



Chu, C. J., Johnston, R. L., Buscombe, C., Sallam, A. B., Mohamed, Q., & Yang, Y. C. (2017). Reply: to Re: Chu et al.: Risk factors and incidence of macular edema after cataract surgery. *Ophthalmology*, *124*(2), e17-e18. https://doi.org/10.1016/j.ophtha.2016.05.031

Peer reviewed version

License (if available): CC BY-NC-ND

Link to published version (if available): 10.1016/j.ophtha.2016.05.031

Link to publication record in Explore Bristol Research PDF-document

This is the author accepted manuscript (AAM). The final published version (version of record) is available online via Elsevier at https://www.sciencedirect.com/science/article/pii/S0161642016303931?via%3Dihub. Please refer to any applicable terms of use of the publisher.

University of Bristol - Explore Bristol Research General rights

This document is made available in accordance with publisher policies. Please cite only the published version using the reference above. Full terms of use are available: http://www.bristol.ac.uk/pure/about/ebr-terms

We thank Drs Kim and Grzybowski for their interest in our paper¹ and for highlighting their concern about the lack of strict diagnostic criteria for macular edema and the lack of preoperative OCT scans which might have affected the quality of case reporting of pseudophakic macular edema (PME) in our study.

We fully agree that strict selection of diagnostic criteria is needed in prospective studies designed to answer specific questions about the change in macular status between preoperative and postoperative periods. In our study, the aim was to describe in the real world setting, how frequently clinicians were encountering PME and documenting it in everyday practice on an electronic patient record (EPR) system. Therefore a retrospective design with a large and representative cohort of consecutive patients was ideal for this purpose with the two most crucial factors in determining accuracy of case reporting being: i) the ability of clinicians to make a diagnosis of macular edema in everyday practice following cataract surgery and ii) the reliability of those clinicians at making an entry onto the EPR system. We felt confident that in all our sites (which had experienced clinicians, spectral domain OCT facilities and robust cataract management pathways), these two systematic causes of potential under-reporting were unlikely to be significant. We were further reassured as our results were similar to other database studies which focussed on real world outcomes.^{2,3}

We agree with their comment that comparison of pre and post preoperative OCT scans is essential for quantitative assessment of the effect of cataract surgery on macular edema, and note Dr Kim's prospective study on 50 eyes of patients with diabetes⁴, which reported increasing macular thickening with diabetic retinopathy grade and we are pleased to have been able to subsequently demonstrate his findings in a large real-world context. It was our aim to quantify and compare the rates of PME between eyes with not only diabetic retinopathy but also other co-morbidities. The unique feature in our study was the availability of accurately documented data fields on several risk factors for PME in a very large consecutive cohort of eyes undergoing cataract surgery in a real world setting. We are unaware of any similar study providing quantitative comparisons between the different risk factors for PME that are encountered in everyday clinical practice.

We are grateful to Drs Kim and Grzybowski for highlighting the fine details of methodology in our study. A high standard of rigour is important in explanatory, prospective studies using strict protocols on very homogenous groups of patients to answer questions which further our scientific knowledge. Indeed, it is equally important in pragmatic trials and real world studies which inform us of the experiences and outcomes of everyday clinical practice and are valuable for clinical decision making and the development of guidelines and policies. The PME incidence rates of between 1.17% to 12.07% pose a significant morbidity risk when one considers the much lower risks of other complications such as posterior capsule rupture in modern cataract surgery. It is possible that this kind of real world evidence could influence policy makers to introduce preoperative OCT scanning and even prophylactic therapy such as topical bromfenac or nepafenac which are currently not recommended in clinical guidelines. Total

Colin J Chu, Robert L Johnston, Charlotte Buscombe, Ahmed B Sallam, Quresh Mohamed and Yit C Yang for the United Kingdom Pseudophakic Macular Edema Study Group.

References

- 1. Chu CJ, Johnston RL, Buscombe C, Sallam AB, Mohamed Q, Yang YC; United Kingdom Pseudophakic Macular Edema Study Group. Risk Factors and Incidence of Macular Edema after Cataract Surgery: A Database Study of 81984 Eyes. *Ophthalmology*. 2016; 123(2): 316-23.
- **2.** Packer M, Lowe J, Fine H. Incidence of acute postoperative cystoid macular edema in clinical practice. *Journal of Cataract & Refractive Surgery*. 2012; 38(12): 2108–2111.
- 3. Schmier JK, HALPERN MT, COVERT DW, MATTHEWS GP. Evaluation of costs for cystoid macular edema among patients after cataract surgery. *Retina (Philadelphia, Pa)*. 2007; 27(5): 621–628.
- 4. Kim SJ, Equi R, Bressler NM. Analysis of macular edema after cataract surgery in patients with diabetes using optical coherence tomography. *Ophthalmology*. 2007; 114(5):881-9.
- 5. Diabetic Retinopathy Clinical Research Network Authors/Writing Committee, Baker CW, Almukhtar T, Bressler NM, Glassman AR, Grover S, Kim SJ, Murtha TJ, Rauser ME, Stockdale C. Macular edema after cataract surgery in eyes without preoperative central-involved diabetic macular edema. *JAMA Ophthalmol.* 2013; 131(7):870-9.
- 6. Maclure M. Explaining pragmatic trials to pragmatic policy-makers. CMAJ. May 12, 2009; 180(10): 1001-10003.
- 7. Kowalski CJ and Mrdjenovich AJ. Studying group behaviour: cluster randomized clinical trials. American Journal of Clinical and Experimental Medicine. Vol. 1(1), 2013: 5-15.
- 8. Rawlins M. De testimonio: on the evidence for decisions about the use of therapeutic interventions. *Lancet* 2008; 372: 2152–2161.
- 9. Roche N, Reddel HK, Agusti A, *et al.* Integrating real life studies in the global therapeutic research framework. *Lancet Respir Med* 2013; 1: 30–32.
- 10. AAO Cataract in the Adult Eye Preferred Practice Pattern 2011, http://www.aao.org/preferred-practice-pattern/cataract-in-adult-eye-ppp--october-2011.
- 11. The Royal College of Ophthalmology, Cataract Surgery Guidelines, September 2010, https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2010-SCI-069-Cataract-Surgery-Guidelines-2010-SEPTEMBER-2010.pdf.