyes with short axial lengths, the Hoffer Q formula was similarly effective to the Haigis in predictive accuracy. Barrett Universal II and SRK/T formulas were the best options for eyes with average or medium long axial lengths. For eyes with a history of corneal refractive surgery, it was not possible to identify

formulas that provided consistently better results than others, as there was considerable uncertainty and heterogeneity in the evidence base.

New evidence

The enquirer submitted 11 studies for consideration, of which 4 were ineligible (for example a narrative review or not comparing different formulas) but 7 were included and each is discussed.

A retrospective chart review (Blehm et al. 2024) included 445 eyes of 247 patients, using the Argos for preoperative biometry and the Barrett Universal II (BUII) formula for intraocular lens (IOL) power calculations, with back calculations performed using the BTAL formula. Data on postoperative absolute prediction error (APE), refractive outcomes, and monocular uncorrected (UDVA) and distance corrected visual acuities (CDVA) were collected. The mean APE was 0.36 ± 0.33 diopters (D) for BUII and 0.34 ± 0.32 D for BTAL, with BTAL showing significantly lower APE in short AL eyes. No significant differences were found for long or medium AL eyes. The percentages of eyes with APE of 0.5 D or less were higher for BTAL in short eyes. The authors concluded that both formulas demonstrated high prediction accuracy and excellent refractive outcomes, with BTAL potentially offering lower APE in short eyes.

A retrospective, comparative case-series examined 554 eyes of patients with long eyes who underwent cataract surgery (Cione et al. August 2024). The eyes were divided into 3 groups based on AL: 26.00≤AL<28.00 mm, 28.00≤AL<30.00 mm, and AL≥30.00 mm. Eight formulas that do not require ACD were evaluated, including BUII, Emmetropia Verifying Optical (EVO) 2.0, Ladas Super Formula (LSF), Hoffer Q, Holladay 1, SRKT, T2, and T2.2. The study used lens constants from the ULIB and IOLCon databases and analysed mean absolute error (MAE), median absolute error (MedAE), and the percentage of eyes within ±0.50 and ±1.00 diopters (D) of prediction error. T2-ALu provided the best outcomes for AL between 26.00 mm and 28.00 mm, while EVO 2.0-ALc was best for AL between 28.00 mm and 30.00 mm, and EVO 2.0-CMALe was best for AL≥30.00 mm. The study concluded that selecting the appropriate AL adjustment and IOL power calculation formula for each AL subrange can improve refractive outcomes in patients with long eyes undergoing cataract surgery.

A retrospective, comparative case-series examined 150 eyes of 160 patients with previous myopic Photorefractive Keratectomy (PRK) or laser-assisted in situ keratomileusis (LASIK) who underwent uneventful cataract surgery and intraocular lens (IOL) implantation (Cione

et al. September 2024). The ALMA formula was used to calculate refractive prediction error (PE), analysing nominal and optimised A-Constants for SRKT from the ULIB and IOL Con platforms. An additional analysis evaluated the impact of a decreased ULIB optimised constant (DUOC) with fixed factors (-1.2 to -1.5). The study measured MedAE and the percentage of eyes within ±0.50 and ±1.00 diopters (D) of PE. Results showed that the ALMA formula with ULIB nominal constants had a lower MedAE and higher percentages of eyes with PE within 1.0 D. Using DUOC (-1.3) significantly improved MedAE and the percentage of eyes with PE within ±0.50 D. The study concluded that different lens factors significantly impact IOL power calculations after myopic laser refractive surgery (LRS), recommending the ALMA formula with a DUOC of -1.3 in the absence of optimised constants. Further studies were suggested to determine the best constants for post-refractive surgery formulas.

Kojima et al. 2024 was a retrospective observational study which included 461 eyes of 461 patients (mean age 73.8 ± 8.4 years) who underwent cataract surgery. The predicted refractive error (PRE) was compared between the SRI (ARGOS) and the equivalent refractive index (ERI) biometers (IOLMaster 700). Patients were divided into a learning group and a validation group, with optimisation constants determined in the learning group and applied to the validation group. Results showed that using the SRK/T and BUII (BU II) formulas, the validation group's PRE with optimised SRI constants was significantly smaller than with the ERI biometer. The arithmetic PRE of the Barrett UII formula with SRI improved significantly after optimisation in both long (group L) and short (group S) eyes. The study concluded that optimising the SRK/T and Barrett formula constants for the SRI biometer improved refractive outcomes after cataract surgery.

