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Immediately Sequential Bilateral Cataract Surgery (ISBCS): An Increasingly Common Global Practice

By Steve A. Arshinoff, MD, FRCSC

The mid 1990s saw a surge in interest, originating in Canada, the United Kingdom, Finland and Spain, in immediately sequential bilateral cataract surgery (ISBCS). Within 10 years, ISBCS was a topic of common discussion and the practice had become generally accepted by a significant minority of ophthalmologists in those countries, and was spreading globally. This challenge to one of the fundamental paradigms of cataract surgery was occurring because of the progressive decrease in cataract surgical and post-operative complication rates due to improved technology and techniques, and decreasing cataract surgical times. Emerging data demonstrate that ISBCS carries many benefits to the patient, his/her family, the surgical facility, and society. The feared risks for simultaneous bilateral endophthalmitis, the requirement to adjust intraocular lens (IOL) power selection for second eyes, based on first eye results, and other concerns have simply not been borne out under scrutiny. ISBCS is now rapidly increasing in its performance and acceptance globally, but the financial factors – which remain the principal impediment to the performance of ISBCS – remain to be solved in many jurisdictions, including all Canadian provinces. This issue of *Ophthalmology Rounds* reviews the controversy, history, and evolution of ISBCS.

The serious discussion of immediately sequential bilateral cataract surgery (ISBCS) appears to have begun in Spain. In 1986 del Castillo, in his review of ISBCS, observed: "The argument of whether to operate bilateral cataracts in a single session, or in two different sessions, is as old as the operation itself, and the controversy between supporters of one option and the other had already, in the Middle Ages, become fiercely heated. So it has stayed, over the centuries, up to the present day."[1] Current advocates of the procedure list benefits such as the immediacy of visual improvement, the ability to rehabilitate the visual system (as opposed to only 1 eye) right away, patient convenience, and reduced patient visits.[2-4] ISBCS opponents warn of risks of potentially catastrophic adverse outcomes such as simultaneous bilateral endophthalmitis (SBE), despite the fact that these risks have never been documented in fact.[5,6]

I began practicing ISBCS routinely in 1996, after my experience with the case of a 35-year-old racing car driver, who demanded that her 2 cataract surgeries be performed at the same sitting. She explained that her careful research of cataract surgery and surgeons led her to the conclusion that the risk of ISBCS was far lower than that of her usual occupation, and she wanted me to perform her surgery. Her outcome was excellent and she expressed great satisfaction in recovering bilateral vision in one day. Based on her and subsequent patients' very positive results, ISBCS is now offered in my practice to all patients requiring bilateral cataract surgery. In more than 9800 phacoemulsification procedures as ISBCS, no complications (eg, bilateral postoperative endophthalmitis, corneal edema, or macular edema) related to the bilaterality of the procedure have occurred. Concern remains, however, about any possible increased risk for the procedure compared with delayed sequential bilateral cataract surgery (DSBCS). The International Society of Bilateral Cataract Surgeons (*i*SBCS) was formed on September 1, 2008; I was founding president and remain as co-president. My own "essential steps to ensure safe performance of ISBCS" are listed in Table 1. These precautions became the basis of the iSBCS General Principles for Excellence in ISBCS 2009 (Table 2).

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Table 1: Strict procedures for safe immediately sequential bilateral cataract surgery (ISBCS) – Humber River Hospital (Toronto)

- Intracameral antibiotics are used in every case (personal preference is moxifloxacin)
- Complete sterile separation of the 2 procedures
  - Repreparation and redraping between eyes
  - Use of different sets of instruments
  - Use of different lots of balanced salt solution, disposables, and ophthalmic viscosurgical devices
- If any unmanaged complication occurs with the first eye, the second eye is deferred
  - This has been an extremely rare occurrence (~5 cases in nearly 20 years), most of which were due to nonocular issues
- Information of right and left eye IOL and astigmatism are clearly marked on a board in the OR for all staff to see
- OR nurses are trained to read and interpret biometric data
  - Nurses check this information and read it out loud as they pass the IOL, which the surgeon has selected and placed on a table beside the patient's chart, from the circulating table to the scrub nurse, confirming the IOL choice
  - No IOL errors have occurred since this policy was adopted, but the policy has resulted in a few corrections of the selected IOL before insertion due to this policy

