

Immediately Sequential Bilateral Cataract Surgery

Steve A. Arshinoff MD FRCSC June 7, 2020.

The world is changing due to COVID-19 and the interest in ISBCS is exploding as surgeons realize that the requirements for room cleaning will cause a huge decrease in the volume of unilateral procedures they can perform in one day. I would have preferred if cataract surgeons and third party payors were being moved by what, to me for over 20 years, have been the obvious benefits to patients of ISBCS, but, I guess, one must adapt. I have been performing routine immediately sequential bilateral cataract surgery (ISBCS) for 25 years, with uptake of the procedure in most countries being between 5 and 10 percent, with some much higher, and some lower. Lately, I have been asked to give numerous webinars and to provide quick advice everywhere because surgeons feel pushed by COVID-19 to perform ISBCS rather than DSBCS (delayed sequential bilateral cataract surgery).

The Canadian Ophthalmological Society has published (with my help) and circulated a document to serve as guidance for ISBCS but did so in one page with very general recommendations, which is not surprising for a society that has to please numerous different sub-groups. I strongly believe that if a surgeon wishes to adopt ISBCS, it is not excessive to suggest that he/she read 6-8 pages rather than 1.

The requirements of social distancing and isolation brought on by the COVID-19 pandemic are clearly big problems in our usual performance of cataract surgery. ISBCS halves the patient's required visits. It results in both eyes being done at the same sitting, taking very little more time than doing only one eye under our modern COVID-19 era restrictions. We, in Canada, perform a significant number of our cataract procedures in private centres (and a respectable volume of ISBCS compared to many countries). We have seen reimbursements to ophthalmologists and to cataract centres diminish sharply in the past two decades, and COVID-19 will just about kill any financial incentive to be a cataract surgeon or to own a cataract centre in Canada if we persist with DSBCS only. ISBCS resolves most of the issues, especially if we can convince governments to reimburse ISBCS fairly (unlike in the past).

I have written dozens of articles on ISBCS, but this one is different. It is being written primarily to provide guidance for my colleagues in the performance of **safe** ISBCS. Having performed over 11,000 procedures, I would feel terrible if Canadian and global surgeons took up ISBCS and developed unnecessary complications, because they did not follow what those of us who have been practicing ISBCS for many years have found to be preferable and safe procedures. I

feel morally compelled to circulate this document, unencumbered by the need to appease anybody or any group in presenting what I strongly believe to be critical safety issues in ISBCS.

It is important to recount the benefits of ISBCS, aside from financial, in the COVID-19 era, before addressing guidance for performing ISBCS as safely as possible. So, let us turn to "why do ISBCS?" first.

With Yi Ning Strube and Ronit Yagev, I wrote the first comprehensive paper of the modern era in 2003, reviewing my series of 1020 consecutive ISBCS patients operated upon between January 1996 and January 2002, showing an overall low complication rate for the time, and no complications referable to the bilaterality of the surgery.¹ I was doing the largest number of ISBCS cases, as far as I knew, globally, but I was not alone in the world. Bjorn Johansson published a much smaller series in the BJO just before ours got published. Charles Claoué and Jon Bolger in London, UK, and Johann Kruger in South Africa were starting to perform ISBCS. The Finns and the ophthalmic group on the Canary Islands of Spain were adopting routine ISBCS at around the same time. In 2010 the government of Spain published a document recognizing ISBCS to equally safe and effective as DSBCS. I later discovered that we were by no means the first. On April 8, 1747, Jacques Daviel performed the first planned extracapsular cataract extractions (ECCE), having been unhappy with his previous 4,000 couching operations. He did his first ECCEs as ISBCS, left eye first, and continued to perform them as ISBCS. We have learned a lot since Daviel, and ISBCS is much easier for us now, than it was for him.

