



## Comparison of 1-field, 2-fields, and 3-fields fundus photography for detection and grading of diabetic retinopathy

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### ABSTRACT

**Aim:** To evaluate the sensitivity and specificity of 1-, 2-, and 3-fields, nonmydriatic (NM), 45° color photography compared with mydriatic ophthalmoscopy for detection of diabetic retinopathy (DR).

**Methods:** Masked, comparative case series was performed utilizing a group of 128 diabetic patients (256 eyes) with various stages of DR who underwent both 3-fields NM color photography and ophthalmologic examination. In a blinded manner, the same optometrist who read the original 3-fields images for a patient read the 1- and 2-fields photographs on separate dates later.

**Results:** The sensitivity and specificity of digital retinal photography compared with dilated ophthalmoscopy were, respectively: 88% and 76% for 1-field; 94% and 69% for 2-fields; and 100% and 79% for 3-fields. The proportion of agreement between fundus photography reading and exam DR diagnosis were 58% for 1-field, 58% for 2-fields, and 77% for 3-fields. Kappa and Cramer's V statistics for 1-, 2-, and 3-fields were 0.55 and 0.60, 0.52 and 0.57, and 0.72 and 0.74, respectively. Three-fields measurement of DR was most similar to the dilated ophthalmological exam overall and across all DR severity levels.

**Conclusions:** Compared to 1- and 2-fields fundus photography, 3-fields is superior for detecting vision-threatening DR. One- and 2-fields have reasonable sensitivity for DR screening.

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### 1. Introduction

Diabetes mellitus (DM) is a major health problem with significant morbidity. Diabetic retinopathy (DR) is the leading cause of severe visual impairment in working age American adults.<sup>1</sup> Approximately one-third of patients with DM will have diabetic retinopathy (DR) and one-tenth will have proliferative diabetic retinopathy (PDR) or diabetic macular edema (ME).<sup>2–4</sup> Yet many patients with DR remain undiagnosed. In the United States, only about 60% of diabetic patients receive an annual dilated eye exam.<sup>5</sup>

The American Academy of Ophthalmology (AAO) recommends annual dilated screening examinations for diabetic patients beginning five years after diagnosis in Type 1 DM and at time of diagnosis in Type 2 DM.<sup>6</sup> Minorities, the young, and financially disadvantaged individuals are less likely to follow through with screening.<sup>7</sup> In addition, the absence of a recommendation by a health-care provider has been identified as a main barrier to annual eye exams.<sup>8</sup>

Teleretinal imaging (TRI) is one strategy to increase the availability of screening in at risk populations. TRI is cost-effective, screens more

patients for DR, and improves access to higher levels of ophthalmologic care.<sup>9</sup> Three 45° stereoscopic, NM fields was found to be as effective for DR screening as the Early Treatment Diabetic Retinopathy Study (ETDRS) seven standard fields.<sup>10</sup> Fewer fields have been proposed as efficacious for DR screening and are in use due to decreased time and cost. Studies have indicated that 2-fields fundus photography, which is the standard used in the United Kingdom, is suitable for DR screening.<sup>11–14</sup> Other studies have reported on the adequacy of 1-field diabetic retinal photography, which is the current practice in Singapore.<sup>15–17</sup> However, disagreement still exists over the suitability of 1-field photography for DR screening.<sup>18–22</sup> In 2004, an AAO report concluded that 1-field fundus photography can serve as a screening tool to identify patients with DR needing referral, but 1-field fundus photography was not a substitute for a comprehensive eye exam.<sup>23</sup> The aim of this study was, therefore, to examine and directly compare one, two, and three 45° NM, stereoscopic fundus fields to determine the most effective screening method for DR.

### 2. Methods

This study was approved by the Institutional Review Board of The University of Texas Southwestern Medical Center and conformed to the requirements of the U.S. Health Insurance Portability and Privacy

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Act. The electronic health record system at Parkland Health and Hospital System (PHHS) was used to identify diabetic patients who underwent 3-fields NM tele-retinal imaging to screen for DR between July 2016 and August 2017 and underwent a dilated ophthalmologic exam by an ophthalmologist within six months of the photographs being taken. Patients were excluded if they were <18 years old or had received surgery for diabetic retinopathy in either eye.