IOL = intraocular lens; OR = operating room

ISBCS is being performed with increased frequency in many countries.[7] For example, nearly 50% of bilateral cataract surgeries in Finland are conducted in a single sitting, and 10% of European Society of Cataract and Refractive Surgery members report routine performance of ISBCS.[8] The majority of patients requiring bilateral removal of cataracts are candidates for an immediately sequential procedure. Exclusion criteria for ISBCS have been outlined by Smith and Liu[9] and by Lansingh et al;[10] however, as surgeons gain experience with ISBCS the number of absolute exclusions decrease dramatically as the surgeon becomes comfortable with ISBCS. Lansingh et al underlined the necessity of appropriate presurgical management of ocular comorbidities and to weigh patient eligibility against the potential risks that these conditions pose.[10] This paper simply echoes the *i*SBCS principle #2: "Any concomitant relevant ocular or periocular disease should be managed." One particular clinical scenario requiring evaluation of benefits and risks is cataract surgeries involving femtosecond laser where it is procedurally desirable to perform the femtosecond laser part of the surgery on both eyes before performing the phacoemulsification on the first eye. If a problem occurs during phacoemulsification with the first eye, it will be too late to defer the second eye surgery for more than a few days if the femtosecond laser portion has already been completed. This issue is being studied in detail by a large femtosecond laser cataract group in Quebec, and the *i*SBCS eagerly anticipates their report at our 2016 meeting in Copenhagen, as more data are currently required on the safety and efficacy of this clinical procedure.

Advantages of ISBCS

Performance of ISBCS is associated with several potential advantages.

Improved visual function

A meta-analysis by Malvankar-Mehta et al (11 studies; N=3657)[11] found a nonsignificant improvement in best-corrected visual acuity (BCVA) with ISBCS versus DSBCS (standard mean difference -0.18; 95% confidence interval: -0.37 to 0.01). Utility score results from various instruments showed a nonsignificant advantage with DSBCS versus ISBCS; the lone statistically significant difference was that patients preferred ISBCS over DSBCS on Catquest questionnaire. This report of equivalence of surgical outcomes is exactly what we would expect when comparing ISBCS to DSBCS. The difference in the procedures is strictly temporal, and no outcome differences should be significant if the study groups are sufficiently large The reported nonsignificant advantages and differences above really mean that there were no significant differences.

More notably, restoration of significantly better vision to both eyes results in a quicker visual rehabilitation.[12] Patients waiting for their second eye surgery can be visually incapacitated; anisometropia has been identified as an independent risk factor for falls in older patients.[13,14] Several studies have demonstrated that functional visual improvement is greater following the second procedure than the first.[15-19] The United Kingdom (UK) Royal College of Ophthalmologists 2010 Cataract Surgery Guidelines[20] state that "over one third of all National Health Service cataract operations are performed on the second eye.[21] 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.[22]" This is entirely believable for a number of reasons, including that most surgeries in the UK are done unilaterally, some of the patients may have had a unilateral traumatic cataract, and a few may die of unrelated diseases before having their second eye done in a jurisdiction with long waiting lists. It is mathematically obvious that when unilateral surgery is the norm, second eye surgery will never approach 50%. A corollary to this is that where unilateral cataract surgery remains the norm, a significant portion of patients will be at increased risk of orthopedic injury due to reduced binocularity waiting for, or electing not to undergo, second eye surgery.

There appears to be no significant benefit of adjusting second eye intraocular lens (IOL) power based upon the result in the first eye

Performers of ISBCS have been accused of abandoning the potential to improve adjustment of biometric results for the second eye based upon the refractive result in the first eye.[23]

The earliest biometric study by Jabbour et al[24] found that second eye IOL power adjustment based on

Table 2: *i*SBCS General Principles for Excellence in ISBCS 2009

iSBCS General Principles for Excellence in ISBCS2009

This document was reviewed and approved by the membership at the 2nd annual meeting of iSBCS, Sept. 14, 2009.

