

Implementation of Corneal Confocal Microscopy in Primary Care Optometry Practices to Screen for Diabetic Peripheral Neuropathy: a Feasibility and Acceptability study

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Background

Diabetic Peripheral Neuropathy (DPN) is a common and costly complication of diabetes. Early diagnosis is critical as patients with neuropathy are at greater risk of foot ulceration and amputation.

Corneal Confocal Microscopy (CCM) is a new ophthalmic technique which, through examination of the cornea, aims to detect DPN in its earliest stages, in a non-invasive manner and with high sensitivity.

At present, CCM is only performed in research centres by experienced operators, therefore the primary aim of this study was to investigate the feasibility and acceptability in high-street optometry practices to screen for DPN.

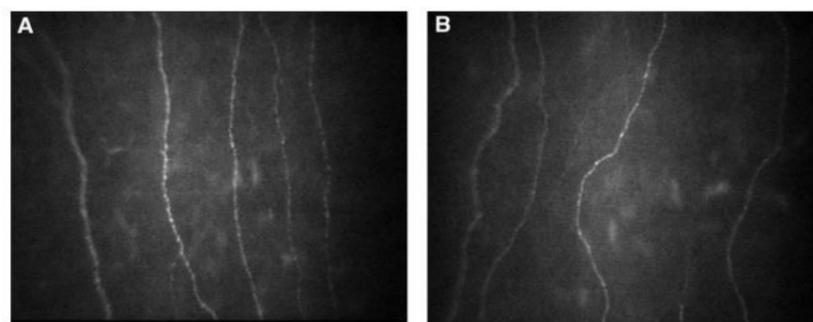


Figure 1. Images of corneal nerves in Bowman layer, obtained with CCM. Image A shows abundant nerve fibers and adequate branching in a control subject, whereas image B is a typical image from a diabetic patient with mild neuropathy. Source: Tavakoli M, Quattrini C, Abbott C at al. Corneal Confocal Microscopy. Diabetes Care 33 (8) 1792-1797, 2010.

Methods

This was a cross-sectional observational study. Four optometry practices were recruited from those participating in the South Manchester Diabetic Retinopathy Screening Service (SMDRSS). Optometrists were supplied with CCM equipment, trained over a two-days workshop and supported throughout the study. Reception staff in the practices also received training on data collection and patient recruitment.

During the recruitment period (Apr – Sep 2015):

- practices offered CCM to every patient booking a retinopathy appointment (via SMDRSS)
- for patients who wished to participate, practices booked a CCM scan alongside their annual retinopathy screening test
- optometrists checked eligibility, took informed consent and carried out CCM
- optometrists captured relevant patient and test details
- patients completed an information form and anonymised satisfaction questionnaire
- optometrists transferred captured CCM images to the Chief Investigator for assessment of their quality and for determination of a DPN diagnosis

At the end of the study qualitative interviews were conducted with optometrists to explore their experience of performing CCM. Furthermore, a budget impact analysis was carried out retrospectively to assess the potential economic impact of the test if brought into routine practice.

Results

Recruitment. 449 patients were successfully recruited; above the 400 target and ahead of schedule. The test was attempted in all eligible consenting patients, and was successfully completed in 92% of cases.

Evaluation of the training. Optometrists indicated the training was useful, appropriate and sufficient. They indicated that future training could benefit from: 1) including more practice performing the test and 2) instruction on determining the quality of images for diagnosis.

Patient acceptability. Patients reported the test was comfortable (87%), pain free (90%), and stated they would agree to do it again (97%).

Duration of the test: The average duration of performing CCM decreased over the course of the study from 16 to 10 minutes.

Quality of images: 95% of images assessed by the CI were determined to be of sufficient quality to permit diagnosis, whereas optometrists were more cautious, rating 79% of images as having acceptable quality. Optometrists reported the test was difficult to complete in 40% of cases due to patient characteristics and/or equipment design.

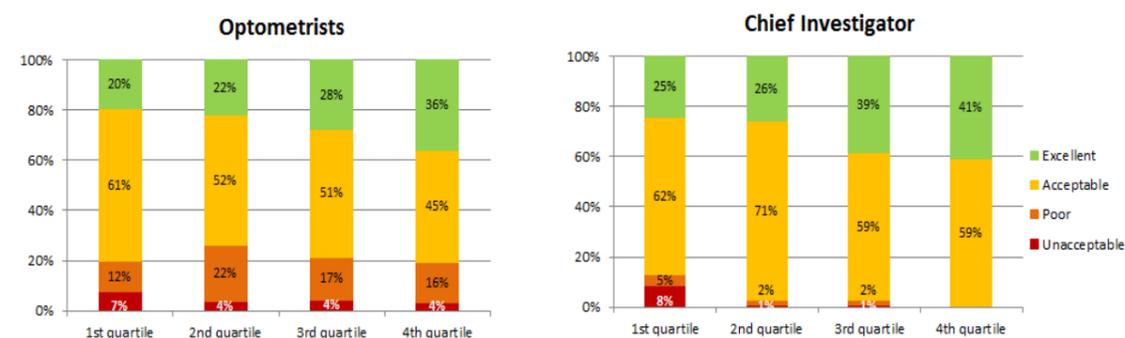


Figure 2. Optometrists and Chief Investigator grading of image quality by quartiles. The quality grading provided for each test represents the average across all images captured for a patient. Quartile 1 contains the first 25% of patients screened at each practice, quartile 2 contains the next 25% and so on.

Budget Impact Analysis. The cost of the existing retinopathy screening test is approximately £12 per person per year. If CCM were introduced alongside this, it would cost an additional £20 if the test was performed in optometry practices, or £15 if done using mobile equipment in roving vans.

Implications

This was the first feasibility and acceptability study of CCM performed in optometry practices. Our results indicate CCM was acceptable to patients. To be implemented in routine practice; resources, technological improvements, and the impact of earlier diagnosis on diabetic management (as no treatment for DPN is currently available) warrants further investigation.