The Arclight: A New, Low-Cost Ophthalmoscope for Medical Student Teaching

CURRENT STATUS: POSTED

Sahib Yuvraj Tuteja
University of Manchester
ORCiD: https://orcid.org/0000-0003-2887-9793

Obaid Kousha
NHS Fife

Andrew Blaikie
Corresponding Author
ORCiD: https://orcid.org/0000-0001-7913-6872

DOI: 10.21203/rs.2.11109/v1

SUBJECT AREAS
Ophthalmology  Educational Philosophy and Theory

KEYWORDS
Ophthalmoscopy, Arclight Ophthalmoscope, Diabetic Retinopathy, Undergraduate Curriculum, Medical Students
Abstract

Introduction

Many physicians lack confidence in performing ophthalmoscopy. Limited training at the undergraduate level, low ophthalmoscope ownership rates, and lack of access in wards have been identified as potential factors that contribute to the negative cycle that precludes development of this vital skill. We evaluated the Arclight (AO), a new low-cost (£50) pocket ophthalmoscope, against a ‘traditional’ direct ophthalmoscope (TDO) to assess whether it maybe a suitable alternative for medical student training.

Methods

18 third year medical students were split into two groups to use either the AO or the TDO device to perform two tasks: 1) Identify a range of core retinal pathologies on seven simulated eyes and; 2) Identify specific signs of diabetic retinopathy on four simulated eyes.

Results

For the first task, the mean score for correct identification of pathologies for the AO group (n=9) was 4.33 (95% confidence interval (CI): 2.90 to 5.77) and the mean score for the TDO group (n=9) was 3.78 (95% CI: 5.10 to 2.46). For the second task, the mean score for the AO group (n=9) was 7.17 (95% CI: 5.11 to 9.23) and for the TDO group (n=9) was 5.61 (95% CI: 4.43 to 6.79). There was no statistically significant difference between the two groups’ results for the first (p = 0.52), or the second task (p = 0.15).

Conclusions

Our results show that the AO performs just as well as the TDO in examination of both general retinal clinical signs and specific signs of diabetic retinopathy. The equal clinical effectiveness combined with low cost, consumable-independence and portability of the AO make it a suitable alternative to the TDO in medical schools. If the device was more widely adopted by students we would envisage greater and more confident use as a post-graduate doctor, improving quality of care.

Background

Direct ophthalmoscopy (DO) is an essential skill for all physicians(1); from assessing the red reflex in
a new born baby on the labour ward, identifying papilloedema in an unconscious teenager in A&E or diagnosing sight threatening diabetic retinopathy in an elderly patient in the community.

Despite the importance of DO there is evidence that it is only briefly and poorly taught in at an undergraduate level. Many traditional direct ophthalmoscopes (TDO) are unnecessarily complex and challenging to use. The need for replacement bulbs and batteries leads to many devices being found in a non-functional state on wards. They can also be relatively bulky and therefore hard to carry around on clinical attachments limiting access and use. Low ownership rates driven by the expense of buying and maintaining devices as well limited access to working ophthalmoscopes on the ward are all factors in the infrequent use of ophthalmoscopes(2) compounding lack of confidence and skill in performing DO. Lack of confidence and skill(2,3) drives a negative cycle further reducing the likelihood of fundoscopy being performed.

Some studies have shown fundal photographs to be a better method for interpretation of fundal findings with DO being an unreliable means to detect and interpret retinal signs. With the growth of more accessible retinal imaging devices there is now a debate regarding whether DO should even still be taught to undergraduate medical students(4). The alternative view is that a quick on the spot decision using an ophthalmoscope is a cost and time-efficient means to provide prompt care maintaining patient flow. Improving accessibility to easy to use working devices on clinical attachments is likely to increase the frequency of performing fundoscopy reinforcing skill acquisition and potentially breaking the negative cycle of ever diminishing fundal examinations.