When a new cataract patient appears in the office of an ophthalmologist complaining about his/her vision, it may come as a surprise to most to recognize that in the majority of cases it is the vision in the better eye the patient is complaining about. Older patients complain when they can no longer do the things they want to (the good eye gets blurry) more often than they complain that one eye is getting blurry. Many of these patients complain after unilateral cataract surgery that they see no better, as the eye that was not their concern is better, but the eye they were using seems worse by comparison to the operated eye.

Patients and families always express their great preference for ISBCS to me, and they also found at Colorado Permanente, in 2013, that when given free choice, 80% of potential patients request ISBCS, preferring fewer visits and faster recovery, as the risk is similar to DSBCS. There is no loss of binocularity between the first and second surgeries with ISBCS, so patients do not suffer falls. They return to their normal lifestyle in 1-2 days. Patients more rapidly adapt to their new vision when both eyes are the same, whether a large change in refractive error for high ametropes or new multifocal IOLs altering perception (but summation makes the loss of

contrast sensitivity much less noticeable) are performed. ISBCS encourages surgery on amblyopic eyes, which often show a surprisingly good result, but would not usually undergo unilateral surgery. Patients requiring special care, such as inherited genetic disorders, severe kyphosis or scoliosis, moribund patients wanting to see to read for the last 6 months of their lives, or psychiatric problems are all much easier to operate on only once. The list of benefits goes on and on once you begin to perform ISBCS and get accustomed to it.

When the International Society of Bilateral Cataract Surgeons ([iSBCS](#)) was formed in 2008, we decided upon a single rule: *"If any problem occurs with the first eye that cannot be fully resolved at surgery, the second eye should be deferred"*. The statement is worded the way it is because every bilateral cataract surgeon has learned that the best time to operate upon a difficult case is immediately after learning about unusual problems to expect by operating upon the patient's other eye.

Nevertheless, ISBCS requires an extra level of care and a willingness to investigate any unusual result in great detail, to solve the problem and avoid repeating it. There have been about 8 cases of bilateral simultaneous post-operative endophthalmitis (POE) reported since 1978, and in every case that has been carefully investigated, a severe breach in sterile protocol occurred. Alternatively, in a study of 125,000 eyes the International Society of Bilateral Cataract Surgeons ([iSBCS](#)) ophthalmologists experienced an infection rate of 1:16,800 (0.006%) in patients who received intracameral antibiotics and no cases of bilateral POE; the lowest rate yet reported anywhere.²

Much has been written about the fear of performing ISBCS because of the need to adjust the IOL power for the second eye after checking the result of the first eye. Such errors simply do not occur if biometry is performed with IOL Master or Lenstar, confirmed with back-up ultrasonography and corneal topography or tomography. Every test should have a back-up confirmatory test, as Warren Hill has stated, and everything should match. If the tests do not match they should be repeated. Doing that, I have never had to change an IOL in my last 10,000 ISBCS eyes, and only in one case was the result off by enough to require a small "touch-up" refractive laser procedure.

The surgeon just embarking upon ISBCS will have a number of patients that are excluded, such as diabetics with macular edema, lid infections such as blepharitis or chalazia, Fuchs' endothelial dystrophy with pachymetry > 630-650 microns, complex cases, such as cataracts with colobomas, severe pseudoexfoliation, IFIS, and anyone younger than age 25-30. With practice

and confidence, the number of exclusions will gradually decrease as it has for me and now are very few.

Femtosecond cataract surgery brings a unique problem. I initially performed femto-phaco on one eye and then repeated the steps for the other eye. However, one patient who had asked for a bit more anesthetic from the anesthetist, fell when she got up to return to the laser. I have done my last 200 cases as Femto-Femto-Phaco-Phaco with no problems and happier patients. I learned this from Laurent Lalonde MD FRCSC, of Boisbriand, Quebec, who first presented his results at the [iSBCS](#) annual meeting in Copenhagen, Sept. 12, 2016.

