

Same-day Cataract Surgery Should Be the Standard of Care for Patients With Bilateral Visually Significant Cataract

Steve A. Arshinoff, MD, FRCSC

York Finch Eye Associates, Humber River Regional Hospital, and the University of Toronto, Toronto, Ontario, Canada; McMaster University, Hamilton, Ontario, Canada; and Ben Gurion University of the Negev, Beer-Sheva, Israel

Abstract. Same-day, or immediately sequential, bilateral cataract surgery (ISBCS) is being practiced with increasing frequency worldwide. It provides many advantages including convenience for the patient and the patient's family. ISBCS repairs the visual system, not merely one eye, restoring normal binocularity as well as unilateral clarity, creates a much more relaxed surgical atmosphere in harried operating rooms, and saves money for society. It is often preferred by busy professionals. The purported risks of ISBCS have been unsupported by the literature, including bilateral retinal detachment, bilateral corneal decompensation, bilateral diabetic macular edema, bilateral severe cystoid macular edema, significant IOL power errors in the first eye that could be refined and thereby prevented in the second eye, and toxic anterior segment syndrome. The greatest fear of ISBCS has been possible simultaneous bilateral endophthalmitis, which did not occur in a series of nearly 100,000 ISBCS cases and has only occurred elsewhere when complete separation of the two eyes and strict sterile protocol were not followed. The International Society of Bilateral Cataract Surgeons (www.isbcs.org) has prepared the "ISBCS General Principles for Excellence in ISBCS," which should be followed for safe ISBCS. (*Surv Ophthalmol* 57:574–579, 2012. © 2012 Elsevier Inc. All rights reserved.)

Key words. bilateral cataract surgery • immediately sequential bilateral cataract surgery • same-day cataract surgery • sequential cataract surgery • cataract surgery

Same-day or simultaneous bilateral cataract surgery (SBCS) is increasing in popularity worldwide. I began its practice in 1996, encouraged by a 35-year-old race-car driver who, having been to other surgeons, was aware of the risks attending the procedure, but was unwilling to undergo two procedures for her bilateral cataracts and could not be convinced otherwise. She forced me to rethink the paradigms I had been taught as a resident. Were there really compelling reasons not to perform same-day bilateral modern phacoemulsification with in-the-bag posterior chamber intraocular lens (IOL) implantation or were we just following the practices of our forbears, who did not have access to technology and techniques remotely as safe and effective as those that are currently available?

The International Society of Bilateral Cataract Surgeons (ISBCS www.isbcs.org) was formed in 2008 in response to increasing practice of bilateral cataract surgery and the desires of its practitioners to share information and improve their techniques. SBCS is currently more commonly referred to, by most of its frequent practitioners, as *Immediately Sequential Bilateral Cataract Surgery (ISBCS)*, to differentiate it clearly from *Delayed Sequential Bilateral Cataract Surgeries (DSBCS)*. In Ontario, Canada, in fiscal year

2003–2004 I was performing almost 50% of all ISBCS, which made up 1% of all cataract cases in the province. In the 2009–10 fiscal year my consistent share was reduced to less than 20% of ISBCS cases in Ontario, which at the time made up 2.4% of all cataract cases. There was a 40% increase in total cataract cases over the same period (to 38,619)—3,276 eyes of which underwent ISBCS.^A The data show that ISBCS is now increasing at a rate of about 0.45% of total provincial cataract volume per year in Ontario (Fig. 1, Table 1). We are led to believe that ISBCS is rarely performed in the United States (only 0.4% of ASCRS 2008 [www.analyz.com] respondents admit to SBCS); the same survey showed that 7% of US surgeons routinely perform ISBCS in refractive lens exchange procedures, however. In Leaming's 2009 ESCRS study, 10% of responding ESCRS members stated that they routinely perform ISBCS, with the highest rates being in Finland and Sweden. The government of Spain has recently recognized ISBCS to be as equally safe and effective as two unilateral procedures. The ISBCS has members from Australia, Belgium, Canada, Colombia, Finland, Germany, Greece, India, Japan, Korea, Malaysia, Norway, Portugal, Spain, Sweden, Switzerland, Syria, United Kingdom, USA, and other countries.^B

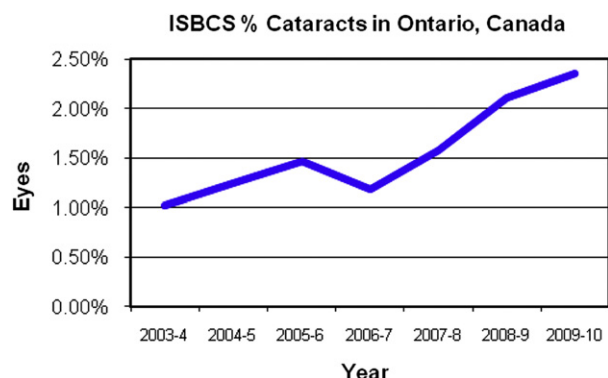


Fig. 1. Bilateral cataract surgical procedures as a percentage of all cataract surgeries performed in the province of Ontario, Canada, by government fiscal year. ISBCS = Immediately sequential, bilateral cataract surgery.

