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# An 8-year retrospective study of cataract surgery and postoperative endophthalmitis: injectable intraocular lenses may reduce the incidence of postoperative endophthalmitis

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## ABSTRACT

**Background/aims** Postoperative endophthalmitis (POE) is a rare but potentially devastating complication of modern cataract surgery. We examine whether the use of injectable intraocular lenses (IOLs) is associated with a lower rate of POE after cataract surgery compared with forceps-inserted foldable IOLs.

**Methods** A single-centre retrospective cohort study of 25 410 cataract operations was performed over an 8-year period when standard practice in cataract surgery changed from the use of forceps-inserted foldable IOLs to injectable IOLs. Cases of POE were identified and the rates compared between the two groups.

**Results** Twelve cases of POE were identified in the study period. The rate of POE was significantly lower in the injectable IOL group compared with the forceps-inserted foldable IOL group (0.008% vs 0.081%,  $p=0.008$ ). This difference remained significant when controlling for posterior capsular rupture and lens material.

**Conclusions** This study, the largest of its kind to date, supports the use of injectable IOLs over forceps-inserted foldable IOLs as a significant measure in reducing the risk of POE.

## INTRODUCTION

Cataract surgery is the most commonly performed therapeutic surgical procedure in England.<sup>1</sup> Infective postoperative endophthalmitis (POE) following cataract surgery is a rare but potentially devastating complication of cataract surgery, which may result in severe vision loss and long-term morbidity, including intractable ocular pain, persistent inflammation and ocular phthisis.

There is a wide variation in the reported incidence of POE. Population and large multicentre studies report incidence rates between 0.02% and 0.265%.<sup>2–12</sup> The rate of POE in the UK was reported by the British Ophthalmic Surveillance Unit as 0.085%, with a corrected rate of 0.140% after adjusting for under-reporting.<sup>13</sup> A systematic review of international data, which pooled over three million cataract extractions over a 40-year period (1963–2003), estimated a combined POE incidence rate of 0.128%.<sup>12</sup>

Coagulase-negative staphylococcus is the most commonly cultured micro-organism in POE,<sup>2 8 14 15</sup> and is thought to originate from the lid and ocular surface flora.<sup>16</sup> A variety of factors that may have an impact on the rate of POE have been studied. These include surgical technique,<sup>7</sup> intraocular lens (IOL)

implant material,<sup>3</sup> method of IOL insertion,<sup>5 10</sup> pre-operative conjunctival sac disinfection<sup>15</sup> and use of intracameral antibiotics.<sup>7 9 11 17</sup>

There is some evidence to suggest that the insertion of the IOL implant is one of the vehicles by which bacterial flora from the ocular surface gains entry into the anterior chamber.<sup>18 19</sup> Elimination of any contact between the IOL and the ocular surface by injecting the IOL folded inside a sterile sleeve is therefore thought to reduce the risk of POE as compared to inserting a foldable IOL held with forceps directly through the surgical wound. In a reported series of POE cases, there were twice as many cases in the group that received foldable IOLs than in the group that received injectable IOLs.<sup>10</sup> Data published from a UK single-centre eye unit also found a lower incidence of POE associated with the use of injectable IOLs as compared with manually folded IOLs.<sup>5</sup>

Injectable IOLs have gained significant popularity in many UK centres, rapidly becoming the industry standard as the preferred IOL insertion technique. This study aims to investigate whether the rate of POE is reduced by using an injectable IOL, which eliminates contact between the ocular surface and the IOL, as compared with using a foldable IOL held with IOL forceps and inserted directly through the surgical wound. The study will compare two large cohorts using each method of IOL implantation with other factors remaining comparable, including the use of preoperative intracameral cefuroxime as is current standard practice.<sup>20</sup>

## METHODS

Retrospective data from a single centre covering an 8-year period were collected. In the initial 4 years, foldable IOLs were used routinely. These were manually folded and held with IOL forceps, and inserted directly through the corneal incision. In the later 4 years, a preloaded injectable IOL was used routinely. These were inserted into the anterior chamber within a sterile sleeve. Data collected included electronic and handwritten records of all cataract surgery carried out between April 2004 and March 2012. Surgical details of cataract operations were recorded at the time of surgery both manually and on an electronic patient database. Electronic patient data was cross-referenced with the handwritten logbooks to ensure all cataract operations were included, and theatre logbooks were also examined for vitreous biopsy and



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intravitreal antibiotic procedures to ensure catchment of all cases of POE over the 8-year period. Data was tabulated on an electronic spreadsheet (Excel, Microsoft) and calculated using built-in functions. Incidence rates with 95% exact Poisson CIs were computed using StatsDirect and incidence rates compared using two-sided Fisher's tests.