In response to the recognised limitations of the TDO the Arclight Ophthalmoscope (AO) has been developed(5). The device was primarily designed to provide healthcare workers in low resource settings with an affordable but high quality device for eye as well as ear examination with a direct ophthalmoscope at one end and a X4 magnification loupe/otoscope at the opposite end (see Figure 1). The device is small (110mm x 26mm x 9mm) and light (18g) as it uniquely does not use a mirror to redirect light within the body of the device. A small Light Emitting Diode (LED) is placed directly below the viewing hole, facing the patient, creating a novel means to create an axial light source. A slim low power rechargeable Li-Po battery further reduces the size of the device which is powered
through an integrated solar panel on the surface. This is in contrast to most TDOs which use filament bulbs powered by standard AA batteries or mains electricity and are consequently bulkier and more likely to be found in a non-functional state onwards.

As consequence of the Arclight’s innovative design it is potentially attractive to medical students overcoming the challenges of ownership, functional accessibility and perceived difficulty of use that currently exist.

In this study we therefore aimed to perform a prospective non-crossover comparative evaluation of the Arclight Ophthalmoscope with a TDO amongst medical students. Simulated eyes were used as examination subjects and students were scored based on accuracy in identifying clinical signs.

Methods
This study was approved by the University Teaching and Research Ethics Committee (UTREC) of The University of St Andrews. As per the Declaration of Helsinki, written informed consent was obtained from 18 third year medical students and data collected was fully anonymised to protect the identities of the participants. All students had been exposed to lectures on general ophthalmic pathology and a one hour compulsory teaching session on using a TDO within the previous 4 months.

A Keeler Pocket ophthalmoscope (model 1102-P-1041, Keeler Ltd, Windsor, UK – Figure 2, left) was selected as the TDO. Its relatively small size and low cost making it most comparable to the AO (Figure 2, right). 35mm slides with a range of pathologies provided by the manufacturer were inserted into the eyes of Adam, Rouilly AR303 Eye Examination Trainers (Adam, Rouilly Ltd, Kent, UK) with 5mm pupil diameters. Immediately preceding the study, participants were given a brief presentation which outlined the basics of ophthalmoscopy, how to operate both devices, and some reminders on common retinal pathologies.

Task 1: Recognition of general retinal pathologies on simulated model eyes.

The participants were randomly selected to start with either the TDO or the AO using a coin toss. 9 students were recruited to use the TDO first and 9 the AO. Each participant was given 45 seconds to examine one of 7 different simulated eyes. After examining each eye, the participants were given 30 seconds to complete an extended matching question (EMQ - see appendix 1) on the pathology or
pathologies they had observed in the simulated eye. Each option could be chosen as many times as required or not at all. The participants were given 1 mark for each correct answer and 0 marks for either an incorrect or missing answer, with the maximum possible mark being 7. There was no negative marking. The 7 simulated eyes used in this study were: 1. Toxoplasma scar, 2. Dry age-related macular degeneration (AMD), 3. Glaucomatous disc 4. Central retinal vein occlusion (CRVO), 5. Papilloedema, 6. Central retinal artery occlusion (CRAO) and 7. Normal retina (appendix 2 for images). These slides were chosen as they represent the core diseases that undergraduate students are commonly taught.

Task 2: Recognition of specific signs and grading of diabetic retinopathy on simulated eyes.

Participants were again given 45 seconds each to examine one of 4 different diabetic retinopathy (DR) simulated eyes (DR - Appendix 3) with 30 seconds to complete a scoring sheet (Appendix 4) recording: a) signs of DR observed; b) grade of DR in terms of severity c) record if maculopathy was present or not. The study participants response was converted into a numerical score based on the following criteria:

Scoring of DR signs: The participants were given 1 mark for each correctly identified sign, 0 marks for each correct sign that was not identified and -0.5 marks for each incorrect answer. 1 mark was also awarded for identifying the correct grade of diabetic retinopathy. For the evaluation of maculopathy, 1 mark was given for the correct answer, 0 marks for a blank response and -0.5 for a wrong answer. The total number of marks available was 21.

Grading of Diabetic Retinopathy: The International Clinical Diabetic Retinopathy Disease Severity Scale(6) (ICDRDSS - Table 1) was used. The participants were allowed to refer to the table while conducting the examinations and were not required to grade the maculopathy, but simply note its presence or absence. As the 35mm slides are two-dimensional and viewing is monocular, retinal thickening cannot be accurately portrayed or observed. For the purposes of this task therefore the sole criteria for the presence of maculopathy was whether hard exudates were present within the macular region or not.

