BMJ Open Ophthalmology

EyeCee One preloaded intraocular lens: are patients with glaucoma more at risk?

Ruth K Jones ,[1] Joel Lee Zher Jong ,[1,2] Vipul Ramjiani,[1] Jennifer H Y Tan[1]

To cite: Jones RK, Jong JLZ, Ramjiani V, *et al*. EyeCee One preloaded intraocular lens: are patients with glaucoma more at risk? *BMJ Open Ophthalmology* 2023;**8**:e001433. doi:10.1136/bmjophth-2023-001433

Received 31 July 2023
Accepted 25 August 2023

[1]Ophthalmology Department, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK
[2]Faculty of Medicine, Dentistry and Health, The University of Sheffield, Sheffield, UK

Correspondence to
Dr Ruth K Jones; ruth.jones23@nhs.net

ABSTRACT

Objective The Medicine and Healthcare products Regulatory Agency reported links of raised intraocular pressure (IOP) with recently implanted EyeCee One intraocular lens (IOL). This work investigates if glaucomatous eyes were more susceptible to these postoperative IOP rises and if they required more intensive management.

Methods Retrospective observational study of all phacoemulsification surgery with implanted EyeCee One IOL, performed between 1 October 2022 and 26 January 2023 inclusive.

Analysis A significant IOP elevation was defined as an IOP rise of 10 mm Hg or more from preoperative to maximal postoperative IOP reading. The management of all patients who had a significant IOP elevation was reviewed. Glaucoma/ocular hypertension cases were identified and analysed against non-glaucomatous eyes and statistical analysis performed.

Results 112 glaucoma and 671 non-glaucoma cases identified; 19.6% of the glaucoma cohort had a significant postoperative IOP rise compared with 8.9% of patients without glaucoma (OR 2.49 (95% CI 1.45 to 4.20) p=0.0014). In the glaucoma cohort, 12.5% had an increase in the number of topical IOP-lowering agents (mean increase 1.65±1.58), 6.3% required systemic treatment and 2.7% surgical intervention. In the non-glaucoma group, 3.3% required topical treatment (mean number of agents 0.88±1.34), 0.8% required systemic treatment and 0.2% surgical intervention.

Conclusion This study shows that during the time frame in question, patients with glaucoma or ocular hypertension who had an EyeCee One IOL were almost two and a half times more likely to have a postoperative rise of 10 mm Hg or more in IOP following routine cataract surgery, requiring more aggressive management.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ A widespread recall of an intraocular lens (IOL) has not been seen before. As the EyeCee One IOL recall has been due to its issues with postoperative intraocular pressure (IOP) elevations, we feel it would be of value to investigate how this has impacted the glaucoma and ocular hypertensive cohort.

WHAT THIS STUDY ADDS

⇒ This study shows that during the time frame in question, patients with glaucoma or ocular hypertension who had an EyeCee One IOL were almost two and a half times more likely to have a postoperative rise of 10 mm Hg or more in IOP following routine cataract surgery, requiring more aggressive management in all treatment modalities.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Patients with known glaucoma and ocular hypertension need to be monitored more closely as they are more likely to require escalation of IOP management.

INTRODUCTION

On 26 January 2023, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a Device Safety Information notification: *EyeCee One preloaded and EyeCee One Crystal preloaded intraocular lenses (IOLs): stop using immediately and quarantine all preloaded EyeCee One lenses DSI/2023/001.*[1] The MHRA is aware of reports of increased intraocular pressure (IOP) in patients recently implanted with EyeCee One preloaded and EyeCee One Crystal preloaded IOLs, manufactured by NIDEK and distributed by Bausch+Lomb. The root cause had not been identified and further investigations are ongoing. Actions to be taken immediately included but not confined to: stopping use of impacted products immediately, quarantining these impacted IOLs until further notice and finding a suitable alternative product.

On the same day, NIDEK issued an urgent Field Safety Notice (FSN)[2] stating a full investigation was underway relating to the same issue and advised similar actions to be undertaken immediately. They stated an update of the investigation, and the actions customers should take with the quarantined products will be provided once the investigation has been completed. Sales representatives' contacts were given for France, Italy, Spain, the Netherlands and the UK, suggesting how widespread the issue was.