In the PHHS, diabetic patients appropriate for diabetic TRI have fundus photographs taken in the primary care setting. A Topcon TRC-NW8 nonmydriatic fundus camera (Topcon, Tokyo, Japan) is used. The camera acquires 16.2 megapixel images, and utilizes auto focus and auto shoot technology. A trained technician takes three undilated 45° retinal photographs in each eye: one field is centered on the macula; another is centered on the optic disc; and the third is focused superior temporal to the macula. This third field corresponds to Joslin Vision Network field NM-2 and provides an image of more peripheral retina. For the third field the camera is centered laterally approximately one-half disc diameter to the center of the macula with the lower edge of the field tangent to a horizontal line passing through the upper edge of the optic disc.<sup>10</sup> Images are then transmitted electronically to one of five optometrists who assess the three photographs. The retinal images are given a grade of diabetic retinopathy based on the eye with the most severe retinopathy, and appropriate referral for a complete ophthalmologic examination is then made for patients with retinopathy. Grade 0 was assigned to patients with no DR, grade 1 for mild or moderate nonproliferative DR (NPDR) without ME, grade 2 for severe NPDR without ME, grade 3 for NPDR with ME, and grade 4 for PDR with or without ME. The ophthalmologic exam was performed by an ophthalmologist. The exam diagnosis by which patients were divided into DR severity level subgroups was based on the diagnosis and findings on dilated fundus exam documented in the patient's chart. Grading of diabetic retinopathy by image readers and ophthalmologists used the International Clinical Diabetic Retinopathy Disease Severity Scale.<sup>24</sup> In our system, patients without DR on fundus photography are rescreened annually, while those with mild to moderate NPDR are referred for the next available dilated examination by either an optometrist or ophthalmologist. Patients with higher grades of DR are referred to see an ophthalmologist. Patients with severe NPDR on fundus photography are seen within 3 months, with ME within 1 month and with PDR within 2 weeks.

It was determined that in a test of agreement between two graders, a sample size of 120 subjects using the five category rating scale would achieve 80% power to detect a true  $\kappa$  of 0.74 versus the null hypothesis that  $\kappa = 0.60$  based on a two-tailed test with  $P = 0.05$ . Thus, at least 24 subjects were found that met the inclusion criteria in each diagnostic category. One-field (macula-centered) and 2-fields (macula-centered, optic-disc centered) images for an individual subject were sent to the original reader of the 3-fields images in a blinded manner, with several months passing between presentations of an individual subject's images to prevent recall by the reader. The separately later presented 1- and 2-fields were part of the initial 3-fields interpreted by the original reader. Therefore, the same reader graded the 1-, 2-, and 3-fields images for a given subject.

Sensitivity and specificity for each screening strategy were calculated. Sensitivity for each level of DR severity was also calculated for each screening method. The reference standard was taken as the dilated ophthalmologic exam by an ophthalmologist. Proportion of agreement was defined as the total percentages of responses matching the reference standard. Two-sided Fisher Exact test was used to examine the association between the proportions of agreement and ungradable photographs by DR grades for each screening strategy. Unweighted  $\kappa$  statistics were calculated to measure inter- and intra-grader reliability between the fundus field readings. Kappa values <0.4 were interpreted as weak agreement; 0.4–0.6 were interpreted as moderate agreement; and >0.6 as substantial agreement. Cramer's V, a correlation coefficient between two nominal variables giving a value between 0 and +1, was

