

Original Research

Results of Implementation of the DigiScope for Diabetic Retinopathy Assessment in the Primary Care Environment

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ABSTRACT

Approximately 50% of patients with diabetes in the United States do not undergo recommended ocular evaluations for diabetic retinopathy. The DigiScope (EyeTel Imaging, Inc., Columbia, MD) was developed as a cost-effective and practical telemedicine digital imaging system to screen for diabetic retinopathy in the primary care physician's (PCP) office. The DigiScope has been validated against seven-field stereo color fundus photography for the detection of diabetic retinopathy. *Objective:* This study reports on the implementation of the DigiScope for diabetic retinopathy assessment in the primary care environment. *Materials and Methods:* In PCP's offices, patients with diabetes who had not undergone an eye examination in the past year were imaged with the DigiScope. The images were transmitted to a reading center where the need for referral to an ophthalmologist was determined. Nonurgent referral was recommended for patients with diabetic retinopathy greater than a few microaneurysms, other ocular pathology, or unreadable images. Referral was deemed "urgent" for patients with sight-threatening disease and evaluation by an ophthalmologist within 72 hours was recommended. *Results:* Between October 1, 2002 and March 31, 2771 patients with diabetes underwent DigiScope imaging at multiple sites. Nonurgent referral was recommended for 468 patients (17%). Urgent referral was recommended for 71 patients (3%). The images were unreadable in 295 cases (11%). *Conclusions:* This study indicates that implementation of the DigiScope in the primary care setting is practical and allows screening of patients with diabetes who are otherwise not receiving recommended eye examinations.

INTRODUCTION

DIABETIC RETINOPATHY is the leading cause of blindness among working-age adults in the United States. It is estimated that 75,000 new cases of macular edema, 65,000 cases of proliferative retinopathy and 8000 cases of

blindness arise from diabetic eye disease each year.^{1,2} Landmark prospective clinical trials have demonstrated that timely treatment of diabetic retinopathy is highly effective in reducing the risk of vision loss² and regular screening or assessment for diabetic retinopathy is widely recommended.^{1,3} Unfortunately, less

than half of patients with diabetes undergo recommended eye examinations⁴ and only 60% of patients who would benefit from treatment receive appropriate care.⁵

It has been shown that retinal photographs assessed by an experienced ophthalmic clinical assistant achieved higher sensitivity for detection of sight-threatening retinopathy than ophthalmoscopy by ophthalmologists (89% versus 65%).⁶ For detection of moderate to severe non-proliferative and proliferative diabetic retinopathy, assessment of mydriatic retinal photographs by trained graders was significantly more sensitive than ophthalmoscopy by an ophthalmologist (84% versus 33%; $p < 0.0001$).⁶ This has led a number of groups to use telemedicine imaging systems with remote image reading centers to successfully increase the size of the population being assessed for diabetic retinopathy.⁷⁻¹¹ Many imaging systems currently used in telemedicine are costly and often must be operated by trained professional photographers thus limiting possibilities for their implementation.

It has been postulated that the offices of primary care physicians (PCPs) may be the best environment to assess diabetic patients for retinopathy.⁴ Most patients with diabetes visit their PCP at least once every year. However, many PCPs have limited ability diagnosing diabetic retinopathy ophthalmoscopically. Also, implementation of most currently available telemedicine imaging systems is practically and financially difficult in the primary care setting where few patients with diabetes requiring assessment for retinopathy are evaluated on any given day.¹²

A new, validated diabetic retinopathy assessment system, involving placement of a semiautomated fundus camera in the primary care environment, was designed to facilitate referral of patients with diabetic retinopathy. It is based on the DigiScope (EyeTel Imaging Inc., Columbia, MD),¹³ which is operated by existing staff in the PCP's office, to acquire digital fundus images of patients with diabetes. The DigiScope facilitates automatic transmission of data over the Internet to a remote reading center where the image data is interpreted by certified, trained readers under the supervision of a retina specialist. A determination is made from the DigiScope findings as to whether re-

ferred to an ophthalmologist for further evaluation is necessary and a report is returned to the PCP. Currently, referral is recommended for patients with mild or worse levels of diabetic retinopathy based on the International Classification of Clinical Diabetic Retinopathy and Macular Edema Severity Scale.¹⁴ All patients with images inadequate for grading and with significant pathologies other than diabetic retinopathy are also referred.