On 1 February 2023, the MHRA issued a National Patient Safety Alert (NPSA) for action by all providers of ophthalmic surgery and community optometrists: *NIDEK EyeCee One preloaded and EyeCee One Crystal preloaded intraocular lenses (IOLs): risk of increased intraocular pressure, reference no: NatPSA/2023/003/*

MHRA.[3] The additional information provided here outlined tasks to be performed in certain time frames to protect patient safety. All patients who were implanted with the preloaded EyeCee IOLs since 1 October 2022 (preferably by telephone) were contacted and advised to have the pressure in their eye tested. These actions were required to be fully completed by 16 February 2023. Community optometrists could be visited in the screening of IOPs, but an action plan for a rapid access pathway to the cataract surgery provider was required for those patients found to have high IOPs at screening.

Our unit is a large public teaching hospital ophthalmology department in the UK (Sheffield Teaching Hospital National Health Service (NHS) Trust) and used the EyeCee One preloaded IOL as its stocked lens bank. No EyeCee One Crystal preloaded IOLs were used. As a directorate, the decision was made to review all patients implanted with EyeCee One IOLs between the dates 1 October 2022 (date given by MHRA) and 26 January 2023 (date use of EyeCee One IOL was ceased in our trust). Review was undertaken face to face at our cataract unit, Northern General Eye Centre (NGEC), to identify and treat any elevated IOP, and to perform our duty of candour.

At the time of the NPSA, the MHRA was aware of four centres with patients experiencing higher than normal rates of high postoperative IOP, with one site with patients experiencing a rate of approximately 2–4% and most affected patients experienced minimal symptoms.[3] Our department identified that 6.2% of patients in this time frame implanted with an EyeCee One IOL had an IOP of equal and above 30 mm Hg at their first postoperative visit. The vast majority of these increased IOP cases (92.2%) were managed medically with either topical, systemic IOP-lowering medications or both.[4]

Although high IOP is a concern to all our patients, the objective of this paper was to evaluate the IOP response in the glaucoma and ocular hypertension (OHT) cohort. Were the glaucoma and OHT cohorts more susceptible to IOP elevations and did they require more aggressive management following implantation of an EyeCee One IOL between 1 October 2022 and 26 January 2023 during routine cataract surgery?

MATERIALS AND METHODS

Data collection

A retrospective observational study of all cataract surgery was performed in Sheffield Teaching Hospital NHS Trust; this covers two units, the NGEC and the Royal Hallamshire Hospital between 1 October 2022 and 26 January 2023 inclusive. Cases were identified via electronic patient record (EPR) (Medisoft, Leeds, UK).

Uneventful cataract surgery was performed using local (topical and intracameral or sub-Tenon's anaesthetic) or general anaesthesia. Standard phacoemulsification technique was used, and cases requiring pupil expansion were included. All cases had a preloaded EyeCee One IOL inserted into the capsular bag. After cataract surgery, patients were given topical steroid (betamethasone or dexamethasone) and chloramphenicol. Ketorolac was also given if the patient was diabetic or at higher risk of postoperative cystoid macular oedema. Oral acetazolamide, 500 mg, was given preoperatively in glaucoma cases where there was evidence of marked optic nerve damage. Intravenous mannitol was given at surgeons' discretion in cases with shallow anterior chamber.

Unilateral and immediate sequential bilateral cataract surgery was included.

Exclusion criteria

Combined cases that might influence postoperative IOP, such as vitreoretinal (vitrectomy with gas insertion) or glaucoma procedures combined with phacoemulsification and IOL, or those lacking both preoperative and postoperative IOP readings.

Identification of glaucoma cases and OHT

Cases had to meet at least one of the following criteria: previous glaucoma diagnosis recorded on EPR, documented as being on pressure-lowering drops or having an IOP documented as 24 mm Hg or higher on their preoperative assessment visit, any previous glaucoma surgery performed in the same eye prior to the cataract surgery date.

