



Changing operating room practices: the effect on postoperative endophthalmitis rates following cataract surgery

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ABSTRACT

Purpose To determine whether four new operating room (OR) protocols instituted because of COVID-19 reduced the cataract surgical postoperative endophthalmitis rate (POE).

Design Retrospective, sequential, clinical registry study.

Methods 85 552 sequential patients undergoing cataract surgery at the Aravind Eye Hospitals between 1 January 2020 and 25 March 2020 (56 551 in group 1) and 3 May 2020 and 31 August 2020 (29 011 in group 2). In group 1, patients were not gowned, surgical gloves were disinfected but not changed between cases, OR floors were not cleaned between every case, and multiple patients underwent preparation and surgery in the same OR. In group 2, each patient was gowned, surgical gloves were changed between each case, OR floors and counters were cleaned between patients, and only one patient at a time underwent preparation and surgery in the OR.

Results Group 1 was older, had slightly more females, and better preoperative vision. More eyes in group 2 underwent phacoemulsification ($p=0.18$). Three eyes (0.005%) in group 1 and 2 eyes (0.006%) in group 2 developed POE ($p=0.77$). Only one eye that underwent phacoemulsification developed POE; this was in group 1. There was no difference in posterior capsule rupture rate between the two groups.

Conclusions Adopting a set of four temporary OR protocols that are often mandatory in the Western world did not reduce the POE rate. Along with previously published studies, these results challenge the necessity of these common practices which may be needlessly costly and wasteful, arguing for the reevaluation of empiric and potentially unnecessary guidelines that govern ophthalmic surgeries.

The healthcare sector has a surprisingly large carbon footprint, responsible for approximately 1/10 of the US's greenhouse gas emissions and 9% of the air pollutants.^{1,2} One study of the environmental footprint of cataract surgery found that one phacoemulsification procedure in the UK generates the same carbon emissions as driving a car 500 km (310 miles).³ A large percentage of this carbon footprint is attributable to pharmaceuticals and supplies.^{3–6} Cataract surgery is one of the most frequently performed surgeries, with approximately 29 million performed globally in 2019, of which 4.2 million were performed within the USA and 7.4 million in India.⁷ This volume greatly

amplifies the financial and environmental impact of this single procedure.

In a recently published survey involving more than 1000 respondents, 93% of cataract surgeons felt that operating room (OR) waste was excessive and that approaches to reduce waste should be developed.⁸ Although not wanting to compromise safety, they felt that hospitals, regulatory agencies and manufacturers were overly restrictive and should permit greater surgeon discretion over which products could be used for multiple patients.

The Aravind Eye Care System (AECS) is composed of 14 regional eye hospitals in Southern India. In 2019–2020, Aravind saw over 4.6 million outpatients and performed over 317 000 cataract surgeries. Approximately 60% of their total surgical volume is free or highly subsidised to indigent patients. To maximise surgical safety, efficiency, volume and cost-effectiveness, the AECS standardises surgical and perioperative protocols across all 14 centres. Many long-standing practices at AECS, including simultaneous surgery on multiple patients in the same OR, not changing gowns or gloves between patients, and patients not donning gowns over street clothes, are not allowed in most areas of the Western world. Despite marked deviations from Western standards, the postoperative endophthalmitis (POE) rate in more than 335 000 consecutive phacoemulsification cases at AECS was 0.01%.⁹ This is lower than the 0.04% POE rate following cataract surgery reported by the American Academy of Ophthalmology (AAO) Intelligent Research in Sight Registry (IRIS) registry.¹⁰

Along with the rest of the world, elective cataract surgery at AECS was initially halted during the COVID-19 pandemic.¹¹ When cataract surgery resumed, AECS instituted new protocols designed to potentially minimise potential COVID-19 contagion. Under the new protocols the following changes were made: only one patient at a time occupied each OR, floors and surfaces were cleaned in between each patient, patients donned gowns over their clothing, and surgical gloves were changed after every case. These pandemic-related changes provided a unique opportunity to assess whether adopting these four new OR practices at AECS affected the POE rate following cataract surgery.

