Use of Handheld Aurora Camera for Diabetic Eye Screening in Tayside – a Pilot Study

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Incentive for Trialling Handheld Camera in Tayside

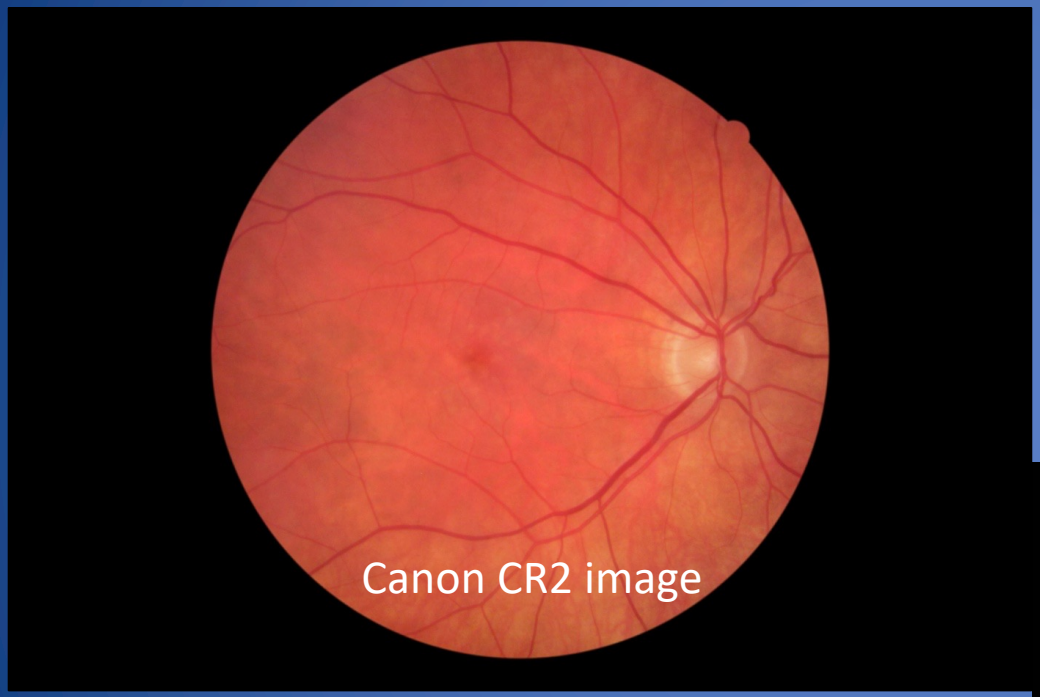
- Expanding workload - prevalence of diabetes increasing
- Mobile service in Tayside covers wide geographical area, including remote communities – need to facilitate coverage of such areas
- More difficult to procure eye screening equipment such as trolleys, tables, transport etc for table-top cameras
- Health inequalities needing addressed – improving access to DRS

Hand-held Cameras in Practice

- Use of hand-held cameras in diabetic eye screening increasing
- Many advantages to hand-held devices - light-weight, easily transportable
- Some drawbacks too – not yet validated for UK screening, variable image quality
- Balance needs struck between delivering large scale screening programme and realistic medicine

Image quality standards met by Canon & Aurora cameras:

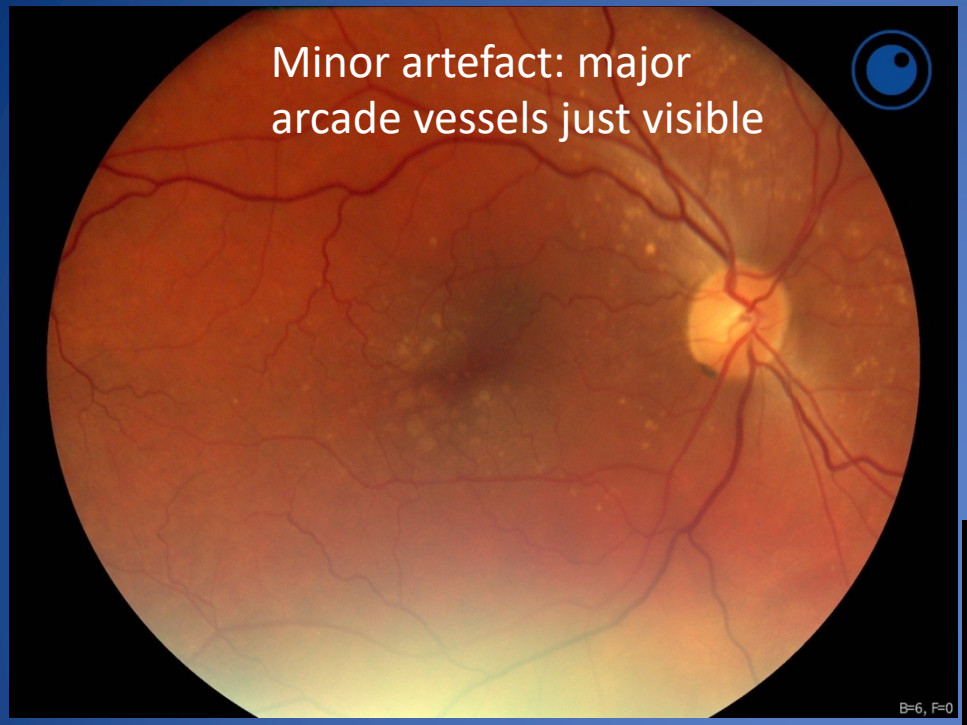
- Optic disc clearly visible
- Macula at least 2 disc diameters from edge of image
- 3rd generation vessels around fovea clearly visible

