Title: The Royal College of Ophthalmologists' National Ophthalmology Database study of cataract surgery: Report 14, cohort analysis – the impact of CapsuleGuard® utilisation on cataract surgery posterior capsule rupture rates.

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Short Heading: Impact of adoption of CapsuleGuard silicone-tipped I/A handpiece on PCR rates

Summary

What was known before:

- Posterior Capsule Rupture (PCR) rates during phacoemulsification and foldable intraocular lens implantation have been reducing since the introduction of phacoemulsification in the 1980's
- Historic studies showed that silicone-tipped irrigation/aspiration handpieces were associated with lower posterior capsule rupture rates; this was in the context of phacoemulsification machines which are now obsolete, and the benefits may no longer be present with modern machines

What this study adds:

- Cataract surgical providers adopting the use of CapsuleGuard® for the majority of their cataract operations experienced a median reduction in PCR rates of 21.7%
- By extrapolation from published studies reporting the phase of surgery during which PCR occurred, this reduction in PCR rate is likely to represent a high proportion of the PCR events that occur during irrigation/aspiration
- Despite the other advances in the technology available for cataract extraction which promotes surgical safety, this silicone-tipped handpiece still offers surgeons a means to reduce their PCR rates

Key Words: cataract, phacoemulsification, posterior capsule rupture, silicone, irrigation, aspiration

Conflict of Interest

The authors declare that they have no conflict of interest.

Funding

The analysis in this study was funded by Bausch + Lomb, however the data collection from centres, analysis and write up was independent of Bausch + Lomb. No editorial rights were assigned to Bausch + Lomb and the commitment to publish the findings regardless of the direction of results was established by the authors prior to commencement.

The RCOphth National Ophthalmology Database Cataract Audit is currently funded through participation fees from centres as well as unrestricted financial contributions from Alcon and Bausch + Lomb.

Authorship Contribution statement

All authors discussed the original idea regarding how to evaluate the introduction of new technology to UK cataract service provision using NOD data; JB, CN and PD developed the details of the data collection and analysis plan. CN and PD undertook statistical analysis and JB led the writing of the paper with all authors discussing conclusions and reviewing the final manuscript.

Data Availability Statement

The RCOphth NOD Cataract Audit data supporting the results reported in this article are available by application to the RCOphth; associated costs for data preparation and provision would be covered by those applying to access the data. Data used to identify centres utilising CapsuleGuard™ is commercially sensitive and not publicly available.

Word Count: 2546

Abstract (words 247)

Background/Objectives

The aim of this study was to investigate whether the use of the silicone tipped irrigation/aspiration (I/A) handpiece CapsuleGuard® (Bausch + Lomb, Laval, Canada) reduced rates of posterior capsule rupture (PCR) during cataract surgery.

Methods

Royal College of Ophthalmologists' National Ophthalmology Database (NOD) Cataract Audit data from 01/04/2010 and 31/03/2021 and Bausch + Lomb sales figures were combined to identify centres participating in national cataract audit who have routinely adopted the silicone tipped I/A handpiece, CapsuleGuard®. Data were included only from centres with eligible cataract operations recorded on the NOD both before and after adopting CapsuleGuard®.

Review of the literature was undertaken to estimate the proportion of PCR that occurs during I/A, to evaluate the impact of adoption of CapsuleGuard® on PCR occurring in this phase of surgery.

Results

Within the study period, 267 371 eligible cataract operations were performed in 14 centres with >50 eligible operations both before and after adopting CapsuleGuard®.

Within centres adopting CapsuleGuard®, the rate of PCR occurrence reduction was 16.4%. Before and after the adoption of CapsuleGuard® the median change of PCR was 21.7% reduction (IQR: 4.8% to 37.7% reduction).

Conclusions

A reduction in the rate of PCR was seen after regular adoption of CapsuleGuard® during cataract operations. Review of published studies attributing PCR to various components of the cataract operation suggest around 25% of PCR may occur during I/A; adoption of CapsuleGuard may, therefore, be associated with avoidance of a substantial proportion of the PCR during that phase of surgery.

Introduction

Despite the safety and cost-effectiveness of cataract surgery making it one of the most frequently performed operations in the world each year, there are still associated risks.(1) The most important intra-operative complication of cataract surgery is rupture of the posterior capsule (PCR) which brings a seven-fold increase in post-operative endophthalmitis rate,(2) a twenty-fold increased risk of retinal detachment in the year following surgery,(3) more than doubling the risk of cystoid macular oedema,(4) an odds ratio of 17.6 of suprachoroidal haemorrhage intraoperatively(5) and a reduction of over 75% in the odds of achieving a good post-operative visual acuity (≤0.3 logMAR).(6) The average cost associated with PCR due to additional procedures and follow up visits has been estimated at US$ 1 111 (2020 USA estimate).(7) Interventions that offer the opportunity to reduce the risk of PCR are, therefore, very attractive for patients, surgeons and the wider health economy and PCR rate has been widely adopted as a primary outcome of interest for cataract surgical audit as a marker of the surgical safety of individual surgeons and centres.