Advantages of ISBCS

There are many reasons to perform ISBCS. Bilaterally operated patients experience almost immediate rehabilitation of their visual system, whereas DSBCS patients suffer loss of full binocularity until considerably after their second operation.¹⁵ Fewer medical visits are required for ISBCS patients (about 60%), yielding much happier patients and family members who transport them. ISBCS yields efficiencies in operating rooms and less hurried cataract surgery days, despite the ability of performing more cases per day. ISBCS patients receive more personal care by less harried operating room staff who view ISBCS patients as “special.”³ ISBCS reduces patient fear, and is definitely preferred for patients needing general anesthesia or other special accommodations for surgery.

Surgeons who frequently practice ISBCS are usually willing to operate on an amblyopic or previously injured or disfiguring eye, at the same sitting as a “bonus” benefit to the patient, often yielding surprisingly good results. In most cases these eyes would be left functionally blind or cosmetically poor by surgeons who do not perform ISBCS and are unwilling to take a patient to the

operating room for the sake of an eye with a marginal prognosis. In the practice of the author, ISBCS is greatly preferred by busy doctors, lawyers, and politicians. Finally, ISBCS saves the medical system money—billions of US dollars per potential case of bilateral endophthalmitis (a denominator chosen to illustrate benefit/risk by Leivo et al¹⁴). This risk occurs anyway with separate operations, just at different times, which although not a reason to judge any medical procedure, is important in the current worldwide financial crunch in medicine.¹⁸

Objections to ISBCS

A number of objections have been raised against ISBCS and have given rise to broad controversy. These objections deserve to be reviewed.

Preferred practice documents of many countries do not recognize ISBCS as a standard acceptable form of practice. Preferred practice documents are “historical” documents that recount the state of standard practice at a time (usually about 1 year) before they are published. They look backwards and not forward. Therefore they cannot possibly encompass any new procedure as accepted standard practice, whether that new procedure is terrible or fantastic. By their nature and source, preferred practice documents are incapable of passing judgment on anything new. For example, intraocular lenses, and more recently, anti-vascular endothelial growth factor injections, were unaccepted just before they became standard of care.

Post-operative bilateral retinal detachment has been offered as an unacceptable risk of ISBCS; retinal detachment generally occurs months or years after the procedure, however, and is most common in an identifiable population of white males with pre-operative refractions of −4 to −8 diopters and a history of trauma.^{1,12,21,24} The timing of postoperative detachments make it irrelevant if the patient’s operations occur 3 minutes or 3 months apart, and the identifiability of the population most at risk enables

TABLE 1
ISBCS Eyes Undergoing Cataract Surgery in Ontario, Canada

Year (Apr 1–Mar 31)	Author	All Ontario	AUTHOR/Ontario (%)	Ontario Cataract	Ontario SBCS % of Cataracts
2003–4	498	1,016	49.02	99,825	1.02
2004–5	488	1,346	36.26	108,480	1.24
2005–6	682	1,862	36.63	126,384	1.47
2006–7	556	1,642	33.86	139,387	1.18
2007–8	538	2,196	24.50	139,101	1.58
2008–9	560	2,944	19.02	139,779	2.11
2009–10	624	3,276	19.05	138,619	2.36

ISBCS = immediately sequential, bilateral cataract surgery; SBCS = sequential, bilateral cataract surgery.

pre- and postoperative retinal assessments for prophylactic treatment.³

Bilateral cystoid macular edema, diabetic macular edema, and corneal decompensation in cases of Fuchs dystrophy have been cited as significant risks, have been reported after bilateral surgery, and are indeed specific relative contraindications for ISBCS in the minds of the majority of ISBCS surgeons.^{8,22} The risk of diabetic macular edema or corneal decompensation can be assessed prior to surgery, so caution should prevent most simultaneous bilateral occurrences. We measure pachymetry, check corneas for early Fuchs dystrophy, and adopt specific ophthalmic viscosurgical device strategies minimizing endothelial damage in higher-risk patients, and in the highest risk patients, we perform DSBCS. Similarly, in diabetics, we have macular assessments performed by retinal surgeons. If there is early diabetic macular edema on fluorescein or optical coherence tomography, we advise DSBCS unless the cataracts are so dense that they prevent proper retinal management, and then there is no real choice but to perform cataract surgery anyway; however cystoid macular edema (CME) may be unpredictable and most ISBCS surgeons use perioperative non-steroidal anti-inflammatory drugs to minimize that risk. Having performed ISBCS on over 7,000 eyes to date, bilateral CME sufficient to impair the patient's normal activities has yet to occur in my practice.