**Table 1**  
Demographic information for the study participants.

|   | DR Level          |                  |                  |                   |                  | Total (%)   |
|---|-------------------|------------------|------------------|-------------------|------------------|-------------|
|   | 0                 | 1                | 2                | 3                 | 4                |             |
| <i>n</i>                                | 29                | 26               | 25               | 24                | 24               | 128 (100.0) |
| Sex                                     |                   |                  |                  |                   |                  |             |
| Male                                    | 9                 | 17               | 11               | 15                | 12               | 64 (50.0)   |
| Female                                  | 20                | 9                | 14               | 9                 | 12               | 64 (50.0)   |
| Age (yr), mean $\pm$ SD                 | 55.27 $\pm$ 12.13 | 50.23 $\pm$ 8.46 | 53.31 $\pm$ 9.96 | 51.90 $\pm$ 15.97 | 51.49 $\pm$ 8.75 |             |
| BMI (kg/m <sup>2</sup> ), mean $\pm$ SD | 33.12 $\pm$ 6.42  | 31.37 $\pm$ 5.89 | 29.78 $\pm$ 5.32 | 32.75 $\pm$ 6.88  | 30.71 $\pm$ 5.46 |             |
| Diabetes                                |                   |                  |                  |                   |                  |             |
| Type 1                                  | 0                 | 0                | 0                | 0                 | 1                | 1 (0.8)     |
| Type 2                                  | 29                | 26               | 25               | 24                | 23               | 127 (99.2)  |
| Race                                    |                   |                  |                  |                   |                  |             |
| Hispanic white                          | 19                | 19               | 22               | 17                | 19               | 96 (75.0)   |
| Non-Hispanic white                      | 3                 | 3                | 1                | 1                 | 0                | 8 (6.3)     |
| Black                                   | 6                 | 4                | 0                | 6                 | 5                | 21 (16.4)   |
| Asian                                   | 1                 | 0                | 2                | 0                 | 0                | 3 (2.3)     |

DR Levels: 0 = No DR, 1 = mild or moderate NPDR without ME, 2 = severe NPDR without ME, 3 = NPDR with ME, 4 = PDR with or without ME; BMI: body mass index; SD: standard deviation.

calculated as a measure of association. All statistical analyses were performed with SPSS version 25 (International Business Machines Corporation, Armonk, New York, USA).

### 3. Results

A total of 256 eyes from 128 subjects with diabetes were used. The number of patients by degree of DR and patient demographics are detailed in Table 1. All had type 2 diabetes mellitus except for one subject. According to the reference standard of mydriatic ophthalmoscopy, 29 patients did not have DR and 99 patients had DR. Three-quarters of the subjects were Hispanic.

Sensitivity, specificity, underestimation, overestimation, and agreement ( $\kappa$  statistics) are presented in Table 2. Sensitivity to detect any degree of diabetic retinopathy ranged from 87.9% (1-field) to 100% (3-fields), while specificity ranged from 69.0% (2-fields) to 79.3% (3-fields), and agreement ranged from  $\kappa$  values of 0.52 (2-fields) to 0.72 (3-fields). Proportion of agreement with DR stage ranged from 57.8% for 1- and 2-fields to 77.3% for 3-fields. Proportion of agreement, or sensitivity for DR grade, is provided in Table 3. Three-fields screening had the highest proportion of agreement with DR stage for every severity level compared to the other two screening strategies. Agreement varied significantly by DR severity for 1- and 2-fields ( $P < 0.001$ ). One-field correctly identified no DR and the earliest stage DR (level 1) 75.9% and 69.2% of the time, respectively, while only correctly identifying severe NPDR without ME (level 2) in 16.0%. The DR level 2 subgroup also had the lowest sensitivity for 2-fields with 20.0% correctly graded. Twenty-six percent of 1-

**Table 2**  
Sensitivity, specificity, under-reads, over-reads, proportion of agreement, and agreement ( $\kappa$ ) statistics for each screening strategy.\*

| Screening Strategy | Sensitivity (n = 99) | Specificity (n = 29) | Under (n = 99) | Over (n = 104) | Proportion of agreement (n = 128) | Kappa Statistic** |
|--------------------|----------------------|----------------------|----------------|----------------|-----------------------------------|-------------------|
| 1-field            | 87.88%               | 75.86%               | 26.26%         | 15.38%         | 57.81%                            | 0.55              |
| 2-field            | 93.94%               | 68.97%               | 20.20%         | 25.96%         | 57.81%                            | 0.52              |
| 3-field            | 100%                 | 79.31%               | 5.05%          | 23.08%         | 77.34%                            | 0.72              |

Under: underestimation of DR stage; Over: overestimation of DR stage.

