Immediate Sequential Bilateral Cataract Surgery (ISBCS)
COVID-19 Considerations
October 2020

Preamble

This document, which is subject to regular updates, provides best practice evidence informed perspectives for ophthalmologists in Canada and can be viewed as a supplement to the June 3, 2020 COS issued document entitled “Immediately Sequential Bilateral Cataract Surgery (ISBCS) - Key Points”. (Appendix 1).

DISCLAIMER: This document should not be viewed as advocating widespread adoption of ISBCS; however, if individuals or groups are considering this or already engaging in the practice in the context of the COVID-19 pandemic, then we hope that the perspectives shared will be helpful. It will be important for those doing ISBCS to follow best practice recommendations so as to optimize outcomes and minimize the risk of complications. It is also important to note that standards of ISBCS and restrictions due to COVID are evolving and all surgeons must stay updated and use clinical acumen and judgement when deciding what is best-care for their patients.

This document is based on the “ISBCS for the Edmonton Zone: COVID-19 Considerations” May 24, 2020 put together for the Eye Institute of Alberta/Department of Ophthalmology and Visual Sciences at the University of Alberta by Kam Kassiri MD, Khaliq Kurji MD, Sim Sandhu MD and reviewed by Chris Rudnisky MD. This committee also reviewed this present document.

The following represents a review of the most recent literature, as well as a review of practices cited above. The Edmonton committee has also reviewed the current CPSBC guidelines1 and also consulted CMPA with regards to medicolegal considerations.

The Edmonton document was modified for ACUPO by Marie Eve Légaré MD, Department of Ophthalmology at Laval University, September 30, 2020, and reviewed by ISBCS - Key Points authors. Acknowledgement to Susan Ruyu Qi, PGY-3 Laval University for literature review. If you have any feedback related to this document please contact Dr. Légaré at: marie-eve.legare@fmed.ulaval.ca

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Current Situation in Canada
1. COVID-19 OR shut-down markedly increased wait lists
2. New physical distancing rules result in a reduction in surgical volume for an indeterminate period
3. Further waves could further increase wait lists

ISBCS Facts
ISBCS (with both eyes undergoing cataract surgery on the same day) has been performed since the 90’s. It has become progressively common practice globally e.g., Finland has a rate of 40% of all cases in many hospitals, Sweden 40%,2,3,4 Canary Islands 80%.5 Contrarily, a recent study reported an ISCBS rate of less than 0.5% in UK.6 Global statistics for United States and Canada are not available at this point. However, prevalence rate of ISBCS in specific populations, areas or surgical groups from US and Canada have been reported:

1. Kaiser Permanente Health Maintenance Organization, has reported on 3 561 ISBCS (7 122 eyes)7,8,9
2. An estimated total of 10 856 ISBCS (21 712 eyes) done in 6 Canadian surgical centers between 1996 and 2009.3
3. In 2012 in Ontario, a rate of 0.84% of all cataract surgeries were reported as ISBCS.10
4. Centre Universitaire d’Ophtalmologie du CHU de Québec - Université Laval reports over 6,500 ISBCS (13,000 eyes) over 4 years, including resident performed ISBCS. Over 50% of eyes were operated as ISBCS in 2019-20 (manuscript in process).11

These groups have reported no case of bilateral POE nor bilateral TASS while following the General Principles for Excellence in ISBCS established by iSBCS in 2009.12

Historically, the main barrier to general acceptance of ISBCS, is the possibility of bilateral complications such as POE or TASS. With the introduction of 4th generation fluoroquinolones, and new intraoperative standards these risks have been reduced considerably.13 However, the risk is still present.