McNeely et al. 2024 compared the accuracy of intraocular lens (IOL) power calculation formulas, including SRK/T, HofferQ, Holladay 1, Haigis, MM, BUII, EVO, and AS-OCT ray tracing, in 100 eyes implanted with either Rayone EMV RAO200E or Artis Symbiose IOLs. Biometry was obtained using IOLMaster 700 and MS-39 AS-OCT. The study measured MAE, MedAE, and the percentage of eyes within ±0.25, ±0.50, ±0.75, and ±1.00 diopters (D) of the target. The highest percentage within ±0.75 D was achieved by MM (96%) for enhanced monofocal IOLs and SRK/T (94%) for multifocal IOLs. EVO showed the lowest MAE for enhanced monofocal IOLs, and ray tracing for multifocal IOLs. Both EVO and ray tracing had the lowest MedAE for their respective IOLs. The study found high accuracy across all formulas, with MM and ray tracing showing similar accuracy to established formulas and a high percentage of eyes within ±0.75 D.

Shammas et al. 2024 was a retrospective observational study which analysed 2 large

series of cataractous eyes with prior myopic laser vision correction (M-LVC). The training set (BPEI series of 330 eyes) was used to derive a new corneal power conversion equation for the Shammas-Cooke formula, while the testing set (165 eyes from the DMEI series) compared this updated formula with 3 other M-LVC no-history (NH) formulas on the ASCRS calculator: Shammas PL, Haigis-L, and Barrett True-K NH. The mean PE was 0.09 ± 0.56 diopters (D) for Shammas-Cooke, -0.44 ± 0.61 D for Shammas PL, -0.47 ± 0.59 D for Haigis-L, and -0.18 ± 0.56 D for Barrett True-K NH. The MAE was 0.43 D, 0.60 D, 0.61 D, and 0.45 D, respectively. The percentage of eyes within ±0.50 D of the target was 66.7% for Shammas-Cooke, compared to 47.9%, 48.5%, and 65.5% for the other formulas. The authors concluded that the Shammas-Cooke formula outperformed Shammas PL and Haigis-L and performed similarly to Barrett True-K NH.

A retrospective case-series analysed 24 eyes of 24 patients who underwent combined posterior chamber phakic intraocular lens (PC-pIOL) removal and cataract surgery at Xiamen Eye Centre, China (Zeng et al. 2024). The IOLMaster 700 biometer measured AL and anterior segment parameters. Traditional formulas (SRK/T, Holladay 1, Haigis) with or without Wang-Koch (WK) AL adjustment, and new-generation formulas (Barrett Universal II [BUII], Emmetropia Verifying Optical [EVO] v2.0, Kane, Pearl-DGS) were used for IOL power calculation. The MedAE was lowest for EVO 2.0 (0.33) and highest for Holladay 1 (1.32). The root-mean-square absolute error (RMS AE) was lowest for Haigis-WKC1 (0.591) and highest for Holladay 1 (1.513). Analysing ACD and lens thickness (LT) measurement errors showed negligible impact on refractive outcomes for BUII and EVO 2.0. The study concluded that the Kane, EVO 2.0, and traditional formulas with WK AL adjustment had high prediction accuracy, and ACD and LT measurement errors did not significantly affect IOL power calculations in highly myopic eyes with PC-pIOL.

System intelligence

The RCOphth stated that since 2017 the Barrett IOL formula has been more widely adopted.

Comparison of new evidence and intelligence with the guideline evidence base

The previous guideline evidence base showed that the Haigis formula was among the best options for 3 of the 4 AL subgroups. For eyes with short axial lengths, the Hoffer Q formula was similarly effective to the Haigis in predictive accuracy. BUII and SRK/T formulas were the best options for eyes with average or medium long axial lengths. For eyes with a

history of corneal refractive surgery, it was not possible to identify formulas that provided consistently better results than others. As such the guideline makes recommendations for formulas based on axial length.

The new evidence evaluated a range of biometry formulas, IOLs and platforms in a range of different axial lengths and patient types. No single formula appeared superior for the different axial lengths, with several studies showing high accuracy across a range of formulas and some studies calling for further research. Evidence for Barrett formulas was likewise heterogeneous but generally supported current guideline recommendations.