Results
Task 1: Diagnosis of retinal pathologies on simulated eyes (maximum score 7).

For the AO group, the minimum score was 2 and maximum 7 with a median of 4. The mean score for identification correctly of pathologies for the AO group (n=9) was 4.33 (95% confidence interval (CI): 2.90 to 5.77) (Figure 3, left). For the TDO group, the minimum score was 1 and the maximum 6 with a median of 4. The mean score for the TDO group (n=9) was 3.78 (95% CI: 5.10 to 2.46) (Figure 3, right). An independent samples t-test showed that there was no statistical significance between the mean scores for the two groups (p = 0.52).

Task 2: Recognition of specific signs and grading of diabetic retinopathy on simulated eyes (maximum score 21)

For the AO group, the minimum score was 4.0 and the maximum 12.50 with a median of 6.50. The mean score for the AO group (n=9) was 7.17 (95% CI: 5.11 to 9.23) (Figure 4, left). For the TDO group, the minimum score was 2.50 and the maximum 7.5 with the median 6.00. The mean score for the TDO group (n=9) was 5.61 (95% CI: 4.43 to 6.79) (Figure 4, right). An independent samples t-test showed that there was no significant difference between the two groups (p = 0.15)

Discussion
This study has for the first time compared the performance of the AO with a TDO in identifying retinal signs in simulated eyes amongst a group of medical students studying in a high resource country. We found that there was no statistically significant difference between the two devices in accuracy of identifying general retina clinical signs (p = 0.52) or signs of diabetic retinopathy (p = 0.15).

Our findings are consistent with the only other two published studies comparing the AO with a TDO. In the first study(7), final year medical students in Tanzania obtained vertical cup to disc ratio (VCDR) estimates using the AO and a TDO comparing against a previously acquired gold standard examination. EOU (ease-of-use) scores were also collected from the participants. It was found that the AO led to significantly more successful examinations and higher EOU scores when compared to a TDO.
There was no significant difference between the accuracy of the AO and the TDO for the VCDR estimation.

The second study(8), conducted in Malawi, recruited a range of healthcare workers who examined simulated eyes in an Adam-Rouilly training head similar to our study. The study participants were scored on their ability to identify clinical signs, to make a diagnosis and the time taken to make a diagnosis. The study demonstrated that there was no statistically significant difference between the two devices, both in terms of being able to make the correct diagnosis and the time taken to do so. The AO was found to be easier to use than the traditional device, receiving significantly higher EOU scores in the study.

Our findings amongst a group of students in the United Kingdom are consistent with these previous studies showing no difference between the AO and the TDO in accuracy of identifying clinical signs. Although not statistically significant, student performance was better with the AO receiving higher scores in both assessments.

The decline in the frequency and competency of performing direct ophthalmoscopy has a number of recognized causes: low ownership rates and access to functional devices, the technical challenge of performing the examination, lack of confidence of teachers in teaching the technique, and difficulty of interpreting clinical signs. (3).

Studies so far suggest that the Arclight direct ophthalmoscope has the potential to overcome several of these obstacles showing promise in breaking the negative cycle of ever diminishing fundal examinations in clinical practice but importantly among medical students.

The low cost and small size of the AO makes it attractive to medical students who can carry it in their top pocket creating access to a functional device at all times. This is comparison to most TDOs which tend to be bigger and heavier meaning they are less likely to be carried by a student all the time. If more students owned a genuinely ‘pocket’ ophthalmoscope like the AO they are likely to be more
inclined to practice fundoscopy outside of their ophthalmology attachments leading to greater skill and confidence improving quality of care. A standard stethoscope costs about £50 and ownership is compulsory at most medical schools. Students typically carry one around their necks and are regularly encouraged to use them, improving competency in performing what is a challenging examination skill. The Arclight in the United Kingdom is a similar cost to that of a stethoscope and therefore price and portability may no longer be barriers to ownership. With increased opportunities for ophthalmoscopy, students may graduate with greater proficiency in diagnosis of retinal conditions and life-threatening signs such as papilloedema. Importantly, they would be more likely to perform fundoscopy routinely.

