

Novel Methods of Delivery



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Introduction

Cataract surgery is the most commonly performed operation in ophthalmology. It is predicted that the need for cataract surgery will increase sharply in the coming decades due to increase in life expectancy. This presents a significant burden on eye services and health economy in general. The technique of cataract surgery has been revolutionised since the invention of phacoemulsification. It yields a high success rate with a low risk of complications [1]. Although the application of femtosecond in cataract surgery brings hope for improvement in outcomes of cataract surgery, future studies and improvements will be needed. It seems that optimising delivery of cataract surgery is one way to promote the efficiency of cataract surgery units. One promising approach is immediately sequential bilateral cataract surgery (ISBCS). There is clear evidence that cataract surgery of second eye improves vision-related quality of life. Although surgical and rehabilitation time is short and risk of surgical complications is low in comparison to intra-capsular and extra-capsular cataract surgery, ophthalmologists in most countries prefer delayed sequential bilateral cataract surgery (DSBCS) regardless of technique and complexity of cataract surgery. However, ISBCS is done for a considerable percentage of cataract surgery in countries like Finland and Sweden. There is also a growing trend toward ISBCS especially since the onset of the COVID-19 pandemic. Another approach is to develop new systems to improve efficacy of referral for cataract surgery and patient flow from pre-assessment before cataract surgery to discharge afterwards.

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Bilateral Surgery in Ophthalmology

Lids and strabismus operation are routinely performed bilaterally. Infection is easier to manage and less vision threatening in these operations. Further, corneal refractive surgery (LASIK and PRK) is also done on both eyes at the same sitting despite the risk of infective keratitis [2, 3]. Phakic IOLs are also implanted bilaterally on the same day by some surgeons. Intravitreal injection of anti-VEGF is commonly done bilaterally. Therefore, the concept of doing bilateral extraocular and intra-ocular surgery is not only common; it is well-acceptable in the field of ophthalmology. Unexpectedly, considering modern cataract surgery as less invasive operation, bilateral cataract surgery is still viewed as a taboo by some ophthalmologists in several countries.

Suggested Protocol for ISBCS

A patient with clinically significant cataract in both eyes may be considered for ISBCS. All necessary examinations should be done including visual acuity, refraction, IOP measurement, optic disc and retinal examination. Surgeons should exclude patients who have:

- Higher risk for infection e.g.
 - Diabetes/immunosuppression
 - Iodine allergy
- Risk of corneal decompensation
 - Fuchs endothelial dystrophy, previous corneal pathologies, scarring, HSK, corneal grafts
- Cataract type and lenticular abnormalities
 - pseudoexfoliation, subluxation, phacodonesis, previous trauma, posterior polar cataract, mature cataract, dense nuclear cataract
- History of glaucoma
- Risk of RD
 - High myopia
 - Retinal break
 - History of retinal laser or vitrectomy
- Risk of biometry error
 - Axial length of <20 mm or >26 mm
 - Previous history of corneal refractive surgery
 - Irregular cornea
- Risk of intraocular inflammation.

It is estimated that about half of patients may be suitable for ISBCS [4]. If a patient with bilaterally significant cataract is suitable for ISBCS, they should have been clearly informed about the possible advantages and disadvantages of this method. The final decision to choose between delayed or simultaneous cataract surgery should be done by the patient with unbiased guidance of the surgeon.

The surgeon can choose these types of anaesthesia: topical, subtenons or general anaesthesia. One common combination is topical and intracameral for the first eye, and subtenons for the second eye. ISBCS should only be offered by an experienced surgeon and team in an operating room with good track record and low rate of complications including endophthalmitis.