The Early Treatment Diabetic Retinopathy Study (ETDRS) was a landmark multicentered, national clinical trial which demonstrated that laser photocoagulation treatment of diabetic retinopathy can reduce the risk of vision loss.^{15,16} Seven-field color stereo slide photographs based on the ETDRS protocol are considered the current gold standard against which to compare other imaging systems for the ability to detect diabetic retinopathy.^{17,18} The American Telemedicine Association has recently endorsed guidelines for diabetic retinopathy programs and an important recommendation is the need for validation of such programs against the reference standard, ETDRS photographs, prior to implementation.¹⁹ As recommended by these guidelines, the DigiScope previously underwent a Category 1 validation that allows identification of patients with no or minimal diabetic retinopathy and those who have more than minimal diabetic retinopathy.²⁰

Performing ETDRS photographs is time-consuming, requires skilled ophthalmic photographers and costly photographic equipment, and is therefore generally not applicable for diabetic retinopathy assessment purposes. Nonmydriatic fundus photography has been suggested as an alternative. A report by the American Academy of Ophthalmology (AAO) on screening for diabetic retinopathy cites four studies utilizing nonmydriatic fundus photography that used ETDRS photographs as the reference.¹⁷ The sensitivity ranged between 61% and 78% and specificity ranged between 85% and 88%. The report concluded that nonmydriatic single field fundus photography "can serve as a screening tool to identify patients with diabetic retinopathy for referral for evaluation and management."

An independent validation study was performed to evaluate the DigiScope as an assess-

ment tool²⁰ for diabetic retinopathy. This masked, randomized trial of 111 consecutive patients with diabetes (222 eyes) showed excellent agreement between the DigiScope and ETDRS seven-field color stereo photographs. The proportion of patients for whom determination of need for referral could be made was similar between the DigiScope and ETDRS seven-field photographs (DigiScope, 85%; ETDRS stereo photographs, 88%). Comparing the two modalities for distinguishing between no retinopathy and any retinopathy revealed a sensitivity of 99% and specificity of 96%. The differentiation between eyes with “few microaneurysms or less severe retinopathy” and “retinal hemorrhage or more severe retinopathy,” the level of disease requiring referral with this system, was found to have a sensitivity of 97% and a specificity of 84%. These results are better than those cited in the AAO report likely because of factors including use of mydriasis, larger area of the posterior pole imaged, and use of a dedicated technology. This report is a retrospective observational cohort that reviews the results of implementation of the validated DigiScope in the primary care environment.

MATERIALS AND METHODS

DigiScopes were placed in 51 offices (in 7 states and the District of Columbia) of PCPs who expressed an interest in use of this tech-

nology. This report is based on the results of implementation of the DigiScope at these sites over a 6-month period between October 1, 2002 and March 31, 2003.

Staff members in the PCPs office were trained to operate the DigiScope and on average required less than 1 hour of training. Patients with diabetes who came into the office for a visit with their PCP were queried whether they had an eye examination in the preceding 12 months. If not, an assessment with the DigiScope was recommended. Patients were informed that this procedure does not replace a comprehensive eye examination. The patient's pupils were then dilated with 0.5% tropicamide that was allowed to take effect during the physician encounter. The DigiScope assessment was performed (Fig. 1) as described below.¹³ The image data and encrypted patient information were uploaded automatically through regular phone lines from the PCP office to the Wilmer-EyeTel Reading Center (Fig. 2). The reading center procedure is described below. A report based on the review of the images was generated and sent to the PCP with a recommendation regarding the need for referral to an ophthalmologist for further evaluation and treatment.