IOP measurements were recorded by Reichert tonometry or Goldmann applanation tonometry if validation required. Baseline IOP was the measurement taken at the cataract preoperative assessment prior to the surgery in question and IOP was recorded at all postoperative interactions.

A significant IOP elevation was defined as an IOP rise of 10 mm Hg or more from baseline to the maximal postoperative IOP measurement.

All patients with glaucoma/OHT and patients without glaucoma who had an IOP elevation 10 mm Hg or more had their EPR reviewed. Management of their raised IOP was recorded, including number of topical glaucoma agents required (at maximal intervention), if systemic treatment was given (either acetazolamide or intravenous mannitol) and which patients required surgical intervention and what that entailed.

Control group

During the same time frame, our NGEC site was trialling alternative IOLs. An EPR search was performed to identify all uneventful cataract surgery performed at NGEC, between 1 October 2022 and 26 January 2023 inclusive. Lens models were identified, and all non-EyeCee One preloaded IOLs grouped. The IOP at the visit prior to surgery was the preoperative IOP measurement and the IOP recorded at the initial visit following cataract surgery was the postoperative IOP measurement. The non-EyeCee One group also had patients divided into glaucoma/OHT and non-glaucoma cohorts using the same identification methods detailed above, and results compared with the EyeCee One IOL cohort.

Data analysis

Data were presented as number of cases, means with SDs and percentages. All data were processed using GraphPad Prisms (V.9.5.1 for Mac, GraphPad Software, San Diego, California, USA). Statistical analysis was performed between two independent samples, the glaucoma cohort and the non-glaucoma cohort; unpaired t-test and Mann-Whitney test were used to compare variables between two groups for parametric and non-parametric data, respectively. If contingency table was created for comparison between two variables, Fisher's exact test was used for p values. Statistical significance was set at $p<0.05$.

Patient and public involvement

Due to the retrospective observational nature of this study, it was considered not appropriate to involve patients or the public in the design, conduct, reporting or dissemination plans of our research.

RESULTS

The study identified 783 eyes which met the inclusion and exclusion criteria: 112 identified as glaucoma and 671 non-glaucoma. Figure 1 shows flow of patients included and excluded in the study. The patient demographics and preoperative characteristics are comparable, except preoperative IOP: glaucoma group (age: 75.06±10.98