In the event of a complication occurring during the first eye surgery, it would be wise to not proceed with the second eye at the same setting. This should be explicitly explained to the patient preoperatively. Surgeons and assistants should change gloves and gowns and redo draping for the second eye operation. A new trolley of instruments should be used for the second eye. Ideally a phaco set packed a week previously should be used for one eye as that would have been of proven sterility following the week's operations using instruments from the same sterilisation cohort. This may reduce the error in the sterilization cycle on a single day putting both eyes at risk. If IOL power for both eyes are the same, it is better to use implants with different lot numbers, or use an implant of 0.5 dioptre less or more in power for one of the two eyes in order to be sure that they have not been manufactured on the same day. For any solution entering the eye e.g. balanced salt solution (BSS), ophthalmic viscosurgical devices (OVDs), anaesthetic, antibiotic, etc. different manufacturers or different lot numbers should be used. Any unfamiliar device or material should be avoided. Manufacture-packed right eye and left eye sets of instruments would decrease workload in theatre and chances of error. Disposable instruments are also preferable if possible.

Health Economy and ISBCS

DSBCS mandates second preoperative assessment and patients' preparation in operating room. Therefore, it imposes more steps and is less time-efficient than ISBCS. There are several reports that ISBCS is more cost-effective for both patients and health system. National savings by implementation of ISBCS is substantial. For instance, it is estimated to be of €5.7 million annually in Finland [5]. In a US-based study, it is reported that Medicare and patients would save approximately US\$522 million, and US\$261 million annually by implementation of ISBCS; respectively [6]. One study found that ISBCS is 14% less expensive compared to DSBCS in Sweden [7]. Another study in Finland reported savings of €449 for each patient in medical costs and this amount increased to €849–€1631 when non-healthcare costs were included [5]. This saving to society can be invested in other fields of ophthalmology or medicine. This economical advantage of ISBCS will be a big drive for prompting ISBCS by healthcare commissioners.

Patient Quality of Life After ISBCS

Both DSBCS and ISBCS improve patients' quality of life [11]. Patients after DSBCS will experience short term anisometropia, loss of stereopsis and delay in new eyeglass prescription that cause a delay in visual rehabilitation. Furthermore, these patients will need more postoperative visits, pre-assessment and admission for surgery. Patients' daily activity and life enjoyment will be affected by eye surgery and coexisting perioperative stress. The increased number of total leave days and its consequences is also noticeable. ISBCS will ease all these issues for patients. A combination of these factors may provide better short term quality of life after ISBCS. Qualitative analysis will be need to evaluate these issues in future studies.

Barriers and Concerns About ISBCS

Ethics

There is no evidence that ISBCS is not as safe as DSBCS [8, 9]. Therefore, ISBCS observes the principle of non-maleficence. After all information about ISBCS given to patients, they should be free to choose between immediate or delayed cataract surgery if they meet all criteria for ISBCS. The autonomy of patients is therefore respected. As ISBCS is more cost-effective, it should be considered a valid approach for conserving resources for patients and society.

Tariff and Reimbursement Rate

In many countries, the tariff for second eye surgery in simultaneous bilateral fashion is less than first eyes [9]. The US Medicare will pay 50% for second eye. It is the same in Australia. In some countries like Japan, no fee will be paid for the second eye. Therefore; although ISBCS saves money for health systems, it brings financial penalties to ophthalmologists and hospitals. This issue can explain differences in popularity of ISBCS among countries to some extent.

Presumed Risk of Bilateral Complications

One of the main concerns about ISBCS is the possibility of bilateral complications. Robust inclusion criteria and protocol for ISBCS decrease the likelihood of bilateral or any complications. Systematic reviews reported no difference in improvement of best spectacle corrected visual acuity (BSCVA) after ISBCS or DSBCS [10, 11].

Postoperative Refractive Error

There is some evidence that input of first eye refraction can be used to adjust second eye IOL power to improve refractive outcomes [12]. However, patients who are at higher risk of IOL power calculation errors like short or long axial lengths and history of previous refractive surgery are excluded from ISBCS. Moreover, optical biometry and modern IOL calculation formula have improved the results of post cataract surgery refraction. Also, it is not clear that what percentage of ophthalmologists routinely optimise second eye IOL powers based on refractive result of the first eye. Therefore; further studies will be needed to compare clinical significance of postoperative refractive error difference between ISBCS and DSBCS by applying recent improvement in IOL power calculation.