As such, it does not appear that the evidence is sufficient to update biometry formula recommendations at this time.

Intraocular lenses selection

Evidence considered when developing the guideline

Recommendations 1.4.1 and 1.4.4 related to IOL design and materials were underpinned by the review question: Are different lens designs (square-edged versus round-edge, plate versus loop) and materials (hydrophilic acrylic, hydrophobic acrylic, collagen, hydroxyethyl methacrylate-based versus silicone-based) effective in preventing PCO in cataract surgery? In the guideline this question was combined with the review question: Are different lens designs (aspheric versus spheric, plate versus loop) effective in improving postoperative vision (refractive outcomes, optical aberrations) in cataract surgery?

A Cochrane review including 31 RCTs (Findl et al. 2010) and 44 additional RCTs were identified, which equated to a total of 75 RCTs which were included in the final review: 27 contained comparisons of different lens materials; 23 contained comparisons of aspheric versus spheric lenses; 18 contained comparison of 1-piece (loop or plate) versus 3-piece lenses; and 15 contained comparisons of square-edged versus round-edged lenses.

In terms of PCO, the evidence appeared to indicate that hydrophobic acrylic or silicone lenses had lower rates of PCO compared with hydrophilic acrylic or polymethyl methacrylate (PMMA) lenses. The evidence also indicated that square-edged had lower rates of PCO compared with round-edged IOLs.

However, there was uncertainty at the time of guideline consultation which resulted in the

recommendations related to IOL material and design being removed to allow for further consideration.

New evidence

A total of 4 systematic reviews, 2 RCTs and 1 UK cohort study were identified in the rapid search. An additional 10 studies were submitted by the RCOphth, of which 9 were already identified in other searches or ineligible for inclusion (for example a narrative review) but an additional real-world UK study was included (Ursell et al. 2018). Each study is discussed.

Systematic reviews

Maedel et al. 2021 undertook a Cochrane review which compared different IOL optic edge designs to prevent PCO after cataract surgery. It included 10 studies with 1,065 participants and found that sharp-edged IOLs were likely associated with less PCO formation and fewer neodymium-doped yttrium aluminum garnet (Nd:YAG) capsulotomies compared to round-edged IOLs. The evidence suggested that sharp-edged IOLs might also lead to clearer vision, although the impact on visual acuity was less certain. The review highlighted the need for standardised PCO measurement and further research on quality of life and adverse events.

Wu et al. 2020 undertook a meta-analysis to compare hydrophobic and hydrophilic acrylic IOLs regarding PCO development. Analysing 13 randomised controlled trials with 939 patients, the study found that hydrophobic acrylic IOLs significantly reduced PCO scores and the need for Nd:YAG capsulotomy compared to hydrophilic acrylic IOLs. The authors considered that these results suggested that hydrophobic acrylic IOLs are more effective for patients post-cataract surgery, especially in Western countries.

Yu et al. 2022 conducted a systematic review and meta-analysis to evaluate long-term complications and visual function after cataract surgery using hydrophobic acrylic and silicone IOLs (17 studies). It found that hydrophobic acrylic IOLs were associated with higher PCO values and Nd:YAG capsulotomy rates compared to silicone IOLs during long-term follow-up (≥6 years). The authors concluded that while hydrophobic acrylic IOLs were popular for reducing complications and optimising vision, they resulted in more significant long-term complications than silicone IOLs.

Zhao et al. 2017 evaluated the effectiveness of hydrophobic versus hydrophilic IOLs in

preventing PCO after cataract surgery. It included 11 studies with 889 eyes/patients. The results showed that hydrophobic IOLs are associated with lower rates of Nd:YAG laser capsulotomy and lower subjective and estimated PCO scores compared to hydrophilic IOLs. However, there was no significant difference in visual acuity between the 2 types of lenses. Overall, the authors concluded that hydrophobic IOLs are superior in reducing PCO and the need for Nd:YAG laser capsulotomy.

