Comparison of 135° field Scanning Confocal Ophthalmoscope in staged-mydriatic mode and mydriatic two 45° field digital imaging in the NHS Diabetic Eye Screening

Authors: Anthony Vukic[1], Marta H Gruszka-Goh[1,2], Paul Galsworthy[1], Scott Vallance[1], Peter H Scanlon[1,3,4]

1: Gloucestershire Hospitals NHS Foundation Trust, 2: The Royal College of Ophthalmologists' National Ophthalmology Database Audit, 3: Nuffield Department of Clinical Neuroscience, University of Oxford, 4: University of Gloucestershire

Aim:

The CONCORDIA study is a project looking at the accuracy of Scanning Confocal Ophthalmoscope and Broad Line Fundus Imaging camera devices in detection of any eye disease caused by diabetes.

The over-arching objective of this work was to determine if these cameras can be used in the non-mydriatic mode, and to determine if they are cost-effective to use in the NHS Diabetic Eye Screening Programme (DESP).

Methods:

The trial participants were 1,497 individuals (2,993 eyes) aged 15 to 94 with diabetes mellitus that participated in DESP.

Optos California(SCO) images were taken before the pupils were dilated and compared to two-field 45 degrees mydriatic digital photography.

When image quality was poor or pupil size was less than 3mm, images were taken with SCO before and after dilation.

In case when the non-mydriatic images were gradable, they were used in comparison to the 45 degrees mydriatic digital images, otherwise the mydriatic image was utilised.

All images were graded by two graders with arbitration for differences of opinion by a third grader.

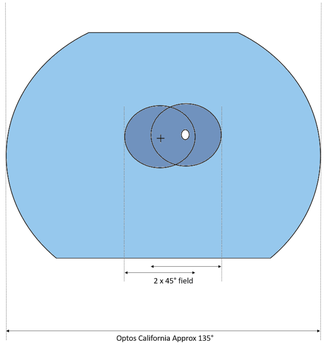


Figure 1: *Diagram of areas of images from a Optos California superimposed on the two 45-degree fields*

To compare the same areas of the eyes, SCO images were graded with a two 45° field overlay and using the DESP grading criteria.

Sensitivity and specificity comparing SCO device with the reference standard were calculated for any and referable levels of DR. The ungradable images for both types of devices were excluded from the sensitivity, specificity, positive and negative predictive value analysis. All statistics were calculated with exact binomial confidence intervals.

Demographics:

906 (60.5%) of patients were male and 591 (39.5%) female.

Median age at the time of trial was 64.0 years with IQR (55.0-72.0) years, and was one year higher for male patients. The most frequent (31.0%) trial participants were patients aged 65 to 74 years and the least frequent (1.1%) those aged between 15 and 24 years.

Large majority (92.7%) of patients were of White Caucasian descent and proportions of individuals from another ethnic groups ranged between 0.9% and 3.1%.

Results:

60.8% of images taken with Optos California and 55.0% taken with 2-field 45° mydriatic digital photography have been graded as those with any diabetic retinopathy.

For the SCO, the sensitivity and specificity for any retinopathy 91.9% with 95% CI (90.5% - 93.2%) and 78.1% with 95% CI (75.7% - 80.3%) respectively, Table 1 and Figure 2.

		95% CI
Sensitivity	91.9%	90.5% - 93.2%
Specificity	78.1%	75.7% - 80.3%
Positive predictive value	83.9%	82.1% - 85.6%
Negative predictive value	88.6%	86.6% - 90.4%

Table 1: *Sensitivity, specificity, positive and negative predictive values for any DR*

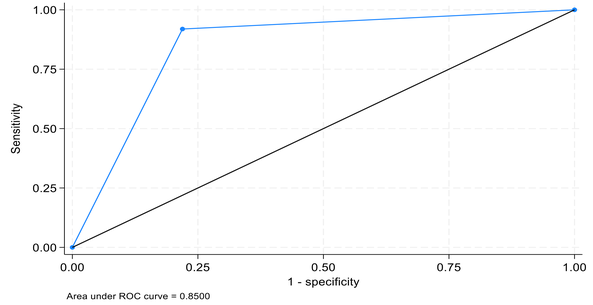


Figure 2: *ROC curve for any Diabetic Retinopathy*

19.3% of images taken with the Optos California and 20.1% taken with 2-field 45° mydriatic digital images have been graded as those with referable diabetic retinopathy.

