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Evaluation of a combination digital retinal camera with spectral-domain optical coherence tomography (SD-OCT) that might be used for the screening of diabetic retinopathy with telemedicine: A pilot study

George E. Sanborn [a,*], John J. Wroblewski [b]

[a] Private Practice, Robert W. Jacey, MD, PC, Richmond, VA, United States of America
[b] Cumberland Valley Retina Consultants, Hagerstown, MD, United States of America

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ABSTRACT

Aims: Pilot study to determine whether an instrument combining a non-mydriatic retinal camera and spectral domain optical coherence tomography (SD-OCT) is effective for screening patients with diabetic retinopathy (DR).
Methods: Case series conducted between 2012 and 2013. DR imaged with a retinal camera/SD-OCT instrument viewed remotely was compared to a dilated examination by a retina specialist.
Results: The combination instrument was better than the retina specialist in detecting more severe retinopathy, primarily because of the SD-OCT. For severe retinopathy (grade ≥ 3), the image grader had better sensitivity (87.3% [95% CI: 75.5%, 94.7%]) than the retina examiner (76.4% [95% CI: 63.0%, 86.8%]). Specificities were similar between the instrument grader (96.0% [95% CI: 86.3%, 99.5%]) and retina examiner (100.0% [95% CI: 92.9%, 100.0%]). When identifying diabetic macular edema (ME), the retina examiner only identified 47.6% (20/42) of eyes with ME detected by SD-OCT. The instrument was better than a dilated retinal examination in detecting ME and not as good at detecting mild or proliferative retinopathy.
Conclusions: As used in this study, the instrument was more effective in identifying DR than was the current recommendation of a dilated and comprehensive eye examination. SD-OCT is needed to accurately identify DR in a screening setting.

1. Introduction

Diabetes mellitus is a significant public health problem. The Centers for Disease and Control and Prevention estimated that 20.9 million people in the United States had diabetes in 2010, a number that has tripled since 1980.[1] The National Health and Nutrition Examination Survey reported that nearly 30% of patients with diabetes have some degree of vision-threatening diabetic retinopathy (DR) between 2005 and 2008.[2] Diabetic retinopathy is the leading cause of new blindness among US-based residents aged 20–74 years.[3] The American Academy of Ophthalmology[4] and American Diabetes Association[5] recommend that patients with diabetes receive regular "dilated eye examinations" for DR. Well-designed clinical trials of pharmacotherapies have demonstrated efficacy for preventing vision loss in patients with certain types of retinopathy.[6,7] Recommended evaluations and treatment, if necessary, can prevent up to 98% of vision loss from DR.[8]

Despite these recommendations for regular, comprehensive eye examinations, one- to two-thirds of all patients with diabetes do not receive them.[9,10] Even if all patients with diabetes were examined as recommended, it is unlikely that the number of practicing ophthalmologists could accommodate the increasing number of patients with type 2 diabetes in the future.[11,12] A variety of screening methods have been implemented to improve the diagnosis and evaluation of DR. Most efforts involve some form of photography, and the images are sent or transmitted to a remote reading center, termed telemedicine.[13–18] Although photographic screening has resulted in more patients being referred to and examined by an ophthalmologist, it is usually conducted in specialty centers, by professional photographers with pupillary dilation. The most successful are based in the United Kingdom (UK), where the National Health Service offers free screening to all patients with diabetes.[19] As a result, diabetic eye disease is no longer the leading cause of vision loss in UK-based patients aged 19–64 years.[20]

One problem with photography screening is that it is not the best current technology for the detection of macular edema (ME),[21–24] which is the primary cause of vision loss in patients with diabetes.[25] The introduction of optical coherence tomography (OCT)

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* Corresponding author at: 2821 North Parham Road, Suite 105, Richmond, VA 23294, United States of America.
E-mail address: sanborn1g@gmail.com (G.E. Sanborn).

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fundamentally changed the ability to diagnosis diabetic ME, as OCT is more sensitive than stereoscopic slit-lamp bio-microscopy.[21,22] Several groups have investigated the use of OCT as a screening tool for a variety of retinal disorders including DR.[26–28]

One potential methodology to increase patient compliance is to perform screening in a physician's office, whether primary care, internal medicine, or endocrinology. Ideally, screening for significant DR, including ME, would be performed by clinic personnel in non-dilated patients, and the images would be sent for remote evaluation. Any instrument that would be used in this setting would have to show a good correlation between results from a comprehensive eye examination and the instrument. We evaluated one such instrument with the potential to screen for DR in an office setting.

2. Methods

2.1. Study design and patient population

This was an observational case series conducted between April 2012 and January 2013 at Cumberland Valley Retina Specialists (Hagerstown, MD). The study was approved by the Institutional Review Board of the Virginia Eye Institute (Richmond, VA) and conducted in accordance with the Declaration of Helsinki and in compliance with the Health Insurance Portability and Accountability Act of 1996.