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DigiScope Procedure

After pupillary dilation, patients were positioned in front of the DigiScope (Fig. 1) and

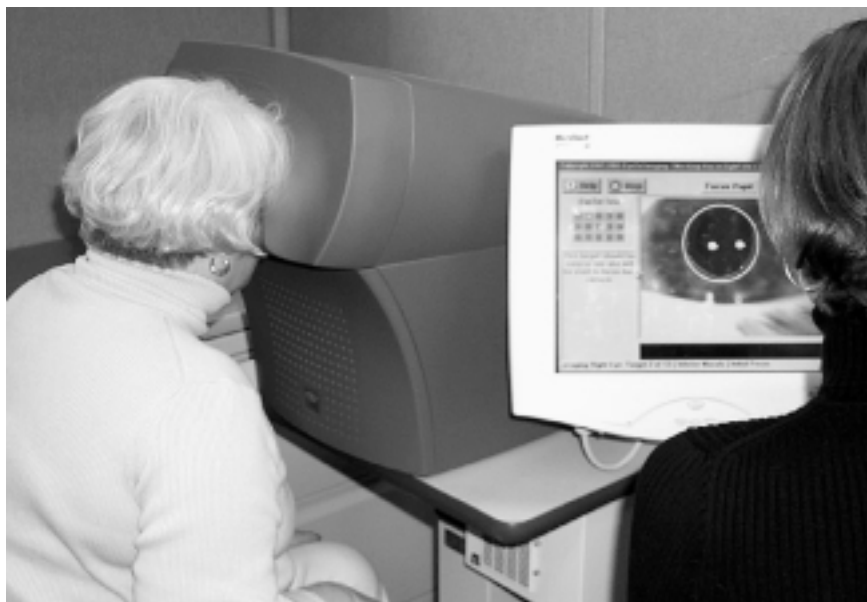


FIG. 1. The DigiScope (EyeTel Imaging Inc., Columbia, MD) in operation in a primary care physician's office.



FIG. 2. General view of a DigiScope Reading Center station (EyeTel Imaging Inc., Columbia, MD).

were asked to look at a target light inside the DigiScope. The operator viewed an image of the subject's pupil on the DigiScope touch screen. By touching the screen in the center of the pupil image, the DigiScope camera head moved automatically to center the pupil. A series of pupil images were acquired over a range of distances from the cornea. This series of images was presented to the operator who selected the image in best focus on the touch screen. The optical head was then set to the corresponding location and a series of fundus images were acquired with illumination from a red-free light. Ten internal fixation lights were used to orient the eye so that 10 fundus images at different locations were acquired covering a posterior pole area approximately 55 degrees in diameter. The procedure was repeated for the fellow eye. Imaging of both eyes required approximately 10 minutes per patient.

Reading center procedure

The DigiScope procedure resulted in the storage of digital data containing the images, encrypted patient information, and instrumental parameters. An algorithm automatically identified the best of each of the images acquired at each fixation location. At night, or after business hours, in the PCP office, these data were uploaded automatically to the Wilmer-EyeTel Reading Center server via a standard

phone line to which the DigiScope was connected. For each subject, the data were presented to a trained, certified reader on three monitors (Fig. 2). The three monitors allowed all images of each eye to be viewed on a separate monitor with the third monitor to view each individual image at full resolution. The reader reviewed the images for retinal pathologies, selected the nature of the pathology from a pull-down menu on the screen, and used a cursor to mark the lesion on the screen. Eyes with unreadable images were recorded as such. An eye was marked as unreadable if the image of the central macula was unreadable or absent, if more than 1 other image location was unreadable or absent, or if there was any reason pathology could not be adequately identified. In ambiguous cases, the reader transferred the DigiScope data to a separate reading center for further review by a retina specialist at the Wilmer Eye Institute (Johns Hopkins Hospital). Additionally, all urgent referrals as well as data from all patients insured by Medicare were reviewed by a retina specialist. For this study, all DigiScope data were reviewed by a retina specialist.