For the SCO, the sensitivity and specificity for referable retinopathy were 77.6% with 95% CI (73.9% - 80.9%) and 95.4% with 95% CI (94.5% - 96.2%) respectively, Table 2 and Figure 3.

		95% CI
Sensitivity	77.6%	73.9% - 80.9%
Specificity	95.4%	94.5% - 96.2%
Positive predictive value	80.9%	77.4% - 84.1%
Negative predictive value	94.4%	93.4% - 95.3%

Table 2: *Sensitivity, specificity, positive and negative predictive values for referable DR*

The difference in sensitivity of referable DR was mostly due to grading of maculopathy, where the differences were caused by:

- interpretation – 20 eyes
- varied appearance – 21 eyes
- not observed on Optos California – 29 eyes
- masked by artefact – 16 eyes
- 1DD measure – 4 eyes.

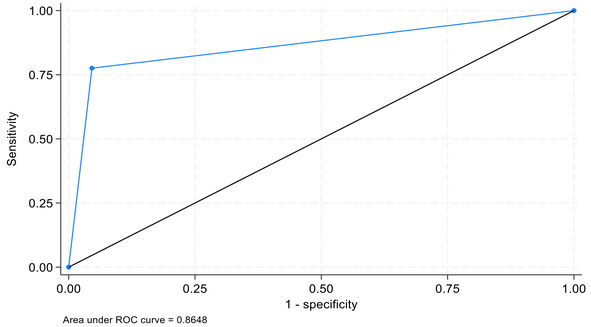


Figure 3: *ROC curve for referable Diabetic Retinopathy*

Out of 2,993 images taken in staged dilation process using Optos California, 3.4% (n=102) with 95% CI (2.8% - 4.2%) were ungradable.

There was one ungradable images in groups aged under 35 years and the highest percentage (44.1%) of cases belonged to 65-74 age group.

79 (77.5%) of the ungradable images came from patients aged 65 and over 65 years old, Figure 4.

The highest percentage of the ungradable eyes came from the age groups 75-84 years (4.0%) and 85 and over (3.4%), Figure 5.

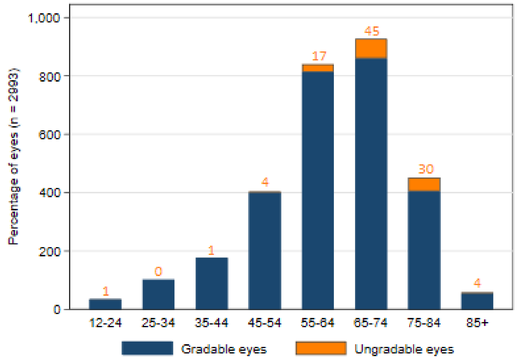


Figure 4: *Age distribution of all study eyes by gradable status*

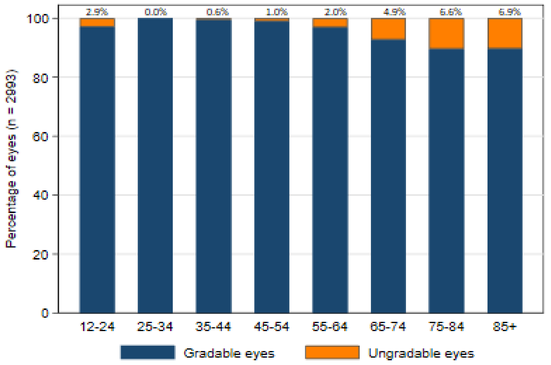


Figure 5: *Percentage of gradable and ungradable eyes by the age group for staged-mydriasis Optos California*

The microaneurysm (MA) count was defined as non-inferior, when the number of microaneurysms detected within 1DD of the centre of the fovea on images taken using the SCO was equal to or higher than on the images taken using two 45-degree field digital cameras.

For staged-mydriasis images taken with Optos California in 89.6% with 95% CI (88.5% - 90.7%) of cases SCO MA count was non-inferior to the 45° mydriatic digital photography used as a diabetic screening standard.

Conclusions:

The ungradable image rate of 5.1% for Optos without mydriasis in a predominantly White Caucasian population was lower than reports for digital cameras.

The Optos California performed accurately in detecting any level of diabetic retinopathy using staged mydriasis with a sensitivity of 91.9% with 95% CI (90.5% - 93.2%) and specificity of 78.1% with 95% CI (75.7% - 80.3%) compared to the reference standard of two 45° mydriatic digital photography used in the English NHS DESP.

There was a steep learning curve for the grading team with some novel presentations of acquisition artefacts and colour differences in DR features.

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