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Postoperative endophthalmitis rate associated with routine off-label reuse of single-use phacoemulsification cassettes in more than 1,000,000 consecutive surgeries☆

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ABSTRACT

According to a 2025 APAO survey, reuse of phacoemulsification tubing and cassettes appears to be more common in Asian-Pacific countries compared to Europe and North America. We analyzed the phacoemulsification postoperative endophthalmitis (POE) rate from 2016 to 2024 at the Aravind Eye Care System's 15 hospital network. Single-use phacoemulsification cassettes were routinely reused all day (off label) at every facility during this 9-year period. The POE rate was 0.01 % in 1,133,959 consecutive cases. This rate was consistent from year to year and compared favorably with contemporaneous POE data from the American Academy of Ophthalmology Intelligent Research in Sight (IRIS) Registry (0.06 %), where presumably no reuse of phacoemulsification cassettes would have been allowed. We found no evidence that reusing the same phacoemulsification tubing and cassette all day increased the rate of POE.

In addition to generating a disproportionately large amount of greenhouse gas emissions (GHG), the global healthcare sector is also responsible for a large amount of plastic waste.[1] It is estimated that the United States (U.S.) generates more than 3000 tons of plastic waste each day.[2] Most of this is not recyclable because of contamination concerns, and therefore more than 90 % of this plastic ends up in landfill, incinerators, or the natural environment.

Multiple organizations have pronounced that the climate crisis poses a major threat to global public health. These include the World Health Organization, *The Lancet* Climate Change Commission, and Healthcare without Harm.[1,3,4] The projected increased burden of morbidity and mortality will be disproportionately borne by the poorest patients and societies. There is also increasing awareness about the health risks from microplastics in the environment.[5,6] Because of this rising threat to public health, the healthcare sector should be especially motivated to mitigate unnecessary carbon emissions and plastic waste. Within medicine, the highest procedural specialties, such as ophthalmology, have the greatest opportunity and obligation to impact and advance sustainable health care.[7–9]

In some countries, such as the United States (U.S.), single use labels on surgical devices and supplies are strictly enforced.[10] This results in virtually all phacoemulsification tubing and cassettes being discarded after every case, because only one machine with negligible market share has a reusable cassette approved in the U.S. In many other countries, however, off label reuse of the phacoemulsification cassette and tubing is practiced at the surgeon's discretion. In addition to decreasing waste, such reuse also reduces facility costs and this practice is therefore popular in many low to middle income countries. Although facilities around the world have been reusing single-use phacoemulsification tubing/-cassettes for years, estimates of the prevalence of this practice have not been available until publication of a recent survey by the Asia-Pacific Academy of Ophthalmology (APAO).[11] In this anonymous survey querying Asian-Pacific cataract surgeons about operating room (OR) waste and sustainable practices, 41 % of the 1929 respondents said that they were currently reusing phacoemulsification tubing/cassettes.

If a surgical product is labeled single use, the manufacturer is not required to submit data on the safety of reuse as part of the regulatory approval process. Therefore, data on complications arising from off-label reuse of phacoemulsification tubing/cassettes would not be available from the manufacturer. We were also unable to find published

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clinical data on postoperative endophthalmitis (POE) rates associated with this practice.

The Aravind Eye Care System (AECS) is a network of 15 regional eye hospitals in southern India performing high volumes of cataract surgeries. Off label reuse of phacoemulsification cassette tubing and cassettes has been routinely employed at AECS for many years. A previous AECS microbiology study found no growth in cultures of phacoemulsification handpieces and tubing that had been reused without resterilization throughout the OR day.[12] We analyzed POE rates at AECS during the past 9 years during which time reusing single-use phacoemulsification tubing/cassettes all day was the standard protocol at all AECS facilities.

Methods

The 15-hospital AECS network annually performs approximately 450,000 cataract surgeries, of which approximately 60 % are provided at little to no cost to the patient. The case mix includes both phacoemulsification and manual small incision cataract surgery (MSICS) in which the undivided nucleus is manually extracted through a scleral pocket incision. To maximize efficiency, all AECS surgeons and facilities follow standardized cataract surgical protocols, including using the same equipment, instruments, processing and sterilization procedures, perioperative drugs, and surgical supplies such as irrigation solution and ophthalmic viscosurgical devices (OVDs). We have previously detailed AECS' surgical and operating room protocols in earlier publications.[12–14]

Every AECS surgical facility primarily uses some combination of Alcon's Centurion, Legion, or Laureate phacoemulsification machines. Aurolab and J&J machines are also used at a few of the lower volume centers. Cortical cleanup is performed with either coaxial or biaxial irrigation/aspiration (IA) handpieces. Because the IA tips cannot be detached from biaxial IA handpieces, these handpieces undergo flash or immediate use steam sterilization (IUSS) after each use. With the phacoemulsification and coaxial IA handpieces, the ultrasound or IA tip and sleeve are removed following each case for processing and IUSS prior to reuse. Because the phacoemulsification handpiece, coaxial IA handpiece, cassette, and tubing set do not contact the eye or ocular surface, they are not reprocessed, resterilized, or discarded after each case. Instead, each of these items is continuously reused throughout the entire OR day on approximately 20–25 eyes.