PCR can occur at many points during a cataract operation, however the steps most likely to results in PCR are the nuclear disassembly by phacoemulsification, and the irrigation/aspiration (I/A) of the cortical lens matter.(8-13) Much industry investment and clinical academic effort has gone into refining the fluidics and function of the phaco-machines and strategies for the phacoemulsification of the lens nucleus,(14) but there have also been innovations to improve the safety of I/A.

I/A has traditionally been undertaken either with a metal co-axial I/A handpiece, a Simcoe cannula, or a bimanual system with separate irrigation and aspiration cannulas. These instruments are all metal, and inadvertent aspiration of the capsule during I/A can lead to

rupture of the capsule due to burrs or imperfections in the opening or lumen of the instrument.(15) Silicone tipped I/A handpieces have been available for the past two decades and have grown in popularity due to their alleged improved safety profile. The silicone tip offers a more regular and softer point of contact with the capsule, although reports exist of manufacturing irregularities(16) or capsule contact with the internal metal tubing resulting in PCR(17) despite the distance from the outer aperture to points of manufacturing defect or sharp metal burrs being greatly increased in silicone tipped I/A handpieces compared to purely metal equivalents.(15)

An early report from 2005 described a drop in PCR rates during the I/A phase of cataract surgery from 13/1 072 (1.2%) with a metal I/A instrumentation to 1/805 (0.1%) following transition to a silicone-tipped I/A handpiece.(18) Since such early reports came from a background of higher overall PCR rates than would be expected today, the designs of both silicone-tipped and metal I/A handpieces have changed and the fluidics of phacoemulsification machines have improved, it cannot be assumed that there are similar benefits to be gained from every silicone tipped I/A handpiece introduced in the modern era. More recently, a 2018 retrospective report considering only trainee ophthalmologists suggested that I/A related PCR could be reduced from totalling 12% of all PCR cases to 0% by use of CapsuleGuard®, but this was a relatively small sample and there would be no reason to assume that similar gains could be expected for all grades of surgeons.(19)

The aim of our study, therefore, was to investigate whether surgical centres transitioning to use the Bausch + Lomb CapsuleGuard® silicone-tipped I/A handpieces experienced a reduction in their rates of PCR as a result. As CapsuleGuard® could only be expected to impact the fraction of PCR that occurred during I/A, primarily for the removal of cortical lens material,

search of the peer-reviewed published literature was undertaken to provide an estimate of the proportion of PCR that might occur during I/A, and therefore the extent to which CapsuleGuard® has reduced the risk of that surgical step.

Subjects and Methods

The RCOphth NOD Cataract Audit is open to all providers of National Health Service (NHS) or privately funded cataract surgery in England, Scotland, Northern Ireland, Wales and the Channel Islands. Data are submitted annually for cataract operations using phacoemulsification to treat patients aged 18 years or older, where the primary intention was cataract surgery alone. Combined procedures, 'cataract + other' surgery, were excluded, unless the 'other' surgery formed part of the cataract operation (e.g. an operative manoeuvre to increase the size of the pupil). Further information on audit eligible cataract operation can be found on the RCOphth NOD audit website (www.nodaudit.org.uk).

Eligible operations were performed in the 2010 to 2020 NHS years (1st April 2010 to 31st March 2021) satisfying the eligibility criteria that apply to the RCOphth NOD Cataract Audit, from any EMR enabled contributing centre with at least 50 eligible operations, both before and after adopting CapsuleGuard®. Yearly results follow the NHS year (1st April to 31st March).

The data were recorded on the Medisoft EMR system (Medisoft Ophthalmology, Medisoft Limited, Leeds, UK, www.medisoft.co.uk), the OpenEyes EMR system (www.openeyes.org.uk) or 'in-house' electronic data collection systems compliant with the Cataract National Dataset (https://www.rcophth.ac.uk/standards-publications-research/audit-and-data/clinical-data-sets/cataract-national-data-set/).

