

LETTERS

The future of surgical assessment

We took great interest in the review by Spiteri *et al*¹ regarding the teaching and assessment of cataract surgery skills. We have recently employed the Kitaro wet and dry lab system at the University of Rochester and have found the accuracy of the simulation to be excellent. We believe the fidelity of this system will fundamentally change the role of phacoemulsification training outside the operating theatre. The authors mention virtual reality systems as an alternative to human and animal wet lab models, but we have found the cost of these systems restrictive. The major advantages of the virtual reality system are its instantaneous feedback, its objectivity and its standardisation, but a minority of training programmes in the USA are able to afford the expense.

Regarding assessment of operative performance using video-based methods, we have found the major impediment is time. For an attending to review a single cataract surgery in detail and provide feedback on the case, it can consume more than 30 min. In addition to the time cost of video-based review, its objectivity can be questionable, especially when the input of only one attending is used. We have also had difficulty tracking resident performance over time using video-based assessments because of the time constraints involved and because of objectivity issues.

With the growing number of factors that often limit opportunities for resident surgical education, it is of great importance that effective methods of phacoemulsification training be developed. Objective, valid and reliable tools that provide rapid feedback are essential for training in the wet lab and in the operating theatre. We are not there yet.

Yousuf M Khalifa, Mujahid A Hines, Matthew Gearing

Correspondence to Dr Yousuf M Khalifa, Flaum Eye Institute, University of Rochester, 601 Elmwood Ave, Box 659, Rochester, New York 14642, USA; yousuf_khalifa@urmc.rochester.edu

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REFERENCE

1. Spiteri A, Aggarwal R, Kersey T, *et al*. Phacoemulsification skills training and assessment. *Br J Ophthalmol* 2010;**94**:536–41.

Author's response

I would like to thank Khalifa *et al*. We too believe that simulation technology is here to

stay and that it can only improve with its further development and more research in software validation, highlighting its strengths and weaknesses. To this aim, our group has completed one such validation trial which we hope to share with the published community shortly.

Regarding the cost of these systems, we agree that these are currently restrictive (although we have already witnessed a substantial drop in price). We think that, for this reason, simulation based training works better on a regional training basis rather than individual hospitals investing heavily for a limited number of trainees. However, the increased demand caused by higher trainee to machine ratios will raise issues regarding how much minimum training will be required and for how long. Studies plotting learning curves required to reach standards set by validation trials are thus beckoning. These will produce more targeted training rather than simply 'the-more-the-better' practising.

Although we are not there yet, once these initial obstacles are overcome there are multiple advantages to look forward to. Running costs are minimal; reduced complication rates due to out-of-theatre training would provide financial benefits and the more obvious reduction in morbidity; inbuilt validated scores would obviate the need for assessment by independent assessors thus minimising time constraints on more senior surgeons. Finally, we would be addressing the main issue highlighted regarding the growing number of factors that are limiting opportunities for resident surgical education.

Anthony Spiteri

Correspondence to Dr Anthony Spiteri, Department of Ophthalmology, Frimley Park Hospital NHS Foundation Trust, Portsmouth Road, Camberley, Surrey GU16 7UJ, UK; antspit@yahoo.com

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How much of invasive clinical research is still ethically justified?

Two research studies published in *BJO*^{1 2} were based on invasive procedures. The previous similar studies were conducted in China and related ethical concerns were reported.^{3 4} Although the discussed studies

were conducted in Europe, they raise similar concerns. Both studies were conducted by the same research group and were based on the same studied group of patients: 18 patients with normal-tension glaucoma who underwent cisternography with lumbar puncture (LP). Control group constituted age- and gender-matched individuals without known intracranial or optic nerve disease who underwent CT scanning for maxillary and ethmoid sinus disease.

It should be pointed that a great deal of literature has shown little or no foundation for the idea that low cerebrospinal fluid pressure is related to optic neuropathy.⁵ In 2008, Louis R Pasquale wrote: 'Yet it is probably not feasible or ethical to subject neurologically asymptomatic patients to lumbar puncture to advance scientific knowledge regarding glaucoma. In addition, there is no way clinically to measure the pressure gradient across the lamina cribrosa in a noninvasive manner', which is still true.⁶ Therefore, it seems unreasonable and probably unjustified to expose subjects with low-tension glaucoma to the risks associated with LP in light of the ethical requirement that potential benefits outweigh the risks borne by the subjects. The non-invasive tests, including neuroradiology and/or animal models of intracranial hypotension, were not used, although it was postulated.⁶

One of the many weaknesses of the authors' informed consent process is that they did not mention disclosure to the patient of the risks associated with LP, nor was there any mention of the presence or absence of complications related to the LP in the Results section.

While the authors mention an ethical review process, their description lacks sufficient detail to satisfy concerns that adequate attention was paid to protecting patients during their recruitment as research subjects. Avoiding the so-called 'therapeutic misconception' is an important concern, especially when a study involves an invasive procedure. This aspect of the consent process should be scrupulously observed and clearly documented in a study's publication, yet the authors failed to provide such documentation.

Moreover, the presently discussed studies, similar to previous reports from China in which LP were used in glaucoma and ocular hypertension patients, raise a general ethical concern and question: how much invasive procedure could we propose to the patient in clinical research settings (with no therapeutic context of the procedure as it was in both cases)?

The invasive procedures in human subjects' research should be used rarely, only in clearly justified cases and based on adequate and comprehensive informed consent process.

Andrzej Grzybowski^{1,2}

¹Medical Faculty, University of Warmia and Mazury, Olsztyn, Poland; ²Head of the Department of Ophthalmology, Poznań City Hospital, Poland