IOL power errors that may occur with the first surgery has also been raised as an issue, with some claiming methods that can improve the refractive prediction for the second eye using the results of the first eye's surgery.^{2,9} These studies are, however, problematic, because they used discrete IOL powers for first eyes, but calculated continuous IOL powers for second eyes, which of course, do not exist in reality, and would be expected to yield improved refractive accuracy simply because the IOL choice is more precise.⁴ In all my cases, however, I have only had to exchange an IOL for a more appropriate IOL power half a dozen times (less than 1 case in 1,000), and all of these occurred before the advent of partial coherence interferometry, Haigis post-refractive surgery equations, and the ASCRS post-refractive surgery calculator. Furthermore, all of my IOL exchanges were either in extreme hyperopes or in high myopes in whom the fovea was on the slope of a staphyloma—cases where we know refractive predictions are difficult and often differ between eyes. In almost all, postoperative data from one eye would not have helped for the other eye.³ Simply put, adjustments to correct IOL power errors in the first eye for the second eye surgery have not been a significant problem in bilateral cataract surgery.¹⁰

Toxic anterior segment syndrome (TASS) has been touted as a possible risk that could affect both eyes in ISBCS. TASS usually occurs when something is changed in the surgical protocol—the source of balanced salt solution, brand of gloves used, instrument cleaning detergents or methodology, and so forth.¹⁷ TASS has not been reported with ISBCS. In our recent study of almost 100,000 ISBCS cases to ascertain infection frequency, there were no cases of TASS.⁵ The ISBCS General Principles for Excellence in ISBCS 2009 (Appendix) specifically states in article 7.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.” This was placed in the Principles specifically to avoid TASS.

The largest issue with respect to ISBCS has been the potential for simultaneous bilateral endophthalmitis (SBE). At numerous meetings where I have spoken, someone opposed to ISBCS got up and stated that they would never perform ISBCS because, if even one patient ever suffered SBE, the catastrophe would be unbearable for both the patient and the doctor. I recall speaking at the New England Ophthalmological Society in December 2001. To my great surprise, during my lecture on ISBCS, in the front row, were seated a team of Boston lawyers, who had been invited to attend specifically to comment on my presentation. The doctors expected the lawyers to vilify me and ISBCS. Instead, after my talk ended, the lawyers convened for a few minutes while I took questions, then one representative of the legal team got up and said (I paraphrase somewhat): “New procedures are constantly being performed in the Boston area in our world leading hospitals. Some of these procedures carry significant risk of mortality, not just the risk of vision loss. It is an accepted principle that the patient must be informed of the risks of the planned surgery and then may decide to go ahead or not. Bilateral cataract surgeons must fairly inform their patients of the risks of surgery. That being done, bilateral cataract surgery is not out of line with other new procedures being performed in the Boston area.” So, that being the case, it appears, that like all other procedures in medicine, ISBCS should be judged on the available evidence and not fear, but that appropriate patient informed consent is expected. Even endophthalmitis is treatable and does not always lead to blindness. Prophylactic preventive measures can be taken.

So what is the evidence about ISBCS and possible infection?

The most complete study of infection after ISBCS has been performed by Arshinoff and Bastianelli.⁵ In 95,606 eyes undergoing ISBCS, the infection rate was 1:5,759 for all cases; 1:1,987 for cases not

receiving intracameral (IC) antibiotic prophylaxis; and 1:14,352 for those cases receiving IC cefuroxime, vancomycin, or moxifloxacin at surgery. These infection rates are dramatically lower than the infection rate reported in the IC cefuroxime arm of the ESCRS study (1:1,621), and lower than the weight-averaged aggregate of all the IC cephalosporin studies reported from Europe in the past decade, studying 535,948 cases with an IC prophylaxis infection rate of 1:1,977. Every study, including our ISBCS study, found an 80% or greater reduction in infection rate with IC prophylactic antibiotics, but the ISBCS study had by far the lowest rates. Unquestionably, ISBCS surgeons are among the most accomplished, and higher-volume cataract surgeons with low complication rates have adopted extra precautions (see Appendix), and frequently will perform their most difficult cases (which could be expected to have a higher infection rate) as unilateral surgeries, but the ISBCS numbers present an achievable goal for all cataract surgeons. All of the infections in the ISBCS study were unilateral. Four cases of SBE were reported between 1978 and 2008.^{7,13,19,20} In every case there was a significant lapse in sterile protocol, and the ISBCS General Principles were not followed.⁶ Members of ISBCS strongly recommend that new ISBCS surgeons follow the recommendations in the Appendix.