Our study has several limitations. As the devices used were different in terms of appearance, blinding was not possible. Participant bias for and against a particular device may therefore have influenced how they performed. The simulated eyes lack the realism of examining patients. The eyes have no reflective cornea and do not move or blink in contrast to real eyes and as a result do not accurately reflect the difficulty of performing an exam in the clinic. In addition, simulated eyes present the examiner with a two dimensional retina, making it difficult to accurately represent oedema and other conditions that alter the normal topography of the retina. Therefore, while simulated eyes do have a certain value in the assessment of an ophthalmoscope, the extent of how much these results are applicable to real eyes can be debated. Our study was not a cross over design and consequently the students only used one device or the other and were therefore unable to make a direct comparison between devices. Further, larger scale studies, using real eyes with pathologies should be conducted using cross-over design to better evaluate the strengths and weaknesses of this device are consequently recommended.

Conclusions

Our study demonstrates that the novel ophthalmoscope is equivalent to a traditional device when used by medical students to recognise clinical signs on training eyes. By encouraging ownership of a
cheap yet effective portable direct ophthalmoscope at the medical student level, we would envisage
greater and more confident use by post-graduate doctors, improving quality of care.
List Of Abbreviations
AMD: Age-related Macular Degeneration

AO: Arclight Ophthalmoscope

CI: Confidence Interval

CRAO: Central Retinal Artery Occlusion

CRVO: Central Retinal Vein Occlusion

DO: Direct Ophthalmoscope/ Ophthalmoscopy

DR: Diabetic Retinopathy

ICDRDSS: International Clinical Diabetic Retinopathy Disease Severity Scale

LED: Light Emitting Diode

TDO: Traditional Direct Ophthalmoscope

Declarations

Ethical Approval

The study was approved by the University Teaching and Research Ethics Committee at the University
of St Andrews (Ref number MD11914). Our work was carried out in accordance Declaration of Helsinki,
including, but not limited to the anonymity of participants being guaranteed and the informed consent
of participants being obtained prior to participation in the research.

Consent for Publication
Not applicable.

This submission does not contain any individual’s personal data and therefore cannot be linked back to any person. Full written and informed consent was obtained from each participant for their participation in this study.

Availability of Data and Materials

The dataset supporting the conclusions of this article is included within the supplementary materials.

Competing Interests

We have read and understood your policy on competing interests and declare the following interests: AB is seconded to the University of St Andrews from NHS Fife. The University owns a social enterprise subsidiary company, for which AB acts as an unpaid adviser. The social enterprise business sells the Arclight to users in high resource countries with all profits being used to fund distribution and education exercises of the device in low income countries via the Global Health Implementation team at the University of St Andrews. Both SYT and AB have previously published on the topic of the Arclight.

Funding

This study was performed as part of an undergraduate thesis. It was not funded by any specific grant awarding body.

Author Contributions
SYT and AB were involved in the initial conception of the study and the study design. Data collection was performed by SYT and AB. Analysis of collected data was performed by SYT, AB and OK. The initial draft was written by SYT. OK and AB edited the draft to produce the final version, which has been approved by all authors before submission.

Acknowledgements

The authors would like to thank Ms Christal Grierson at the University of St Andrews for providing us with the equipment used for this study, and Ms Dorothy Currie for advice on statistics.

Ethics and Consent to Participate

The study was approved by the University Teaching and Research Ethics Committee at the University of St Andrews. Our work was carried out in accordance Declaration of Helsinki, including, but not limited to the anonymity of participants being guaranteed and the informed consent of participants being obtained prior to participation in the research.

References
1. Verghese A, Horwitz RI. In praise of the physical examination. BMJ [Internet]. 2009 Dec 16;339:b5448. Available from: http://www.bmj.com/content/339/bmj.b5448.abstract
2. Schulz C, Hodgkins P. Factors associated with confidence in fundoscopy. Clin Teach [Internet]. 2014 Oct 1;11(6):431–5. Available from: https://doi.org/10.1111/tct.12171
3. Gupta RR, Lam W-C. Medical students’ self-confidence in performing direct ophthalmoscopy in clinical training. Can J Ophthalmol [Internet]. 2006;41(2):169–74. Available from: http://dx.doi.org/10.1139/I06-004
4. Yusuf IH, Salmon JF, Patel CK. Direct ophthalmoscopy should be taught to undergraduate medical
students—yes. Eye [Internet]. 2015 Aug;29(8):987–9. Available from: http://dx.doi.org/10.1038/eye.2015.90