Toxic Anterior Segment Syndrome (TASS)

Toxic Anterior Segment Syndrome (TASS) is an acute toxic inflammatory reaction which is due to several etiologies, including intraocular lens materials and several toxic substances enter inside eyes during cataract surgery. It may also be caused by a deficit in the sterilization process. The International Society of Bilateral Cataract Surgeons' (iSBCS) strict guideline to use different sterilization cycle for instruments and different brands or lot numbers for right and left eye would theoretically make the risk of TASS for any eye independent of the other. It is of note that there is one report of bilateral TASS in the literature after DSBCS [13].

Cystoid Macular Oedema

Cystoid macular oedema (CMO) is the most common complication of cataract surgery with incidence rate of 1–2% for clinically significant CMO [14]. The peak incidence of CMO is 4–6 weeks postoperatively. Therefore, DSBCS would not have many advantages over ISBCS when there is a gap of less than six weeks between first and second eyes. Although previous studies have not reported an increase in CMO after ISBCS, there is a real concern about bilateral CMO. It seems that a more effective protocol for prevention and diagnosis of CMO should be designed for ISBCS.

Endophthalmitis

Bilateral visual loss from bilateral endophthalmitis is a great concern with ISBCS. Surgeons have reported this as the main reason why they do not offer ISBCS [15]. It seems that strict guidelines from ISBCS to completely separate the two

operations should be effective to decrease the theoretical chance of bilateral endophthalmitis to a very low level [18]. Due to the proven effectiveness of intracameral antibiotics to decrease the risk of endophthalmitis, the use of intracameral antibiotics for ISBCS is highly recommended [16].

To calculate the probability of bilateral endophthalmitis, the risk of unilateral endophthalmitis should be squared and multiplied by a linkage factor (that shows how much risk of second eye infection is linked to the first eye). Although different rates of endophthalmitis have been reported, the main issue is that there is no agreement about the estimation of average linkage factors. It is also different for each individual. There are four cases of bilateral endophthalmitis in the literature but iSBCS' guidelines were not followed in these cases [17]. There is no report of bilateral endophthalmitis in recent studies about ISBCS [10, 11, 18]. More studies with larger sample sizes would be needed to estimate this risk. Recently, the risk of endophthalmitis after intravitreal injection among more than one hundred thousand eyes in office-based setting was 0.026%; quite the same rate as post-cataract surgery endophthalmitis [19]. They did not report any case of bilateral endophthalmitis. There is no guarantee for zero risk of bilateral endophthalmitis but following iSBCS' guidelines and use of intracameral antibiotics will decrease it to a very low level. It is estimated that the cost of avoiding the possibility of bilateral endophthalmitis would be around 3 billion Euros. On the other hand, due to advances in the treatment of endophthalmitis by vitrectomy, endophthalmitis does not necessarily result in blindness and considerable percentage of patients with endophthalmitis will achieve vision of $\geq 6/12$. A difficult question is what level of risk of bilateral endophthalmitis is acceptable given the many advantages of ISBCS.

Retinal Detachment

Retinal detachment rate increases after cataract surgery [20]. There are two major risk factors of this complication, axial myopia and vitreous loss. Axial myopia is excluded from ISBCS and surgery of second eye will be avoided in a case of posterior capsular tear and vitreous loss in the first eye. However, retinal detachment is a late postoperative complication. Therefore, usual separation of two eyes' surgery by several weeks in DSBCS cannot be helpful for prevention of retinal detachment.

Road Toward ISBCS

In some countries like Finland or Sweden it is not difficult to start ISBCS. In many others, surgeons who would like to do ISBCS may find few colleagues to support them. ISBCS is taboo in many ophthalmology communities. The starting

step for developing ISBCS is talking about it to colleagues in local or national gatherings. It will help both sides to discuss their opinions and concerns and to build up a more robust system for ISBCS. It is pivotal to get some sort of support from national ophthalmology councils or health authorities. It will decrease concern about medico-legal issues for surgeons wishing to do ISBCS. There is also a need for consensus statements, guidelines and protocols for ISBCS developed by national and international workshops. Negotiation with insurance or government payers for more fair reimbursement rate will help to overcome one important obstacle for ISBCS in many countries. More well-designed studies should be done to answer our questions about possible advantages and disadvantages of ISBCS. Mixed methods research will be necessary to compare issues like short-term post-operative quality of life between ISBCS and DSBCS.

