Published in final edited form as:

J Cataract Refract Surg. 2017 March ; 43(3): 318–323. doi:10.1016/j.jcrs.2016.12.025.

Failure Modes and Effects Analysis of bilateral same-day cataract surgery

Neal H. Shorstein, MD,

Kaiser Permanente, Walnut Creek, California, USA

Carol Lucido, MSN,

Kaiser Permanente, Walnut Creek, California, USA

James Carolan, MD,

Kaiser Permanente, San Rafael, California, USA

Liyan Liu, MD, MS,

Kaiser Permanente Division of Research, Oakland, California, USA

Geraldine Slean, MD, and

Kaiser Permanente, Oakland and the California Pacific Medical Center, San Francisco, California, USA

Lisa J. Herrinton, PhD

Kaiser Permanente Division of Research, Oakland, California, USA

Abstract

Corresponding author: Neal H. Shorstein, MD, Departments of Ophthalmology and Quality, Kaiser Permanente, 320 Lennon Lane, Walnut Creek, California 94598, USA. nshorstein@eyeonsight.org.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Presented at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, New Orleans, Louisiana, May 2016, and the annual meeting of the American Academy of Ophthalmology, Las Vegas, Nevada, USA, November 2015.

Doug O'Brien provided analysis of compounded and manufactured pharmaceuticals and U.S. Food and Drug Administration recalls. Pat Vanni provided expertise in cleaning and sterilization standards and practices.

Other Cited Material

A. Institute for Healthcare Improvement. Failure Modes and Effects Analysis (FMEA) Tool. Available at: <http://www.ihl.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx>. Accessed January 5, 2017

B. U.S. Food and Drug Administration. Archive for Recalls, Market Withdrawals & Safety Alerts. Available at: <http://www.fda.gov/Safety/Recalls/ArchiveRecalls/default.htm>. Accessed January 5, 2017

C. U.S. Food and Drug Administration. Outsourcing Facilities. Available at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm393571.htm>. Accessed January 5, 2017

D. International Society of Bilateral Cataract Surgeons. General Principles for Excellence in ISBCS 2009. Available at: <http://isbcs.org/wp-content/uploads/2011/03/2010-07-20-FINAL-ISBCS-SBCS-suggestions-from-ESCRS-Barcelona.pdf>. Accessed January 5, 2017

Disclosure: Dr. Herrinton has a research contract with Medimmune, LLC, which is unrelated to this study. None of the other authors has a financial or proprietary interest in any material or method mentioned.

A systematic assessment of cleaning and sterilization processes, pharmaceutical management, and IOL selection might uncover potential system failures relating to risk for endophthalmitis, TASS, and unintended IOL implantation.

PURPOSE—To systematically analyze potential process failures related to bilateral same-day cataract surgery toward the goal of improving patient safety.

SETTING—Twenty-one Kaiser Permanente surgery centers, Northern California, USA.

DESIGN—Retrospective cohort study.

METHODS—Quality experts performed a Failure Modes and Effects Analysis (FMEA) that included an evaluation of sterile processing, pharmaceuticals, perioperative clinic and surgical center visits, and biometry. Potential failures in human factors and communication (modes) were identified. Rates of endophthalmitis, toxic anterior segment syndrome (TASS), and unintended intraocular lens (IOL) implantation were assessed in eyes having bilateral same-day surgery from 2010 through 2014.

RESULTS—The study comprised 4754 eyes. The analysis identified 15 significant potential failure modes. These included lapses in instrument processing and compounding error of intracameral antibiotic that could lead to endophthalmitis or TASS and ambiguous documentation of IOL selection by surgeons, which could lead to unintended IOL implantation. Of the study sample, 1 eye developed endophthalmitis, 1 eye had unintended IOL implantation (rates, 2 per 10 000; 95% confidence intervals [CI] 0.1–12.0 per 10 000), and no eyes developed TASS (upper 95% CI, 8 per 10 000). Recommendations included improving oversight of cleaning and sterilization practices, separating lots of compounded drugs for each eye, and enhancing IOL verification procedures.