The diagnosis of POE was based on the presence of excessive postoperative intraocular inflammation with typical clinical features within 8 weeks of surgery. All patients diagnosed with POE underwent aqueous and vitreous biopsy, with intravitreal injection of antibiotics (vancomycin 5 mg in 0.5 mL and ceftazidime 10 mg in 0.5 mL), on the day of diagnosis.

In brief, the standard protocol for cataract surgery was as follows: asepsis was achieved using povidone-iodine 5% aqueous solution applied to the lids, lashes and conjunctival sac in the theatre waiting area. A non-permeable adhesive drape was used to isolate the lid margins and lashes away from the surgical field. All cases underwent small incision phacoemulsification cataract surgery through a corneal incision. Intracameral cefuroxime (1 mg per 0.1 mL) was used at the end of surgery. Patients were reviewed by a doctor or nurse practitioner between 2 and 4 weeks postoperatively.

## RESULTS

Over the 8-year period, a total of 25 410 cataract operations were carried out on 17 317 patients. The majority of patients (83%) were between 65 and 89 years of age, 61% of patients

were female and 50.5% of cases were in right eyes. There were complications recorded in 3.4% of operations, and posterior capsular (PC) rupture occurred in 1.4%.

Soflex SE and Clariflex were the foldable silicone IOLs used routinely in the initial 4 years (table 1). The Clariflex IOL can also be manually mounted into a sterile sleeve and used as an injectable IOL. The AcrySof IQ, an acrylic preloaded injectable IOL, was used routinely in the later 4 years. Other IOLs were used, as appropriate for clinical circumstances, based on the decision of the operating surgeon.

Among the 25 410 operations, 12 cases of POE were diagnosed (table 2) giving an overall incidence (95% CI) of POE of 0.047% (0.024% to 0.082%). There were two cases (case 7 and 11) of POE in the 355 cases complicated by posterior capsular rupture, giving an incidence of POE in this group of 0.563% (0.068% to 2.035%). There were 10 cases of POE in the 25 055 cases where posterior capsular rupture did not occur, giving an incidence in this group of 0.040% (0.019% to 0.073%). The difference in the incidence of POE between these two groups was statistically significant ( $p=0.012$ ), with an incidence rate ratio of 14.12 (1.50 to 66.24). Of the 12 cases of POE, 11 patients were female, and all were aged between 60 and 89 years (mean 77 years). The two cases of POE with posterior capsular rupture had both undergone primary foldable IOL implantation with further pars plana vitrectomy within 24 h for retained lens fragment.

Of the 25 410 operations, folded IOLs were used in 13 536 operations, preloaded injectable IOLs were used in 10 332 operations and manually mounted injectable IOLs were used in 1510 operations. For the purposes of analyses, all models of IOL inserted through the corneal wound folded were considered as foldable IOLs and all injected IOLs, whether preloaded or manually mounted, were considered as injectable IOLs. The incidence of POE was 0.081% (0.041% to 0.145%) in cases where foldable IOLs were used and 0.008% (0.00% to 0.047%) in cases where injectable IOLs were used (table 3). The difference in incidence of POE between the foldable IOL group and injectable IOL group was statistically significant with an estimated rate ratio of 9.62 (1.40 to 414.22),  $p=0.008$ . It should be noted that while the CIs of POE cases in the two groups overlap, this does not demonstrate non-significance.<sup>21</sup>