General Principles Committee 2008-9: Steve Arshinoff MD FRCSC, Toronto, Canada
Charles Claoué MD FRCS, FRCOphth, FEBO, London, UK
Bjorn Johansson MD, PhD, Linkoping, Sweden.

The committee would like to thank the membership of iSBCS for their constructive input into this document: Drs David & Miguel Perez Silguero, FJ Goas Iglesias de Ussel, & Ramon Henriques de la Fe, all of the Canary Islands, Spain, & others.

1. Cataract or refractive lens surgery should be indicated in both eyes.
2. Any concomitant relevant ocular or periocular disease should be managed.
3. The complexity of the proposed ISBCS procedure should be easily within the competence of the surgeon.
4. The patient should provide suitable informed consent for ISBCS, being free to choose ISBCS or DSBCS.
5. The risk for Right – Left eye errors should be minimized by listing all surgical parameters (selected IOL, astigmatism, etc.) for both eyes on a board visible to all in the operating room (OR), at the beginning of each ISBCS case. The WHO operative checklists should also be used if possible.[1]
6. Intraocular lens power errors are minimized by having OR personnel familiar with the calculation methods used. The original patient charts should be available in the OR, and everybody passing the IOL to the surgical table should confirm the IOL choice. ISBCS nursing staff should be specifically trained and experienced.
7. Complete aseptic separation of the first and second eye surgeries is mandatory to minimize the risk of postoperative bilateral simultaneous endophthalmitis (BSE).
   a. Nothing in physical contact with the 1st eye surgery should be used for the 2nd.
   b. The separate instrument trays for the two eyes should go through complete and separate sterilization cycles with indicators.
   c. There should be no cross-over of instruments, drugs or devices between the two trays for the two eyes at any time before or during the surgery of either eye.
   d. Different OVDs, and different manufacturers or lots of surgical supplies should be used, whenever reasonable (where the device or drug type has ever been found to be causative of endophthalmitis or toxic anterior segment syndrome) and possible (if different lots or manufacturers are available) for the Right and Left eyes.
   e. Nothing should be changed with respect to suppliers or devices used in surgery without a thorough review by the entire surgical team, to assure the safety of proposed changes.
   f. Before the operation of the second eye, the surgeon and nurse shall use acceptable sterile routines of at least re-gloving after independent preparation of the second eye's operative field.
   g. Intracameral antibiotics have been shown to dramatically reduce the risk of post-operative endophthalmitis. Their use is strongly recommended for ISBCS.
8. Any complication with the first eye surgery must be resolved before proceeding. Patient safety and benefit is paramount in deciding to proceed to the 2nd eye.
9. ISBCS patients should not be patched. Post-operative topical drops are most effective immediately postoperatively and should be begun immediately post-op, in high doses, which can be tapered after the first few days. Other ophthalmic medications (e.g. for glaucoma) should be continued uninterrupted.
10. ISBCS surgeons should routinely review their cases and the international literature to be sure that they are experiencing no more than acceptable levels of surgical and post-operative complications. Membership in the *International Society of Bilateral Cataract Surgeons* (www.iSBCS.org) is highly recommended to keep abreast of the latest ISBCS information.

[1] Haynes AB, Weiser TG, Berry WR, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. *N Engl J Med* 360; 5: 491-499 (Jan. 29, 2009).

the refractive result from the first cataract surgery did not significantly improve the second procedure's results. Subsequent studies, however, seem to show small improvements in outcome. A retrospective consecutive case series (N=1235) by Olsen et al[25] summarizes all aspects of this debate. The researchers compared refractive outcomes associated with IOL power calculations using 3 methods: the original Sanders-Retzlaff-Kraff (SRK) II formula, the updated SRK/T formula, and the Olsen formula. The investigators found that the benefit of adjusting biometric calculation error for the second eye based upon the result from the first eye is inversely proportional to the quality of the biometry used. The benefit of IOL adjustment was 0.1 D using SRK II, 0.06 D with SRK/T, and only 0.02 D using the Olden formula with the Lenstar. Thus, the potential benefit of adjustment decrease with increasingly precise measurements and formulae, becoming vanishingly small with the Olsen formula and the Lenstar.