METHODS

This is a retrospective, sequential, clinical registry-based study including all charity as well as private

Table 1 Summary of changes in group 1 and group 2

Intraoperative change	January–March 2020 (n=56 551) Group 1	May–August 2020 (n=29 011) Group 2
Change 1	2–4 patients were in same OR simultaneously on adjacent tables. At the completion of a surgery, the surgeon moved the microscope head to the adjacent OR table, disinfected gloves, and immediately commenced surgery on the second patient.	Only 1 patient was in the OR at a time for each cataract surgeon.
Change 2	The OR floor was cleaned every 3 hours and OR table and other surfaces were cleaned with antiseptic at end of day.	The OR table, floor and surfaces were cleaned with antiseptic after every case.
Change 3	Neither the surgeon nor the scrub nurse changed gowns or gloves in between cases. Alcohol and chlorhexidine were used to disinfect gloves between cases.	The surgeon and scrub nurse wore double gloves and the outer glove was changed after each case.
Change 4	Patients wore their own clothing in the OR without wearing gowns.	Patients wore masks and laundered gowns over their clothing.

OR, operating room.

patients undergoing cataract surgery between 1 January 2020 and 31 August 2020 at the 14 regional AECS hospitals in South India.

The Indian government initiated a mandatory nationwide COVID-19 lockdown on March 25, 2020.¹¹ Because of health concerns regarding the potential spread of COVID-19, AECS proactively changed OR protocols. During the month of April 2020, surgery was limited to emergency or non-elective procedures; this period was excluded from this analysis. When elective cataract surgery resumed on 3 May 2020, AECS introduced four standardised modifications of OR protocols across all AECS surgery centres. These new protocol changes were based on recommendations issued by the All-India Ophthalmic Society.¹² Before launching these protocol changes, each AECS hospital held training sessions and conducted drills with all surgical personnel. To assess the impact of the new cataract surgical protocols on POE rates, we included all cataract surgery cases performed from 1 January 2020 to 25 March 2020 as our pre-pandemic baseline (group 1); these were compared with all cataract surgery cases performed from 3 May 2020 to 31 August 2020 (group 2). A longer period was selected for group 2, as lower cataract surgery volume was anticipated due to the pandemic restrictions. AECS resumed allowing multiple patients in the OR starting in September 2020, to reduce the large backlog caused by the lockdown.

Identical surgical and perioperative protocols were used during both study periods apart from the four changes described in table 1. Surgical methodology, equipment, intraocular lens (IOL), supplies and perioperative topical ophthalmic medications (dilating and anaesthetic) were administered by trained technicians and a single bottle was administered to multiple patients, remained the same and there were no additional changes to surgical indications, OR personnel or surgeon staffing. We used both topical and sub-tenon's anaesthesia. When subtenon's anaesthesia was performed, we used a single vial of anaesthetic on multiple patients; but each patient a unique syringe and needle.

Aravind's pre-COVID-19 OR protocols have been previously reported.^{13 14} At Aravind, private patients pay customary fees to undergo phacoemulsification with a foldable IOL, while most charity patients receive manual small-incision cataract surgery (MSICS) with a PMMA IOL, as this is typically more cost-effective. MSICS with a PMMA IOL is also performed in a few private patients presenting with extremely dense cataracts. AECS routinely reuses many surgical supplies, including phacoemulsification tips and tubing, irrigation solutions, intraocular drugs and surgical gowns; these policies were continued during the pandemic. We used laundered sheets to cover patients from shoulder to feet. Disposable eye drapes that

extended down to the chest were placed on all patients. We adhered to stringent sterilisation protocols prior to and during the pandemic to ensure all instruments used in surgery were sterilised.¹³