Criteria for referral to an ophthalmologist

Patients were nonurgently referred to an ophthalmologist in the presence of any level of retinopathy greater than mild nonproliferative

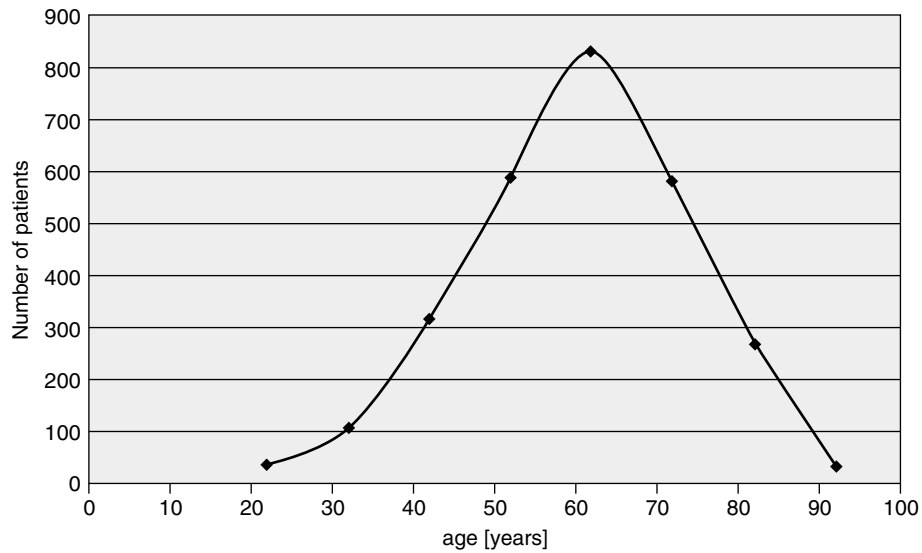


FIG. 3. Age distribution of the population screened with the DigiScope (EyeTel Imaging Inc., Columbia, MD).

diabetic retinopathy based on the International Classification of Clinical Diabetic Retinopathy and Macular Edema Severity Scale.¹⁴ Patients were urgently referred (recommendation that the patient be seen within 72 hours) to an ophthalmologist in the presence of disease felt to be vision-threatening—neovascularization of the disc or elsewhere, preretinal hemorrhage, vitreous hemorrhage, and any exudates in the central macular field suggesting macular edema. Referral (urgent or nonurgent) was also recommended for patients with other suspected pathology such as age-related macular degeneration or glaucoma based on the appearance of the macula and optic discs. Patients were automatically referred if the images were deemed unreadable.

RESULTS

During the study period from October 1, 2002 to March 31, 2003, 2771 patients with diabetes underwent DigiScope imaging in their PCP's office. The age ranged from 20 to 93 years (mean 60 years). The age distribution is shown in Figure 3. For this study, race, gender, and specifics about duration of diabetes and diabetic therapy were not determined to maintain patient confidentiality and Health Insurance Portability and Accountability Act (HIPAA)

compliance. The disposition of the 2771 patients is shown Table 1. Seventy percent of patients did not require referral while 19% were referred for pathology noted on the DigiScope images. An additional 11% of patients were referred because of unreadable images. Of the patients referred, 456 were nonurgent referrals and 72 were urgent referrals. As expected, the pathology leading to referral was overwhelmingly diabetic retinopathy.

From the group of nonurgent referrals (Table 2), 73% of patients were noted to have more than mild diabetic retinopathy. In the absence of diabetic retinopathy requiring referral, 21% of nonurgent referrals were for findings suggestive of age-related macular degeneration (AMD). Other pathologies found included disc appearance suggestive of glaucoma (2%), myopic degeneration (1%), and miscellaneous reti-

TABLE 1. READING CENTER DISPOSITION BY CATEGORY OF REFERRAL

Disposition	Number of patients	Percent of patients
No referral	1939	70
Nonvision-threatening pathology	456	16
Vision-threatening pathology	72	3
Unreadable	304	11
Total	2771	100

F3

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TABLE 2. REASON FOR NONURGENT REFERRAL DUE TO PATHOLOGY

Pathology	Percent
Diabetic retinopathy	73
AMD	21
Increased cup/disc ratio	2
Myopic degeneration	1
Miscellaneous	3
Total	100

AMD, acute macular degeneration.

nal pathologies (3%). Of the 72 urgent referrals, 94% were because of vision-threatening diabetic retinopathy including findings suggestive of proliferative diabetic retinopathy or macular edema. Findings suggestive of neovascular AMD were noted in three patients while one patient had possible optic nerve swelling.