CONCLUSIONS—Potential failure modes and recommended actions in bilateral same-day cataract surgery were determined using a FMEA. These findings might help improve the reliability and safety of bilateral same-day cataract surgery based on current evidence and standards.

Bilateral same-day cataract surgery, also referred to as immediate or same-day sequential bilateral cataract surgery, offers patients a convenient and cost-effective alternative to traditional bilateral delayed surgery.^{1,2} This modality can reduce the number of perioperative appointments, meaning fewer days of miss work and less travel time for the patient.³ This is particularly advantageous for patients in rural or congested urban settings.⁴ Cost savings might accrue to patients, employers, and taxpayers.

Some ophthalmologists argue against bilateral same-day surgery because it creates a risk for bilateral endophthalmitis⁵ and toxic anterior segment syndrome (TASS), either of which can lead to bilateral blindness. Another potential risk is unintended intraocular lens (IOL) implantation, which could lead to an unanticipated or undesired refractive error⁶ in 1 or both eyes. There is also a concern that the refractive outcomes in the first eye are not available to tweak the IOL selection for the second eye,⁵ a topic beyond the scope of the current study.

Recent innovations in cataract surgery have reduced the risk for adverse events and advanced the argument for bilateral same-day surgery. Intracameral antibiotic injection has been strongly associated with a reduced risk for endophthalmitis,^{7–10} to approximately 1 in 7 per 12 000 cases.¹¹ Improvements in instrument cleaning practices have been linked to a declining incidence of TASS.¹² Arshinoff¹³ and Arshinoff and Odorcic¹⁴ created workflows for reducing the risk for bilateral adverse events by separating instrument trays and sterile

setups in bilateral same-day surgery. Others have described mechanisms to prevent implantation of an unintended IOL.^{6,15}

We conducted a Failure Modes and Effects Analysis (FMEA) to assess perioperative practices in a single surgery center compared with prevailing regulatory requirements and current evidence-based recommendations.

PATIENTS AND METHODS

This study was approved by the Kaiser Foundation Research Institute's institutional review board. Established in 1946, Kaiser Permanente is a closed staff model integrated healthcare delivery system with a capitated payment system that provides comprehensive care to 3.9 million members in Northern California. All surgeons are employed by the Permanente Medical Group.

The FMEA is a tool widely used in the automotive, aerospace, and electronics industries to identify, prioritize, and eliminate known potential failures, problems, and errors from systems under design.¹⁶ Failure Modes and Effects Analysis methodology is ideal for new or redesigned systems and processes, in particular in complex work environments, and it has been successfully adapted to the healthcare industry.^{17,18,A} This study used the FMEA methodology to delineate the risks associated with bilateral same-day surgery to patient safety and to identify additional steps that would further improve system reliability in a community-based surgery center in the Diablo Service Area of Kaiser Permanente. To help estimate the likelihood of the occurrence of surgically related adverse events for some failure modes in the FMEA, data were analyzed from the 21 surgery centers in Kaiser Permanente Northern California that performed bilateral same-day surgery during 2010 through 2014.

Failure Modes and Effects Analysis

An FMEA identifies workflows, process steps within each workflow, potential modes of failure at each step, failure effects (severity and likelihood), and recommended actions. The study co-leaders (N.H.S., C.L.) focused the FMEA on the following 3 patient safety concerns as the failure effects of concern: endophthalmitis, TASS, and unintended IOL implantation. They then formed a work group of key stakeholders and subject matter experts, including staff of the medical center (pharmacists, infection prevention nurse, sterile processing), surgery center (director, manager, nurses, and scrub technicians), and outpatient ophthalmology department (physician chair, clinic director, manager, and medical assistants). The work group also included regional leaders (perioperative nursing, sterile processing, materials management, and pharmacy) with operational experience from all 21 surgery centers. The work group met every 1 to 2 months between July 2014 and April 2015.