To continually reuse the same phacoemulsification cassette and tubing set all day, a hole is made in the collection bag so that the aspirated contents can drain dependently into a nonsterile collection bucket (Fig. 1). The cassette and tubing are discarded at the end of the surgical day, and the phacoemulsification and coaxial handpieces are cleaned and autoclaved with a full terminal sterilization cycle (standard autoclave, Nat Steel Equipment Private Limited) prior to overnight storage. The same 500 mL irrigating solution bag is reused for multiple consecutive cases until the bag is nearly empty before it is replaced.

Povidone–iodine from a multiuse bottle is used to prepare the periorbital area (10 % Aurodone DS, Aurolab, Madurai, India) and the conjunctival cul-de-sac (5 % Aurodone). Antibiotic prophylaxis for cataract surgery at AECS is standardized to include topical ofloxacin 0.3 % (Auroflox, Aurolab, Madurai, India) for 1 day preoperatively and 10 days postoperatively, and intracameral injection of 0.1 mL of 0.5 % moxifloxacin (Auromox, Aurolab, Madurai, India) at the conclusion of surgery. All cataract surgical patients are examined on the first postoperative day and approximately 3–4 weeks postoperatively. The criteria for diagnosing POE at AECS have been detailed in prior publications.[14] Any eye suspected of having POE underwent a vitreous tap for culture and simultaneous antibiotic injection. A core vitrectomy was performed if indicated.

AECS utilizes an electronic medical record system with standard protocols for recordkeeping and data collection. From this registry, we retrospectively analyzed phacoemulsification POE rates at AECS from January 1, 2016, through December 31, 2024. Because all patient data was de-identified, IRB approval was not necessary. January 2016 was chosen as the starting point because routine intracameral moxifloxacin prophylaxis had been universally adopted across the entire AECS hospital network by that time. We included every case of phacoemulsification performed during this period and did not exclude higher risk eyes, cases performed by trainees, or cases with intraoperative complications. MSICS cases were excluded.

Results

During the 9-year study period, 1,133,959 consecutive phacoemulsification cases were performed at AECS's network of 15 surgical facilities. The annual volumes of phacoemulsification during the study period are shown in Fig. 2, alongside the total number of POE cases diagnosed that year. The overall POE rate for the 9-year period was

Fig. 1. To use the aspiration fluid collection bag all day, a green drainage tube is inserted through a cut opening into the collection bag for gravity drainage into a non-sterile collection bucket on the floor. The same method is used with the Alcon Centurion (a) and the Alcon Legion (b) phacoemulsification machines.