The images were unreadable or ungradable in 11% of cases (304 patients). One office accounted for 7% of all unreadable images while the remainder of the unreadable images was evenly disturbed across the remaining sites. The reasons for poor images are not always clearly delineated and there may be several causes for each unreadable image. In many cases, the cause of an unreadable image may be inferred from the video image of the pupil included with each fundus image. Reasons for unreadable images included poor patient fixation, poor pupil centering, small pupil size, media opacity, and instrument and operator problems. It was estimated that one fourth of the unreadable images were primarily because of poor patient fixation, one fourth were primarily because of poor focus and pupil centering, and one fourth were thought to be because of small pupil size, media opacity, and instrument failure. A specific cause for the unreadable image could not be determined for the remainder. The influence of age on the rate of ungradable images was also investigated. The rate of unreadable images increased significantly above the age of 70 years (Fig. 4). Fixation problems appeared to occur with nearly equal frequency in subjects less than 70 years of age and 70 years of age or older. As expected, small pupil size and media opacity occurred more frequently in the older age group as reasons for unreadable DigiScope images.

F4

DISCUSSION

The results of this implementation study indicate that the DigiScope system can be used in the primary care setting to identify patients with diabetes not currently under the care of an eye care specialist who require referral to an ophthalmologist for evaluation and management of retinopathy. The DigiScope has been previously validated against the gold standard seven-field stereo color fundus photographs as a telemedicine tool that can be used to detect a level of diabetic retinopathy that requires referral.²⁰ With this system, referral is recommended for any patient identified as having more than mild nonproliferative diabetic retinopathy. The DigiScope is not used to grade higher levels of retinopathy or manage disease. Likewise, the DigiScope is not a substitute for a comprehensive eye examination. The DigiScope also allows detection of nondiabetic eye disease and may prove to be useful in identifying other ocular pathology requiring referral.²¹

To date, few large-scale implementation studies for diabetic retinopathy screening have been reported. The findings in this study are

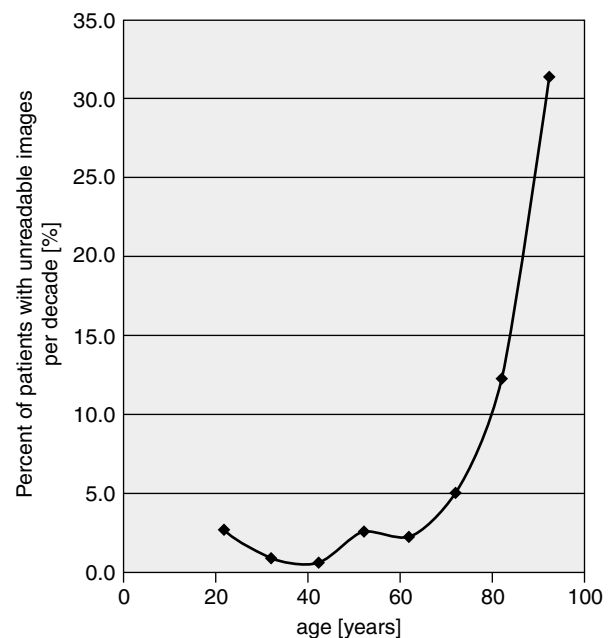


FIG. 4. Percent of patients with unreadable images per decade. For each decade, the ratio between the numbers of patients with unreadable images over the population whose age is in the decade was calculated. Note the dramatic increase at the 7th decade of age.

T3

comparable to results reported in smaller series evaluating diabetic retinopathy screening systems (Table 3). The age distribution in this study cohort is comparable to that of the adult diabetic population. This similarity is interesting because our cohort does not include patients who are under the care of an ophthalmologist or those who do not visit a primary care physician.