Key process steps were identified throughout each patient's continuum of care and then combined with similar and connected process steps into workflows. Next, communications, decisions, and actions associated with each process step were identified using the methods

detailed by Brown et al.¹⁷ For each process step, potential failure modes were identified, and for each failure mode, a failure effect was estimated.

The failure effect is composed of the following 2 parts: the severity of harm based on the worst credible clinical outcome to a patient and the likelihood of occurrence (Figure 1). The severity of harm was assigned based on information reported in the literature and historical adverse events from the 21 surgery centers. The failure modes resulting in endophthalmitis or TASS were classified as high severity of harm, and those resulting in unintended IOL implantation were classified as minimal severity because of the correctable nature of refractive errors. The likelihood of occurrence was based on an analysis of historical adverse events, reports in the literature, and the judgment of the work group's subject matter experts.

A level of risk was assigned to each failure mode based on the severity of harm and likelihood of occurrence. Finally, recommended actions were developed and prioritized for medium-risk and high-risk failure modes.

Adverse Event Rates and Product Recalls

To obtain the most precise FMEA results, the incidences of endophthalmitis, TASS, and unintended IOL implantation were computed using data from the health plan's 21 surgery centers for the years 2010 through 2014. The electronic medical records (EMRs) for bilateral same-day surgery were searched using the Current Procedure Terminology code 66984 with modifier 50 and included cases scheduled as bilateral same-day surgery with completion of at least 1 eye. Endophthalmitis was identified from the International Classification of Diseases, 9th Edition (ICD-9) codes 360.00, 360.01, 360.03, 360.13, 360.19, 098.42. Toxic anterior segment syndrome was ascertained from ICD-9 code 379.8 and from the regional risk-management reporting system. An ophthalmologist involved in the study (N.H.S.) validated adverse events by reviewing visit notes in the EMRs. The 95% confidence interval (CI) was determined using the exact binomial method.¹⁹

To help further characterize a risk for contaminated manufactured products, which could result in endophthalmitis or TASS, the U.S. Food and Drug Administration (FDA)^B and internal databases were searched for recalls, market withdrawals, and safety alerts for pharmaceutical products procured for cataract surgery by Kaiser Permanente during the study period.

RESULTS

Adverse Event Rates and Product Recalls

Kaiser Permanente surgeons performed surgery on 4754 eyes scheduled for bilateral same-day surgery during 2010 through 2014. Of these, 1 eye developed culture-negative endophthalmitis (rate, 2 per 10 000; 95% CI, 0.1–12.0 per 10 000) 49 days after uneventful phacoemulsification with injection of intracameral moxifloxacin 0.1%. The visual acuity on the day of presentation was 20/400, and it returned to 20/20 within 5 days of diagnosis and injection of intravitreal antibiotics. No bilateral same-day surgery eye was identified with TASS (upper 95% CI, 8 per 10 000).

A review of risk-management records identified a dilution error from onsite compounding of cefuroxime that resulted in the injection of a 9-fold greater dose than intended in 4 eyes of 2 bilateral same-day surgery patients (rate, 4/4754 or 8/10 000; 95% CI, 2–22 per 10 000) operated during the same day. The surgeon and retinologist observed temporary macular edema that resolved within 1 week. In addition, records indicated 1 eye with implantation of an unintended IOL (rate, 2 per 10 000; 95% CI, 0.1–1.0 per 10 000). A root-cause analysis found that a 22.0 diopter (D) IOL intended for the second eye had been implanted during surgery in the first eye instead of a 22.5 D IOL. The correct IOL was implanted in the second eye.

U.S. Food and Drug Administration warnings were issued for 2 products in 2012 (Amvisc and Amvisc Plus, Bausch & Lomb, Inc.) because of a faulty cannula design that was subsequently corrected with a locking cap.