Patient Benefits of ISBCS:
1. 50% decrease in the number of hospital/clinic/pharmacy visits (OR day and post-op visits)
2. 50% decrease in close contact with caregiver for drops application and shield taping
3. Faster glasses adjustment (ex.: able to read medication bottles)
4. Faster restoration of binocular vision and stereopsis (important for driving, reduces risk of fall)
5. Reduced discomfort and morbidity between surgeries in patients with high levels of anisometropia
6. Decreased time off work and transport costs for the patient
7. Decreased time off work and transport costs for the accompanying person; and length/burden of care for the caregiver
8. Only one “stress” of undergoing eye surgery
9. Only one general anesthesia in patients unsuitable for local anesthesia. Bhambhwani & al. reported the use of ISBCS in young children with equivalent results to DSBCS.14
10. Reduced waiting time for cataract surgery

Patient Risks of ISBCS:
1) Bilateral POE:
1. Bilateral POE is a rare complication with only few cases reported in the literature (Table 1). Likely other cases have occurred but are not reported in the literature. The cases reported showed breaches in the current recommendations (iSBCS 2009\textsuperscript{12} and NIHCE(UK) 2017\textsuperscript{15})

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ECCE: extracapsular cataract extraction; F: female; HM: hand motion; IC: intracameral; ICCE: intracapsular cataract extraction; M: male; NLP: no light perception; OVD: ophthalmic viscosurgical device; PCIOL: posterior capsule intraocular lens; POE: postoperative endophthalmitis; pt: patient; Staph Epi: staphylococcus epidermidis; UK: United Kingdom

2. Using guidelines outlined in the iSBCS, Arshinoff and Bastianelli from the iSBCS group reported a rate of zero bilateral POE in 95,606 cases\textsuperscript{3} and a rate of unilateral POE of 1 in 14,352 to 16,800 (0.006 to 0.007%) \textsuperscript{3}

3. Kaiser Permanente reported 1 unilateral POE in 10,494 eyes (5,247 ISBCS) and 2 unilateral POE in 38,736 eyes DSBCS.\textsuperscript{8}

Therefore, it is important to inform the patient of an estimated risk of less than approximately 1 / 1000 000 of bilateral POE resulting in permanent decrease in vision including bilateral blindness or loss of both eyes.

2) Bilateral TASS
No cases of bilateral TASS following ISBCS have been reported in the literature as of the writing of this document. In the rare event of a series of TASS happening at one institution, the strict guidelines of the ISBCS 2009 are meant to minimise the risk of TASS in both eyes. Intracameral use of moxifloxacin using Moxeza® has been reported to cause TASS due the presence of xanthan gum,\textsuperscript{22} and must not be used. It is mandatory to review the list of inactive ingredients, the literature and warnings from health authorities for reported case of TASS, before using moxifloxacin from any manufacturer. Also, the FDA recommends to avoid using more than 0.3ml of 0.5% moxifloxacin.\textsuperscript{22} (Appendix 32)

3) Refractive Error (IOL selection of second eye based on result of the first eye in DSBCS)
1. Kaiser Permanente 2017\textsuperscript{8} reported post-operative SE within 0.5D:
   - 13 711 DSBCS: 61% of first eye and 61% of second eye
   - 3 561 ISBCS: 63% of OD and 63% of OS
2. A prospective study showed no difference in UCVA, BCVA and self-perceived visual function between ISBCS (834 eyes) and DSBCS (780 eyes) at one year.\textsuperscript{23}
3. In 2015, a retrospective study evaluated 110 sequential ISBCS. The achieved refraction was within ±1.0D of the target in 83% of eyes. In only 5% of cases (n=6) DSBCS instead of ISBCS could potentially have altered IOL choice.\textsuperscript{24}

4) Bilateral CME
Post-operative macular edema may occur more than 4 weeks after surgery and would likely not be identified prior to surgery of the second eye in DSBCS. CME is usually treatable either by drops, injections or surgery. Careful selection of patients for ISBCS minimizes these risks.
5) Corneal Edema
Corneal decompensation can occur after phacoemulsification. Mild corneal edema may resolve, but moderate and severe corneal edema may require further surgery. Wait times for corneal grafts can be in excess of one year. Patients could have bilateral corneal blindness until grafted. Preoperative corneal examination to identify patients at risk is crucial and risks discussed appropriately.