Using data contributing to the RCOphth NOD Cataract Audit and sales figures provided by Bausch + Lomb, centres who started using CapsuleGuard® routinely for cataract surgery were identified by comparing the number of operations performed annually in each centre to the sales figures for CapsuleGuard®. Where the number of units of CapsuleGuard® accounted for at least 50% of all operations performed in a centre within an NHS year, the centre was deemed to have adopted CapsuleGuard® in routine practice. After the year of adoption, a centre continued to use CapsuleGuard® where the percentage of operations accounted for by sales data remained above the 50% threshold. Eligible for analysis were centres with data both before and after adopting CapsuleGuard®. Excluded were RCOphth NOD centres who had no record of purchasing CapsuleGuard®, centres with data for fewer than 50 operations annually before or after the adoption of CapsuleGuard®, and centres not fulfilling the 50% threshold criteria.

EMR systems require the surgeon recording the operation note to specifically indicate a 'Yes / No' response to whether a surgical complication occurred. This EMR record (or its printed output) constitutes the medicolegal documentation of the patient's operation record. The definition of PCR set out by the RCOphth NOD was utilised for this study (https://nodaudit.org.uk/sites/default/files/2022-07/Annual%20Report%202022%20National%20Cataract%20Audit_0.pdf [Accessed 3 June 2023]), and PCR rates before and after the year of adoption of CapsuleGuard® between centres were compared. The percentage change in PCR rates were calculated by the difference between the PCR rates before and after adopting CapsuleGuard®, divided by the before PCR rate. A proportions test was used to assess statistical significance, and PCR rates are

reported to two decimal places. All analyses were performed using STATA 17 (StataCorp. 2021. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC).

The lead clinician and Caldicott Guardian (responsible nominee for data protection) at each centre provided written approval for anonymised data extraction. Anonymized database analyses of this type do not require ethical permission due to being viewed as audit or service evaluation (see http://www.hra.nhs.uk/research-community/before-you-apply/determinewhether-your-study-is-research/). This study was conducted in accordance with the declaration of Helsinki, and the UK's Data Protection Act.

Results

Within the study period, 267 371 eligible cataract operations were performed in 14 centres with at least 50 eligible operations before and after the adoption of CapsuleGuard®. The operations were performed on 132 047 (49.4%) left eyes and 135 324 (50.6%) right eyes from 176 745 patients, where the median number of operations per centre was 15 438 (range; 8 348 – 43 926).

The operations were performed by 932 surgeons, 181 of whom had data for >1 grade, where 307 consultant surgeons performed 169 696 (63.5%) operations, 84 career grade non-consultant surgeons performed 28 301 (10.6%) operations, 420 more experienced trainee surgeons performed 56 044 (21.0%) operations and 121 less experienced trainee surgeons performed 13 330 (5.0%) operations.

Patient demographics

There were 176 745 patients, of which 101 301 (57.3%) were female and 75 444 (42.7%) were male. The median age at first eye treatment was 76.8 years (IQR: 69.4 to 82.8 years). Of the 176 745 patients, 90 626 (51.3%) had cataract surgery to both eyes including 475 (0.3%) patients who had immediate sequential bilateral cataract surgery (ISBCS). For the 90 151 non-ISCBS patients, the median time between their two operations was 4.5 months (Range: 1 day – 10.5 years). Of the patients who had treatment to both eyes, there were 46 559 (51.4%) patients who had both eyes operated on before the adoption of CapsuleGuard®, 37 465 (41.3%) patients who had both eyes operated on after the adoption of CapsuleGuard® and 6 602 (7.3%) patients who had one eye before and one eye after the adoption of CapsuleGuard®.

Known risk factors for PCR, including grade of operating surgeon and individual co-pathology/ known PCR risk factors remained very similar before and after the implementation of CapsuleGuard®, Table 1.

Table 1: Operating grade of surgeon and ocular co-pathology or known risk factor for PCR for eyes in centres before and after commencement of CapsuleGuard® usage.