5. Blaikie A, Sandford-Smith J, Tuteja SY, Williams CD, O’Callaghan C. Arclight: a pocket ophthalmoscope for the 21st century. BMJ [Internet]. 2016;355. Available from: http://www.bmj.com/content/355/bmj.i6637

6. Wilkinson CP, Ferris FL, Klein RE, Lee PP, Agardh CD, Davis M, et al. Proposed international clinical diabetic retinopathy and diabetic macular edema disease severity scales. Ophthalmology. 2003;110(9):1677–82.

7. Lowe J, Cleland CR, Mgaya E, Furahini G, Gilbert CE, Burton MJ, et al. The Arclight Ophthalmoscope: A Reliable Low-Cost Alternative to the Standard Direct Ophthalmoscope. J Ophthalmol. 2015;2015.

8. Blundell R, Roberts D, Fioratou E, Abraham C, Msosa J, Chirambo T, et al. Comparative evaluation of a novel solar powered low-cost ophthalmoscope (Arclight) by eye healthcare workers in Malawi. BMJ Innov. 2018;4(2):98–102.

9. IAPB. Arclight - IAPB Standard List [Internet]. 2016 [cited 2016 Mar 7]. Available from: http://iapb.standardlist.org/arclight.html

Table
Table 1: The International Clinical Diabetic Retinopathy Disease Severity Scale.
| Severity Level                                      | Signs observed on ophthalmoscopy                                      |
|---------------------------------------------------|---------------------------------------------------------------------|
| No Apparent Retinopathy                          | No abnormalities                                                    |
| Mild Non-Proliferative Diabetic Retinopathy       | Microaneurysms only                                                 |
| Moderate Non-Proliferative Diabetic Retinopathy   | More than just microaneurysms but less than Severe NPDR             |
| Severe Non-Proliferative Diabetic Retinopathy     | Any of the following:                                               |
|                                                   | · More than 20 intraretinal hemorrhages in each of 4 quadrants       |
|                                                   | · Definite venous beading in 2+ quadrants                           |
|                                                   | · Prominent IRMA in 1+ quadrant                                      |
| Proliferative Diabetic Retinopathy                | One or more of the following:                                       |
|                                                   | · Neovascularization                                                |
|                                                   | · Vitreous/preretinal hemorrhage                                    |

Appendix Legend
Appendix 1: Answer sheet for Task 1.

Appendix 2: Scans of the 35mm slides representing various retinal pathologies. Top row, left to right: toxoplasma scar, dry age-related macular degeneration, glaucomatous disc. Middle row, left to right: central retinal vein occlusion, papilloedema, central retinal artery occlusion. Bottom row: normal retina.

Appendix 3: Slides representing diabetic retinopathies used in task 2. Slide 1 is top left, slide 2 is top right, slide 3 is bottom left and slide 4 is bottom right.

Appendix 4: Answer sheet for Task 2.

Figures
Figure 1
The Arclight Ophthalmoscope (AO). Key parts are annotated.

Figure 2
The Keeler Pocket Traditional Direct Ophthalmoscope (TDO - left) and the Arclight Ophthalmoscope (AO - right).

Figure 3
A graph of the mean score in a test of identification of common retinal pathologies (out of a maximum possible score of 7), against the ophthalmoscope used. AO (n=9) and TDO (n=9) groups show no statistically significant difference (p = 0.52). Error bars represent the 95% confidence interval.

Figure 4
A graph of the mean score in a test of identification of diabetic retinopathy signs (out of a maximum possible score of 21), against the ophthalmoscope used. AO (n=9) and TDO (n=9) groups show no statistically significant difference (p = 0.15). Error bars represent the 95% confidence interval.

Supplementary Files
This is a list of supplementary files associated with this preprint. Click to download.

Appendix 3.docx
Appendix 2.docx
Appendix 4.docx
Additional File 1 - Dataset.xlsx
Appendix 1.docx