Enhanced patient choice of final refractive state

ISBCS also offers the advantage of giving the patient the preoperative choice of refraction – ie, plano, myopia, monovision, multifocal IOLs, etc. – for which the surgeon can then plan without the complication of interprocedure anisometropia. This is of particular benefit in the context of high preoperative hyperopia, astigmatism, or myopia.[26]

Cataract surgery for amblyopic eyes

ISBCS also provides the opportunity to operate on refractive amblyopia that may not otherwise have been performed in patients who present for unilateral surgery on their "good eye." In my own clinical experience, results have been surprisingly good in most cases. We have achieved postoperative VA >20/40 in many -15 to -25 D myopic eyes with mild cataracts and VA <20/200, as well as VA of 20/30 to 20/60 in many anisometropic hyperopic eyes with and without significant astigmatism with preoperative VA ≤20/200. Furthermore, some of these eyes continue to improve by a few lines of VA over the ensuing few years. These positive outcomes have challenged the inherited paradigm of a definite extremely poor visual prognosis for amblyopic eyes in the opinions of several refractive cataract surgeons. A recent article in *Science* lends support to our finding that amblyopia may not be as hopeless as we once thought.[27]

Fewer patient visits

The reduction in patient visits is a benefit not only to patients, who typically suffer from reduced mobility in the perioperative period of DSBCS, but to their families and to the healthcare system. ISBCS avoids the duplication of each step in the procedure, including presurgical preparation of the patient, anesthesia, patient transport in and out of the surgical theatre, and postoperative visits.[9] Bolger[28] showed mathematically that the risk of bilateral endophthalmitis with ISBCS is lower than the risk of dying in a traffic accident while driving back and forth to the extra visits required by DSBCS.

Incapacitating fear of second eye surgery due to an adverse experience with the first operation

It is the experience of most ophthalmic surgeons, including myself, that a few patients who have suffered seriously negative complications in association with their first cataract surgery elsewhere, and come to a second surgeon seeking another treatment for cataracts, are in mortal fear of undergoing a second cataract procedure. Two of my patients are gripped with surgical phobia further to their previous procedure to the extent that they prefer remaining functionally blind with an operable cataract in their only eye, rather than proceed to a second surgery. ISBCS avoids this potentially life-altering situation. Fortunately, this scenario is becoming less common as surgical techniques improve.

Safety of ISBCS

Despite expressed concerns regarding the purported increased risks associated with ISBCS, especially for unilateral or bilateral postoperative endophthalmitis, ISBCS has not been demonstrated to confer additional risk compared with DSBCS.[27-32] The study by Serrano Aguilar et al[29] was conducted in association with the government of Spain, using residents of the Canary Islands undergoing bilateral cataract surgery in a specific time period (N=807), and concluded that ISBCS was as effective and safe as DSBCS. The multicentre study of endophthalmitis after cataract surgery performed by Arshinoff and Bastianelli[30] revealed postoperative infection rates of 1 in 17 000, and no bilateral infections in >100 000 eyes. Li et al[32] reported that the risk for SBE after ISBCS is lower than the risk of death after general anesthesia. Each of the 4 published cases of SBE was associated with significant breaches of aseptic protocols published by the ISBCS and the Royal College of Ophthalmologists.[33-36] Li et al estimated that performance of ISBCS according to these protocols would confer a risk of SBE in the order of 1 in 4 million procedures, and a reduction of bilateral vision below the minimal driving standard in 1 in 9 million.[32]

Noncatastrophic possible complications of ISBCS and DSBCS include retinal detachment, macular and corneal edema, iris prolapse, hyphema, and transient elevations in intraocular pressure.[9] Patients at high risk for these conditions represent relative contraindications, or cases in which special precautions may be needed; eg, pre- and postoperative retinal assessments or endothelial cell counts. Macular edema is a particular consideration in patients with diabetes mellitus; however, in my personal experience more patients with known diabetic macular edema (DME) are referred to me from their retinal surgeons, who are requesting bilateral cataract surgery. Many of the patients presenting with a request for a bilateral cataract procedure have a long history of diabetes, which places them in a higher DME risk group, but the ability of the retinal specialist to carefully evaluate the retina is compromised by the presence of a dense cataract.