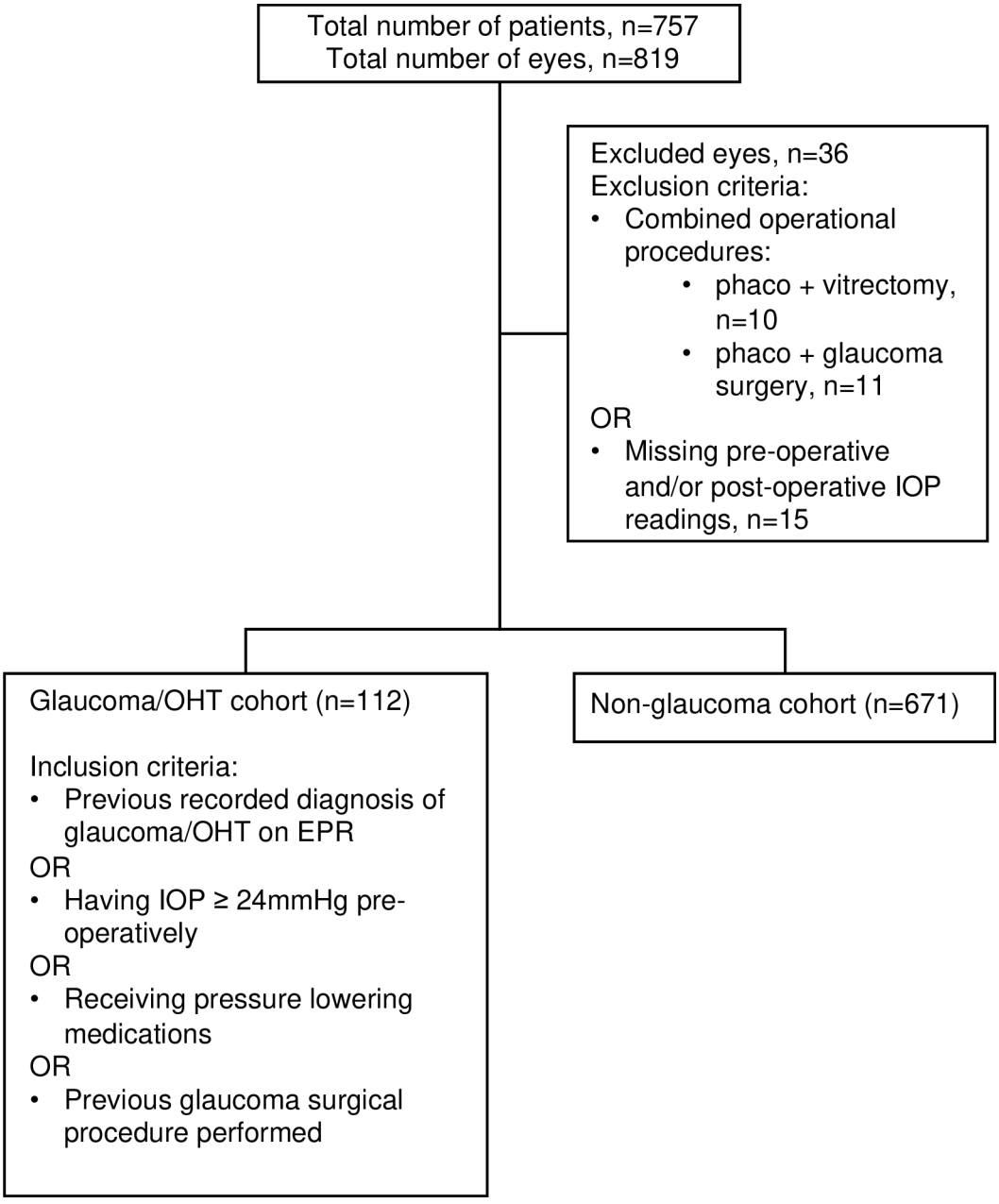

Figure 1 Flow of patients included and excluded in the study. EPR, electronic patient record; IOP, intraocular pressure; OHT, ocular hypertension.

Table 1 Patient demographics, preoperative characteristics and postoperative IOP elevations, EyeCee One cohort

	Glaucoma (n=112)	Non-glaucoma (n=671)	P value
Age, years, mean±SD	75.06±10.98	74.37±10.64	0.525
Female gender, n (%)	61 (54.5)	382 (56.9)	0.681
Average preoperative IOP, mm Hg, mean±SD	18.80±8.82	14.76±3.77	<0.001
Axial length, mm, mean±SD	23.47±1.22	23.65±1.18	0.136
IOP changes post-operation			**Total, n (%)**
IOP rise ≥10 mm Hg, n (%)	22 (19.6)	60 (8.9)	82 (10.5)
IOP rise <10 mm Hg, n (%)	90 (80.4)	611 (91.1)	701 (89.5)

IOP, intraocular pressure.

years, axial length (AL): 23.47±1.22 mm, preoperative IOP: 18.80±8.82 mm Hg), non-glaucoma group (age: 74.37±10.64, AL: 23.65±1.18 mm, preoperative IOP: 14.76±3.77 mm Hg). With regard to postoperative IOP elevations, of the glaucoma cohort, 19.6% had an IOP rise greater or equal to 10 mm Hg, compared with 8.9% of patients without glaucoma (OR 2.49 (95% CI 1.45 to 4.20) p=0.0014) (table 1).

To manage these postoperative IOP elevations, 12.5% of the glaucoma cohort had an increase in the number of topical IOP-lowering agents (with a mean increase in number of 1.65±1.58), 6.3% required systemic treatment and 2.7% required surgical intervention. Compared with the non-glaucoma group, 3.3% required topical treatment (mean number of agents was 0.88±1.34), 0.8% required systemic treatment and 0.2% had surgical intervention (table 2).

