1	Identification of Amblyogenic Risk Factors
2	with the Brückner Reflex Test using the low-
3	cost 'Arclight' Direct Ophthalmoscope
4	
5	Dr Sahib Y. Tuteia
6	Equidation Year 1 Doctor
7	Boyal Victoria Infirmary, Newcastle-Unon-Type, England
, 8	Noyal victoria inimitary, Newcastie opon Tyrie, England
9	
10	Dr Andrew Blaikie
11	(corresponding author)
12	Senior Lecturer
13	University of St Andrews School of Medicine, St Andrews, Scotland
14	Email: <u>ab312@st-andrews.ac.uk</u>
15	
16	Consultant Ophthalmologist
17	Department of Ophthalmology
18	Queen Margaret Hospital
19	Dunfermline, Scotland
20	
21	
22	Dr Ramesh Kekunnaya
23	Consultant Ophthalmologist,
24	L V Prasad Eye Institute (LVPEI), Hyderabad, India
25	
26 27	
28	Conflict of interest statement: Dr Blaikie is seconded to the University of St Andrews from NHS
29 30	adviser. The social enterprise business sells the Arclight to users in high resource countries with
31 32	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 Dr
33	Tuteja and Dr Blaikie have previously published on the topic of the Arclight. Dr Kekunnaya does
34	not declare any potential conflict of interest.

35 Abstract

36

Background/Objectives: The Arclight is a novel, low-cost, solar powered direct 37 38 ophthalmoscope developed for low resource settings as an alternative to more expensive, 39 conventional devices. The Brückner reflex test (BRT) is a quick and effective means to 40 screen for eye disease and amblyogenic risk factors. This test is however rarely performed 41 in low resource settings due to lack of access to ophthalmoscopes and trained health care 42 workers. Our aim was to establish the sensitivity and specificity of the BRT when 43 performed by a non-expert using an Arclight and compare to an expert as well as the results of a full clinic workup. 44 45 46 Subjects/Methods: In this prospective, blinded study, 64 patients referred to a paediatric 47 ophthalmology clinic had the BRT performed by a 'non-expert' observer (medical student) then an 'expert' observer (consultant ophthalmologist). These results were then 48 49 compared against the 'gold standard' outcomes of a full clinical workup. 50 51 **Results:** BRT screening by the expert observer led to a sensitivity of 75.0% [95%CI:57.9% 52 to 86.8%] and a specificity of 90.6% [95%CI:75.8% to 96.8%] in picking up media opacity, 53 strabismus, refractive error, or a combination of the above. For the non-expert, the 54 sensitivity and specificity were 71.9% [95%CI:54.6% to 84.4%] and 84.4% [95%CI:68.3% 55 to 93.1%] respectively. 56

57 Conclusions: The Arclight can be effectively used to perform the BRT and identify eye
58 disease and common amblyogenic risk factors. Even when performed by a non-expert
59 the results are highly specific and moderately sensitive. This study consequently offers

- 60 support for the use of this low-cost ophthalmoscope in the expansion of eye screening
- 61 by health care workers in low resource settings.

63 Introduction

64

Sight loss is greatest in low and middle income countries (LMIC's) where eye health worker numbers and their access to diagnostic tools is least (1). While childhood visual impairment is less prevalent than in adults, the overall loss of life years is second only to that of adult cataract. Importantly, if identified early nearly half of such disability is treatable and preventable by known cost-effective means (2).

70

The Brückner reflex test (3) (BRT) (Figure 1) is a simple yet effective means to identify the
early signs of childhood eye disease such as corneal scarring, cataract and retinoblastoma
as well as risk factors for amblyopia including strabismus, high refractive error and
anisometropia.

75

The BRT is performed using a direct ophthalmoscope, ideally in a dim room at arm's 76 77 length, illuminating both eyes of the patient at the same time. The child should be seated 78 comfortably ideally on a parent's lap. The reflected light (reflex) from both eyes is 79 observed simultaneously. The relative colour, brightness and position of the crescents 80 within the pupil space are compared. This is called the 'red reflex' test. It is important to 81 note that the colour of the central 'red' reflex can be very variable and although orange-82 red in Caucasians can be almost blue-white in darker pigmented eyes (3). In addition the 83 centration of the small 'corneal' reflex is noted. This is known as the Hirschberg Test (4). 84 The combination of these two tests is the BRT.