Failure Modes and Effects Analysis

Six workflows were defined for the FMEA; 3 were visit based (preoperative outpatient clinic, surgery center, and postoperative outpatient clinic) and 3 were process based (sterile processing, pharmaceuticals, and biometry). Four of the 6 workflows were linked to failure modes leading to potential endophthalmitis or TASS, whereas 2 were linked to unintended IOL implantation. Table S1 (available at <http://jcrsjournal.org>) shows the biometry process steps.

Endophthalmitis and Toxic Anterior Segment Syndrome

Four workflows and 7 failure modes, with more than a rare likelihood of occurrence that could lead to endophthalmitis or TASS, were identified. Because the potential severity of harm was high, these failure modes were classified as high risk and recommended actions were developed to help prevent failures (Figure 2).

In the Sterile Processing workflow, inspection of the surgery center by subject matter experts identified rust residue on instruments, cracks in internal peel-pack enclosures of sterilized instruments, drying of instruments before washing, and processing incongruities that did not comply with the manufacturers' directions for use.

Figure 2 lists the recommended actions for the Sterile Processing workflow; Surgery Center processes; the Pharmaceuticals workflow, which includes a recommendation to procure compounded drugs from a pharmacy registered with the FDA as a 503B outsourcing facility^C; and the Postoperative Outpatient Clinic workflow, which includes a recommendation to more clearly identify signs for infection that would necessitate an urgent examination by a surgeon.

Unintended Intraocular Lens

Eight failure modes with more than a rare likelihood of occurrence that could lead to unintended IOL implantation were identified. Because the potential severity of harm was minimal, these failure modes were classified as medium risk (Figure 3).

Figure 3 lists the recommended actions for the Preoperative Outpatient Clinic workflow and Biometry. For document verification, the recommended actions are that 2 staff members would be required to independently validate all data elements related to bilateral same-day surgery (name, medical record number, eye laterality, IOL type, model, power, and working distance) using 2 independent primary sources of verification. This method of verification would begin in the outpatient clinic where staff would perform an audit comparing the data elements on the consent form, biometry scan, and surgery schedule 3 days before surgery. The verification would continue through each process step in the surgery center until the IOL is finally implanted.

DISCUSSION

Advancements in cataract surgery have been associated with decreased rates of endophthalmitis and TASS in recent years.^{8,12} An important concern in the adoption of bilateral same-day cataract surgery, however, has been the fear of bilateral vision loss from endophthalmitis and TASS. There are 4 reports in the literature, discussed in the editorial by Li et al.,²⁰ of bilateral endophthalmitis from bilateral same-day cataract surgery, all stemming from inadequate sterilization and the lack of separating instrument trays between the 2 eyes. Although 2 cases of unilateral suspected TASS have been reported in 2 patients having bilateral same-day surgery²¹ and a case of suspected bilateral TASS has been reported in a patient following bilateral surgery separated by 2 days,²² we are unaware of any reports of bilateral TASS in patients having bilateral same-day surgery. Before performing high volume bilateral same-day surgery, we performed an FMEA to uncover potential process failures with the goal of reducing patient risk for endophthalmitis, TASS, and unintended IOL implantation.

We identified process steps in 6 separate workflows, from initial patient consultation through the 1-week postoperative visit. We analyzed each process step for failure modes and classified each of these by the severity of harm and the likelihood of occurrence. To determine our classification of failure modes, we computed adverse event rates from regional historical data. We then prioritized the failure modes into risk categories and recommended corrective actions to address the high-risk and medium-risk groups.

As a result of the FMEA, we found opportunities to improve the training, assessment, and oversight of our sterile processing department. These included inconsistencies in following instrument manufacturers' directions for use. We did not recommend separating instrument trays from different sterilization cycles for each eye of bilateral same-day surgery because of the redundant safety features used in our operating center. These include audible autoclave temperature and pressure alarms; placing multiple chemical indicators or integrators throughout each instrument tray, which are then verified during the time out; and daily biologic spore testing, which is more frequent than required by directions for use.