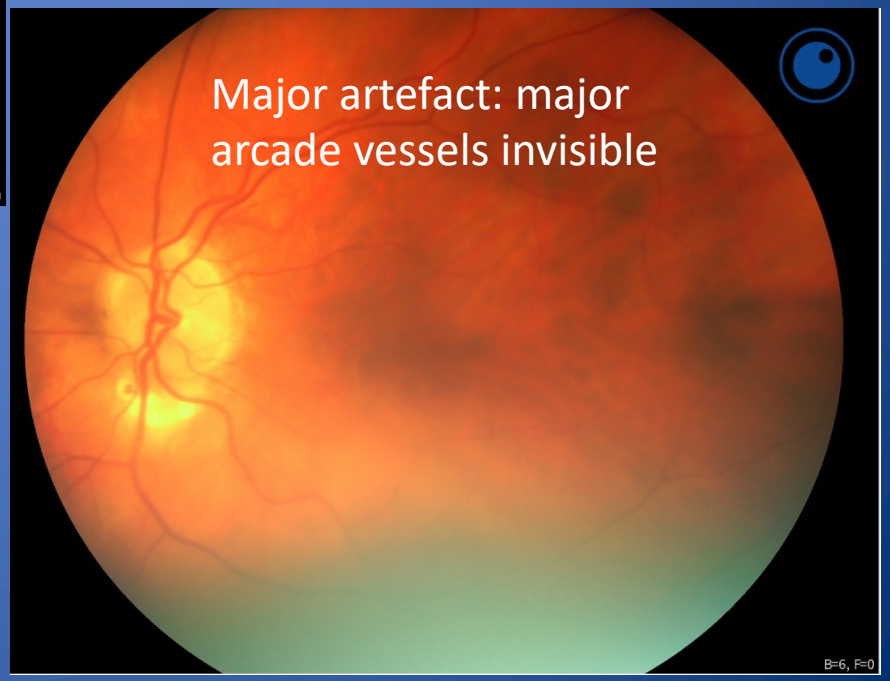


Canon CR2 image

Optomed Aurora image

Major/minor Aurora camera artefact identified early on in study





Aims of study

Primary aim:

- To assess if hand-held Aurora camera was no worse than the standard table-top Canon CR2 camera

Secondary aims:

- To establish whether age influenced image quality
- To establish if image quality improved over time (as screener became more skilled at operating the device)

Literature review of handheld cameras in Diabetic Retinopathy Screening

- Few trials comparing handheld camera with standard table-top
- Aurora camera generally found to have sufficient image quality but no mention of artefact in any studies
- Studies generally had higher prevalence rates of sight-threatening retinopathy compared to our study population (tertiary referral centres)

Methodology

- Participants in the NHS Tayside Diabetic Eye screening (DES) were offered a usual eye screen (Canon table-top camera) and an additional screen using Aurora hand-held camera
- Informed consent was sought
- Caldicott application submitted for storage and matching of patient images
- All Canon images were reviewed and graded as per usual practice
- Aurora images were anonymised (not possible to 'blind images') and graded* – outcome was matched to the Canon image grading outcomes

*All Aurora images were graded by JW

Results

- 186 patients
- 371 eyes (one only-eyed patient)
- Average age 66 (range 24-91)
- M:F ratio approx 3:2
- Predominantly Caucasian population