85

86 This non-touch arm's length combination test lets users make swift on-the-spot decisions,87 to identify disease early for better outcomes. Despite the benefits of routinely performing

the BRT, in LMIC's it is rarely performed by primary or mid-level health care workers; with
disease presenting often sadly very late (5,6). Absence of appropriate frugal kit and the
circular lack of teaching of practical and interpretation skills are perpetual well observed
challenges.

92

The Arclight(7–9) (Figure 2) is a DO developed specifically with the needs of users in low
resource settings in mind. Low cost (~£10), portable, LED illuminated and solar powered:
it does not rely on expensive and hard to find consumables such as batteries and bulbs.
Studies amongst mid-level eye care workers in LMIC's have demonstrated it to be easier
to use than more expensive traditional devices yet remaining as effective for fundoscopy
and 'red' reflex examination (9,10).

Our study aims to describe the effectiveness in children, of the BRT in identifying eye disease that can lead to amblyopia, using this new low cost Arclight ophthalmoscope. The results of an 'expert' ophthalmology consultant and a 'non-expert' medical student were compared with each other, and then against the results of a 'gold standard' full clinic workup.

105

106 Materials and Methods

107

108 This blinded, prospective study was approved by the institutional review board of the 109 hospital and the ethics review committee of the University of St Andrews. Signed 110 informed consent was obtained from the parents of all study participants. Children between the ages of 3 months and 14 years presenting consecutively to the paediatric
ophthalmology clinic at LVPEI were enrolled in the study. Patients previously known to
the expert observer were excluded.

114

Prior to the study, the non-expert examiner participated in an Arclight training workshop on how to use the device as well as perform and interpret the BRT. This included 1 hour with a pediatric ophthalmologist familiar with the device and then examination of simulation red reflex eyes displaying pathology as well as normal adult eyes.

119

120 Study participants were seated comfortably, typically on a parent's lap in a dimly lit room.

Using the brightest light on the Arclight with the lens set to zero both eyes were observed un-dilated at arm's length. The expert and non-expert examiners recorded their observations as either normal or abnormal. If abnormal, the examiners classified their observations into further subcategories of media opacity, strabismus, refractive error or a combination of the above.

126

127 After the BRT each patient underwent routine full clinic workup involving history taking, 128 orthoptic assessment, slit lamp examination, dilated fundoscopy and refraction. The 129 findings of the a 'gold standard' full clinic workup were then used to classify the cases 130 into the same subcategories described above by a different and independent 131 experienced paediatric ophthalmologist.

132

133

134 Results

135 136	
137	64 patients (36 male and 28 female) were enrolled into the study. The participants ranged
138	from 8 months to 14 years with a mean age of 6 years. 3 patients were excluded as they
139	were previously known to the expert observer. Full clinic workup identified 32 patients
140	having either media opacity, strabismus, anisometropia (\geq 1.00D SPH) or high refractive
141	error (>+5.00 D SPH or <-5.00 D SPH). The remaining 32 participants based on the full
142	clinic workup were deemed to have findings that would be consistent with a normal BRT.
143	
144	The results of both examiners BRT and the 'gold standard' full clinic workup are
145	summarised in Table 1. Table 2 displays the results of the non-expert and expert's BRT
146	findings.
147	
148	The non-expert and expert BRT findings produced similar sensitivities and specificities to
149	each other [Table 3]. Both observers despite their difference in level of experience
150	achieved sensitivities of over 70% and specificities of over 80% compared to the 'full clinic
151	workup' with the expert being statistically higher at 90.6% [95% CI: 75.8% to 96.8%]. As
152	a consequence good agreement between both observers was found with a Cohen's
153	kappa of 0.71 [95% CI: 0.47 to 0.96]. Cohen's kappa showed moderate agreement with
154	the gold standard results of the full clinic workup: 0.56 [95% CI: 0.32 to 0.81] for the non-
155	expert observer and slightly higher agreement of 0.66 [95% CI: 0.41 to 0.89] for the expert.
156	

Of the 24 cases that the expert observer felt had abnormal BRTs 23 were correctly
subclassified based on the results of the full clinic workup. The non-expert observer
identified 23 cases with abnormal BRT and subclassified 17 of these correctly.

160

161 Of the 8 patients incorrectly identified by the expert as having a normal reflex (false 162 negatives) when based on the findings of the full clinic work up they were classified as an 163 'abnormal' BRT, 1 had anisometropia, 2 had symmetrical significant refractive error, 3 164 patients had esotropia of 10PD, 12PD and 35PD, and 2 had a combination of 165 anisometropia (dominant pathology) and strabismus. The non-expert observer 166 incorrectly identified 9 patients as having a normal reflex (false negatives). 7 of these 167 cases were the same as the expert with the other 2 being anisometropia with strabismus 168 and anisometropia only.

169 170

171 Discussion

172

173 Our results show that the BRT when performed with the Arclight ophthalmoscope can be 174 used as a quick means to identify risk factors for amblyopia in a high volume paediatric 175 ophthalmology clinic. When performed by an expert, it has a sensitivity of 75% and a 176 specificity of 91%. An important finding of this study is that the non-ophthalmic medical 177 student observer's performance was statistically comparable to the expert observer. This 178 is consistent with a previous study where Gole et al (11) reported 85.6% sensitivity and 179 65% specificity when the BRT was performed by a non-ophthalmologist with an experienced ophthalmologist reporting 73% sensitivity and 87% specificity. Closer 180 analysis of the cases identified and missed suggests that the BRT is best suited to the 181 182 identification of media opacities and larger angled strabismus (>35PD). The BRT as

BRÜCKNER TEST USING THE ARCLIGHT OPHTHALMOSCOPE

expected, was less effective at identifying cases of smaller strabismus (<35PD) and 183 184 refractive error with clear media. Symmetrical refractive errors were typically hard to 185 identify. For example two patients with symmetrical myopia of -4.00 dioptres as well as 186 a patient with a refraction of -5.00 dioptres in the right eye and -6.00 in the left eye were 187 falsely classified as normal by both observers. These patients were noted to demonstrate 188 an increasingly dim reflex but the brighter lower crescent associated with myopia was 189 not appreciable(12–14). Another group of patients with a combination of both 190 strabismus and refractive error were also found in the false negative results. This could 191 be due to the brighter reflex from the manifestly squinting eye being neutralised by the 192 dimming effect of a high refractive reflex.

193

194 A similar study from Pakistan assessed the effectiveness of the BRT in identifying 195 refractive errors in children. They reported sensitivity of 97% and specificity of 79% (12), 196 higher than in our study. Another study reported similarly accurate detection rates of 197 refractive errors with a sensitivity of 91% and specificity of 72.9% (13). One study (14) 198 evaluated the BRT of paediatric patients using a camera (in place of a direct 199 ophthalmoscope) and reported 86% sensitivity and 85% specificity. There are a number 200 of possible reasons for these different findings including different age groups of 201 participating children, varying degrees of appreciable pathology and the use of different 202 brands of ophthalmoscope. Even though there are differences in sensitivity and 203 specificity they are generally high and clinically useful confirming the potential benefits 204 of using this simple and non-invasive the test more widely. This is especially the case now 205 that a low cost and consumable independent device such as the Arclight is available.

BRÜCKNER TEST USING THE ARCLIGHT OPHTHALMOSCOPE

207 Performing a formal comprehensive eye examination in babies and young children is 208 challenging. The attraction of the BRT reflex lies in its simplicity; it takes just a few 209 seconds of the child looking straight at the light to make an assessment. Non-ophthalmic 210 staff who provide care to children, such as pediatricians, staff delivering immunisation 211 programmes and neonatal/obstetric nurses could be trained to perform the BRT both 212 opportunistically and systematically in their daily work. The feasibility of this approach 213 has recently been evaluated in Tanzania demonstrating the Arclight to have sensitivity 214 and specificity of over 90%(15). This could lead to earlier identification of eye conditions 215 benefiting from intervention potentially improving outcomes of treatment and reducing 216 the burden of visual impairment in children.

217

Importantly the Arclight can also be attached to the camera of a mobile phone to acquire an image or video (8,16). Telemedicine could complement expansion of the use of the BRT with electronic transfer of suspect findings to remote experts for an opinion or interpretation of the images in real time by an algorithm within the mobile phone. This approach could further assist in reducing the burden of eye disease and associated visual impairment amongst children particularly in low resource settings where local access to paediatric ophthalmology services can be limited.

225

The main limitations of this study include the small number of very young participants (who would benefit most from early diagnosis) and of performing the 'screening' in a contrived 'pathology-rich' paediatric ophthalmology clinic. Future work should aim to assess the real-world feasibility of implementing high volume screening of infants and babies in immunisation clinics (17), birthing facilities and child health clinics by primary

BRÜCKNER TEST USING THE ARCLIGHT OPHTHALMOSCOPE

231	health care workers. These are settings where it would be more beneficial to screen but
232	also challenging to successfully implement. One such initiative which piggybacks onto
233	routine national child health surveillance programmes has been rolled out in Kenya and
234	Uganda(18), with positive results(19) and is now being expanded to Tanzania.
235 236	Overall these findings raise the prospect of being able to equip at low cost and effectively
237	train non-expert primary health care workers (PHCWs) to perform the BRT in LMICs
238	complementing other on-going blindness reduction strategies.
239	

241 Acknowledgements

- 242 We would like to thank William J Williams for his assistance in preparing illustrations
- and all of our colleagues at LVPEI for their support in carrying out this study.

244 Conflict of Interest

- 245 Dr Blaikie is seconded to the University of St Andrews from NHS Fife. The University owns a
- 246 social enterprise subsidiary company, for which he acts as an unpaid adviser. The social
- 247 enterprise business sells the Arclight to users in high resource countries with all profits being
- 248 used to fund distribution and education exercises of the device in low income countries via the
- 249 Global Health Implementation team at the University of St Andrews. Both Dr Tuteja and Dr
- 250 Blaikie have previously published on the topic of the Arclight. Dr Kekunnaya does not declare
- any potential conflict of interest.

252 Funding

- 253 This study was performed as part of an undergraduate medical elective. It was not
- 254 funded by any specific grant-awarding body.
- 255
- 256
- 257

258 References

259		
260	1.	Bastawrous A, Hennig BD. The global inverse care law: a distorted map of
261		blindness. Br J Ophthalmol [Internet]. 2012 Oct 1;96(10):1357 LP – 1358.
262		Available from: http://bjo.bmj.com/content/96/10/1357.2.abstract
263	2.	Gilbert C, Foster A. Childhood blindness in the context of VISION 2020the right
264		to sight. Bull World Health Organ [Internet]. 2003/07/07. 2001;79(3):227–32.
265		Available from: https://pubmed.ncbi.nlm.nih.gov/11285667
266	3.	Brückner R. Exakte Strabismusdiagnostik bei 1/2–3jährigen Kindern mit einem
267		einfachen Verfahren, dem «Durchleuchtungstest». Ophthalmologica [Internet].
268		1962;144(3):184–98. Available from:
269		https://www.karger.com/DOI/10.1159/000304320
270	4.	Kanski JJ, Bowling B. Clinical Ophthalmology: A Systematic Approach. Edinburgh,
271		Elsevier/Saunders; 2015. 316 p.
272	5.	Sheeladevi S, Lawrenson JG, Fielder A, Kekunnaya R, Ali R, Borah RR, et al. Delay
273		in presentation to hospital for childhood cataract surgery in India. Eye [Internet].
274		2018;1811–8. Available from: http://dx.doi.org/10.1038/s41433-018-0176-2
275	6.	Bronsard A, Geneau R, Shirima S, Courtright P, Mwende J. Why are Children
276		Brought Late for Cataract Surgery? Qualitative Findings from Tanzania.
277		Ophthalmic Epidemiol [Internet]. 2008 Jan 1;15(6):383–8. Available from:
278		https://doi.org/10.1080/09286580802488624
279	7.	Blaikie A, Sandford-Smith J, Tuteja SY, Williams CD, O'Callaghan C. Arclight: a
280		pocket ophthalmoscope for the 21st century. BMJ [Internet]. 2016;355. Available
281		from: http://www.bmj.com/content/355/bmj.i6637
282	8.	Kousha O, Blaikie A. The Arclight and how to use it. Community eye Heal
283		[Internet]. 2019/12/17. 2019;32(107):50–1. Available from:
284		https://pubmed.ncbi.nlm.nih.gov/32123473
285	9.	Dooley E, Kousha O, Msosa J, Ndaule E, Abraham C, Parr J, et al. Comparative
286		evaluation of a low cost direct ophthalmoscope (Arclight) for red reflex
287		assessment among healthcare workers in Malawi. BMJ Innov [Internet]. 2020 Apr
288		9;bmjinnov-2019-000361. Available from:
289		http://innovations.bmj.com/content/early/2020/04/09/bmjinnov-2019-
290		000361.abstract
291	10.	Blundell R, Roberts D, Fioratou E, Abraham C, Msosa J, Chirambo T, et al.
292		Comparative evaluation of a novel solar powered low-cost ophthalmoscope
293		(Arclight) by eye healthcare workers in Malawi. BMJ Innov. 2018;4(2):98–102.
294	11.	Gole GA, Douglas LM. Validity of the Bruckner reflex in the detection of
295		amblyopia. Aust N Z J Ophthalmol. 1995;23(4):281–5.
296	12.	Jalis M, Ashfaq MW, Imdad A. Use of Bruckner Test for the Detection of
297		Significant Refractive Errors in Children. J Rawalpindi Med Coll [Internet].
298		2015;19(3):200–3. Available from:
299		https://pdfs.semanticscholar.org/7ab0/a5ca99ecf21c28bce70cd09c79f5f5cd8e1
300		7.pdf
301	13.	Kothari M. Can the Bruckner test be used as a rapid screening test to detect
302		significant refractive errors in children? Indian J Ophthalmol [Internet]. 2007 May
303		1;55(3):213–5. Available from: http://www.ijo.in/article.asp?issn=0301-4738
304	14.	Bani SAO, Amitava AK, Sharma R, Danish A. Beyond photography: Evaluation of

305 306 307 308 309 310 311	15.	the consumer digital camera to identify strabismus and anisometropia by analyzing the Bruckner's reflex. Indian J Ophthalmol [Internet]. 2013 Oct 1;61(10):608–11. Available from: http://www.ijo.in/article.asp?issn=0301-4738 Mndeme FG, Mmbaga BT, Kim MJ, Sinke L, Allen L, Mgaya E, et al. Red reflex examination in reproductive and child health clinics for early detection of paediatric cataract and ocular media disorders: cross-sectional diagnostic accuracy and feasibility studies from Kilimaniaro. Tanzania. Eve [Internet]. 2020:
312		Available from: https://doi.org/10.1038/s41433-020-1019-5
313	16.	Wu GT, Kang JM, Mirza RG, Bidwell AE, Gray JP. The Use and Evaluation of an
314 315		Inexpensive Eye Model in Direct Ophthalmoscopy Training. J Acad Ophthalmol. 2014:1(212).
316	17.	Jac-okereke CC, Jac-okereke CA, Ezegwui IR, Okoye O. Vision Screening in Infants
317		Attending Immunization Clinics in a Developing Country. J Prim Care Community
318		Health [Internet]. 2020;11:2150132720907430–2150132720907430. Available
319		from: https://pubmed.ncbi.nlm.nih.gov/32100627
320	18.	Sense International. Sense International launches pioneering screening
321		programme for infant deafblindness in Kenya and Uganda [Internet]. 2017 [cited
322		2020 Nov 10]. Available from: https://senseinternational.org.uk/news/sense-
323		international-launches-pioneering-screening-programme-infant-deafblindness-
324		kenya-and
325	19.	Sense International. Celebrating the results of the screening and early
326		intervention programme funded by the 'Finding Grace' appeal [Internet]. 2020
327		[cited 2020 Nov 10]. Available from:
328		https://www.senseinternational.org.uk/news/celebrating-results-screening-and-
329		early-intervention-programme-funded-finding-grace-appeal
33U		
331		
332		

333 Titles and legends to figures

334 Figure 1: Left panel; The room should be dimly lit and quiet. The child should be sat 335 comfortably on parent's lap with undilated pupils. The ophthalmoscope should be set at 336 the brightest setting and lens at zero. It should be held at arm's length away and reflex 337 should be viewed simultaneously in both eyes. Right panel; A; Normal: central corneal 338 reflections, symmetrical brightness & colour. B; Media opacity left eye: dark reflex. C; 339 Esotropia left eye: corneal reflection displaced temporally & reflex lighter. D; Exotropia 340 right eye: corneal reflection displaced nasally & reflex lighter. E; Hypermetropia right: 341 prominent bright crescent superiorly and myopia left: prominent bright crescent 342 inferiorly

- 343 Figure 2: The Arclight Direct Ophthalmoscope
- Table 1: BRT results of the expert and non-expert observer compared against the goldstandard.
- 346 Table 2: Non-expert BRT compared against the expert BRT
- 347 Table 3: Statistical analysis of the BRT examination results of both observers

348