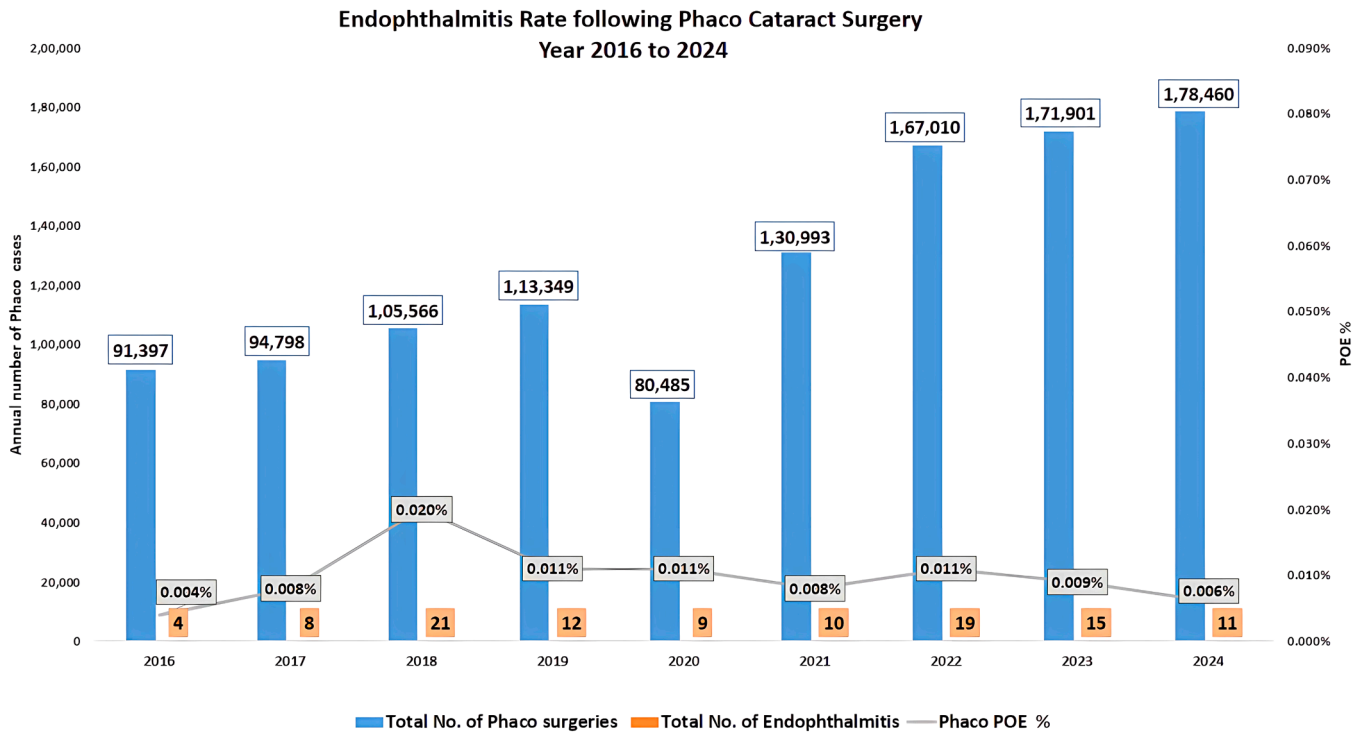

Fig. 2. Annual phacoemulsification volume, number of postoperative endophthalmitis (POE) cases, and POE rate at the Aravind Eye Care System hospital network from 2016 to 2024. The surgical volume was lower in 2020 due to the COVID-19 pandemic.

0.01 %. Fig. 2 shows that the annual POE rates were consistent from year to year with little variation.

Discussion

If the manufacturer does not validate multiple uses in their regulatory submission, a surgical product such as a phacoemulsification cassette is labeled single use by default.[10] This does not mean that the manufacturer has demonstrated or claimed that reuse is dangerous or ineffective – only that the safety of reuse was not validated during regulatory submission. Off-label practices are generally allowed based on the physician's medical judgment and the best available evidence. Globally, many surgical facilities therefore reuse a single-use phacoemulsification cassette on multiple consecutive same-day cases.

Three different regional surveys have queried cataract surgeons worldwide about sustainability opinions and practices, including a 2025 survey of APAO members.[11,15,16] The latter was conducted with the same questionnaire used in prior surveys of both North American and European cataract surgeons. This allowed for direct comparisons to determine potential regional differences. At least 81 % of the more than 1900 APAO survey respondents were willing to consider reusing phacoemulsification tubing/cassettes, compared to 76 % of respondents in each of the other two surveys. However, 41 % of Asian-Pacific surgeons said they were currently reusing phacoemulsification tubing/-cassettes, which was much higher than their counterparts in Europe (21 %) or North America (7 %). These large differences likely reflected varying regional and country differences in the ability to reuse these products off label. As previously mentioned, U.S. regulations prohibit facilities from reusing a surgical product that is labeled single use.[10]

The rationale for reusing a phacoemulsification cassette is that it and the aspiration tubing contain only sterile aqueous, irrigation fluid, OVD, intraocular pharmaceuticals, and lens material. Reflux of aspirated material from the cassette or collection bag back to the phacoemulsification tip would be highly unlikely because of the length of intervening tubing. Clinical studies to determine if reusing phacoemulsification cassettes increases the risk of complications such as POE, however, have been lacking.

A clinical study at the Pondicherry Aravind hospital evaluated the potential for cross contamination by culturing multiple phacoemulsification handpieces (185) and tubing (185) that had been reused all day according to the standard AECS protocol described earlier.[12] Residual irrigation fluid from 185 bags that had been used on multiple consecutive patients was also cultured. Reassuringly, all 555 of these cultures were negative. To this microbiologic study, we can now add this 9-year analysis of POE rates in more than 1.1 million consecutive phacoemulsification cases at AECS utilizing this multiuse cassette protocol. The 0.01 % POE rate is certainly at the low end of the 0.01–0.07 % range of published POE rates in the literature.[14,17–20] Being a retrospective registry study, our analysis lacked a control group. Although desirable, randomized controlled trials sufficiently powered to detect such a rare event as POE would be impractically large and expensive. Considering this reality, large registry studies can at least provide some level of quality evidence. A recent review of registry publications in cataract surgery discussed the value of these studies, such as from AECS, in analyzing rare events such as POE.[21]