6) Conversion to DSBCS Due to Complication in the First Eye
Kaiser Permanente\(^8\) reported a conversion rate to DSBCS of 0.7%. Patients should be informed of this possibility.

7) OD / OS IOL implantation error
OR protocols must be strictly followed to avoid preventable errors as wrong IOL implantation.

**System/Hospital Benefits of ISBCS:** Decrease in waiting lists and hospital costs
1. Hospital/office administration only schedules one day per patient rather two days; this is a 50% decrease in their scheduling per ISBCS patient (1 OR day, 1 post-op day 1, 1 post-op 1 month)
2. Fewer patients requiring preoperative processing
3. Preoperative and recovery areas less crowded:
   a. Reduced physical space needs per surgeon
   b. Allows more surgeries done while respecting COVID guidelines
4. Quicker turn over time, more efficient use of OR time, more cases done per day
5. Decreased need for porter and stretcher
6. More efficient use of anaesthesiology time when anesthesiologist present
7. In Canada, each ISCBS could save around 500$ in overall costs.\(^25,26\)

**Hospital Risks of ISBCS:**
1. Embedding new protocols (sterilisation and OR)
2. Increased long-term surveillance associated with new protocols
3. Potential medico-legal issues
4. ISBCS implementation should include wait-list monitoring to ensure wait list targets are not negatively impacted for those undergoing monocular surgeries
5. Surgical wait lists should be monitored:
   a. To ensure wait list targets are not negatively impacted for those undergoing monocular surgeries.
   b. To avoid exceeding wait list targets tied to financial penalties, for the hospitals submitted to such financial penalties, which would affect the delivery of care.

**Preoperative Considerations for ISBCS:**

**Candidacy:**
1. **Patient consent:** every patient must be free to choose DSBCS over ISBCS
2. Qualification to undergo cataract surgery should follow the current COS guidelines in each eye
3. Psychosocial issues including lack of support to attend surgery and visits
4. Potential loss of independence - living alone without/distant care providers with limited/no ability to take time off to attend to the patient
5. In patients with high refractive errors due to potential refractive surprise and risks associated with temporary high anisometropia
6. Patients where loss of fusion can affect recovery
7. Patients travelling long distances
8. Medical comorbidity requiring the patient to undergo general anesthesia (i.e., dementia, psychiatric illness, developmental delay)

**Potential Contraindications:**
Based on literature, feedback from centers currently performing ISBCS, surgeons are discouraged from performing ISBCS in:
1. Unilateral cataract
2. Patient uncertainty about ISBCS
3. Lenticular abnormalities:
   a. Severe / dense cataracts (at the surgeon discretion based on experience)
   b. History of ocular trauma
   c. Phacodonesis
d. Moderate to severe pseudoexfoliation (Mild pseudoexfoliation at the surgeon discretion)
e. Posterior polar cataracts
4. Increased risk for infection:
a. Active ocular surface infection (untreated blepharitis, mucocele, dacryocystitis)
b. Poorly controlled diabetes mellitus (surgeon discretion)
c. Immunosuppression and immunodeficiency (including systemic steroids)
d. Leukemia/lymphoma
e. Any environmental consideration that could increase the risk of endophthalmitis (e.g., construction in an adjacent operating theatre, a change in cleaning/sterilization practices)
5. Increased risk for corneal decompensation:
a. Endothelial dystrophy
b. Guttata (at the surgeon discretion based on experience and degree of guttata)
c. Small anterior chamber or axial length (AL) less than 21.0 mm.
6. Increased risks of inaccurate biometry (although with current technology and new formulas, this is becoming less of a factor.)
a. Previous refractive surgery
b. Difference in AL > 1 mm between eyes (unexplainable with history and/or exam)
7. Advanced glaucoma or increased risk for high IOP
8. Uveitis (depending on risk of severe post-operative inflammation)
9. Retinal pathologies with potential for worsening (surgeon discretion + comfort with Anti-VEGF use)
10. Intraoperative Floppy Iris Syndrome or AL > 27.0 mm (at the surgeon discretion based on experience)

