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

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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 errors of intracameral antibiotics 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 interval [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 an FMEA. These findings might help improve the reliability and safety of bilateral same-day cataract surgery based on current evidence and standards.

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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 missed 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 endophthalmitis[5] 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 error[6] 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 10 000 cases.[11]

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Improvements in instrument cleaning practices have been linked to a declining incidence of TASS.[12] Arshinoff[13] and Arshinoff and Odorcic[14] 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 where bilateral same-day surgery was performed 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, and 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

			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)	≤20/200	1	1	1	1	2	2
	Moderate	20/40	1	1	1	2	3	3
	Mild	20/30	2	2	2	2	3	3
	Minimal (Unintended IOL)	20/20	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 distance visual acuity in a single eye of a bilateral same-day cataract surgery patient.