AECS' perioperative medication regimens for cataract surgery are standardised and were identical in all hospitals in both groups. Preoperative topical medications were applied by either the patient or by his or her accompanying individual. Preoperatively, all patients received a regimen of topical ofloxacin 0.3% eye-drops (Auroflox, Aurolab, Madurai, India) every 3 hours on the day before surgery and twice on the morning of surgery. We used topical povidone iodine (10% Aurodone DS, Aurolab, Madurai, India) immediately prior to surgery to prepare the periorbital area and the conjunctival cul-de-sac (5% Aurodone, Aurolab, Madurai, India). Multidose bottles of povidone iodine, as with other topical medications, were administered by well-trained staff to multiple patients. This was allowed to dry for several minutes, after which a sterile drape was placed on the operative eye and speculum applied such that the lids and lashes were isolated from the surgical field. All patients received an intracameral injection of 0.1 mL of moxifloxacin 0.5% w/v (Aumox, Aurolab, Madurai, India) at the conclusion of surgery. Topical ofloxacin 0.3% drops were again instilled three times daily for the first 15 days postoperatively. The same bottle that was administered preoperatively, was also used by the patient in the postoperative period. During both periods, most surgeons wore sandals without shoe coverings. These were only worn within the OR suites. In addition, topical dexamethasone 0.1% (Dexa eye-drops, Aurolab, India) was administered six times per day for the first postoperative week, and then tapered off over the next 6 weeks. All patients were examined on the first postoperative day and at approximately 1 month postoperatively. In any eye suspected of having POE, we performed a vitreous tap for culture and simultaneous antibiotic injection and core vitrectomy if required.

For the study period, we retrieved data from the universal AECS electronic medical record system used by all of our facilities. We reviewed records for every patient with a diagnosis of posterior capsule rupture (PCR), zonular dialysis (ZD) or POE occurring during the 6-week postoperative period. To assess the effect of the OR protocol changes, we compared the POE rates and complication rates between the two groups. We tabulated all cases with PCR or ZD, with and without vitrectomy, to determine the PCR/ZD rate during these two periods and the POE rate among this subset of eyes. To assess the effect of surgical inexperience, we also compared the case distribution between staff and trainee surgeons within these two groups as we have in the past.¹⁵ The latter category included residents, fellows and visiting trainees who were practicing ophthalmologists from

Table 2 Demographics

Parameters	January–March 2020 (n=56 551)		May–August 2020 (n=29 011) Group 2	Overall (n=85 552)	Mean difference (95% CI)	P value
	Group 1					
Age (years)					2.86 (2.71 to 3.02)	<0.0001
Mean (SD)	62.7 (9.9)		59.8 (10.1)	61.7 (10.07)		
Range	17–102		17–99	17–102		
Gender						<0.0001
Male	46.7		49.0	47.5		
Female	53.3		51.0	52.5		
Eye						0.027
Right	51.7		52.5	52.0		
Left	48.3		47.5	48.0		
Preoperative logMAR VA					−0.193 (−0.204 to −0.181)	<0.0001
Median (Snellen VA)	1.0 (6/60)		1.08 (5/60)	1.08 (5/60)		
IQR	0.6–1.18		0.78–1.78	0.6–1.48		

VA, visual acuity.

other centres or countries and were enrolled in surgical skill transfer programmes at AECS.

Statistical analysis

We performed the statistical analysis using STATA V.1 software. The distribution of data was given with frequency (percentage) and mean (SD/median (IQR)). The mean differences between two groups were reported with 95% CIs. We used Mann-Whitney U tests to compare continuous variables and χ^2 tests to compare categorical variables. Two sample proportion tests were used to compare the overall POE, PCR and ZD rates between the two time periods and by type of surgical technique (phacoemulsification vs MSICS). We considered a $p < 0.05$ as statistically significant. The sample sizes in this study (56 551 in group 1 vs 29 011 in group 2) allow for the detection of a sixfold difference in POE rates between the two groups based on the 0.005% rate of POE in group 1 with a type I error probability of 0.05 (one sided), and the statistical power of 85.5%.