**Patient Consent:** discussion and chart should include:
1. Patient must be informed of the comparative risks of ISBCS versus DSBCS
2. Possibility that the surgeon delays the surgery for the second eye to a later date, in case of issues with the first eye (such as central endothelial damage, PCR, zonular instability and vitreous prolapse)
3. Surgical complications are possible, may require additional treatment and surgical procedures, and may result in permanent loss of vision in one or both eyes.
4. Lens options discussion and selection for each eye
5. Documentation in the chart: The consent discussion is documented in the patient’s health-care record and includes the nature of the care proposed, the risks, benefits and alternative(s) discussed with the patient (i.e., DSBCS) and any specific additional issues or concerns that arose through the discussion and how they were addressed

6. **Patient uncertainty about ISBCS should be an absolute contraindication**

**Patient Registry to track outcomes**
Consider if there is an opportunity for academic networks to share their data as to outcomes including complications. Non-academic networks can be encouraged to participate as well.

**Resident Involvement and Teaching**
1. Residents can still be involved based on patient consent, resident skill level, and complexity of the cases. In the future these need to be compared with the pre-ISBCS period to ensure adequate teaching.
2. As both cataracts of a same patient often have the same features, the resident can immediately integrate the feedback from the first surgery on the second eye.
3. As for DSBCS, patient consent to the potential participation of an ophthalmology resident during surgery must be discussed and documented.

**Medicolegal Consideration**
1. ISBCS has been offered to patients in Ontario since 1996, Quebec and British Columbia since 2010.
2. ISBCS is currently being considered in many Canadian provinces to decrease risk of exposure during COVID-19 pandemic.
3. Contact the CMPA for any medical or legal issue concerning the practice of ISBCS.

Additional comments or suggestions to the original document: **ISBCS General Principles for Excellence in ISBCS – iISBCS 2009**(Appendix 2).
Concerning the risk for Right – Left eye errors:

**ADDITIONAL SUGGESTIONS:**

a. Double time-out prior to the start of surgery for each patient prior to sedation as per local protocol with local institution Surgical Safety Check List
b. Use original biometry or IOL calculation printout to identify name, eye and IOL power selected instead of rewriting to avoid transcription errors
c. The second lens does not become available to OR staff until the turn over time (either does not enter the room or is not given by the surgeon until turn over time).
d. When possible, having a set routine for all ISBSC patients is suggested, such as same sequence of eyes.

Concerning the complete aseptic separation of the first and second eye:

a) Separate sterilization cycles

**ADDITIONAL COMMENTS:**

a. Shorstein\(^9\) reported that instruments trays do not absolutely need to be from separate cycles if a center observes and documents the following measures: complete sterilization cycles; performs daily biologic spore testing; has audible autoclave temperature and pressure alarms; and chemical indicators or integrators in instrument trays are strictly verified during time out. Perhaps something to be noted for centers that are not able to keep instruments from separate cycles.

b. Different Ophthalmic Viscosurgical Devices (OVD) and different manufacturers or lots of surgical supplies:

**ADDITIONAL COMMENTS and SUGGESTIONS:**

a. While some OVDs have the same standard bioburden requirement as other surgical supplies (1:1,000,000), some OVDs have a bioburden of 1:1,000. Hence the recommendation to have different lot numbers or coming from different manufacturer for the second eye, when reasonable and possible.\(^9\)
b. Tracking of LOT numbers suggested

c. Sterile routines:

**ADDITIONAL SUGGESTIONS:**

a. Complete re-scrubbing for all (surgeon, nurse, resident), as per institution protocols.

d. Intracameral antibiotics:

**ADDITIONAL COMMENTS:**

a. Safety of intracameral moxifloxacin (ICM) has been demonstrated in many studies.\(^{27,28,29}\)

In a Canadian prospective database, Rudinsky & al.\(^{27}\) demonstrated the superiority of topical 4\(^{th}\) generation fluoroquinolone (4\(^{th}\)G FQ) over other topical antibiotic drops, and no difference in the POE rate with the addition of ICM to topical 4\(^{th}\)G FQ. On the other hand, a recent meta-analysis showed no difference in efficacy between IC plus topical antibiotics versus IC alone\(^{29}\); and a retrospective study reported a reduction in POE rate by 3.0-fold (up to 6-fold after phacoemulsification) with the use of ICM.\(^{29}\) Therefore, considering the safety of ICM, its proven efficacy and the conflicting evidence of the role of topical versus IC 4\(^{th}\)G FQ, both ICM and topical 4\(^{th}\)G FQ is recommended.