In the procurement of pharmaceuticals and material management, we identified high-risk failures in the onsite compounding of intracameral agents.²³ Because of the annual volume of cataract surgery and the number of facilities in our region, we recommended sourcing agents from vetted pharmacies registered with the FDA as 503B outsourcing facilities,^C

which must follow current good manufacturing processes. In addition, we recommended that injections for each eye come from separately prepared lots to help minimize the risk for bilateral endophthalmitis or TASS if a lot were to be contaminated or compounded incorrectly. Separate lots of a balanced salt solution and ophthalmic viscosurgical devices for each eye have also been recommended based on a report of associated TASS in 2009¹⁴ and a variable threshold of allowable bioburden for these products.^D A review of FDA recall notices for this study showed that such manufactured products are highly reliable. In addition, our organization maintains a centralized FDA product recall surveillance and notification system to constituent medical centers, which further enhances safety. As a result, we did not recommend separating lots for FDA-approved, manufactured pharmaceutical products. Before making changes or additions in the procurement of pharmaceuticals intended for intraocular use, we also recommended that appropriate personnel should review the intended manufacturer's history of product safety, reliability, and equivalence.^D Backup sources should be vetted and maintained in case of shortages by current pharmaceutical suppliers.

Because of recent reports associating retinal vasculitis in both eyes after delayed bilateral cataract surgery with injection of intracameral vancomycin,²⁴ we recommended against the routine intraocular administration of vancomycin in bilateral same-day surgery.

To help prevent implantation of an unintended IOL, we recommended a revised system of independent double checks of IOL parameters in the clinic, preoperative holding area, and in the operating room; clearly identifying the order of surgery and the patient's desired working distances for each eye; and allowing only the IOL box and its attendant documentation into the operating room for the current eye having surgery.

In summary, although it is unlikely that an FMEA can uncover every potential failure mode in cataract surgery, we found several opportunities to improve our systems and processes to the standards and practices that have been associated with reduction in risk for endophthalmitis, TASS, and unintended IOL implantation. The effectiveness of the FMEA and the implemented corrective actions are difficult to assess given the low incidence of the failure effects/adverse outcomes under study. This will be an area for further research. The current, noncapitated United States Medicare formula reimburses physicians and surgery centers only 50% for the second eye in same-day surgery, which might be a significant deterrent against wide adoption in the U.S.^{2,25} Despite this, bilateral same-day cataract surgery can offer patients, employers, and payers a more efficient and economic method of visual rehabilitation than delayed sequential surgery.² Further scientific and policy developments are needed to advance bilateral same-day surgery so that patients, their families, and payers receive optimum benefit.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Supported by a community benefit grant and the Garfield Memorial Fund from Kaiser Permanente and by the National Eye Institute (R21 EY022989), Bethesda, Maryland, USA, for computer programs used in the analysis.

Biography

References

1. Leivo T, Sarikkola A-U, Uusitalo RJ, Hellstedt T, Ess S-L, Kivelä T. Simultaneous bilateral cataract surgery: economic analysis; Helsinki Simultaneous Bilateral Cataract Surgery Study report 2. *J Cataract Refract Surg.* 2011; 37:1003–1008. [PubMed: 21596243]
2. Rush SW, Gerald AE, Smith JC, Rush JA, Rush RB. Prospective analysis of outcomes and economic factors of same-day bilateral cataract surgery in the United States. *J Cataract Refract Surg.* 2015; 41:732–739. [PubMed: 25754380]
3. Neel ST. A cost-minimization analysis comparing immediate sequential cataract surgery and delayed sequential cataract surgery from the payer, patient, and societal perspectives in the united states. *JAMA Ophthalmol.* 2014; 132:1282–1288. Available at: <http://jamanetwork.com/journals/jamaophthalmology/fullarticle/1888112>. Accessed January 5, 2017. [PubMed: 25033037]
4. Arshinoff SA, Chen SH. Simultaneous bilateral cataract surgery: financial differences among nations and jurisdictions. *J Cataract Refract Surg.* 2006; 32:1355–1360. [PubMed: 16863975]
5. Schachat AP. Simultaneous bilateral endophthalmitis after immediate sequential bilateral cataract surgery: what's the risk of functional blindness? [letter]. *Am J Ophthalmol.* 2014; 158:410–411. reply by Li O, Kapetanakis V, Claoué C, 411–412. [PubMed: 25085107]
6. Neily J, Chomsky A, Orcutt J, Paull DE, Mills PD, Gilbert C, Hemphill RR, Gunnar W. Examining wrong eye implant adverse events in the Veterans Health Administration with a focus on prevention: A preliminary report. *J Patient Saf.* 2015 Mar.;16. Epub ahead of print.
7. ESCRS Endophthalmitis Study Group. Prophylaxis of postoperative endophthalmitis following cataract surgery: results of the ESCRS multicenter study and identification of risk factors. *J Cataract Refract Surg.* 2007; 33:978–988. [PubMed: 17531690]
8. Herrinton LJ, Shorstein NH, Paschal JF, Liu L, Contreras R, Winthrop KL, Chang WJ, Melles RB, Fong DS. Comparative effectiveness of antibiotic prophylaxis in cataract surgery. *Ophthalmology.* 2016; 123:287–294. Available at: [http://www.aaojournal.org/article/S0161-6420\(15\)00895-7/pdf](http://www.aaojournal.org/article/S0161-6420(15)00895-7/pdf). Accessed January 5, 2017. [PubMed: 26459998]
9. Creuzot-Garcher C, Benzenine E, Mariet A-S, de Lazzer A, Chiquet C, Bron AM, Quantin C. Incidence of acute postoperative endophthalmitis after cataract surgery; a nationwide study in France from 2005 to 2014. *Ophthalmology.* 2016; 123:1414–1420. [PubMed: 26992840]
10. Friling E, Lundström M, Stenevi U, Montan P. Six-year incidence of endophthalmitis after cataract surgery: Swedish national study. *J Cataract Refract Surg.* 2013; 39:15–21. [PubMed: 23245359]
11. Carnahan MC, Chang WJ, Shorstein NH, Herrinton LJ. New benchmark in preventing phacoemulsification-related endophthalmitis. *J Cataract Refract Surg.* 2014; 40:1568.
12. Bodnar Z, Clouser S, Mamalis N. Toxic anterior segment syndrome: update on the most common causes. *J Cataract Refract Surg.* 2012; 38:1902–1910. [PubMed: 22999515]