RESULTS

We performed 56 551 cataract surgeries between 1 January 2020 and 25 March 2020, (group 1) and 29 011 between 2 May 2020 and 31 August 2020, (group 2). The demographics are found in table 2. Those in group 1 were slightly older, were more likely to be female, and had slightly better preoperative visual acuity. Phacoemulsification and MSICS each accounted for approximately half of the cases within each group, although the percentage for phacoemulsification was slightly higher in group 2. Staff surgeons performed more cataract surgeries than trainees in group 2 vs group 1 (78% vs 69%; $p < 0.0001$), however, this did not seem to affect rates of POE or other complications.

There was no significant difference in the POE rate between the two groups, as the rate of POE in Group 1 was 0.005% (3 eyes) compared with 0.006% (2 eyes) in group 2 ($p = 0.77$) (table 3). All samples were culture negative in the five eyes with POE. Of all eyes that underwent phacoemulsification, only one eye from group 1 developed POE, although there was no difference in POE rates between the two techniques (phacoemulsification and MSICS). Although not significantly different, a possible reason for the increased rates of POE in the MSICS group may be that the surgical tunnel incision is far larger in the MSICS group. Two patients in group 1 and both in group 2 presented with POE between the first and third week of surgery. The third patient in group one presented after the fifth postoperative week. PCR and ZD were rare (both $< 1.5\%$), without a significant difference between the two groups (table 4). Their occurrence did not seem to be related to the occurrence of POE.

DISCUSSION

This clinical registry study demonstrated that OR protocols that are commonly compulsory in Western healthcare systems did not reduce the POE rate following cataract surgery at AECS. Of note, the post-cataract surgery endophthalmitis rate in our study (0.006%) was lower than that reported in the IRIS registry (0.04%). This is in agreement with prior studies at AECS⁹ and suggests that AECS can offer highly cost-effective cataract surgical practices without compromising patient safety.^{4 5} By continually and carefully monitoring outcomes and safety through an electronic health registry capturing every procedure and outcome, AECS critically assesses the necessity of every supply item and protocol. As a result, AECS centres routinely reuse surgical attire, instruments and drugs and use intracameral

Table 3 Comparison of post-operative endophthalmitis by both group and type of cataract surgery

Cataract surgery type	January–March 2020 Group 1 (n=56 551)		May–August 2020 Group 2 (n=29 011)		Difference (95% CI)	P value
	No of surgeries	No of POE (%)	No of surgeries	No of POE (%)		
Phaco	27 454 (49%)	1 (0.003%)	15 061 (52%)	0 (0.00%)	0.000036 (−0.000035 to 0.000107)	0.46
M-SICS	29 097 (51%)	2 (0.006%)	13 950 (48%)	2 (0.014%)	0.00007 (−0.0001874 to 0.00033)	0.45
Total	56 551	3 (0.005%)	29 011	2 (0.006%)	−0.000015 (−0.00013 to 0.00009)	0.77

M-SICS, manual small incision cataract surgery; Phaco, phacoemulsification; POE, postoperative endophthalmitis.

Table 4 Comparison of posterior capsular rupture and zonular dialysis rates during the two periods with different protocols

Type of complication	January–March 2020 (n=56 551) Group 1			May–August 2020 (n=29 011) Group 2			Difference (95% CI)	P value for POE
	No of cases	PCR rate	No of POE (%)	No of cases	PCR rate	No of POE (%)		
PCR/ZD without vitrectomy	208	0.37%	1 (0.48%)	138	0.48%	0	0.005 (–0.0045 to 0.0145)	
PCR/ZD Requiring vitrectomy	576	1.02%	0	229	0.78%	1 (0.43%)	–0.0044 (–0.0129 to 0.004)	
Total	784	1.39%*	1 (0.13%)	367	1.26%*	1 (0.27%)	–0.0014 (–0.007 to 0.004)	0.58