N (column %)	Before CapsuleGuard® use	After CapsuleGuard® use	Overall
Number of operations/ eyes	**122 428**	**144 943**	**267 371**
Consultant surgeon	77 596 (63.4)	92 100 (63.5)	169 696 (63.5)
Career grade non-consultant surgeon	13 573 (11.1)	14 728 (10.2)	28 301 (10.6)
More experienced trainee surgeon	26 467 (21.6)	29 577 (20.4)	56 044 (21.0)
Less experienced trainee surgeon	4 729 (3.9)	8 538 (5.9)	13 330 (5.0)
Individual co-pathology/ known PCR risk factor			
Age-related macular degeneration	13 492 (11.0)	18 521 (12.8)	32 013 (12.0)
Glaucoma	10 845 (8.9)	16 144 (11.1)	26 989 (10.1)
Diabetic retinopathy	9 124 (7.5)	12 123 (8.4)	21 247 (8.0)
Brunescent/ white/ mature cataract	6 181 (5.1)	7 770 (5.4)	13 951 (5.2)
Corneal pathology	4 753 (3.9)	6 605 (4.6)	11 358 (4.3)
Previous vitrectomy surgery	1 929 (1.6)	2 337 (1.6)	4 266 (1.6)
Amblyopia	2 309 (1.9)	3 399 (2.4)	5 708 (2.1)
No fundal view/ vitreous opacities	1 546 (1.3)	2 278 (1.6)	3 824 (1.4)
Pseudoexfoliation/ phacodonesis	1 702 (1.4)	1 962 (1.4)	3 664 (1.4)
Other retinal vascular pathology	1 532 (1.3)	1 966 (1.4)	3 498 (1.3)
Uveitis/ synechiae	1 253 (1.0)	1 238 (0.9)	2 491 (0.9)
Optic nerve/ CNS disease	593 (0.5)	849 (0.6)	1 442 (0.5)
Previous trabeculectomy surgery	586 (0.5)	574 (0.4)	1 160 (0.4)
Inherited eye disease	176 (0.1)	249 (0.2)	425 (0.2)
Other unspecified ocular co-pathology	7 984 (6.5)	11 467 (7.9)	19 451 (7.3)

PCR rates with CapsuleGuard® Use

Overall, within the 14 centres who adopted regular CapsuleGuard® usage, the rate of PCR was higher at 1.65% before the regular use of CapsuleGuard® compared to 1.38% afterwards, resulting in a 16.4% reduction in PCR ($p < 0.01$).

The median change in the PCR rate between before and after the adoption of CapsuleGuard® was a 21.7% reduction (IQR: 4.8% to 37.7% reduction). There were 9/14 (64.3%) centres who had a >15% reduction in PCR rates after regular CapsuleGuard® use. Comparison of adopters' and non-adopters' PCR rates in each NHS audit year is shown in figure 1.

Discussion

With a median 21.7% reduction in the PCR rate experienced by centres adopting CapsuleGuard®, this is encouraging for the ongoing relevance of silicone-tipped I/A handpieces despite the other advances in surgical safety that might have been conveyed by improved fluidics of the phaco machines which could make accidental aspiration of the capsule less likely. This figure for PCR reduction has to be seen in light of the proportion of PCR that occurs during I/A, as there would be no possibility of CapsuleGuard® improving the PCR in the other higher risk parts of the surgery such as nuclear disassembly or IOL insertion.

Reduction in PCR due to CapsuleGuard® as a proportion of I/A related PCR events

There is uncertainty about the proportion of PCR caused by I/A, and this likely varies with the experience of the operating surgeon.(13) The stage of surgery at which PCR occurs is not systematically recorded on EPR or routinely collected for the NOD – so to estimate the likely

proportion of PCR occurring during I/A we would have to extrapolate from more granular studies of PCR from relevant settings.

Of studies identified that report the stage of surgery where PCR was noted to have occurred (table 2), the most relevant report is that by Ti, et al, from Singapore which includes 48 377 cataract operations performed by surgeons with varying experience levels and with an overall PCR rate (1.8%) similar to that reported by the NOD for the time period under question. They recorded 24.8% of the PCR to have occurred during I/A. Taking this 24.8% figure as the maximum proportion of PCR that could be achieved by improvements in I/A, both the median 21.7% reduction observed in centres adopting CapsuleGuard® and the mean 16.4% reduction in PCR over the whole dataset adopting CapsuleGuard® would represent the avoidance of over half the cases of PCR experienced in this phase of surgery.

Table 2: Summary of studies reporting the proportion of PCR occurring during I/A

First Author / Country / Year / reference	Surgeon Grade	Overall PCR Rate	%_PCR from I/A
Osher, USA, 1990, (10)	Consultant	48/4 800 (1%)	28%
Cruz, USA, 1992, (8)	Trainees	18/181 (9.9%)	72%
Gimbel, Canada, 2001, (9)	Consultant	83/18 470 (0.45%)	39.7%
Ti, Singapore, 2014, (11)	Mixed Experienced Surgeons	887/48 377 (1.8%)	24.8%
Thanigasalam, Malaysia, 2015, (12)	Mixed Experienced Surgeons	77/2 519 (3.06%)	35.2%
Maubon, UK, 2018, (19)	Trainees	43/1 715 (2.5%)	5%
Bai, China, 2020, (13)	Trainees	39/1 200 (3.25%)	36%

With the NHS providing around 500 000 cataract operations annually in England and Wales alone, and a current PCR rate around 1%, we expect 5 000 operations each year to experience PCR during surgery. Adoption of an intervention that reduces PCR rates by 16.4% might therefore protect 818 eyes each year from PCR.