\* Each screening strategy was compared to exam DR diagnosis.

\*\* All Kappa statistics are significant ( $P < 0.001$ ) representing a significant association between DR diagnosis and screening strategy.

**Table 3**

Association between exam diagnosis by DR severity level for each screening strategy.

| DR severity Level | Ophthalmologic exam<br>n | 1-Field |        | 2-Fields |        | 3-Fields |        |
|-------------------|--------------------------|---------|--------|----------|--------|----------|--------|
|                   |                          | n agree | (%)    | n agree  | (%)    | n agree  | (%)    |
| 0                 | 29                       | 22      | (75.9) | 20       | (69.0) | 23       | (79.3) |
| 1                 | 26                       | 18      | (69.2) | 17       | (65.4) | 18       | (69.2) |
| 2                 | 25                       | 4       | (16.0) | 5        | (20.0) | 18       | (72.0) |
| 3                 | 24                       | 15      | (62.5) | 12       | (50.0) | 17       | (70.8) |
| 4                 | 24                       | 15      | (62.5) | 20       | (83.3) | 23       | (95.8) |
| Total             | 128                      | 74      | (57.8) | 74       | (57.8) | 99       | (77.3) |
| P value           |                          | <0.001  |        | <0.001   |        | 0.102    |        |

field images were underestimated compared to 5% of 3-fields (Table 2). In contrast, 2- and 3-fields had higher proportions of overestimation than underestimation, with comparable overestimation frequencies of 26% and 23%, respectively. The number of ungradable photographs are detailed in Table 4. 9.4% of 1-field and 5.5% of 2-fields photographs were determined ungradable. Ungradable photographs did not vary significantly by DR severity. Cramer's V statistics were largely consistent with  $\kappa$  statistics (Table 5). While there were slightly different rank orders for Cramer's V and the  $\kappa$  statistic among the five reading optometrists, the  $\kappa$  statistics were generally the lowest for the 2-fields strategy and the highest for all optometrists using the 3-fields strategy (range 0.67–0.81, all  $P < 0.001$ ).

#### 4. Discussion

Effective screening is paramount to reduce vision loss secondary to DR, a leading cause of blindness worldwide. In 2001, Bursell *et al* determined that 3-fields 45° NM stereoscopic color fundus images are comparable with the gold standard 7-fields 30° mydriatic stereoscopic color EDTRS images for determining clinical DR.<sup>10</sup> The EDTRS 7-fields is not commonly used to screen due to increased time requirement, patient discomfort, and decreased patient adherence due to mydriasis.<sup>10,15</sup> Fewer fields for DR screening has been of continual interest over the last two decades, and numerous alternative screening strategies have been proposed and implemented in various countries. Additionally, DR screening has been moving towards improved accuracy of grading clinical DR on imaging.

In this study, NM 1-, 2-, and 3-fields TRI were all found to be very sensitive for detecting the presence of DR. Three-fields demonstrated the highest sensitivity for DR and for DR grading. Fewer fundus fields had higher percentages of ungradable readings. Ungradable photographs were mostly due to poor pupillary dilation or media opacity. Underestimations, or when the imaging DR grade was read as any level below the exam diagnosis grade, were more prevalent with decreasing number of fields with over 25% of 1-field photographs underestimated. Nearly 25% of 2- and 3-fields photographs were overestimated, or when the imaging DR grade was read as any level above the exam diagnosis grade. From a clinician standpoint, overestimations are less problematic

compared to underestimations, which run the risk of missing DR in patients.