Based upon this data, I have calculated an approximate risk for SBE if the ISBCS General Principles are followed and IC antibiotics are used, as follows:

$$\text{SBE Risk} = (\text{unilateral surgery risk})^2 \times \text{linkage factor}$$

The linkage factor is the factor representing the extra risk for the second eye in a bilateral case where the first eye was infected. In reviewing the literature and the experience of ISBCS members, I do not believe the linkage factor would exceed 3. So:

$$\text{SBE Risk} \approx (1 : 14,352)^2 \times 3 \approx 1 : 70 \text{ million cases}$$

We reported that choosing which antibiotic to use intracamerally is difficult, as cefuroxime, vancomycin, and moxifloxacin were effective, but in our study none was significantly superior to the others. There are, however, a number of reasons to prefer moxifloxacin. Moxifloxacin and vancomycin have broader spectra of activity against common endophthalmitis pathogens and less reported resistance than cefuroxime. Unlike the others, moxifloxacin demonstrates dose-dependent, rather than time-dependent, kinetics in bacterial killing and anti-nuclear rather than anti-cell wall efficacy. It has a low risk of allergy (especially compared to cephalosporins) and is the simplest to prepare

(from available topical Vigamox eye drops), making dilution errors unlikely. Importantly, in the unfortunate but ultimately inevitable periodic failure, moxifloxacin is most likely to yield a strain of *Staphylococcus* that will probably be sensitive to the usual anti-endophthalmitis drugs of choice, vancomycin and ceftazidime, which act by different mechanisms. It is more logical microbiologically to use an agent for prophylaxis that is unrelated chemically and by mechanism of action to the current endophthalmitis drugs of choice, vancomycin and ceftazidime, reserving them for rare failures, than to use our agents of last resort, vancomycin or cefuroxime (chemically and microbiologically similar to ceftazidime) as primary prophylactic agents. Finally, even dilute moxifloxacin has a faint yellow color, making administration from the wrong syringe unlikely.^B

Conclusion and Summary

Like all medical procedures, ISBCS should be judged on its medical merits alone. There is currently no evidence that ISBCS is unsafe. History has shown that life tends to ever increasing complexity as long as the simpler units merging into a more complex unity show a nonzero sum ultimate benefit.²³ The universal addition of IOL implantation into cataract surgery is a typical example of this.

ISBCS has not been shown to have any demonstrable downside, but it does treat the visual system, restoring binocularity as well as monocular clarity simultaneously, whereas unilateral surgery restores monocular clarity, but often impairs binocularity until the second eye is done. It has been demonstrated that patients gain more benefit from second eye cataract surgery than from first eye surgery, and this is the likely reason.^{11,16} ISBCS provides many benefits for the patient, the patient's caregivers, and for society, saving significant amounts of money that can be spent productively elsewhere. The only downside is that in many jurisdictions surgeons are paid less for the second eye than for the first, essentially penalizing them for performing ISBCS. No matter how you look at this, it is an incredibly foolish policy. We have a safe procedure, with many benefits for the patient, and we discourage it by economically penalizing the surgeon who performs it. It would be much more intelligent to reward surgeons for ISBCS, thus sharing a small amount of the savings society reaps with the surgeon responsible for those savings. It is not surprising that surgeons are reluctant to perform ISBCS. Therein lies the real root of the controversy and argument about ISBCS.

Disclosure

The author reported no proprietary or commercial interest in any product mentioned or concept discussed in this article. The author is a paid consultant for Alcon laboratories, Abbott Medical Optics, and Bausch & Lomb.

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- A. Government of Ontario OHIP database
- B. Paper presented by the author at the 34th Annual Meeting of the United Kingdom & Ireland Society of Cataract and Refractive Surgeons, Brighton, UK, 11 November 2010

Reprint address: Steve A. Arshinoff, MD, FRCSC, York Finch Eye Associates, 2115 Finch Ave. W. #316, Toronto, Ontario, Canada, M3N 2V6. e-mail: ifix2is@sympatico.ca

APPENDIX



President:	Steve A. Arshinoff MD
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iSBSCS General Principles for Excellence in ISBCS 2009

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

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

The committee would like to thank the membership of iSBSCS for their constructive input into this document: Drs David & Miguel Perez Silguero, FJ Goas Jglesias 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 post-operative 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 of 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 post-operatively 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.iSBSCS.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).