Concentrating on the patients who had a documented IOP rise greater or equal to 10 mm Hg in both the EyeCee One IOL glaucoma and non-glaucoma groups, the most aggressive treatment modality they required was documented, with monitoring/no intervention being the first-line management, topical drops being the second line, systemic treatment being third and surgical intervention fourth and most aggressive management.

Of the patient group with a significant postoperative IOP rise, 68.2% of the glaucoma cohort received treatment and 31.8% were observed, compared with the non-glaucoma cohort with 36.7% who received treatment and 63.3% were observed. When these treatment modalities were broken down, 36.4% of the glaucoma cohort required addition of the number of drop agents to manage their IOP rise; 18.2% required drops and systemic treatment; and 13.6% required drops, systemic and surgical intervention. Compared with the non-glaucoma cohort, 28.3% received just topical management, 6.7% drops and systemic treatment and 1.7% required all three (table 3).

In the EyeCee One IOL glaucoma cohort with IOP rises greater or equal to 10 mm Hg (n=22), the average duration to their highest postoperative IOP was 1.9 weeks (SD 1.3). At last review of these patients' EPR (30 July 2023), we can see 90.9% (20 of 22) now have an IOP under 24 mm Hg.

Comparing the EyeCee One group with the control group (non-EyeCee One IOL), 307 patients were identified who had cataract surgery but did not have an EyeCee One IOL inserted. Alternative IOLs included: Alcon AcrySof SA60, Alcon UltraSert ACU0T0, AMO Sensar AR40, AMO Tecnis DCBOO, AMO Tecnis ZCBOO, B&L enVista, B&L LuxGood, Primus HD and Rayner RayOne.

Of these non-EyeCee One IOL patients, 41 had glaucoma and 266 were non-glaucomatous. Mean preoperative IOP readings were comparable between groups. Significantly higher mean IOP readings on the first postoperative visit in eyes implanted with EyeCee One IOLs compared with non-EyeCee One IOLs are seen. In the glaucoma/OHT group, the EyeCee One mean postoperative IOP was 21.4±10.2 mm Hg compared with 17.8±6.78 mm Hg in the non-EyeCee One (p=0.040); while in the non-glaucoma group, EyeCee One

Table 2 Treatment required for management of the IOP elevation ≥10 mm Hg, glaucoma versus non-glaucoma, EyeCee One cohort

	Glaucoma (n=112)	Non-glaucoma (n=671)	P value
Topical, increase in number of agents required, n (% of total cohort)	14 (12.5)	22 (3.3)	0.04
Topical, mean increase in number of agents required, mean±SD	1.65±1.58	0.88±1.34	0.02
Systemic treatment, n (%)	7 (6.3) (oral: 5, IV: 2)	5 (0.8) (oral: 2, IV: 3)	0.01
Surgery, n (%)	3 (2.7)	1 (0.2)	0.06

IOP, intraocular pressure; IV, intravenous.

Table 3 Management of patients who had an IOP elevation ≥10 mm Hg, EyeCee One cohort

	Glaucoma (n=22) n (%)	Non-glaucoma (n=60) n (%)
No treatment	7 (31.8)	38 (63.3)
Topical treatment	8 (36.4)	17 (28.3)
Systemic treatment	4 (18.2) (oral: 3, IV: 1)	4 (6.7) (oral: 2, IV: 2)
Surgery	3 (13.6)	1 (1.7)
Total receiving treatment	15 (68.2)	22 (36.7)

IOP, intraocular pressure; IV, intravenous.

mean postoperative IOP was 16.6±7.56 mm Hg compared with 14.5±4.07 mm Hg in the non-EyeCee One (p<0.001) (table 4).

DISCUSSION

Early postoperative IOP elevation following cataract surgery is a frequent adverse event and represents 88% of early postoperative complications.[5] The release of the MHRA statement added yet another cause for early postoperative rise in IOP. Between January 2022 and September 2022 (before the study period in question), 3% of patients implanted with EyeCee One IOL had an IOP of 30 mm Hg or greater on their first postoperative visit. Between October 2022 and January 2023, 6.2% had an IOP of 30 mm Hg or more on their first postoperative visit after being implanted with an EyeCee One IOL,[4] more than double the usual rate.

On 13 July 2023, NIDEK released an updated urgent FSN,[6] which states that from their internal investigations, they identified a material used in the coating process to be the causal factor. This coating agent is used to aid the smoothness of the IOL injection, but specific lots have been identified which have physically obstructed the drainage pathway of aqueous humour, likely resulting in abnormally elevated IOP.

This study suggests that in the time frame in question, significant IOP elevations are more likely to occur in patients with glaucoma; 19.6% of the glaucoma cohort had an IOP rise greater or equal to 10 mm Hg, compared with 8.9% of patients without glaucoma (OR 2.49 (95% CI 1.45 to 4.20) p=0.0014). Patients with glaucoma receiving cataract surgery are known to experience more severe IOP rises postoperatively. Shingleton *et al*[7] found IOP greater than 30 mm Hg on the first postoperative day in 8.1% of normal eyes and 15.6% of eyes with glaucoma. But the question is, are patients with glaucoma and OHT even more susceptible to or at a greater risk of the EyeCee One IOL postoperative IOP elevations? As we compared eyes implanted with EyeCee One IOLs with non-EyeCee One IOLs during our study period, we saw significantly higher mean IOP readings on the first postoperative visit in eyes implanted with EyeCee One IOLs compared with non-EyeCee One IOLs, in both glaucoma/OHT (EyeCee One mean postoperative IOP 21.4±10.2 mm Hg compared with 17.8±6.78 mm Hg non-EyeCee One, p=0.040) and non-glaucoma groups (EyeCee One mean postoperative IOP 16.6±7.56 mm Hg compared with 14.5±4.07 mm Hg non EyeCee One, p<0.001), even when the average preoperative IOP was comparable. In fact, in the eyes implanted with EyeCee One IOLs, mean IOP increased from preoperative visit to initial postoperative visit (glaucoma/OHT: preoperative visit 18.8±8.82 mm Hg to postoperative visit 21.4±10.2 mm Hg; non-glaucoma: preoperative visit 14.8±3.77 mm Hg to postoperative visit 16.6±7.56 mm Hg); while in the eyes implanted with non-EyeCee One IOLs, mean IOP decreased (glaucoma/OHT: preoperative visit 18.7±6.50 mm Hg to postoperative visit 17.8±6.78 mm Hg; non-glaucoma: preoperative visit 14.9±3.66 mm Hg to postoperative visit 14.5±4.07 mm Hg).

Table 4 Comparison of IOP EyeCee One cohort and non-EyeCee One cohort

	EyeCee One IOL (n=783)	Non-EyeCee One IOL (n=307)	P value
Mean preoperative IOP	15.3±5.03	15.4±4.34	0.905
Glaucomatous eyes	**n=112**	**n=41**	
Preoperative IOP, mm Hg, mean±SD	18.8±8.82	18.7±6.50	0.939
Postoperative IOP, mm Hg, mean±SD	21.4±10.2	17.8±6.78	0.040
Non-glaucomatous eyes	**n=671**	**n=266**	
Preoperative IOP, mm Hg, mean±SD	14.8±3.77	14.9±3.66	0.693
Postoperative IOP, mm Hg, mean±SD	16.6±7.56	14.5±4.07	<0.001

IOL, intraocular lens; IOP, intraocular pressure.

The EyeCee One glaucoma cohort with a significant IOP rise required more aggressive management in all treatment domains: drops, systemic and surgery. Twelve and a half per cent of the whole glaucoma cohort had an increase in the number of topical IOP-lowering agents (mean increase in agents 1.65±1.58) and 3.3% in the non-glaucoma cohort required topical agents (mean increase in agents 0.88±1.34). A total of 6.3% patients required systemic treatment in the glaucoma cohort and 0.8% in the non-glaucoma cohort; while 2.7% of the glaucoma cohort required surgical intervention compared with the non-glaucoma group where 0.2% required surgical intervention. All differences were statistically significant between the glaucoma and non-glaucoma groups, except surgical intervention where numbers of cases were too small (glaucoma, n=3; non-glaucoma, n=1).