RCTs

Leydolt et al. 2024 undertook an RCT to compare the incidence and intensity of PCO and Nd:YAG capsulotomy rates between 2 hydrophobic acrylic IOLs over 3 years. The RCT included 100 patients who received a Vivinex XY1 IOL in one eye and a Clareon CNA0T0 IOL in the other. After 3 years, 67 patients were evaluated. The Vivinex XY1 IOL showed a lower PCO score (1.0 ± 1.0) compared to the Clareon CNA0T0 IOL (1.5 ± 1.2), with a statistically significant difference. Nd:YAG capsulotomy rates were 7.5% for Vivinex XY1 and 9.0% for Clareon CNA0T0, with no significant difference. Both IOLs demonstrated low PCO and YAG rates, with a slight advantage for the Vivinex XY1 IOL.

Sheetal et al. 2023 undertook an RCT that compared the 1-year clinical outcomes of 3 monofocal aspheric IOLs: Optiflex Genesis, Eyecryl Plus (ASHFY 600), and Tecnis-1. It included 159 eyes from 140 patients who underwent cataract surgery. The results showed no significant differences among the 3 IOLs in terms of visual acuity, refractive accuracy, higher-order aberrations, contrast sensitivity, and PCO. All lenses demonstrated similar safety, efficacy, and patient satisfaction, with no major complications reported. Further follow-up is needed to assess long-term outcomes.

UK real-world evidence

Donachie et al. 2023 analysed 500,872 cataract surgeries from the Royal College of Ophthalmologists' National Ophthalmology Database to identify risk factors for PCO. PCO was observed in 12.3% of eyes, with rates increasing over time. Risk factors included hydrophilic IOL material, AL >26 mm, high myopia, lower IOL powers, previous vitrectomy, younger age, and female gender. The study concluded that modifiable factors, such as IOL material, present opportunities to reduce PCO rates, benefiting patients and the NHS.

Ursell et al. 2018 retrospectively collected data from 7 UK ophthalmology clinics from patients aged 65 and older who underwent cataract surgery with acrylic monofocal IOLs between 2010 and 2013. The incidence of neodymium-doped yttrium aluminum garnet

(Nd:YAG) capsulotomy and PCO was reported for 3 IOL cohorts: AcrySof, other hydrophobic, and hydrophilic acrylic IOLs. The AcrySof cohort had significantly lower 3-year Nd:YAG capsulotomy and PCO incidences compared to the other IOLs. Logistic regression showed higher odds ratios (OR) for Nd:YAG capsulotomy in non-AcrySof cohorts. The trends were consistent in a subgroup analysis of single-piece IOLs. The study concluded that AcrySof IOLs were superior in reducing Nd:YAG capsulotomy and PCO incidence within 3 years post-implantation. Note this study was funded by Alcon, manufacturer of AcrySof lenses.

System intelligence

The RCOphth 2021 report on a feasibility study of PCO used the RCOphth National Ophthalmology Database (NOD) Cataract Audit dataset of 601,084 cataract operations performed by 2,566 surgeons in 58 centres. Overall, the PCO rates were 4% at 1 year, 18.0% at 3 years and 31% at 5 years. Many IOL models and centres had higher observed PCO rates, as did lenses with a hydrophilic component. The data also showed that hydrophobic and silicone IOLs had reduced rates of PCO compared with hydrophilic lenses. However, a lot of the variation was also thought to be due to differences in how PCO rates were captured over time which made assessing specific IOL models difficult. A study limitation was noted that patient data could not be linked if patients had the original cataract operation in 1 centre but had PCO YAG in another centre. The authors recommended that centres should aim to better capture PCO data and compare PCO rates for different IOLs. The authors also noted that the cost of YAG laser capsulotomy (£132) was likely to exceed price differences between IOLs, thus opting for cheaper IOLs with higher PCO rates would be a false economy to the NHS.

The topic suggestion form submitted by the RCOphth also noted that there was likely to be support from clinical practice for an update to these recommendations.

Comparison of new evidence and intelligence with the guideline evidence base

The previous guideline evidence base showed that hydrophobic acrylic or silicone IOLs, and IOLs with square edges may reduce rates of PCO. However, this was challenged during consultation and the recommendations were removed to allow for further consideration.

The new evidence base continues to show a benefit of hydrophobic lenses. There is also

an indication that sharp-edged IOLs are likely associated with less PCO formation compared to round-edged IOLs.