It is reasonable to assume that the centres which transitioned to using CapsuleGuard® during the study period did so because they perceived that they had the need and opportunity to improve their surgical safety during I/A. There is, therefore, potential bias caused by the self-selection inherent in an observational study of this nature, as centres with already low PCR rates during I/A might be less likely to look for solutions to a problem they are not experiencing. However, the 14 centres that transitioned to this product dropped their PCR rate from 1.65% before adoption to 1.38% after – and analysis of the NOD dataset for all other centres not identified from the Bausch + Lomb sales figures as CapsuleGuard® users found those centres to have an overall 1.69% PCR rate during the overall study period, suggesting that the centres adopting CapsuleGuard® use were not initially outliers experiencing unusually high PCR rates. This suggests that the effect of the potential selection bias is not large, and that further reduction in PCR rates by adoption of silicone-tipped I/A technology may be on offer and could be considered.

The overall PCR rate has been decreasing since the beginning of the study period for all centres for centres contributing data to the RCOphth NOD. Any before and after study of an intervention to reduce PCR rates could demonstrate improvement due to this secular trend, however, the overall lower rate of PCR for centres post-adoption of CapsuleGuard® is shown to outperform the non-adopters in Figure 1.

This study is limited by the fact that the NOD does not collect data regarding the type of I/A device being used in each operation, or during which step of the surgery PCR occurred, so it is not possible to comment on where the most benefit lies and for which surgeons. If this data were to start to be recorded, analysis of PCR rates during I/A experienced with silicone-tipped

I/A devices could be compared with bimanual or coaxial metal I/A devices and stronger conclusions drawn. The surgeons who stand to gain the most from adoption of this technology could also be explored with more granular data. One study reported that less experienced surgeons had a higher proportion of PCR cases caused by nuclear disassembly with the phacoemulsification probe, whereas the proportion of PCR events attributable to I/A rose as they gained experience and improved the safety of their phacoemulsification technique.(13)

Another limitation of the study was that we did not know which operations used CapsuleGuard® and which did not from within centres, so we assigned the entire dataset from centres with >50% usage of CapsuleGuard® to the group labelled as having adopted this as routine practice within a given NHS year. This may result in an under-estimate of the impact of CapsuleGuard® than might have been seen if the product had been used on every case within a unit.

Before advocating uptake of any technology, which will have procurement cost implications and potential additional costs associated with changing practice and the learning curve, it is important to consider the cost-effectiveness of the proposed intervention. It was beyond the scope of this study to estimate the cost savings provided by the avoidance of PCR, or to estimate the costs associated with the variety of I/A options that exist, however this would be a useful follow-on study from this work.

Acknowledgments

It is with gratitude that we remember our friend and colleague Robert Johnston, who sadly died in September 2016. Without his inspirational vision, determination and career long commitment to quality improvement in ophthalmology this work would not have been possible.

We acknowledge the support of the hospitals that participated in this National Ophthalmology Database Audit study and thank our medical and non-medical colleagues for the considerable time and effort devoted to data collection.

The participating centres included in this study are listed in alphabetic order below:

Barking, Havering and Redbridge University Hospitals NHS Trust; Bradford Teaching Hospitals NHS Foundation Trust; East Kent Hospitals University NHS Foundation Trust; Epsom and St Helier University Hospitals NHS Trust; Hampshire Hospitals NHS Foundation Trust; Leeds Teaching Hospitals NHS Trust; Liverpool University Hospitals NHS Foundation Trust; Manchester University NHS Foundation Trust; Mid Cheshire Hospitals NHS Foundation Trust; Mid Yorkshire Teaching NHS Trust; Royal Devon University Healthcare NHS Foundation Trust; South Warwickshire University NHS Foundation Trust; University Hospitals Coventry and Warwickshire NHS Trust; Wirral University Teaching Hospital NHS Foundation Trust;

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Table and Figure legends

Figure 1: The PCR rate of centres before and after adoption of CapsuleGuard® by NHS year. The 'before' group, is all operations from before a centre adopted CapsuleGuard® and all operations in RCOphth NOD centres who never adopted CapsuleGuard®. The 'after' group is operations in centres after the year of adoption of CapsuleGuard®.

Table 1: Operating grade of surgeon and ocular co-pathology or known risk factor for PCR for eyes in centres before CapsuleGuard® and after CapsuleGuard® usage.

Table 2: Summary of studies reporting the proportion of PCR occurring during I/A

Figures

Figure 1: