

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	The Only Eye Study (OnES): Surgeon experiences of only eye surgery and recommendations for patient safety
AUTHORS	Jones, Lee; Taylor, Deanna; Sii, Freda; Masood, Imran; Crabb, David; Shah, Peter

VERSION 1 – REVIEW

REVIEWER	Dcclan Flanagan Moorfields Eye Hospital London EC1V 2 PD UK
REVIEW RETURNED	UK 30-Mar-2019

GENERAL COMMENTS	<p>This small study addresses, in a limited way, an extremely important issue for patients, surgeons and operating theatre teams. The subject which is very important professionally to ophthalmic surgeons has had limited discussion in the ophthalmic literature. This paper will stimulate debate about whether ophthalmic practice needs to change to improve the service offered to patients likely to benefit from "only eye" surgery as well as the training and support offered to the many surgeons who perform "only eye" surgery in all subspecialties.</p> <p>The paper would be more informative if some data on the absolute risks of total visual loss from cataract and other procedures was included in the introduction and . Awareness of the low level of risk is important for an informed discussion. of pragmatic feasible improvements - Swedish National Cataract Registry for post op infection data and the UK NOD for outcomes. Additional processes of unproven benefit must not make it more difficult to provide safe timely care.</p> <p>Specialties which use "Star Chambers" or equivalents are normally dealing with far higher absolute levels of risk and also need input from other specialties into the clinical recommendation to the individual patient.</p> <p>The paper would also benefit from input by a number of patients who have benefited or not benefited from "only eye " surgery.</p> <p>Subject to these comments this paper should be published. A more extensive study involving a larger more representative group of surgeons, multidisciplinary staff and patients would be of immense benefit to this important debate.</p>
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REVIEWER	Philip Enders, MD, FEBO, FICO 3 University of Cologne
REVIEW RETURNED	29-Apr-2019

GENERAL COMMENTS	<p>The topic of this manuscript is of high relevance for ophthalmic surgeons in general as well as especially for those treating patients who have only one "good" eye. The manuscript's structure and wording is clear and easy to follow. Areas for improvement are:</p> <ul style="list-style-type: none"> - In the introduction section: When performing eye surgery, some of the most crucial questions are if surgery is necessary to prevent non-reversible vision loss (i.e. in retinal detachment) and what is the chance to risk ratio. This aspect - to which extend the surgical procedure is necessary -, as a decision criterion for the patient is not emphasized clearly enough. - In the introduction section, the authors could provide more details about the risk of intraocular surgery. I would expect current literature findings on rates and impact of major complications (i.e. endophthalmitis, sub-choroidal bleeding...). Currently the manuscript remains too vague. - It remains unclear, why only semi-structured interviews have been conducted. The addition of a structured questionnaire for the surgeons would have been helpful to obtain more quantitative results. - The latter point is my main concern about this manuscript: the derived qualitative results are not helping me a lot for my surgical performance in patients with only one eye. It's rather evident that I would want to use the best instruments available with the best nursing staff... Also some conclusions seem not close to the real life situation. You can't compare eye surgery, i.e. cataract surgery, that lasts 10 min with one surgeon doing all steps with cardiothoracic surgery which last several hours and is always performed by more than one surgeon. - To conclude, while I do find the hypothesis and the topic very interesting, the results and discussed implications do not add a lot of new evidence for me.
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REVIEWER	Brigid Gillespie Professor of Patient Safety School of Nursing and Midwifery, Griffith University Room 2.04, G01, Griffith University, Southport QLD 4222 Phone: +61 7 5552 9718 (Griffith) Gold Coast University Hospital, Gold Coast Health Nursing and Midwifery Education and Research Unit E. 2 016, 1 Hospital Blvd, Southport, QLD, 4215 Phone: +61 7 5687 3245 (GCUH)
REVIEW RETURNED	03-Jun-2019

GENERAL COMMENTS	<p>The aim of this qualitative study was to explore surgeons' perceptions and experiences on performing only eye surgery.</p> <p>Methodological review:</p> <ol style="list-style-type: none"> 1. The authors have undertaken an inductive analysis to derive codes to build themes. More detail about how the codes were sorted and grouped into categories that then underpinned the themes would increase the transparency in reporting. 2. The level of agreement b/ coders was k 0.46, which has been interpreted as being acceptable but is arguably, very lenient.
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	<p>Suggest that the authors also present the percentage of agreement.</p> <p>3. As qualitative studies are largely contextual, please add 2-3 sentences to describe the clinical context in which the surgeons practice.</p> <p>4. Authors, please include a section (to follow data analysis section) detailing the elements of rigor, and how these were addressed in this qualitative study (credibility, transferability, audibility and reflexivity). This will give readers more confidence in the findings.</p> <p>5. Authors please add 1-2 sentences on data saturation under the Analysis section into the methods.</p> <p>6. Presentation of the thematic findings is logical and makes sense. However, some of the themes, e.g., "consent"-but what is it about consent? Suggest linking this concept to make the theme more informative for the reader. Same comment applies to "training", mentorship" and "emotional impact".</p> <p>Discussion supports the findings.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1

This small study addresses, in a limited way, an extremely important issue for patients, surgeons and operating theatre teams. The subject which is very important professionally to ophthalmic surgeons has had limited discussion in the ophthalmic literature. This paper will stimulate debate about whether ophthalmic practice needs to change to improve the service offered to patients likely to benefit from "only eye" surgery as well as the training and support offered to the many surgeons who perform "only eye" surgery in all subspecialties.

We are pleased that the reviewer finds this work to be of high importance and that our findings will encourage debate in the field. We also thank the reviewer for their suggested revisions. We have outlined our response to the individual comments below:

The paper would be more informative if some data on the absolute risks of total visual loss from cataract and other procedures was included in the introduction and awareness of the low level of risk is important for an informed discussion of pragmatic feasible improvements - Swedish National Cataract Registry for post op infection data and the UK NOD for outcomes. Additional processes of unproven benefit must not make it more difficult to provide safe timely care.

We agree with the reviewer that the inclusion of data on risk of visual loss in these surgeries is important. We have now amended the second paragraph of the introduction to include this:

Page 4: The National Ophthalmology Database (NOD) reports on all National Health Service (NHS) funded cataract surgery in England and Wales (10). The 2018 audit highlighted intraoperative complications in 3.2% of all recorded procedures, the most prevalent being posterior capsular rupture (PCR). Over 3000 patients with PCR had post-operative visual acuity (VA) of 6/60 or worse, i.e. unable to read the top line of a typical VA chart. Post-operative complications were more prevalent, with one in twenty (over 8000) eyes having at least one complication. Glaucoma randomised clinical trials report serious complications, including retinal detachment, suprachoroidal haemorrhage, and endophthalmitis occurring in over one in five tube shunt and trabeculectomy patients (11). Approximately half of patients experiencing a complication lost greater than two lines on Snellen VA.

Specialties which use "Star Chambers" or equivalents are normally dealing with far higher absolute levels of risk and also need input from other specialties into the clinical recommendation to the individual patient.

We agree that Star Chambers are typically associated with specialties of medicine concerned with higher absolute risk (i.e. cardiology). With that said, we argue that this should not negate the need for such a system in other areas, such as only eye surgery. In addition to the obvious psychological impact of unsuccessful outcomes in only eye surgery, the economic impact of vision loss is substantial for society. Even in developed countries costs associated with blindness and visual impairment are higher than those of coronary heart disease, and other chronic conditions such as stroke (Taylor et al., 2006). This makes clinical sense as the cost of unsuccessful only eye surgery (e.g. lifetime of severe visual impairment or blindness) will be much greater than unsuccessful outcomes in heart surgeries (e.g. death).

Taylor HR, Pezzullo ML, Keeffe JE. The economic impact and cost of visual impairment in Australia. *British Journal of Ophthalmology*, 2006; 90(3): 272-5.

The paper would also benefit from input by a number of patients who have benefited or not benefited from "only eye" surgery.

This study reports findings from surgeon interviews in the Only Eye Study (OnES), a series of research projects investigating experiences of only eye surgery. We are currently in the process of preparing a manuscript reporting the findings from the patient interviews. Whilst it would be nice to have both surgeon and patient perspectives presented in a single manuscript, BMJ Open (and other academic journals) permit manuscripts to be no more than 4000 words. As is the nature of qualitative manuscripts, the results include several quotations from participant interviews, which add to the word count. We feel that the quotations are essential to illustrate our results. For these reasons, it was decided to prepare a further manuscript focusing specifically on patient perspectives. We are pleased the reviewer agrees this is an important area of investigation.

We have amended the methods section to highlight the upcoming manuscript on patient experiences of only eye surgery:

Page 7: The Only Eye Study (OnES) is a series of research projects designed to investigate only eye surgery. This is the first research output in the series and reports surgeon experiences of only eye surgery. The outcomes of the patient interviews will be described in a subsequent report.

Subject to these comments this paper should be published. A more extensive study involving a larger more representative group of surgeons, multidisciplinary staff and patients would be of immense benefit to this important debate.

This report is the first to qualitatively investigate surgeon experiences of only eye surgery. We agree that our findings should be used as a basis for a larger study, including methods such as surveys.

Reviewer 2

The topic of this manuscript is of high relevance for ophthalmic surgeons in general as well as especially for those treating patients who have only one "good" eye.

We are pleased that this reviewer believes our manuscript to be clinically relevant and thank the reviewer for their comments on how the manuscript can be improved.

The manuscript's structure and wording is clear and easy to follow. Areas for improvement are:

In the introduction section: When performing eye surgery, some of the most crucial questions are if surgery is necessary to prevent non-reversible vision loss (i.e. in retinal detachment) and what is the chance to risk ratio. This aspect - to which extend the surgical procedure is necessary -, as a decision criterion for the patient is not emphasized clearly enough.

We have reviewed recent additions to the evidence-based for ophthalmic surgery. The National Ophthalmology Database (NOD) Audit of 2018 reports 5,841 (3.2%) of the 183,312 eyes undergoing cataract surgery during the one year assessment period experienced at least one intraoperative complication. The most common intraoperative complication was posterior capsular rupture (PCR) occurring in 2,551 (1.4%) procedures. Of 152,663 eyes eligible for postoperative complication analysis, 8,074 (5.3%) had at least one complication, the most common being postoperative uveitis, occurring in approximately 1.5% of eyes. The NOD Audit also identified a loss of >0.10 LogMAR (>1 line) in visual acuity (VA) was experienced by 3,158 (3.2%) eyes. In patients with PCR, 6.4% were left with VA of 6/60 or worse (i.e. unable to read the top line of a typical VA chart). It should be noted that the NOD Audit acknowledges that exact estimation of cases is not possible, and so actual complication incidence will likely be higher. For glaucoma surgery, the Tube Versus Trabeculectomy (TVT) Study reports serious complications (including retinal detachment, suprachoroidal haemorrhage and endophthalmitis) in 24 (22%) patients receiving tube shunt surgery, and 21 (20%) of patients in the trabeculectomy group. Amongst patients experiencing complications, 51% in the tube group and 45% in the trabeculectomy group had a VA (Snellen) loss of ≥ 2 lines. In other words, if these were only eye patients with very good VA (e.g. Snellen 6/6) before surgery, they certainly would no longer satisfy criteria for safe driving eyesight and would lose their driving licence.

We have now added these details to paragraph two of the manuscript introduction.

In the introduction section, the authors could provide more details about the risk of intraocular surgery. I would expect current literature findings on rates and impact of major complications (i.e. endophthalmitis, sub-choroidal bleeding...). Currently the manuscript remains too vague.

Reviewer 1 made a similar suggestion and we have now amended the introduction to include this

Page 4: Incisional ocular surgery generally carries a low complication incidence rate ⁽⁸⁾. Yet, sight-threatening complications, such as post-operative infection and haemorrhage cannot be discounted, and unfortunately do occur ⁽⁹⁻¹⁰⁾. The National Ophthalmology Database (NOD) reports on all National Health Service (NHS) funded cataract surgery in England and Wales ⁽¹⁰⁾. The 2018 audit highlighted intraoperative complications in 3.2% of all recorded procedures, the most prevalent being posterior capsular rupture (PCR). Over 3000 patients with PCR had post-operative visual acuity (VA) of 6/60 or worse, i.e. unable to read the top line of a typical VA chart. Post-operative complications were more prevalent, with one in twenty (over 8000) eyes having at least one complication. Glaucoma randomised clinical trials report serious complications, including retinal detachment, suprachoroidal haemorrhage, and endophthalmitis occurring in over one in five tube shunt and trabeculectomy patients ⁽¹¹⁾. Approximately half of patients experiencing a complication lost greater than two lines on Snellen VA. In other words, if these were only eye patients with very good VA (e.g. Snellen 6/6) before surgery, they certainly would no longer satisfy criteria for safe driving eyesight and would lose their driving licence. Serious complications have been reported in only eye surgery ^(12, 13).

It remains unclear, why only semi-structured interviews have been conducted. The addition of a structured questionnaire for the surgeons would have been helpful to obtain more quantitative results.

We agree with the reviewer that quantitative data to assess experiences and attitudes towards only eye surgery would be a valuable avenue for future research and this is a project we plan to pursue.

Qualitative methods, such as interviews, are believed to provide a 'deeper' understanding of social phenomena than would be obtained from purely quantitative methods, such as questionnaires

(Silverman, 2000). Interviews are, therefore, most appropriate where little is already known about the study phenomenon, such as in the field of only eye surgery. They are also particularly appropriate for exploring potentially sensitive topics like surgical experience. Semi-structured interviews consist of several key questions that help to define the areas to be explored, but also allows the interviewer or interviewee to diverge in order to pursue an idea or response in more detail. The semi-structured interview format is frequently used in healthcare-related research, as it provides participants with some guidance on what to talk about, which many find helpful. The flexibility of this approach, particularly compared to structured interviews or surveys, allows for the discovery or elaboration of information that is important to participants, but may not have previously been thought of as pertinent by the research team.

We have added a statement to our manuscript to explain this:

Page 6: *“We used interviews as this method is particularly useful when little is already known about the study phenomenon, such as in the field of only eye surgery. Interviews are also appropriate for exploring potentially sensitive topics, like surgical experience. Semi-structured interviews consist of several key questions that help define areas to be explored, but also allow the interviewee to diverge in order to pursue an idea or response in more detail. This interview format is frequently used in healthcare-related research, as it provides participants with some guidance on what to talk about, which many find helpful. The flexibility of this approach, particularly compared to structured interviews or surveys, allows for the discovery or elaboration of information that is important to participants, but may not have previously been thought of as pertinent by the research team.”*

The latter point is my main concern about this manuscript: the derived qualitative results are not helping me a lot for my surgical performance in patients with only one eye. It's rather evident that I would want to use the best instruments available with the best nursing staff... Also some conclusions seem not close to the real life situation. You can't compare eye surgery, i.e. cataract surgery that lasts 10 min with one surgeon doing all steps with cardiothoracic surgery which last several hours and is always performed by more than one surgeon.

The aim of this study was to qualitatively explore surgeon experiences of only eye surgery – a study which has not been done previously. By adopting a qualitative approach, important themes have emerged which provide an excellent basis for future work, such as using our themes to construct a survey to be administered to a larger cohort to further our understanding of approaches to only eye surgery. As there was no prior research, this study was essential in order to provide preliminary data and insight into this type of surgery. Regarding the specific point about wanting the best surgical instruments and staff being obvious, there is huge variability in these aspects of surgery within some public healthcare systems, for example the NHS in the UK, and this is discussed in the manuscript

Page 15: *Quality control exercises highlight a strikingly high percentage of defective surgical instruments delivered to UK hospitals⁽²⁶⁾, and operating room incidents with potential to affect quality of care are most commonly equipment-related⁽²⁷⁾.*

To conclude, while I do find the hypothesis and the topic very interesting, the results and discussed implications do not add a lot of new evidence for me.

Reviewer 3

The aim of this qualitative study was to explore surgeons' perceptions and experiences on performing only eye surgery.

We thank the reviewer for their comments, we have now added more detail relating to the study methodology.

The authors have undertaken an inductive analysis to derive codes to build themes. More detail about how the codes were sorted and grouped into categories that then underpinned the themes would increase the transparency in reporting.

We agree that it is necessary to include details on how our codes were generated. We have now added to the methods section:

Page 7: Open coding was used when analysing the data where patterns in participants' responses were recorded. These patterns were further explored by grouping responses into similar categories both within and across interviews and finally were grouped into common themes which best described the content of the data.

The level of agreement b/ coders was k 0.46, which has been interpreted as being acceptable but is arguably, very lenient. Suggest that the authors also present the percentage of agreement.

We have now added to the manuscript to reflect on this point:

Page 8: There is debate in the literature regarding the sufficiency of the kappa statistic, however scores between 0.40 and 0.75 typically reflect fair to good agreement beyond chance ⁽²¹⁾.

As qualitative studies are largely contextual, please add 2-3 sentences to describe the clinical context in which the surgeons practice.

We agree with the reviewer and have added the following statement about the interviewees.

Page 5: The majority of the surgeons worked within large general hospitals, or were based in a specialist eye hospital.

We have also added to the discussion to highlight that the participants mainly worked within similar clinical contexts.

Page 19: The study is limited in that a small number of surgeons were interviewed and they were all experienced glaucoma surgeons, primarily based in large hospital care centres which may restrict the transferability of our findings.

Authors, please include a section (to follow data analysis section) detailing the elements of rigor, and how these were addressed in this qualitative study (credibility, transferability, audibility and reflexivity). This will give readers more confidence in the findings.

We have now added the following to the methods section.

Page 8: A number of methods were employed to ensure the study had appropriate rigour and maintained research integrity. As shown in Figure 1, the project was steered by a number of relevant stakeholders including both patients and surgeons who assisted in the study design and analysis. We piloted the interview topic guide with two surgeons, leading to a slightly revised final topic guide. All members of the research team, including surgeons, were involved in establishing the appropriateness of the generated codes. We contributed to improving descriptive validity through the use of a strict verbatim transcription service. In addition, member-checking was used with three interviewees to assess our choice of coded themes in an attempt to improve the reliability and trustworthiness of our findings. Finally, we ensured the design, conduct and reporting of the study followed COREQ guidelines.

As mentioned in our response to the previous comment, we have added to the discussion relating to the transferability of our findings.

Page 19: *The study is limited in that a small number of surgeons were interviewed and they were all experienced glaucoma surgeons, primarily based in large hospital care centres which may restrict the transferability of our findings.*

Authors please add 1-2 sentences on data saturation under the Analysis section in the methods.

We have now added to the methods section

Page 7: *The study was designed to recruit ten participants and so no direct decision was taken to cease data collection; however, similar themes continued to emerge in the latter interviews and so it is likely that 'data saturation' was achieved.*

Presentation of the thematic findings is logical and makes sense. However, some of the themes, e.g., "consent"-but what is it about consent? Suggest linking this concept to make the theme more informative for the reader. Same comment applies to "training", mentorship" and "emotional impact".

We agree with the reviewer and have now amended the presentation of the key themes. These are now: Differences in approach to consent; Strategies for risk reduction; Unmet training needs; Value of surgical mentor; Emotional impact of unsuccessful outcomes.

VERSION 2 – REVIEW

REVIEWER	Philip Enders, MD, FEBO, FICO Department of Ophthalmology, University of Cologne, Faculty of Medicine and University Hospital Cologne, Cologne, Germany
REVIEW RETURNED	16-Aug-2019
GENERAL COMMENTS	The authors have addressed those reviewer's comments adequately that were modifiable within the design of the conducted study.