Overall, the new evidence base is in keeping with the original evidence base and now provides further evidence to support the generation of recommendations on the material and design of IOLs to help reduce the rates of PCO. System intelligence indicates that an update to the recommendations would likely be supported by clinical practice. As such, an update to the guideline around IOL design and materials appears warranted.

Surgical timing and technique

Evidence considered when developing the guideline

Recommendation 1.6.1 related to surgical timing and technique was underpinned by the review question: What is the effectiveness of laser-assisted phacoemulsification cataract surgery compared with standard ultrasound phacoemulsification cataract surgery?

The review found 16 studies which did not suggest a clinical difference between using laser-assisted and standard phacoemulsification surgery. The only statistically significant difference was a 1 to 1.5 letter improvement in corrected visual acuity at 6 months, and this was judged by the committee not to be a clinically meaningful difference, particularly as it was not replicated at other time points, nor was a difference identified in uncorrected visual acuity.

In terms of economics, 1 cost-effectiveness study was included which found that using simulated complication rates of standard and laser-assisted surgery and assuming visual acuity improvement of 5% in uncomplicated cases, laser-assisted surgery was associated with quality adjusted life year (QALY) gains of 0.06, but was also found to have increased costs, with a resulting incremental cost-effectiveness ratio (ICER) of $AUS92,862 per QALY gained, which is above conventional thresholds of cost-effectiveness.

Given the evidence base, the committee agreed it would be inappropriate for laser-assisted cataract surgery to be regularly used. While the committee did not feel this need was sufficient to justify recommending future trials (particularly in view of current trials known to be ongoing), it agreed that it would be appropriate to recommend that the use of laser-assisted surgery could be justified only within the context of clinical trials.

Following this, key ongoing trials (FEMCAT and FACT) were added to the NICE tracker and were monitored so their results could be assessed as soon as they were published for their impact on the guideline.

Evidence considered in the 2021 exceptional surveillance review focused on surgical timing

The 2021 surveillance review was triggered by the publication of FEMCAT (Schweitzer et al. 2020) and FACT (Day et al. 2021) trials. These RCTs found no clinically meaningful difference in measures of visual acuity, intraoperative or postoperative complications between femtosecond laser-assisted cataract surgery (FLACS) and PCS; and concluded that FLACS, at its current cost, is not considered a cost-effective intervention for the treatment of cataracts. However, the evidence was mixed concerning FLACS improving astigmatism outcomes in people requiring cataract surgery who have significant preoperative astigmatism. The authors concluded that there may therefore be a reason to continue research comparing FLACS with phacoemulsification (PCS) within this subgroup of cataract patients.

The surveillance review concluded that additional meta-analysis is therefore needed to investigate possible differences in rare events as this will provide a more precise estimate of the effect size and improve the generalisability of the results of individual studies. The NICE team contacted the Cochrane Eyes and Vision group to ask whether the 2016 Cochrane review on laser-assisted cataract surgery versus standard ultrasound phacoemulsification cataract surgery could be updated with new RCT evidence and were told that an update is currently underway. As such, no update to the guideline was proposed.

New evidence

The topic suggester submitted 14 studies in relation to recommendation 1.6.1. However, all of these studies had been considered in the 2021 surveillance review on this recommendation or would not be suitable for inclusion in the evidence review (for example a case study or narrative review).

The 2021 surveillance review was awaiting publication of a Cochrane review update, which has since published (Narayan et al. 2023). The Cochrane review included 42 RCTs comparing FLACS with standard PCS and found little or no difference between FLACS and PCS in terms of intraoperative and postoperative complications, postoperative visual

acuity and quality of life. The Cochrane authors suggested that further research was warranted using standardised outcomes and looking at both safety and efficacy.

System intelligence

The RCOphth stated that evidence of using femtosecond laser for cataract is now available (as described above) and suggested that the outcomes of femtosecond laser cataract surgery are not dissimilar to conventional cataract surgery.

Comparison of new evidence and intelligence with the guideline evidence base

The previous guideline evidence base showed no clinical difference between using FLACS and PCS, but that FLACS was unlikely to be cost-effective. The Cochrane review likewise found no difference between FLACS and PCS and suggested further research was warranted. As such, there is no impact on the guideline.

Bilateral simultaneous cataract surgery

Evidence considered when developing the guideline

Recommendations 1.6.2 to 1.6.4 relating to bilateral simultaneous cataract surgery were underpinned by the review question: What is the effectiveness of bilateral simultaneous (rapid sequential) cataract surgery compared with unilateral eye surgery?

Only 3 RCTs were included in the guideline, which found that there were no meaningful differences in levels of intraoperative, postoperative or serious postoperative complications between people undergoing bilateral simultaneous cataract removal and those undergoing sequential surgery.

In terms of economics, 1 published cost-effectiveness study was identified which found that immediate sequential cataract surgery dominates (is more effective and cheaper than) delayed sequential surgery, although uncertainty around the estimate of cost-effectiveness could not be reliably established.

The committee agreed that the evidence presented was robust, both in demonstrating that there were no major differences in the long-term visual outcomes of same day or

different day surgery in the groups recruited but agreed that there were 2 major limitations in the evidence base. Firstly, the sample sizes were too small to pick up potential differences in rare but catastrophic complications, which are the main reason for concern with simultaneous surgery. Secondly, the populations in the trials were very carefully selected to only include those people with low risk of intra- or postoperative complications, and therefore no evidence was available on outcomes for people at higher risk, such as those with ocular comorbidities. Therefore, the committee decided it would only be appropriate to recommend simultaneous surgery as an option in the population covered by the trials, specifically those at low risk of intra- or postoperative complications.

New evidence

The topic suggester submitted 6 studies; 2 of the studies were already in the guideline evidence base and 3 studies would not be eligible for inclusion using the review protocol. The remaining study was a Cochrane review (Dickman et al. 2022) which included 14 studies (2 RCTs; both already included in the guideline) of 276,260 participants which compared immediate sequential bilateral cataract surgery (ISBCS) with delayed sequential bilateral cataract surgery (DSBCS).

The Cochrane review found that refractive outcomes showed no significant differences between groups at 1 to 3 months post-surgery. There was no major difference in intraoperative and postoperative complications between ISBCS and DSBCS, though significant heterogeneity existed between studies. It found limited evidence on the risk of endophthalmitis with ISBCS compared to DSBCS, with a very low risk of unilateral endophthalmitis in both groups and no reports of bilateral endophthalmitis. However, the Cocrane authors noted that none of the studies were powered to detect bilateral endophthalmitis which is considered a very rare event. The authors also noted that all of the studies included low risk patients. Cost-effectiveness results were unreliable due to flawed assumptions, but all studies reported lower costs for ISBCS compared to DSBCS.

Overall, the Cochrane authors concluded that there are probably no clinically important differences in outcomes between immediate and delayed surgery, but with lower costs for immediate surgery. However, the amount of evidence was limited, and the certainty of the evidence was graded moderate to very low. In addition, the authors considered that there was a need for well-designed cost-effectiveness studies.

System intelligence

The RCOphth explained that there is a smaller proportion of ISBCS being done each year since the slight upturn in ISBCS during COVID. They considered that NICE guidance may be partly responsible for this low rate of ISBCS, and that this low rate may cause an unnecessary waste of resources by continuing to do the majority of cataract surgeries in 2 separate operations.

Topic experts

Expert input was sought on the acceptability of a minor update to recommendation 1.6.3 as follows:

Offer a choice of either immediate sequential bilateral cataract surgery or first-eye surgery followed by delayed second eye surgery to people who:

- are at low risk of ocular complications during or after surgery or
- need to have general anaesthesia but for whom general anaesthesia carries an increased risk of complications.

Experts were asked if the change was clinically appropriate. Experts were also asked whether immediate sequential bilateral cataract surgery is the most commonly used term for this procedure in the NHS, and if there are any concerns that the term 'immediate' can be misunderstood by patients and carers to mean an immediate or urgent appointment.

A total of 10 topic experts (including the RCOphth) were contacted and 6 replied. Of the 6 that replied, 4 agreed that this proposed minor update would be clinically appropriate. However, there were 2 experts that considered it would not be clinically appropriate. The major concerns raised were that same day surgery is harder to implement in teaching hospitals and those with a complex case mix. There was also concern about the risk of total blindness and acceptability to patients; this expert also noted that they do not use general anaesthetic often or at all, so this is not a major factor. But another topic expert noted that when general anaesthesia is used, this generally poses a risk due to the older age of most people having cataract surgery, thus there is no need to say, 'for whom general anaesthesia carries an increased risk of complications or distress'.

In terms of terminology, all 6 experts agreed it is the most common terminology used in clinical practice. However, 1 expert did not consider the terminology grammatically correct

and provided alternative wording.

Consultation

Given the lack of consensus among topic experts, this proposed minor update was subsequently consulted on. A total of 7 stakeholders provided comments. Once again there was a lack of consensus, with 2 disagreeing. Please see consultation comments and responses.

Comparison of new evidence and intelligence with the guideline evidence base

The previous guideline evidence base showed no major differences in the long-term visual outcomes of same day or different day surgery in the groups. However, the committee noted that the sample sizes were too small to pick up potential differences in rare but catastrophic complications such as blindness, which are the main reason for concern with simultaneous surgery. Furthermore, the populations in the trials were very carefully selected to only include those people with low risk of intra- or postoperative complications, and therefore no evidence was available on outcomes for people at higher risk, such as those with ocular comorbidities. As such, the committee only recommended bilateral simultaneous cataract surgery in low risk patients or those requiring general anaesthesia in whom anaesthesia might carry risks.

The new evidence from the Cochrane review found similar results. However, it is worth noting that the evidence base in the Cochrane review includes 2 trials that were already included in the guideline; the remaining evidence in the Cochrane review comes from observational studies. The authors of the Cochrane review likewise noted that none of the included studies were powered to detect rare but serious complications such as bilateral blindness, and all of the studies were in lower risk patients. Nevertheless, the evidence base continues to show no difference between ISBCS and DSBCS.

Given this, a minor update to the guideline recommendations around bilateral simultaneous cataract surgery was initially proposed. However, feedback from topic experts and stakeholders was mixed and there was no clear consensus on whether this update would be clinically appropriate and safe. As such, it was decided that an update to these recommendations was not warranted, and to retain the existing recommendations.

Toric lenses for astigmatism

Evidence considered when developing the guideline

The guideline has recommendation for research 1: What is the cost-effectiveness of toric lenses compared with on-axis or limbal-relaxing incision surgery, or non-toric lenses with no further intervention, in an NHS context, taking account of the whole care pathway cost implications from pre- to postoperative phases, stratified by the preoperative level of astigmatism?

This was developed following the evidence review on-axis surgery or limbal-relaxing incisions to reduce postoperative astigmatism. The evidence review identified 1 systematic review reporting 8 RCTs, together with an additional 4 RCTs. The studies found a clinical difference in improving uncorrected visual acuity, reducing residual astigmatism and reduced use of spectacles between using toric and non-toric lenses. However, there was no evidence to demonstrate what impact these changes would have on the overall quality of life of an individual.

In terms of economics, 1 American cost-effectiveness study was identified which suggested that toric IOLs may reduce lifetime patient borne costs by reducing the need for spectacles or contact lenses following cataract removal. However, the study was found to have serious limitations.

The committee agreed that, in practice, the acquisition cost of toric lenses is unlikely to exceed that of standard monofocal lenses by a significant margin. However, it had significant concerns about the increased resource burden that would be incurred by the NHS should toric lenses be recommended. This could include the need for an additional preoperative appointment, additional biometry to measure corneal topography (not available in all centres) and additional minutes of surgical time (committee estimated 5 plus extra minutes). There would also be an additional cost for surgical equipment (toric markers for example).

The committee also discussed the need for more follow-up appointments in patients given toric lenses to check refractive correction, and the need to account for the poor visual satisfaction in patients who may not be able to get a toric lens in both eyes. Surgical members of the committee also raised concerns that implanting toric lenses could increase the likelihood of intraoperative complications because of the additional complexity of the procedure, and this also had implications for staff training. The

committee emphasised that none of these parameters were included in the cost-utility analysis presented.

The committee concluded that the relative benefit in UCVA from toric lenses shown by the evidence (which was not matched by evidence of relative BCVA gains) was not sufficiently robust to justify the trade-off in increased resource use. The committee discussed the often expressed desire by people to be spectacle-free following their surgery but felt that the likely QALY gains of spectacle independence would be extremely small, and many people would still require spectacles for reading as is the case for people without astigmatism undergoing cataract surgery. In the final analysis, the committee reflected that, in the absence of clear advantage in quality of life over standard monofocal lenses, toric lenses are unlikely to represent a cost-effective treatment option for patients with astigmatism compared with standard monofocal lenses.

The committee discussed whether it would be appropriate to make a 'do not do' recommendation with regard to toric lenses (as it had for multifocal lenses, see section 8.3 of the full guideline). It noted that, whereas it had seen evidence of adverse outcomes with multifocal lenses, there were no such concerns for toric lenses. The committee therefore agreed that it should not explicitly recommend against toric lenses but should confine itself to making a positive recommendation about alternative strategies and developed a recommendation for research.

New evidence

The enquirer submitted 11 studies for consideration. However, none of these studies were cost-effectiveness studies and as previously discussed by the committee, it was the cost-effectiveness of these lenses that they were most concerned about.

System intelligence

The RCOphth stated that there is a shift towards using enhanced monofocal IOLs in the NHS during the past 2 years and there is a lot of evidence that newer non-diffractive extended depth of focus lenses gives better distance and intermediate vision outcomes. They stated that it is now evident the diffractive design trifocal IOLs provide better near vision and reduced glare and halos compared to refractive design older version of multifocal IOLs.

Comparison of new evidence and intelligence with the guideline evidence base

The previous guideline evidence base found a clinical difference in improving uncorrected visual acuity, reducing residual astigmatism and reduced use of spectacles between using toric and non-toric lenses. However, there was no evidence to demonstrate what impact these changes would have on the overall quality of life of an individual. There were also concerns about the cost-effectiveness of toric lenses, which led the committee to develop recommendation for research 1, which focusses on the cost-effectiveness of toric lenses.

The new evidence does not address the recommendation for research as none of the studies submitted were cost-effectiveness analyses. As such there is no impact on the guideline.

Budget impact

If changes to the design or material used in IOL could reduce the rates of PCO, then this could free up resource by reduced need for YAG laser. According to the RCOphth, data from NHS Digital showed that over 60,000 YAG capsulotomy HRGs were recorded in England during 2018/19, with a mean cost of £132 each, which equates to approximately £8 million a year.

System impact

If changes to the design or material used in IOL could reduce the rates of PCO, then this could free up staff time by reduced need for YAG.

Population impact

Cataracts are generally an age related condition and the prevalence increases with age, with a prevalence of 24% in people aged 70 to 74 years, 42% in those aged 75 to 79 years, 59% in those aged 80 to 84 years, and 71% in people over 85 years. (CKS Cataracts)

Cataract surgery is the most frequently performed surgical procedure in the UK, with around 472,000 operations carried out annually in the NHS (England and Wales). However, PCO is a common complication after cataract surgery, occurring in roughly 1 in 5 eyes that have undergone the procedure. (RCOphth 2021)

Environmental sustainability

Reducing PCO rates could help reduce unnecessary healthcare use in the form of appointments and YAG laser usage, which should support better environmental sustainability, as outlined in the Delivering a Net Zero NHS report and other NHS guidance.

Health inequalities

No specific inequalities were noted for IOL design and PCO during guideline development. However, Donachie et al. 2023 noted that women have slightly higher rates of PCO compared with men. This difference may be influenced by various factors, including hormonal differences and the higher prevalence of certain conditions like diabetes and uveitis in women, which can increase the risk of PCO.

How this fits with NHS and NICE priorities

Ophthalmology is not mentioned explicitly in the NICE forward view. However, NICE is committed to providing useful and useable content to users. Ophthalmology is currently the busiest outpatient speciality in secondary care and makes up almost 10% of the entire waiting list (NHS England 2023). Reducing rates of PCO is likely to free up capacity and reduce waiting lists.

Overall impact on the guideline

This surveillance review looked at evidence and intelligence across 5 topic areas: biometry formular (recommendations 1.3.5 to 1.3.8); intraocular lens selection (recommendations 1.4.1 and 1.4.4); toric lenses (recommendation for research 1); surgical timing and technique (recommendation 1.6.1) and bilateral simultaneous cataract surgery (recommendations 1.6.2 to 1.6.4).

None of the evidence was deemed to have an impact apart from that on the design and materials used in IOLs, which found evidence that hydrophobic lenses and potentially silicone lenses had lower rates of PCO.

Overall proposal

We propose to update NICE's guideline cataracts in adults: management. The update will focus on intraocular lens selection related to lens material and design.

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