A recent paper reported the POE rate from American Academy of Ophthalmology (AAO) Intelligent Research in Sight (IRIS) Registry during a 10-year period from January 1, 2013 to March 21, 2023.[20] The POE rate of 0.06 % in 9,587,018 cataract surgeries was much higher than that from AECS. Speculating about why the AAO IRIS POE rate was higher is beyond the scope of this paper. However, no approved intraocular antibiotic is commercially available in the U.S. This likely explains why a 2021 American Society of Cataract and Refractive Surgery (ASCRS) survey found that 34 % of respondents were not using intraocular antibiotic prophylaxis for cataract surgery.[22] In contrast, intracameral moxifloxacin prophylaxis was routinely used in all the AECS cataract procedures and is common practice in Asia.[23] Our prior study showed that the POE rate at AECS was reduced 3.5-fold by adopting ICMP.[14]

In addition to overlapping with our study period, the AAO IRIS registry data is particularly relevant to our retrospective study because reuse of phacoemulsification tubing/cassettes is essentially prohibited

by U.S. regulatory agencies. Although not constituting Level 1 evidence, this allows a contemporaneous, retrospective comparison of two large populations. Single-use phacoemulsification tubing/cassettes were routinely reused in more than 1.1 million cases at AECS, and single-use tubing/cassettes would not have been reused in more than 9.5 million cases in the U.S. That the POE rate at AECS was so low strongly supports the safety of their reuse protocol but does not prove that it has zero risk. However, if POE was more likely from reusing single-use phacoemulsification tubing/cassettes, registry studies of this size would have been expected to reveal this trend.

We believe these data contradict the assumption that reusing single-use phacoemulsification tubing/cassettes off label increases the risk of cross contamination and POE. This premise is presumably why off-label reuse of tubing/cassettes is prohibited in markets, such as the U.S. The data also align with the opinions of most surveyed cataract surgeons that regulatory agencies and manufacturers should allow surgeons more discretion to reuse certain surgical supplies and devices.[11,15,16] Finally, these results should encourage more manufacturers to develop and obtain approval for multiuse phacoemulsification tubing/cassettes. Several manufacturers in the European Union and other countries currently offer an approved day cassette that is reused for multiple consecutive same-day surgeries without being removed after each case.[24,25] Day cassettes do not require the irrigation solution bag and tubing to be discarded after each case, and to not need to be autoclaved between cases. These would further lower both emissions and plastic waste. Some manufacturers specify the allowed number of sequential cases per cassette, including the Rayner SOPHI (10 cases), Oertli CataRhex 3 (6 cases), and Zeiss/DORC EVA NEXUS (20 cases).[24,25] Other machines limit the number of hours during which their day cassette can be repeatedly reused, such as the Geuder Megatron S4 HPS (6 h) and Ruck Qube Pro (16 h). Currently, none of the largest phacoemulsification manufacturers that account of the majority of global market share offer a day cassette option.

Compared to reuse, discarding phacoemulsification cassette packs after every case increases cost, non-recycled plastic waste, and carbon emissions from the manufacture, packaging, and shipping of these products.[24,25] This also increases OR turnover time and storage space requirements. Multiple studies have identified that single-use supplies account for a major percentage of the overall carbon footprint of cataract surgery.[7,9,26] One of the authors (DFC) conducted a life cycle analysis of the J&J Compact Intuitive phacoemulsification tubing/cassette pack.[25] This is the only machine in the U.S. to offer the option of either a single-use or a reusable tubing/cassette pack that can be autoclaved up to twenty times. The author's 2-surgeon practice used the approved reusable pack for 2700 cataract procedures during the first year. This reduced the facility's tubing/cassette cost by 66.7 % ($121, 500 USD for single-use vs. $40,500 USD for multiuse). For every 1000 procedures, the reusable tubing/cassette was calculated to save 323 kg of plastic waste and 938 kgCO2eq, equivalent to driving a car 3674 km. With global cataract surgical volumes now approaching 30 million cases annually, the scale of potential cost, emissions, and waste reduction with multiuse tubing/cassette packs is enormous.

With the global mandate to reduce the healthcare sector's environmental impact, high volume specialties such as ophthalmology must find opportunities to reduce unnecessary waste and emissions, such as by safely reusing products required for every procedure.[7–10] The low POE rate associated with AECS's longstanding practice of reusing phacoemulsification tubing/cassettes highlights one such important opportunity to reduce cost, waste, and emissions without compromising patient safety. Transitioning cataract surgery to multiuse day phacoemulsification cassettes should be prioritized by manufacturers, regulatory agencies, policymakers, and surgeons worldwide. Having this become the global standard would be a major step toward making our highest volume procedure more economically and environmentally sustainable.

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