*P value for comparison of PCR rates—0.95

PCR, posterior capsular rupture; POE, postoperative endophthalmitis; ZD, zonular dialysis.

moxifloxacin prophylaxis in all cataract surgery cases.^{13 14} Our results and those of other studies⁹ suggest that if intracameral antibiotic prophylaxis is employed, mandating single use of many supplies and drugs for cataract surgery may be of questionable and unproven benefit.¹⁰ There is no evidence that the Indian eyes are less prone to developing POE or that infectious microbial pathogens are any different in developing countries.¹⁶

At AECS, the unanticipated abrupt cessation of cataract surgery due to the global COVID-19 pandemic was followed by the resumption of surgery with newly modified practices. This provided us with a unique opportunity to assess whether certain measures instituted to prevent COVID-19 contagion might also further reduce the rate of POE. Although group 1 was older, had a larger percentage of females, had more left eyes and had better preoperative vision, it is unlikely that any of these variables are associated with POE, ZD or PCR. Both study groups were similar with respect to case mix (phacoemulsification vs MSICS) and PCR rate, which is a leading POE risk factor. A higher percentage of cases in group 2 were performed by staff surgeons, who were the first to resume operating in May 2020. As a possible confounding variable, this would have potentially conferred an additional advantage to group 2. Despite this, the complication rates were comparable in the two groups.

The Association of periOperative Registered Nurses (AORN) guidelines have been developed to address the entire gamut of surgical procedures throughout the body.¹⁷ Recommendations for full body draping, discarding unused but opened supplies, allowing no more than one patient in the OR at a time, changing surgical masks after each case, changing gowns and gloves and cleaning the floors after each case are all based on regulatory directives, advisory committee consensus, or studies of non-ophthalmic procedures.^{17–19} A review of the pertinent references cited in the 2021 AORN guidelines confirms that the efficacy and necessity of these blanket recommendations have not been specifically evaluated for cataract surgery.¹⁷

Our study found that adopting AORN's guidelines did not affect the POE rate in a cohort that underwent phacoemulsification and MSICS procedures at AECS. Given the high-volume nature of cataract surgery (4.2 million in USA in 2019 alone⁷ and the single use nature of most surgical materials, there is significant potential to reduce the cost and carbon footprint of this procedure by adopting evidence-based OR practices. For instance, the carbon footprint of laundering or disposing of millions of gowns may be prevented by foregoing patient gowning for cataract surgery. We believe that a prospective randomised trial to study the impact of each protocol change on a rare complication such as POE may not be practical nor necessary. Our study included sequential groups of patients from the same population who underwent surgery within the same year

at the same institution; the only variables changed were the four new OR protocols. The short study duration and system-wide standardisation of surgeons, protocols and data collection are strengths of this study.

Although we did not directly compare the carbon footprints of each study group, we feel there would be substantial differences. In addition to reducing the potentially significant economic cost of needless waste, there has been growing interest in reducing the carbon footprint of cataract surgery.^{3–6 8 20–22} This was the conclusion from a survey of more than 1000 cataract surgeons belonging to the AAO, the American Society of Cataract and Refractive Surgery, the Outpatient Ophthalmic Surgery Society and the Canadian Ophthalmology Society that was conducted in 2019 prior to the COVID-19 pandemic.⁸ In order to reduce excessive waste, 78% of surgeons believed that we should reuse more supplies. For example, 44% of surgeons had eliminated the full-body drape and 51% were willing to consider this. Fifty-six per cent did not change patients into hospital gowns and allowed them to stay in their own clothing; 34% were willing to consider this. A smaller percentage would consider reusing surgical gowns (64% willing; 28% unwilling) or surgical gloves (17% willing; 77% unwilling) in between cases.

This willingness on the part of some surgeons to reuse surgical personal protective equipment (PPE) and to reduce patient draping and gowning is supported by the results of this study. POE following cataract surgery is most commonly caused by intraocular contamination with bacteria from the patient's own adnexa and ocular surface.^{23 24} Recent experiments to assess the potential transmissibility of COVID-19 during cataract surgery show that trypan blue dye-stained aqueous is quickly eliminated by ophthalmic viscoelastic injection or irrigation with the phacoemulsification tip.²⁵ Others found that aerosolisation during phacoemulsification is insignificant and would convey irrigation fluid rather than contaminated aqueous.^{26–29} Our study supports the hypothesis that because significant contamination of surgical PPE with bodily fluid or tissue is so unlikely with cataract surgery, the risk of transmission of infectious agents to staff or other patients by not changing these items between cases is remote. Additionally, our study adds to the evidence that it may be unnecessary to have cataract surgery patients don a hospital gown or a full body drape.^{2 5} In addition to the financial and environmental burden of excessive waste, unnecessarily discarding PPE such as masks, gowns and gloves may reduce the healthcare system's resiliency to unforeseen challenges such as pandemics.³⁰

Although airborne microbial transmission from the patient's clothing or from other patients occupying the same OR might pose cross contamination risk for many non-ocular surgical procedures, there is no evidence linking cataract surgical POE to

these sources. Although having multiple patients in a single OR is not feasible at most centres nor is it HIPAA compliant in the United States, this study suggests that cleaning unsoiled counters and floors after each cataract procedure may also be of questionable benefit. Likewise, this study does not support discarding unused supplies and packs simply because they were opened in the presence of another patient.

Our study is limited by its retrospective nature and the lack of sufficient power to detect differences POE rates between the two time intervals for each type of cataract surgery, phacoemulsification and MSICS. While phacoemulsification and MSICS differ in some ways, prior studies at AECS have found that POE rates were comparable between the two procedures.¹⁵ We are limited by the availability of cases during the pandemic period as it would be impractical from cost and sustainability perspectives to randomise patients to the different OR protocols to have an equal number in each of the two groups. Additionally, while the described changes demonstrate some of the differences between AECS and Western ORs, it is important to keep in mind that the AECS ORs routinely reuse surgical instruments such as phacoemulsification tips and tubes, irrigating solutions, etc and these variables may have had an impact on the rate of POE and were not specifically evaluated in this study. Furthermore, while this study was limited to AECS, it included data from 14 sites. We were unable to expand to other hospital systems given that the OR protocols we described are not commonly practiced and the protocol changes may not have been standardised elsewhere.

Carbon footprint analysis is a relatively new concept in ophthalmology. Our prior data found that Aravind generates approximately 5% of the UK's carbon footprint per phacoemulsification. It is important to realise that this substantial decrease in carbon footprint does not decrease the successful outcome or increase POE.⁶

It is difficult to reverse the inertia of longstanding, eminence-based practices. For example, routine laboratory testing prior to cataract surgery was standard in the USA until its value and necessity were disproven.³¹ This reduced preoperative testing costs by 90% and spared patients from significant inconvenience and delay.^{31–33} Although patients wore gowns in the second group but not the first while surgeons did not change gowns, the data we present herein, combined with the AECS POE data accumulated over the past decade, make us question the evidence on which our current practices of changing gowns and gloves between cataract surgeries (when considering phacoemulsification and MSICS procedures in aggregate) and wonder whether we should reexamine its substantiation.⁹ These data also appear to counter theoretical concerns that POE could be caused by exposure to the patient's attire or by cross contamination from other patients that occupied the same OR. We believe that governing and guidance bodies such as The Joint Commission and the Centers for Medicare and Medicaid Services in the USA should permit greater surgeon discretion for certain OR protocols for which good evidence of necessity is lacking. Further studies should evaluate whether other perioperative practices are opinion-based rather than evidence-based and consequently are potentially unnecessary, wasteful and cost-ineffective.

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