In 2009, the International Society of Bilateral Cataract Surgeons ([iSBCS](#)) published "[iSBCS General Principles for Excellence in ISBCS](#)" appended to this document. The [iSBCS Principles](#) has now been used globally and is accepted as the reference standard for how to perform ISBCS safely. It is recommended that it be followed. It is, however, ten years old and specific items may vary slightly at different centres. I will highlight a few points:

Points 5,6: The risk of R-L errors can be minimized by listing all R-L parameters on a board or screen somewhere in the operating room visible to all. The OR staff must be familiar with biometric calculations and the performance of ISBCS. They should announce the patient's name, R or L side, and IOL chosen as it is passed from the circulator to the scrub nurse to the surgeon. The surgeon should confirm the IOL choice and astigmatism by being able to see his/her own written choice as he/she accepts the IOL (I place a card with all critical patient data for the day [in my handwriting] on my microscope for every case). I always perform the left eye first to reduce possible confusion.

Point 7: Complete aseptic separation of R and L procedures **must** be done. **Nothing** should travel from the R to L eye or vice versa. Two completely separate surgical trays, autoclaved independently with indicators, should be used for the two eyes, and the eye should be re-prepped and draped for the second eye the same as for a different patient with the entire team changing their gowns and gloves and using new drapes and everything else. Some things require particular care. OVDs are globally accepted by ISO as "sterile" with a bioburden (risk of contamination) of 1:1,000. Everything else used in medicine and surgery must have a bioburden of only 1:1,000,000. I, therefore, use similar OVDs for R and L eyes, but from different companies, to minimize risk. The minimum would be to use them from different lot numbers. There are some things with which you can be less strict. For example, if you use Vision Blue from a reputable western company. Only a small amount is usually kept by operating rooms, making it hard to stock different lot numbers. However, use as little as you need and make sure

it is washed out well. If BSS is used from a reputable company with a good track record, it is advisable, but not as critical as with OVDs, to use different lot numbers for R and L eyes. In the end, it is simple. If we demand it, the companies will provide it. It may be difficult to obtain things like Miochol or Miostat in different lot numbers, so I prefer to give topical pilocarpine drops from minims post-operatively. Intracameral Vigamox is unique, in that Vigamox bottles are self-sterilized by the antibiotic, so a single bottle can be used to make up the day's supply of IC Vigamox, as long as the solution is then sequestered away from the surgical sites and divided into aliquots to be accessed individually later. However, in general, everything should be different for R and L eyes and preferably from different lot numbers.

Point 9: ISBCS patients should not be patched and should receive their post-operative drops 6x/day for the first 4 days beginning 1 hour post-op (e.g. Vigamox 3 ml/ Acular 10 ml/ Pred Forte 5 ml), then qid until bottles empty (the paper has been submitted for publication to explain why).

ISBCS should not be performed without IC antibiotics. Simply put, the global consensus is: ***If you want to perform ISBCS, use IC antibiotics at the end of each case.*** My preference is diluted IC moxifloxacin – recipe attached at end of document (references available).

Post-operative review of patients should be at 1 day post-operatively, and then 2 weeks followed by prn. It is true as the literature shows, that not many critical problems are discovered on POD1. However, patients do raise questions about their new vision almost always, and it is the best time to discuss them. Furthermore, it does provide the surgeon with the opportunity to see how patients have fared in the first 24 hours post-op. We want ISBCS patients to recover close to normal vision within a few hours, or less, post-operatively, and it is only by seeing them that we can ascertain that and make small changes in our procedures to improve and accelerate recovery.

Surgeons who perform ISBCS should follow the subject and report their data. National societies should consider having ISBCS sessions at their next few meetings, as interest has greatly escalated. The COS should work with the provinces to restructure the financing of ISBCS to eliminate unfair financial penalties. American and other jurisdictions should do the same.

¹ Arshinoff SA, Strube YNJ, Yagev Y. Simultaneous bilateral cataract surgery. J Cataract refract Surg. 2003; 29:1281-1291.

² Arshinoff SA, Bastianelli PA. Incidence of postoperative endophthalmitis after immediate sequential bilateral cataract surgery. J Cataract Refract Surg 2011; 37:2105-2114.

iSBCS General Principles for Excellence in ISBCS 2009

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 FRCS, Toronto, Canada
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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 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 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 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.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).