According to the British Diabetic Association, an acceptable screening program for diabetic retinopathy should have at least 80% sensitivity.<sup>25</sup> The 1-, 2- and 3-fields strategies all exceed this threshold with sensitivities >85%. All three methods have screening utility, especially given different clinical settings, time, and available resources. This reaffirms the AAO's report stating that 1-field screening is adequate to identify DR presence.<sup>23</sup> However, in the present study, the 3-fields screening strategy was more sensitive and specific for identifying the presence of DR and was more sensitive for detection of higher levels of retinopathy. One- and 2-fields had equivalent rates of exact agreement with the reference standard and similar  $\kappa$  statistics. Three-fields outperformed 1- and 2-fields on all measures and missed no cases of retinopathy. This is in contrast to the work of Perrier *et al* who found that adding a third or even a fourth field decreased utility due to poor image quality of extra fields,<sup>12</sup> and a study evaluating 5-fields sensitivity for ophthalmologic exam found it to be 84.5% sensitive, no more sensitive than previously published 3-fields sensitivities or herein.<sup>20,22</sup> Therefore comparing number of fundus fields, three-fields is superior for detecting vision-threatening DR. Accurate grading of DR is important when triaging patients in health care systems with finite resources.

Limitations of this study include a time separation of up to 6 months between the ophthalmologic examination used as the reference standard and the screening fundus photographs. Lin *et al* found that ophthalmoscopy had reduced sensitivity compared to a gold standard of seven-field ETDRS images.<sup>18</sup> However, we used ophthalmoscopy as the reference standard in this study as it is the most common standard in usual clinical practice. Since we selected 3-fields photographs that were able to be read in order to give a grade of DR, this paper does not address the rate of ungradable 3-fields photographs, only the rate of ungradable 1-field and 2-fields photographs in this selected data set.

In conclusion, for 45° nonmydriatic color fundus photography, 3-fields is superior to 1- and 2-fields across all studied outcome measures for DR screening. Yet given the high sensitivities, 1- and 2-fields are suitable for screening for the presence of DR, especially in underserved

**Table 4**

Ungradable photographs by DR severity for each screening strategy.

| Level   | n   | Field |        |       |        |
|---------|-----|-------|--------|-------|--------|
|         |     | 1     | (%)    | 2     | (%)    |
| 0       | 29  | 3     | (10.3) | 3     | (10.3) |
| 1       | 26  | 3     | (11.5) | 2     | (7.7)  |
| 2       | 25  | 1     | (4.0)  | 1     | (4.0)  |
| 3       | 24  | 2     | (8.3)  | 0     | (0)    |
| 4       | 24  | 3     | (12.5) | 1     | (4.2)  |
| Total   | 128 | 12    | (9.4)  | 7     | (5.5)  |
| P value |     | 0.884 |        | 0.636 |        |

**Table 5**  
Cramer's V and weighted kappa statistics for field vs exam diagnosis.

|               | Fields | N   | Cramer's V | Kappa statistic* |
|---------------|--------|-----|------------|------------------|
| Overall       | 1      | 116 | 0.604      | 0.548            |
|               | 2      | 121 | 0.570      | 0.515            |
|               | 3      | 128 | 0.742      | 0.717            |
| Optometrist A | 1      | 28  | 0.686      | 0.493            |
|               | 2      | 30  | 0.614      | 0.475            |
|               | 3      | 30  | 0.827      | 0.703            |
| Optometrist B | 1      | 28  | 0.545      | 0.385            |
|               | 2      | 31  | 0.572      | 0.444            |
|               | 3      | 31  | 0.703      | 0.669            |
| Optometrist C | 1      | 23  | 0.723      | 0.670            |
|               | 2      | 24  | 0.642      | 0.514            |
|               | 3      | 27  | 0.749      | 0.719            |
| Optometrist D | 1      | 24  | 0.750      | 0.685            |
|               | 2      | 24  | 0.756      | 0.632            |
|               | 3      | 26  | 0.736      | 0.708            |
| Optometrist E | 1      | 13  | 0.882      | 0.508            |
|               | 2      | 12  | 0.711      | 0.483            |
|               | 3      | 14  | 0.834      | 0.813            |

\* All Kappa statistics are significant ( $P < 0.0001$ ) representing a significant association between field and exam diagnosis.

countries. Three-fields imaging is superior for detecting vision-threatening DR.

#### Declaration of competing interest

No conflicting proprietary or financial interest exists for any of the authors.

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