Ninety-one per cent of the patients with glaucoma/OHT who had a significant IOP rise had an IOP <24 mm Hg at the time of the last review. Four patients had an IOP documented as >24 mm Hg after 2 months of the recall date. One case with primary open-angle glaucoma failed to respond to medical management. Excision goniotomy (TrabEx+) was performed a month after cataract surgery. IOP control remained poor as surgery was abandoned early due to poor gonioscopic view. Trabeculectomy was performed and bleb needling was required before IOP reduced to normal levels. In the second case, with primary open-angle glaucoma, the IOP improved with continued topical pressure-lowering medication (two agents), but 2 months of topical steroids was required before IOP reduced to under 24 mm Hg. This patient had cataract surgery in the fellow eye with a similar severity of primary open-angle glaucoma with a different lens implanted by the same surgeon. Interestingly, the postoperative IOP remained well controlled in the non-EyeCee One IOL-implanted eye. The remaining two cases had primary angle closure/glaucoma. Phacoemulsification with IOL was performed primarily for IOP control. One case was treated medically but unfortunately, appointments were not attended. Vision deteriorated to hand movements and the patient declined further intervention. The last case was treated medically but remained poorly controlled. Early anterior chamber washout and lens exchange were performed, but better IOP control was required. Eventually, a Baerveldt tube was inserted at 2 months after cataract surgery.

As more frequent cases of high IOP became evident, discussions occurred internally and with other units. It was theorised that an inflammatory reaction at the level of the trabecular meshwork was responsible. At the end of January 2023, our management plan changed, and later supported by the 13 February 2023 Royal College of Ophthalmologists safety report.[8] First-line management was hourly steroid drops alongside IOP-lowering agents. If medical treatment failed, early lens exchange (within 2 weeks) or glaucoma drainage surgery was considered. Since we changed to frequent steroid drop management as first-line therapy, no further surgical interventions, at the time of writing, have been performed to manage sustained raised IOPs, but we acknowledge this is an evolving situation.

As a separate analysis, we looked at patients undergoing cataract surgery (with EyeCee One IOL) combined with excisional goniotomy, namely TrabEx+ (MicroSurgical Technology, Redmond, Washington, USA), a device which mechanically removes a proportion of the trabecular meshwork. These patients were not included in the main body of work as combined glaucoma surgery would affect IOP outcomes. Nine patients received this combined surgery within the same time frame. Of these patients, none had a postoperative IOP elevation of greater or equal to 10 mm Hg, 56% (five out of nine) had no increase in number of drop agents required. In fact, four patients decreased the number of agents they used, with three patients stopping all related glaucoma medications post-procedure. The favourable outcome in this small group supports the theory that the IOP-elevating effect from the IOL is derived from disruption at the level of the trabecular meshwork, which has been prevented by its surgical removal.

Limitations

During the capture of patients, 15 were excluded as they did not have postoperative readings at the time of writing this article.

When analysing data, we did not look at either patients with glaucoma or those without glaucoma who had an IOP rise less than 10 mm Hg. One patient in the glaucoma group whose IOP was less than 10 mm Hg did receive topical treatment, but the focus of this article was on the more significant IOP rises so this case was not included in the analysis. Also, we made no distinction between patients who needed one off-treatment compared with prolonged treatment.

We acknowledge there are several causes for IOP elevations in the early period following cataract surgery; steroid-induced IOP elevation has long been recognised as a big contributor with reports of approximately one-third of normal eyes and over 90% of patients with primary open-angle glaucoma responding with greater than 6 mm Hg of IOP elevation after receiving a 4-week course of topical dexamethasone 0.1%.[9] Bojikian *et al*[10] compared both glaucomatous and non-glaucomatous eyes undergoing routine phacoemulsification surgery response to postoperative steroid (prednisolone acetate 1% four times a day). They defined a steroid response as IOP >50% above the baseline IOP measurement, occurring at or after the second postoperative week. We altered the analysis of our results to compare our rates; both our glaucoma and non-glaucoma cohorts showed significantly higher proportion of patients with IOP >50% above the baseline compared with the literature. In our glaucoma cohort, 29.5% met this criterion compared with 8.4% in the literature. Also, 16.1% of our non-glaucoma cohort met the criterion compared with 2.1% in the literature, suggesting that these increases in IOP are being contributed to by more than just a steroid response.

