Hand-held non-mydriatic digital fundus imaging for the detection of diabetic retinopathy

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BACKGROUND

- Estimated 1 in 29 persons in the United States, age 40 and older, has diabetic retinopathy (DR)[1]
- Prevalence of diabetes expected to increase[1]
- Early detection of DR can be effective in preventing vision loss as disease is often asymptomatic[2]
- Many diabetics do not receive appropriate and mandated screening exams[3]
- More accessible and efficient means of DR screening is necessary given growing prevalence of diabetes and potential workforce shortages in ophthalmology[4]

- DR telemedicine programs can be highly successful in detecting and grading DR[5]
- Cost of equipment, as well as the time and expertise to obtain Early Treatment of Diabetic Retinopathy Study (ETDRS) standardized fundus photographs is impractical to implement in primary care setting

- Other methods for imaging the fundus validated compared to standard seven-fields
  - Non-mydriatic ultrawide-field (UWF) imaging[6]
  - Non-mydriatic imaging with three 45°-fields[7]
  - Cost and portability of the technology remains prohibitive

- This pilot study utilizes the Pictor (Volk®)
  - Hand-held, lightweight (1 lbs), non-mydriatic digital fundus imager
- With appropriate validation, hand-held technology has potential to be integrated into primary care setting as part of an effective telemedicine program

PURPOSE

- To describe early experiences using a hand-held non-mydriatic digital fundus camera for DR screening

- To compare the gradability of images between ophthalmic photographer and non-ophthalmic photographer

METHODS

- Prospective, single-center pilot study
- Diabetic patients presenting to the Kellogg Eye Center Retina Clinic
- Non-mydriatic, hand-held fundus imaging
  - 45°-field fundus images obtained in 3 fields (posterior pole, nasal, superotemporal)
  - Images taken by both a certified ophthalmic photographer and a medical student not trained in ophthalmic photography
- Mydriatic ultrawide-field (UWF) imaging (Optos®)
- Dilated fundus examination by a retina specialist
- Single, masked retina specialist graded all images to assess image quality and presence of DR
- Pupil size assessed using external photographs
- Chi-squared test used to compare images between photographers

RESULTS

- Twenty-three eyes (12 patients); ages 31-73 years
- Mean Hemoglobin A1c 8.0 (6.0-14.0)
- No eyes had significant media opacities
- 21/23 (91%) UWF images were gradable
- 34/68 (50%) hand-held camera images were gradable
- Hand-held images taken by the ophthalmic photographer: 20/35 (57%) gradable; by the medical student: 14/33 (42%) gradable
- Difference in percentage of gradable images between photographers not statistically significant (p=0.2)
- 9/23 (39%) nasal images gradable (least gradable)
- 18/23 (78%) superotemporal images gradable (most gradable field)
- 3/5 (60%) ungradable eyes had small pupil size
- In 5 eyes, all 3 fields were gradable with the hand-held camera. Of these 5 eyes, DR was accurately detected in 4 (80%). One patient had mild nonproliferative DR (NPDR) on exam, not detected on fundus imaging
- Of the eyes that had at least 1 gradable 45°-field, DR was accurately assessed in 14/18 (78%)
- Of the 4 eyes that were not accurately assessed, NPDR was present in 3 eyes (75%) on clinical exam
- Of the 21 gradable UWF images, DR was accurately assessed in 19 (90%)
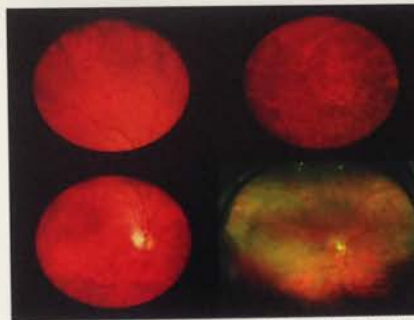
Example of gradable Pictor images and corresponding Optos® image from same patient
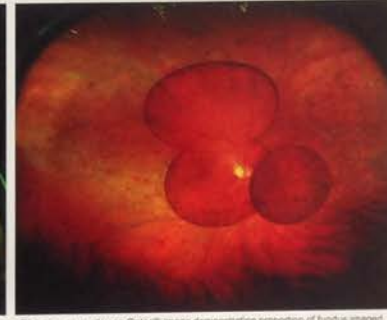
Pictor image overlay on Optos® image demonstrating proportion of fundus imaged

Examples of ungradable Pictor images including glare (upper) and shadowing/incomplete field (lower)

Subject	Age	Gender	HbA1c	DR on Pictor	DR on Optos	DR on exam	Photographer
1	64	F	unknown	unable	-	+	P
2	31	M	14	+	+	+	P
3	66	M	7.1	+	+	+	P
4	73	F	8.3	+	+	+	P
5	64	F	unknown	unable	unable	-	P
6	73	F	8.3	+	-	+	P
7	46	F	6	-	-	-	P
8	31	M	14	+	+	+	P
9	60	M	7	-	-	-	P
10	60	M	7	-	-	-	P
11	66	M	7.1	unable	+	+	P
12	46	F	6	-	-	-	MS
13	66	F	8	-	+	+	MS
14	56	F	7.2	-	+	+	MS
15	55	F	7.6	-	-	-	MS
16	62	F	7.5	unable	unable	-	MS
17	56	F	7.2	+	+	+	MS
18	66	F	8	+	+	+	MS
19	55	F	7.6	-	-	-	MS
20	54	F	unknown	+	+	+	MS
21	54	F	unknown	unable	+	+	MS
22	47	M	7.5	-	+	+	MS
23	47	M	7.5	-	+	+	MS

P=ophthalmic photographer; MS=medical student

DISCUSSION

- Gradable, hand-held images were accurately assessed for DR when compared to UWF images and dilated exam
- Hand-held images had a lower percentage of gradable photos when compared to UWF images
- No significant difference in image gradeability was found between the ophthalmic photographer and the medical student (p=0.2)
- Nasal field images are more difficult to obtain
- Glare and shadowing were sources of artifact preventing grading
- Small pupils may prevent obtaining non-mydriatic hand-held images
- Dilation for UWF images may have resulted in a higher percentage of gradable images

CONCLUSIONS

- Non-mydriatic, hand-held digital fundus imaging may have a useful role in DR screening
- Non-ophthalmic personnel can effectively perform the imaging. Not surprisingly, a greater proportion of higher quality images were taken by the ophthalmic photographer, revealing the importance of training
- Used in a primary care setting or in underserved areas, hand-held imaging may provide a cost-effective screening method to serve the growing diabetic population
- Larger validation studies are needed

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