13. Arshinoff SA. Same-day cataract surgery should be the standard of care for patients with bilateral visually significant cataract. *Surv Ophthalmol.* 2012; 57:574–579. [PubMed: 22995967]
14. Arshinoff SA, Odorcic S. Same-day sequential cataract surgery. *Curr Opin Ophthalmol.* 2009; 20:3–12. [PubMed: 19077823]
15. Schein OD, Banta JT, Chen TC, Pritzker S, Schachat AP. Lessons learned: wrong intraocular lens. *Ophthalmology.* 2012; 119:2059–2064. [PubMed: 22704833]
16. Rhee SJ, Ishii K. Using cost based FMEA to enhance reliability and serviceability. *Advanced Engineering Informatics.* 2003; 17:179–188.
17. Brown DS, Bonacum D, Vonderheide-Liem D. Quality toolbox. The Kaiser Permanente FMEA model—simplified for healthcare personnel. *J Healthcare Quality.* 2005; 27:48–55.
18. Stamatis, D. Failure Mode and Effect Analysis: FMEA From Theory to Execution. Milwaukee, WI: ASQ Quality Press; 1995.
19. Clopper CJ, Pearson ES. The use of confidence intervals or fiducial limits illustrated in the case of the binomial. *Biometrika.* 1934; 26:404–413.
20. Li O, Kapetanakis V, Claoué C. Simultaneous bilateral endophthalmitis after immediate sequential bilateral cataract surgery: what's the risk of functional blindness? [editorial]. *Am J Ophthalmol.* 2014; 157:749–751. [PubMed: 24630205]
21. Guber I, Bergin C, Stürmer J. More than 10 years of experience with immediate sequential bilateral cataract extraction (ISBCE)—a retrospective study. *Open J Ophthalmol.* 2014; 4:139–144. Available at: http://file.scirp.org/pdf/OJOp_2014112710130772.pdf. Accessed January 5, 2017.
22. Lee S-N. Mild toxic anterior segment syndrome mimicking delayed onset toxic anterior segment syndrome after cataract surgery. *Indian J Ophthalmol.* 2014; 62:890–892. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4185172/>. Accessed January 5, 2017. [PubMed: 25230969]
23. Wong DC, Waxman MD, Herrinton LJ, Shorstein NH. Transient macular edema after intracameral injection of a moderately elevated dose of cefuroxime during phacoemulsification surgery. *JAMA Ophthalmol.* 2015; 133:1194–1197. Available at: <http://jamanetwork.com/journals/jamaophthalmology/fullarticle/2397957>. Accessed January 5, 2017. [PubMed: 26226062]
24. Witkin AJ, Shah AR, Engstrom RE, Kron-Gray MM, Bauman CR, Johnson MW, Witkin DI, Leung J, Albin TA, Moshfeghi AA, Batlle IR, Sobrin L, Elliott D. Postoperative hemorrhagic occlusive retinal vasculitis; expanding the clinical spectrum and possible association with vancomycin. *Ophthalmology.* 2015; 122:1438–1451. [PubMed: 25886796]
25. Neel ST. A cost and policy analysis comparing immediate sequential cataract surgery and delayed sequential cataract surgery from the physician perspective in the United States. *JAMA Ophthalmology.* 2014; 132:1359–1362. Available at: <http://jamanetwork.com/journals/jamaophthalmology/fullarticle/1905276>. Accessed January 5, 2017. [PubMed: 25232929]

WHAT WAS KNOWN

- Bilateral same-day cataract surgery can offer convenience to patients and potential savings in time and cost; however, there are concerns of bilateral loss of vision from endophthalmitis or TASS.
- Unintended IOL implantation in unilateral surgery has been studied, although risks associated with bilateral same-day surgery have not been fully described.
- Failure Modes and Effects Analysis has been used in healthcare settings to reduce risks to patients; however, there are no published studies applying this method to bilateral same-day cataract surgery.

WHAT THIS PAPER ADDS

- Failure Modes and Effects Analysis can be tailored for bilateral same-day cataract surgery.
- Several areas for quality improvement that have been associated with a reduced risk for endophthalmitis, TASS, and unintended IOL implantation were identified.

		Likelihood of Occurrence (probability on an annual basis)					
		Frequent	Likely	Occasional	Infrequent	Rare	Very Rare
		1/1	1/10	1/100	1/1,000	1/10,000	≤1/100,000
Severity of Harm (Worst, Credible)*	High (Endophthalmitis/TASS)	1	1	1	1	2	2
	Moderate	1	1	1	2	3	3
	Mild	2	2	2	2	3	3
	Minimal (Unintended IOL)	2	2	2	2	3	3

Figure 1.

Modified FMEA matrix for bilateral same-day cataract surgery. Severity of harm and likelihood of occurrence were estimated for each failure mode and then a risk category was assigned (1 = high risk; 2 = medium risk; 3 = low risk; IOL = intraocular lens; TASS = toxic anterior segment syndrome). *Final Snellen corrected visual acuity in a single eye of a bilateral same-day cataract surgery patient.