CONCLUSION

In summary, we found that during the time frame in question, patients with glaucoma/OHT were almost two and a half times more likely to have a postoperative rise in IOP of 10 mm Hg or more, following routine cataract surgery with implantation of EyeCee One IOL. Of the patients with glaucoma who did have an IOP elevation of 10 mm Hg or more, nearly 10% had a sustained high IOP, despite treatment, and 13.6% required surgical intervention to manage the high IOP.

Acknowledgements Acknowledgements to William Kay and Steve Bantock who helped with data retrieval and analysis.

Contributors RKJ and JLZJ worked on data analysis. All authors contributed to the write-up and revisions of this manuscript. RKJ is guarantor.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval No ethical approval has been sought in creating this study.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Additional data are available upon reasonable request.

ORCID iDs

Ruth K Jones http://orcid.org/0000-0002-2176-0266
Joel Lee Zher Jong http://orcid.org/0000-0002-8339-2083

REFERENCES

1 Eyecee one preloaded and eyecee one crystal preloaded Intraocular lenses (Iols): stop using immediately and quarantine all preloaded eyecee one lenses DSI/2023/001. Available: https://www.gov.uk/drug-device-alerts/eyecee-one-preloaded-and-eyecee-one-crystal-preloaded-intraocular-lenses-iols-stop-using-immediately-and-quarantine-all-preloaded-eyecee-one-lenses-dsi-slash-2023-slash-001

2 NIDEK FSN – urgent field safety notice. Medicines and healthcare products regulatory agency. Available: https://mhra-gov.filecamp.com/s/d/MWjGnAVxprpOgwQl

3 MHRA, NPSA. National patient safety alert: NIDEK eyecee one preloaded and eyecee one crystal preloaded intraocular lenses (Iols): risk of increased intraocular pressure (NatPSA/2023/003/MHRA).. Available: https://www.gov.uk/drug-device-alerts/national-patient-safety-alert-nidek-eyecee-one-preloaded-and-eyecee-one-crystal-preloaded-intraocular-lenses-iols-risk-of-increased-intraocular-pressure-natpsa-slash-2023-slash-003-slash-mhra

4 Wang H, Jong JLZ, Chiu SJ, *et al*. Evaluation of raised intraocular pressure post eyecee one preloaded intraocular lenses implantation. *Eye (Lond)* 2023.

5 Grzybowski A, Kanclerz P. Early postoperative intraocular pressure elevation following cataract surgery. *Curr Opin Ophthalmol* 2019;30:56–62.

6 NIDEK Updated FSN – updated urgent field safety notice. Medicines and healthcare products regulatory agency. Available: https://mhra-gov.filecamp.com/s/d/Obt8ldNjh8qP2HYC

7 Shingleton BJ, Rosenberg RB, Teixeira R, *et al*. Evaluation of intraocular pressure in the immediate postoperative period after phacoemulsification. *J Cataract Refract Surg* 2007;33:1953–7.

8 RCOphth. Safety alert: raised IOP following cataract surgery using eyecee one lenses. Available: https://www.rcophth.ac.uk/news-views/safety-alert-raised-iop-following-cataract-surgery-using-pre-loaded-eyecee-one-lenses/?news_topic=service-planning

9 ARMALY MF. Effect of corticosteroids on intraocular pressure and fluid dynamics. II. The effect of dexamethasone in the glaucomatous eye. *Arch Ophthalmol* 1963;70:492–9.

10 Bojikian KD, Nobrega P, Roldan A, *et al*. Incidence of and risk factors for steroid response after cataract surgery in patients with and without glaucoma. *J Glaucoma* 2021;30:e159–63.