Intracameral Vigamox®

Jan. 1, 2019.

Supplied: Alcon Laboratories: Vigamox® (moxifloxacin) 0.5% eye drops = 500µg / 0.1 ml.

(The Sandoz authorized generic is also OK, the others have not been tested and confirmed safe for IC use)

Goal: 150µg / 0.1 ml (dilution: 3 parts Vigamox + 7 parts BSS)

i.e. to get 150 µg / 0.1 cc. simply dilute eye drops to 30% concentration of supplied Vigamox®

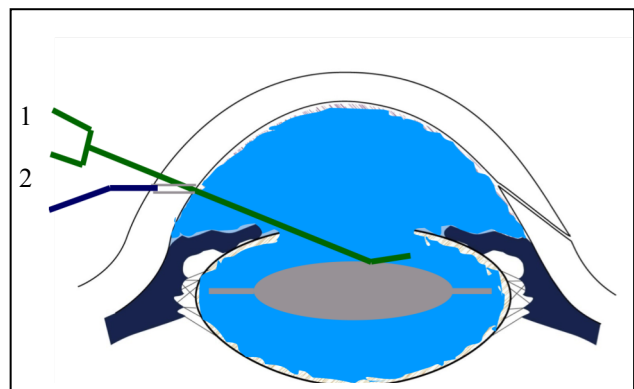
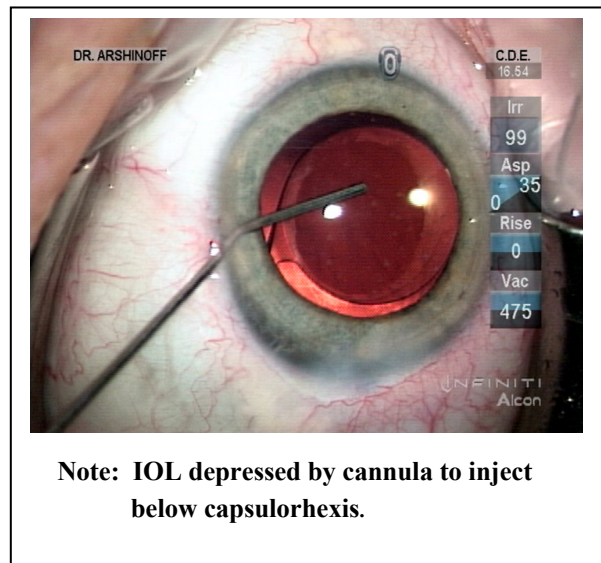
Method: Inject 0.3-0.4 ml Vigamox® 150 µg / 0.1 cc at the end of case = 450-600 µg. → 1.0 - 1.2 mg/ml in AC

(Essentially, this is an exchange of most of newly pseudophakic AC volume [0.5 ml] with the Vigamox® solution.

The volume indicated (0.3-0.4 ml) is what is likely left in the AC at the end of surgery.)

Detailed Instructions:

1. 3 ml Vigamox® withdrawn into a 12 cc syringe with sterile needle, from new Vigamox® bottle.
2. 7 ml BSS drawn into same syringe, from a new 15 ml BSS bottle (mixed by the turbulence of aspiration, and rolling the syringe).
- 0.8 ml injected into medicine cup on surgical tray by circulating nurse.
3. Scrub nurse draws up 0.6 ml Vigamox solution into a TB syringe to hand to surgeon.
4. Surgeon expels 0.1 ml, to be sure of no bubbles, and then injects 0.3 - 0.4 ml via the side port as the last step of surgery, under the distal capsulorhexis edge (1) and then as the eye is exited, with a final spurt of injection at the incision (2), to hydrate the incision and make sure the AC is left pressurized. This is a planned exchange of most of AC contents, and is therefore very easy to do.
5. I have done > 9,000+ cases to date with variations of this method, and have seen no toxicity in any case to date.



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