Other Aspects of Cataract Surgery Delivery

There is a drive to boost quality of service provided to customers in service industries. Health systems that offer cataract surgery should follow this example. All aspects of the service from pre-operative to post-operative period should be looked at. There are dissimilar models for delivery of cataract surgery by health-care providers in different countries. Although there is no robust evidence about which model is the best, different aspects of these models should be considered by ophthalmologists. The Way Forward published by the Royal College of Ophthalmologists is a good example for more thoughts and debates about cataract surgery delivery in the future [21]. It is essential to redesign cataract delivery systems to be more efficient but at the same time not jeopardizing patient safety. It is also vital to consider socioeconomic aspects and national policies of health authorities for the system to evolve. The rise in burden of cataract and limited resources will compel ophthalmology communities and health system managers to seek more efficient pathways for provision of cataract surgery. Robust supervision strategy is needed to monitor outcomes of newly designed systems.

Other Strategies for More Cost-Efficient Cataract Surgery Delivery

Referral System

Improvement in referral system for cataract surgery will boost efficacy of eye care units. It will reduce wastage of time and money. Visual acuity should not be considered a sole criterion for being eligible for cataract surgery. In some models, referral is done by optometrists or general practitioners. Although over-referral is

a big concern, any referral system should be watchful for systematic under-referral of any specific group of patients.

Task Delegation to Health Care Professionals

Health care professionals (HCPs) including optometrists and nurses are recently participating in preoperative assessment, biometry and obtaining informed consent [21]. There are different pathways for deploying HCPs to improve flow of patients. Although these models save time for ophthalmologists, they still have the responsibility of taking a final decision for operation and confirmation of consent in any preoperative pathway. On the other hand, the traditional first-day postoperative visit by ophthalmologists is fading [22]. It is mostly done by HCPs, often by telephone, rather than by ophthalmologists in the UK [21].

Presence of Anaesthetist

Nowadays, routine cataract surgery is done under local anaesthesia rather than general anaesthesia. In some settings, anaesthetists do not attend cataract list without any patient requiring general anaesthesia or intravenous sedation. There should be staff who are trained for cardiopulmonary resuscitation. Reducing or consolidating lists into LA only or anaesthetic cover required may reduce the need and expense of an anaesthetist.

Number of Staff and Cataract Cases Per List

There is a drive to improve productivity of cataract services by doing higher numbers of cataract cases per list. Various factors should be considered in this regard: training surgeon or consultant, number of staff in theatre and level of case complexity (risk stratification system would be helpful). However, employing extra staff may be challenging for some health systems. Finally, it is pivotal to find solutions for rewarding surgeons and theatre staff in addition to avoiding burnout.

References

1. Jaycock P1, Johnston RL, Taylor H, Adams M, Tole DM, Galloway P, Canning C, Sparrow JM. UK EPR user group. The cataract national dataset electronic multi-centre audit of 55,567 operations: updating benchmark standards of care in the United Kingdom and internationally. *Eye (Lond)*. 2009;23(1):38–49.