RESULTS

371 Aurora images*

Gradable images = 255 (69%)

Non-gradable images = 116 (31%)
111 of these were gradable on Canon

Major artefact = 105 (41%)

Minor/No artefact = 150 (59%)

14/105 correctly identified mild retinopathy
85/105 correctly identified with no retinopathy
6/105 incorrectly graded (1 false negative)

7/150 correctly identified mild retinopathy
119/150 correctly identified no retinopathy
24/150 incorrectly graded (10 false negatives)

*39 patients were dilated

Results comparing Aurora and Canon cameras for 253 subjects

	Mild retinopathy (R1M0)		
	Reference standard (Canon)		Total
	Disease present	Disease absent	
Aurora +	13 (True +)	5 (False +)	18
Aurora -	16 (False -)	199 (True -)	215
Total	29	204	233

	Maculopathy (R1M2)		
	Reference Standard (Canon)		Total
	Disease present	Disease absent	
Aurora +	4 (True +)	11 (False +)	15
Aurora -	8 (False -)	230 (True -)	238
Total	12	241	253

Sensitivity/Specificity of Aurora camera

- Sensitivity for mild retinopathy(R1M0) = 49%
- Sensitivity for maculopathy (R1M2) = 33%
- Specificity for mild retinopathy (R1M0) = 98%
- Specificity for maculopathy (R1M2) = 95%

Out of interest……Sensitivity/Specificity with Image manipulation*

- Sensitivity for retinopathy = 86%
- Sensitivity for maculopathy = 42%
- Specificity for retinopathy = 98%
- Specificity for maculopathy = 98%

*All Canon images were graded in 'Optomize' software programme (allows image manipulation/enhancement to detect retinopathy that might not be immediately visible).

All Aurora images were graded at 'face value' as JPEG images, but those images where grading did *not* match that of the Canon camera were transferred into Optomize to see if image enhancement improved sensitivity/specificity

Positive/negative predictive value of the Aurora camera

Positive predictive value

- mild retinopathy (R1M0) = 72%
- maculopathy (R1M2) = 27%

Negative predictive value

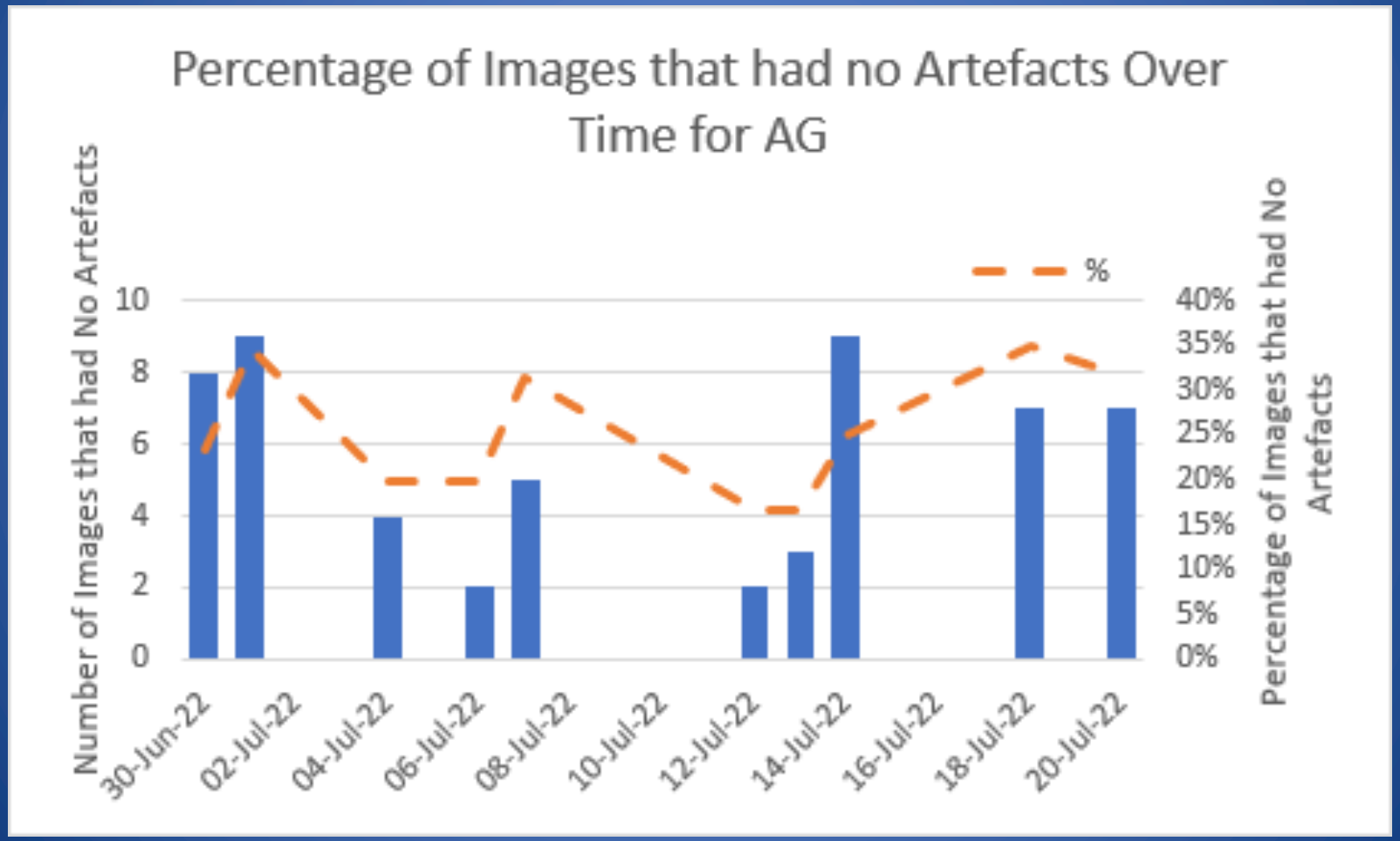
- mild retinopathy (R1M0) = 93%
- maculopathy (R1M2) = 97%

Aurora vs. Canon Camera Statistics

	Aurora		Canon	National Screening Standards
	R1M0	R1M2		
Sensitivity	49%	33%	89%*	>80%
Specificity	98%	95%	86%*	> 95%
PPV	72%	27%	NA	NA
NPV	93%	97%	NA	NA

*SP Harding et al. Sensitivity and Specificity of photography and direct ophthalmoscopy in screening for sight threatening eye disease: the Liverpool Diabetic Eye Study BMJ 1995;311:1131-1135

Images Over Time by Photographer



Relationship between Age vs. Artefact

- NO association found between age and presence of any artefact (p value = 0.14)

Conclusion of Aurora vs. Canon Camera Pilot Study

Primary aim:

- To assess if hand-held Aurora camera was no worse than standard table-top Canon CR2 camera
- ***Not enough evidence to say Aurora is non-inferior to Canon: Aurora less sensitive but more specific***

Secondary aims:

- To establish whether age influenced image quality
- ***Increasing age did not affect image quality/artefact***

- To establish if image quality improved over time (as screener became more skilled at operating the device)
- ***Increasing use of Aurora with time did not appear to reduce the image artefact***

Limitations of study/potential sources of bias

- Small number of patients
- Age: bias towards older age groups
- Gender: slightly more males than females
- Ethnicity: lack of minority groups represented
- There was no moderate or severe disease in our cohort
- Not all Canon images graded by same individual, but all Aurora images were
- Canon images could be ‘manipulated’ in Optomize - Aurora images assessed unaltered
- Limited evidence from literature

Recommendations – next steps

- UK national working group – assessment of approved cameras
- Aurora - explore reducing artefact
- Trial of alternative cameras
- Cost benefit analysis
- Possible Scottish-based study comparing against gold standard: required sample size = 3000+ patients

Thanks to….

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Tayside screeners

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- Gary Henderson
- Dave Mitchell
- Louise Clark
- Dylan Allardice
- Bart Masiukiewcz

Literature review

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- Ahsan S. Haseeb U. Memon M.S. Validity of Hand Held Fundus Camera by Optometrist using Slit lamp 90D bio microscopy as a reference standard for screening of Diabetes Retinopathy.Journal of the Pakistan Medical Association. 72(11) (pp 2189-2192), 2022. Date of Publication: November 2022.
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NULL HYPOTHESIS: Desktop cameras will identify the same proportion of true positives and true negatives as the hand held camera (one tailed t test)

Number of images requiring analysis to minimize error		
	NHS Tayside	**NHS Scotland**
Any retinopathy	**118**	**91**
Referable/sight threatening retinopathy	**2,500**	**6,220** *

*Based on prevalence of sight-threatening retinopathy in Scotland of 0.39%