**Table 1** Intraocular lenses used during study period

Model	Manufacturer	Material	Configuration	Delivery	N
AcrySof IQ (SN6CWS)	Alcon	Acrylic	1-piece posterior chamber	Preloaded injected	10 327
Soflex SE (LI61SE)	Bausch & Lomb	Silicone	3-piece posterior chamber	Folded	10 185
Clariflex (CLRFLX, CLRFLXB, CLRFLXC)	Abbott Medical Optics	Silicone	3-piece posterior chamber	Folded or injected	4431
AcrySof MA50BM	Alcon	Acrylic	3-piece posterior chamber	Folded	152
AcrySof SA60AT	Alcon	Acrylic	1-piece posterior chamber	Folded	129
AcrySof MA60AC	Alcon	Acrylic	3-piece posterior chamber	Folded	125
L122UV	Bausch & Lomb	PMMA	1-piece anterior chamber	Folded	24
AcrySof MA60MA	Alcon	Acrylic	3-piece posterior chamber	Folded	22
S122UV	Bausch & Lomb	PMMA	1-piece anterior chamber	Folded	8
573T/623T/970C	Rayner	Acrylic	1-piece posterior chamber	Preloaded injected	5
AcrySof SN60AT	Alcon	Acrylic	1-piece posterior chamber	Folded	2

PMMA, polymethylmethacrylate.

**Table 2** Characteristics of patients with postoperative endophthalmitis

Case	Age	IOL	Insertion method	Culture
1	83	Soflex SE	Folded	<i>Staphylococcus epidermidis</i>
2	79	Soflex SE	Folded	<i>Pseudomonas</i> sp
3	89	Clariflex	Folded	<i>S. epidermidis</i>
4	86	Clariflex	Folded	<i>Enterococcus faecalis</i>
5	60	Soflex SE	Folded	Sterile
6	86	Soflex SE	Folded	<i>Enterococcus</i> sp
7	78	Soflex SE	Folded	<i>Enterococcus</i> sp
8	61	Soflex SE	Folded	Sterile
9	67	AcrySof SA60AT	Folded	Sterile
10	71	Soflex SE	Folded	<i>Aspergillus fumigatus</i>
11	73	AcrySof MA50BM	Folded	<i>S. epidermidis</i>
12	78	AcrySof IQ	Preloaded injected	<i>Staphylococcus</i> sp and <i>Streptococcus</i> sp

**Table 3** The incidence of endophthalmitis according to lens implantation technique

Phacoemulsification procedures	N	POE cases	Incidence of POE (%)	95% CI
All phacoemulsification	25 410	12	0.047	0.024% to 0.082%
Injected IOL	11 842	1	0.008	0.000% to 0.047%
Folded IOL	13 536	11	0.081	0.041% to 0.145%

IOL, intraocular lens; POE, postoperative endophthalmitis.

As cases with posterior capsular rupture had a significantly higher risk of POE, we repeated our analyses, including only cases without intraoperative posterior capsular rupture; the incidence of POE for foldable IOLs was still found to be significantly higher than the injectable IOL group (incidence rate ratio (IRR): 7.69 (1.07 to 337.47),  $p=0.025$ ). There was no significant difference in the incidence of POE between silicone and acrylic IOLs ( $p=0.258$ ).

## DISCUSSION

Injectable IOLs, whether preloaded or manually mounted, have gained significant popularity in recent years. These lenses offer advantages of ease of use, predictability of insertion and require a smaller incision than foldable IOLs. It has been suggested that injectable IOLs are associated with a lower incidence of POE compared with other methods of IOL insertion because the IOLs are inserted into the anterior chamber within a sterile sleeve, which eliminates contact with the ocular surface flora. Miller *et al*<sup>10</sup> found, in their cohort with POE, twice as many patients with foldable IOLs than with injectable IOLs. Mayer *et al*,<sup>5</sup> in their retrospective comparative study, found a significantly lower incidence of POE in patients with injectable IOLs (0.028%,  $n=10\ 815$ ) than in patients with foldable IOLs (1.21%,  $n=412$ ). Our study analysed a larger sample size with similar-sized cohorts receiving injectable IOLs and forceps-inserted foldable IOLs. Our results supported the findings of Mayer *et al* with a significantly lower incidence of POE in patients with injectable IOLs (0.008%) than in patients with forceps-inserted foldable IOLs (0.081%).