2. Garg P, Bansal AK, Sharma S, Vemuganti GK. Bilateral infectious keratitis after laser in situ keratomileusis: a case report and review of the literature. *Ophthalmology*. 2001;108(1):121–5.
3. Karimian F, Baradaran-Rafii A, Javadi MA, Nazari R, Rabei HM, Jafarinasab MR. Bilateral bacterial keratitis in three patients following photorefractive keratectomy. *J Refract Surg*. 2007;23(3):312–5.
4. Shah V, Naderi K, Maubon L, Jameel A, Patel DS, Gormley J, et al. Acceptability of immediate sequential bilateral cataract surgery (ISBCS) in a public health care setting before and after COVID-19: a prospective patient questionnaire survey. *BMJ Open Ophthalmol*. 2020;5(1):e000554.
5. Leivo T, Sarikkola AU, Uusitalo RJ, Hellstedt T, Ess SL, Kivelä T. Simultaneous bilateral cataract surgery: economic analysis; Helsinki simultaneous bilateral cataract surgery study report 2. *J Cataract Refract Surg*. 2011;37(6):1003–8. <https://doi.org/10.1016/j.jcrs.2010.12.050>.
6. Neel ST. A cost-minimization analysis comparing immediate sequential cataract surgery and delayed sequential cataract surgery from the payer, patient, and societal perspectives in the United States. *JAMA Ophthalmol*. 2014;132(11):1282–8.
7. Lundström M, Albrecht S, Roos P. Immediate versus delayed sequential bilateral cataract surgery: an analysis of costs and patient value. *Acta Ophthalmol*. 2009;87(1):33–8.
8. Herrinton LJ, Liu L, Alexeeff S, Carolan J, Shorstein NH. Immediate sequential vs. delayed sequential bilateral cataract surgery: retrospective comparison of postoperative visual outcomes. *Ophthalmology*. 2017;124(8):1126–35.
9. Singh R, Dohlman TH, Sun G. Immediately sequential bilateral cataract surgery: advantages and disadvantages. *Curr Opin Ophthalmol*. 2017;28(1):81–6.
10. Kessel L, Andresen J, Erngaard D, Flesner P, Tendal B, Hjørtald J. Immediate sequential bilateral cataract surgery: a systematic review and meta-analysis. *J Ophthalmol*. 2015;2015:912481.
11. Malvankar-Mehta MS, Chen YN, Patel S, Leung AP, Merchea MM, Hodge WG. Immediate versus delayed sequential bilateral cataract surgery: a systematic review and meta-analysis. *PLoS One*. 2015;10(6):e0131857.
12. Olsen T. Use of fellow eye data in the calculation of intraocular lens power for the second eye. *Ophthalmology*. 2011;118(9):1710–5.
13. Kim SY, Park YH, Kim HS, Lee YC. Bilateral toxic anterior segment syndrome after cataract surgery. *Can J Ophthalmol*. 2007;42(3):490–1.
14. Yonekawa YI, Kim IK. Pseudophakic cystoid macular edema. *Curr Opin Ophthalmol*. 2012;23(1):26–32.
15. Amsden LB, Shorstein NH, Fevrier H, Liu L, Carolan J, Herrinton LJ. Immediate sequential bilateral cataract surgery: surgeon preferences and concerns. *Can J Ophthalmol*. 2018;53(4):337–41.
16. Gower EW, Lindsley K, Tulenko SE, Nanji AA, Leyngold I, McDonnell PJ. Perioperative antibiotics for prevention of acute endophthalmitis after cataract surgery. *Cochrane Database Syst Rev*. 2017;2:CD006364.
17. Lansingh VC, Eckert KA, Strauss G. Benefits and risks of immediately sequential bilateral cataract surgery: a literature review. *Clin Exp Ophthalmol*. 2015;43(7):666–72.
18. Arshinoff SA, Bastianelli PA. Incidence of postoperative endophthalmitis after immediate sequential bilateral cataract surgery. *J Cataract Refract Surg*. 2011;37(12):2105–14.
19. Borkar DS, Obeid A, Su DC, Storey PP, Gao X, Regillo CD, Kaiser RS, Garg SJ, Hsu J. Wills post injection endophthalmitis (PIE) study group. Endophthalmitis rates after bilateral same-day intravitreal anti-vascular endothelial growth factor injections. *Am J Ophthalmol*. 2018;194:1–6.
20. Day AC, Donachie PHJ, Sparrow JM, Johnston RL. Royal college of ophthalmologists' national ophthalmology database. United Kingdom national ophthalmology database study of cataract surgery: report 3: Pseudophakic retinal detachment. *Ophthalmology*. 2016;123(8):1711–5.

21. The Way Forward Cataract—The Royal College of Ophthalmologists. <https://www.rcophth.ac.uk/wp-content/uploads/2015/10/RCOphth-The-Way-Forward-Cataract-300117.pdf>. Accessed 14 March 2019.
22. Grzybowski A, Kanclerz P. Do we need day-1 postoperative follow-up after cataract surgery? *Graefes Arch Clin Exp Ophthalmol*. 2018.