Financial Considerations

Beyond the pros and cons described above, the most serious barrier to wider global acceptance of ISBCS is economic. Despite ISBCS having been shown to be a cost-saving procedure,[10,38] most healthcare settings and regions around the world impose financial penalties on its performance.[32,39,40] In the United States (US), the penalty Medicare levies on fees of surgeons and institutions performing ISBCS is 50%.[40,41] Health maintenance organizations, however, gain financially from ISBCS,

and are beginning to encourage it. Same-day second-eye surgeries are likewise discounted by 50% in Australia and by 100% in Japan and Israel.[40] Finland, which does not penalize the procedure, has the highest rate of ISBCS (~50% of cataract surgery procedures). Leivo et al[42] estimated that cost savings in Finland with ISBCS compared with DSBCS are €1600 (~US$1827) per patient. They then calculated the additional cost of performing all cataracts as DSBCS under the assumption that it prevents all cases of SBE and applying the unilateral estimated rate of 1:1000[43] to the projected SBE rate yielding the square, or 1 for each 1 million procedures. The calculated extra cost of performing all DSBCS instead of ISBCS for the purpose of preventing SBE would be €739 million, or about US$1 billion per SBE case prevented. It is important to note that endophthalmitis occurs at approximately the same rate whether the procedure is ISBCS or DSBCS, and that performance of DSBCS only prevents the 2 infections from being simultaneous. We repeated Leivo's analysis with Canadian data and determined a per-patient savings of ISBCS of CDN$2000, including social, employment, and costs to the patients' families.[44] Combining this finding with those of the iSBCS bilateral surgeons in the determination of risk for endophthalmitis (1:17 000 when intracameral antibiotics are used) and squared using Leivo's method, the calculated risk of SBE would be 1:289 million, and the additional cost associated with exclusive performance of DSBCS, instead of ISBCS, to prevent a single SBE case would be CDN $250 billion.

In addition to the healthcare system, ISBCS also represents a cost saving for the surgical hospital/clinic, physician, patient, and caregiver by eliminating one procedure event. Payment for ISBCS without penalization compared to DSBCS would share the savings associated with ISBCS among these stakeholders. Unfortunately, in Ontario, the Local Health Integration Network executives severely restrict funding ISBCS with little apparent consideration of evidence or of the procedure itself; they have stated in personal communication that ISBCS can be done where necessary, which is a ridiculous comment as cataract surgery is by its nature nearly always elective. At the same time, the provincial government is working on how to appropriately fund ISBCS. Clearly two hands of the same government are working at cross-purposes. This contrasts markedly with American practices, where, at the 2014 American Society of Cataract and Refractive Surgery (ASCRS) meeting, Kent Stiverson, of the Colorado Permanente Medical Group, reported that 80% of patients who are candidates for ISBCS voluntarily choose it over DSBCS, when allowed to choose freely and the procedure is being performed with increasing frequency in the United States.[43]

Conclusion

Evidence continues to accumulate proving the benefits of ISBCS, and its use is growing globally. A minority of cases persist where DSBCS is generally preferred, as the accumulation of surgical experience is serving to decrease the number of absolute exclusions. iSBCS surgeons maintain that the most opportune time to perform surgery on a second eye is immediately after having gained experience with the other eye of the same patient. The principal barrier to more widespread performance of this procedure remains economic.

In the past 2 years I have been approached with new questions about ISBCS, suggesting much broader interest in the procedure: the issue of adapting femtosecond laser cataract surgery to enable ISBCS has become prominent. At the other extreme I have been asked for advice on performing bilateral small-incision cataract surgery en masse in Africa, to enable delivery of cataract surgery to those who would likely never get the opportunity to get second eye surgery if it was not performed with the first eye as ISBCS. It seems that the world is slowly looking to the evidence about ISBCS, as is starting to get over the initial fear of challenge to a time-honoured paradigm. Although I project that I will surpass 10 000 ISBCS procedures and 20 years of performing routine ISBCS before ISBCS becomes fully accepted and common in most of the world, healthcare change in favour of ISBCS appears to be on the not-too-distant horizon.

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