Workflow	Process Step	Potential Failure Mode	Recommended Action
Sterile Processing	Cleaning and sterilization of instruments in the surgery center	Instrument processing lapses	<ul style="list-style-type: none"> Enhance oversight Additional, ongoing training and inspections Maintain posting of current DFU
		Instruments dry between cases	<ul style="list-style-type: none"> Spray instruments with gel Use bath on transport cart Overlap coverage of personnel during breaks
		Inadequate flushing of the irrigation and aspiration tip	<ul style="list-style-type: none"> Follow DFU for cleaning of non-disposable tips Consider disposable irrigation and aspiration tips
		Deployment of trays prior to biological testing completion	<ul style="list-style-type: none"> Add trays, new workflows, change to 1-hour testing instead of 3-hour
		Separating trays from different lots	<ul style="list-style-type: none"> None – current failsafe redundant systems are robust
Pharmaceuticals	Procurement and management of pharmaceutical products	Contamination/dilution error by compounding personnel	<ul style="list-style-type: none"> Procure sufficient supply from a pharmacy registered with the FDA as a 503B outsourcing facility and avoid onsite compounding Inject antibiotic from different lots for each eye or different antibiotic class for each eye
		Contamination of a manufactured product	<ul style="list-style-type: none"> Separating lots unnecessary due to high reliability Vet new manufacturers and products
Surgery center	Nurse prepares patient for discharge	Inadequate patient hand hygiene	<ul style="list-style-type: none"> Demonstrate proper hand hygiene to patients prior to discharge
Outpatient Clinic Postoperative	Telephone advice through first postoperative week	Delayed triage of postop patient	<ul style="list-style-type: none"> Revise telephone advice protocol

Figure 2.
Failure modes potentially leading to endophthalmitis or TASS (DFU = manufacturers' directions for use; FDA = U.S. Food and Drug Administration).

Workflow	Process Step	Potential Failure Mode	Recommended Action
Preoperative Outpatient Clinic	Surgeon documents lens selection and consent discussion	Variable ways to designate IOL selection and working distance on biometry scan and consent form	<ul style="list-style-type: none"> Standardize biometry/lens order and consent formats using EMR templates
	Biometry machine settings	Incorrect formula/lens constant	<ul style="list-style-type: none"> Limit changes in biometry unit Surgeon verifies formula and constant by circling when designating IOL selection on biometry scan
	Manual data entry by technician or surgeon	Transcription error	<ul style="list-style-type: none"> Limit software on biometry unit or create policy to disallow manual entries by technician Update software to recalculate target based on measurements Update biometry software to calculate toric lenses Clinic technician validates surgeon entries for post-keratorefractive eyes
	Patient chooses IOL type (monofocal, toric or multifocal) and working distance	Surgeon does not elicit or understand patient's choice	<ul style="list-style-type: none"> Surgeon and patient must agree on lens type and working distance for each eye in the office Consent form clearly indicates lens type and working distance for each eye separately Patient verifies each eye preoperatively with nurse and consent form Sedation meds withheld until surgeon confirms lens type and working distance with patient and consent form in surgery center
	Surgeon circles IOL selection on biometry scan	Ambiguous or illegible selection	<ul style="list-style-type: none"> Train surgeons in optimal, standardized notation Surgery center staff rejects ambiguous IOL selection documentation
	Biometry scan faxed to surgery center	Clinic failure to fax; fax illegible; incorrectly filed or lost in surgery center	<ul style="list-style-type: none"> Surgeon designates IOL selection electronically in the EMR Data is viewable/printable in the surgery center
	Patient changes mind for working distance or lens type	Surgeon unaware or does not execute change	<ul style="list-style-type: none"> Patient must speak directly with surgeon for a change in planned lens Surgeon documents in EMR and removes prior information from view Surgeon notifies surgery center directly if within 2 working days of surgery
	IOL boxes for both eyes in operating room	IOL of 2 nd eye is implanted in 1 st eye	<ul style="list-style-type: none"> 2 separate scans, 1 for each eye Only 1 IOL and scan in operating room at a time for each eye White board/monitor with IOL information for only 1 eye at a time

Figure 3.

Failure modes potentially leading to unintended IOL implantation (EMR = electronic medical record; IOL = intraocular lens).