Post-Operative Consideration:

1. This will be surgeon specific. Recommendations include eye protection (glasses or clear shield) to be used immediately after the surgery during the day and tape-on shields for the first 5 to 7 nights
2. Drops regimen should follow that of DSBCS: topical 4\(^{th}\) generation fluoroquinolone, steroid and consider non-steroidal anti-inflammatory
   a. Post-operative topical 4\(^{th}\) generation fluoroquinolone started promptly on the day of surgery\(^{30,31}\)
   b. Patients are recommended to get a different set of bottles for each eye
   c. “Drop-less” cataract surgery is not recommended.
3. Eyes should not be patched to allow prompt start of post-operative drops early after surgery

Follow-Up:

1. Patients are closely followed for signs of endophthalmitis and TASS
2. Inform emergency teams to allow ISBCS patients to be seen with a lower threshold of symptoms (Health-Link in some areas)
3. All complications should be tracked and incidents of TASS reported to the COS TASS task force:
### Immediately Sequential Bilateral Cataract Surgery (ISBCS) - Key Points

*June 3, 2020*

**Steering Committee:** Steve Arshinoff, Kashif Baig, Simon Holland, Yvonne Buys

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### General Management, Logistical and Medico-legal Considerations

- Cataract or refractive lens surgery should be indicated in both eyes
- Any concomitant relevant ocular or periocular disease should be managed
- Relative exclusions: increased infection risk, endothelial dysfunction, weak zonules, IFIS, DME, severe glaucoma, extremes in axial length (eg <21 or >27mm), ocular trauma, previous refractive surgery
- Complexity of proposed ISBCS procedure should be within competence of the surgeon
- Patient should provide suitable informed consent, being free to choose ISBCS or Delayed SBCS
- Risk for Right/Left eye errors and IOL power errors should be minimized by listing all surgical parameters for both eyes in a manner clearly visible to all in OR
- Complete aseptic separation of the first and second eye surgeries is mandatory to minimize the risk of postoperative bilateral endophthalmitis and TASS. When reasonable, instruments from different sterilization cycles and tubing, fluids, OVDs and intraocular medications from different lot numbers or manufacturers is recommended
- Any complication with the first eye surgery must be resolved before proceeding with second eye
- Intracameral antibiotics are strongly recommended
- The protocol for FLACS-ISBCS is currently in evolution
Appendix 2
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 2009: Steve Ashino MD FRCS, Toronto, Canada
Charles Clague MD FRCS, Birmingham, UK
Bjorn Johansson MD, PhD, Linkoping, Sweden

The committee would like to thank the membership of ISBCS for their constructive input into this document: Dr. David & Miguel Perez-Siguenza, Dr. Paulo Alves de Sousa, & Ramon Herreuez de la Pe, 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 perocular 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 checklist should also be used if possible.
6. Intracapsular 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 (BSIE).
   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 possible, for the right and left eye.
   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 prophylactic 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.

Appendix 3

STEVE ARSHINOFF, MD, FRCSC

Intracameral Vigamox®


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

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

Goal: 150 µg / 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.

   Steve Arshinoff MD FRCSC

References

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5 Government of Spain publication. Seguridad, efectividad y coste efectividad de la cirugía de la cataratas bilateral y simula. SESCS 2006-05 (Article in Spanish).
24 Guber I, Remont L, Bergin C. Predictability of refraction following immediate sequential bilateral cataract surgery (ISBCS) performed under general anaesthesia. Eye Vis. 2015;2:13.