The above-mentioned studies, comparing the incidences of POE between different IOL implantation techniques, used a variety of pre- and postoperative antiseptic techniques.<sup>5–10</sup> More recently, peroperative intracameral cefuroxime has been shown to significantly reduce the risk of POE and has become standard practice for both cataract surgery and other intraocular surgeries.<sup>3–7, 9–17, 20</sup> The likely mechanism for its effect is thought to be the antibacterial action of the intracameral cefuroxime on ocular surface flora organisms, which have gained entry into the anterior chamber or become adherent to the IOL surface during insertion. In our study, while intracameral cefuroxime may have reduced the incidence of POE in both groups, the difference in POE between the two IOL implantation methods was still significant.

In our study, as in other studies,<sup>2–7, 11</sup> posterior capsular rupture at the time of cataract surgery increased the incidence rate ratio between the two groups from 9.62 (CI 1.40 to 414.22) to 14.12 (CI 1.50 to 66.24). The UK National Cataract Survey found a similar eightfold increase.<sup>4</sup> With this in mind, we examined the incidence of POE excluding the cases with intraoperative posterior capsular rupture. The incidence of POE, excluding cases with posterior capsular rupture, in the cases with forceps-inserted foldable IOLs were still significantly

higher (0.067%,  $n=13\ 486$ ) than the incidence of POE in cases with injectable IOLs (0.009%,  $n=11\ 537$ ).

It is well known that there are multiple risk factors associated with POE. Any mechanism that enables or increases ocular surface flora entry into the anterior chamber is likely to increase the risk of POE; temporal wound placement,<sup>22</sup> wound defects<sup>23</sup> and postoperative wound leakage<sup>24</sup> have all been found to be associated with POE. It is conceivable that forceps-inserted foldable IOLs on insertion through the surgical wound may allow more ingress of ocular surface flora organisms into the anterior chamber as well as allow adherence of the micro-organisms onto the IOL surface to a much greater extent than injectable IOLs.<sup>25</sup> This difference in the extent of micro-organism entry into the anterior chamber and IOL surface adherence may contribute significantly to the difference in incidence of POE between these two implantation techniques despite the antibacterial action of the intracameral cefuroxime.

Our study suffers from limitations due to its retrospective nature. Patients were not randomised to foldable or injectable IOLs, and the surgeries of each cohort were separated by a time period of up to 8 years and involved different surgeons. Surgical techniques during the 8-year time period were not thought to have differed significantly apart from the change in IOL model and implantation technique, but any systematic change in technique among surgeons over the study period could contribute to outcome bias. Surgical techniques and lens selection were at the surgeons' discretion and not controlled prospectively. The criteria for diagnosis of POE were also retrospective rather than prespecified for the study.

Our study includes a large cohort in each group and is the largest such single-centre study to date. However, caution should be taken when attempting to extrapolate the results of any single-centre study to other centres and regions. A multi-centred prospective randomised controlled trial would provide higher quality evidence to this effect, but as POE is a rare occurrence, any such trial would have to include an extremely large cohort. With the increasing popularity of injectable IOLs due to their advantages other than impact on POE risk, financial support for such a trial is unlikely to be available. It is therefore reassuring that our study and others<sup>5</sup> have indicated that injectable IOLs are likely to be associated with lower incidences of POE.

In conclusion, the incidence of POE was significantly lower if injectable IOLs rather than forceps-inserted IOLs were used, with an estimated rate ratio of 9.62. The overall incidence of POE (0.047%) in our study was similar to, or lower than, other studies. The incidence of POE was increased if posterior capsular rupture had occurred intraoperatively. This difference was significant even with the use of peroperative intracameral cefuroxime, which itself allowed a fivefold reduction in the incidence of POE.<sup>3</sup> As injectable IOLs confer a multitude of useful advantages for modern micro-incisional phacoemulsification cataract surgery, injectable IOLs are likely to continue as the implantation method of choice despite the lack of any evidence from prospective trials. Furthermore, given the results of these observational studies, it may be considered unethical to conduct such a trial.

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**Competing interests** None.

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