Eligible patients (aged ≥21 years) had type 1 or type 2 diabetes and were being examined as part of a new or follow-up examination for diabetic eye disease, including a dilated retinal evaluation. Patients with visible laser scars or a history of vitrectomy surgery were excluded so as to keep the image grader masked to the presence of previous retinopathy. Written, informed consent was obtained from all patients before and procedures were initiated, and patients were de-identified by being assigned a unique study number.

2.2. Procedures

Images were taken by a single, experienced ophthalmic photographer using the Topcon 3D OCT-2000 (Topcon Medical Systems, Inc., Oakland, NJ) in the same room with standardized lighting of 0.01 lm. Patients were imaged undilated, except when the initial images were deemed unsatisfactory in the opinion of the photographer. These patients were dilated and re-imaged. Seven non-stereoscopic, 45° high resolution 12.3 MP (super luminescence diode, wavelength 840 nm, half bandwidth 50 nm) color retinal photographs were taken: (1) centered on the macula; (2) centered on the disc; (3) temporal to the macula at the same distance from the disc to the macula; and (4) supero-nasal, (5) supero-temporal, (6) infero-nasal, and (7) infero-temporal from the macula. Spectral domain-optical coherence tomography (SD-OCT) was acquired by covering a 6 × 6-mm square area to a depth of 2.3 mm, using a 572 × 128 raster pattern of A-scans (27,000/s), a horizontal resolution of 20 μm, and a longitudinal resolution of 5–6 μm.

Of note, the Topcon camera used in this study is no longer available, but an updated model is. We have evaluated this latest model, and in our opinion, it is more user friendly. In addition to this updated model, there is another combination camera/OCT available (Carl Zeiss, Meditec) in the United States.

Patients also were examined after pupillary dilation by an experienced retina specialist (JJW; the retina examiner) using indirect ophthalmoscopy and contact lens bio-microscopy of the posterior retina. The retina examiner performed the dilated examination without knowledge of the retinal images or the SD-OCT, or the content of the patient's medical record. The retina examiner made a detailed drawing and graded the retinopathy on a scale from 0 (no retinopathy) to 4 (proliferative retinopathy) (Table 1). Each eye was examined and graded, but only one grade was assigned to each patient. If the grade of the two eyes differed, the patient was assigned the higher grade.

Table 1
Grading system for retinopathy.

Grade	Pathology	Description
0	No retinopathy	n/a
1	Nonproliferative retinopathy, mild	Microaneurysms only
2	Nonproliferative retinopathy, moderate	More than microaneurysms, but less than Grade 3
3	Nonproliferative retinopathy, severe	Any of the following: • >20 microaneurysms in each quadrant • venous beading in ≥2 quadrants • prominent intraretinal microvascular abnormalities in ≥1 quadrants • macular edema but no proliferative disease
4	Proliferative retinopathy	Evidence of optic disk or retinal neovascularization or vitreous or pre-retinal hemorrhaging

Using software provided by Topcon (Synergy), retinal photographs and SD-OCT data were transmitted via the Internet from Cumberland Valley Retina Consultants to an office in Richmond Virginia, where they were graded by a second experienced retina specialist (GES). GES served as a masked, remote, image grader for the purposes of this study. Images were viewed on a 21-inch HP w2007 color monitor (screen resolution, 1680 × 1050) with factory default settings. Although the ambient lighting in the room was not measured, grading was performed at the same time of day with the same lighting. The image grader determined the extent of retinopathy using the combination of the photographic and SD-OCT images and gave each eye a grade of 0 to 4. The patient was then given a grade and was assigned the higher grade of the two eyes if they differed, exactly as done by the retina examiner. Any eye found to have ME as per SD-OCT imaging was given one grade higher (i.e., if they had microaneurysms only on the retina image, but had ME on the SD-OCT the eye would have been assigned a grade of 2 rather than 1 as indicated by the retina photo). The image grader was free to determine ME on any criteria, but generally relied on the observation of cystic formation, subretinal fluid, or loss of the normal anatomic foveolar contour on the SD-OCT. The Topcon SD-OCT provides a central thickness, but the Synergy software does not. This decision was made by the image grader based on his experience. The image grader had no information on the patients except that they were adults with diabetes.

2.3. Statistical analysis

The primary objective of this study was to compare the DR as provided by the combination camera/SD-OCT instrument with the retina examiner's evaluation of DR. The final diabetic retinopathy grade in this study, which compared the two graders, is defined by the combination of the dilated examination by the retina examiner plus the information obtained by the SD-OCT. Sensitivity and specificity of identifying retinopathy by the image grader were calculated with 95% confidence intervals (CIs). The overall agreement of the two graders was evaluated by Kappa coefficient.

The monitor on the instrument was supplied by the manufacturer and was not calibrated or modified from the factory default settings. Although not a primary objective of the study, it was of interest to determine the extent to which the transmitted images compared with the on-site images. After patient recruitment was complete, the instrument grader traveled to the office where the images were taken to view each image on the instrument.

3. Results

A total of 105 consecutive patients participated in the study (Table 2). The photographic image quality was good to excellent in all but nine patients (11 eyes). In two eyes (one eye in each of two patients), the reason for poor image quality was vitreous hemorrhage.

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