The rate of referral for diabetic retinopathy in this study (20%) is similar to other studies (10%–19%).^{7–11} The dominant reason for referral (87%) in this study was, as expected, diabetic retinopathy. Ocular pathology other than diabetic retinopathy was also identified with the DigiScope. The most common reason for referral in eyes without diabetic retinopathy was for findings suggestive of AMD (21% of all referrals). Other pathology resulting in referral included an enlarged cup-to-disc ratio or optic disc asymmetry suggestive of glaucoma, myopic degeneration, and other miscellaneous pathology. Although a separate study is required to validate referrals for nondiabetic pathology, these referrals were likely justified because they were based on unequivocal findings such as drusen and optic disc appearance.

Because the DigiScope images are not reviewed stereoscopically, there may be a concern that patients with macular edema may not be detected with this imaging modality. Any patient noted to have hard exudates in the central macular field, or within one disc diameter of the center of the macula, was identified as having a “marker for macular edema” and urgent referral for possible vision-threatening pathology was recommended. Based on a screening approach described by Bresnick and collaborators,⁴ such criteria have a sensitivity of 94% for detection of clinically significant macular edema. Additionally, because clinically significant macular edema is likely to be accompanied by other lesions of diabetic retinopathy that will trigger referral with this system, one can expect that very few cases of macular edema will be missed using the DigiScope and our referral criteria.

One of the concerns when using fundus photography outside of the eye care arena has been the potential for a large proportion of unreadable images. In this study, 11% of patients yielded unreadable DigiScope images. This relatively low rate indicates that the DigiScope and its operation by nonophthalmic staff can

TABLE 3. COMPARISON WITH OTHER STUDIES

<i>Authors</i>	<i>Imaging system/ dilation</i>	<i>Cohort size/ age in years (median)</i>	<i>Exclusion of criteria</i>	<i>Referral for ungradable images % of patients</i>	<i>Referral for pathology % of patients</i>
Massin et al. ¹⁰	Topcon TRC-NW6S ^a Nonmydriatic	74 patients 25 to 74 (52)	Previous laser, vitrectomy, vitreous hemorrhage, retinal detachment, blindness	11	16
Shiba et al. ¹¹	Topcon TRC-NW5S ^a Nonmydriatic	94 patients 39 to 70 (56)	>71 years, cataract, previous laser treatment, PDR	12	Not available
Cavallerano et al. ⁷	Topcon TRC-NW5S ^a Nonmydriatic	525 patients 18 to 88 (49)		13	27
Liesenfeld et al. ⁸	Topcon TRC 50X ^a	129 patients 47 ± 18	Laser treatment, retinal detachment, blindness, mature cataract, glaucoma	5	10
Fransen et al. ⁹	Zeiss FF450 ^b Mydriatic	307 patients 72% > 49 years	5% with ungradable film photographs	7 + (≤5)	19
Current	DigiScope ^c Mydriatic	2771 patients 20 to 93 (60) 83% > 49 years	Eye examination within 1 year	11	19

^aLathan & Phillips Ophthalmic Products, Inc. Grove City, OH.

^bCarl Zeiss Instruments, Jena, Germany.

^cEyeTel Imaging, Inc., Columbia, MD.

successfully produce useful fundus images. The number of ungradable images in this study is similar to the percentage of ungradable images reported by other diabetic retinopathy assessment systems (Table 3), in particular those utilizing nonophthalmic personnel to capture images.⁷⁻¹¹ In this study, the incidence of ungradable images was found to increase rapidly with age, resulting in a higher total rate of referral for older patients. It should be noted that the total number of subjects above the age of 70 years was relatively small and specific conclusions cannot be made about the apparent higher referral rate in the older population. However, referral of these patients is not a drawback in a screening program because older individuals are at higher risk for ocular pathology and, ideally, should be seen by an ophthalmologist even if they do not have diabetic retinopathy. Cavallerano and collaborators found that the majority of patients (50/61 patients) who were referred because of unreadable images actually had ocular disease that would have resulted in referral if adequate images had been obtained.⁷

The current protocol for DigiScope imaging utilizes pharmacological pupil dilation in order to increase the proportion of gradable images. A significantly higher rate of ungradable photographs through undilated versus dilated pupils has been reported.¹⁷ Patients with diabetes may have smaller pupils and a greater incidence of cataracts which may limit image quality if performed through an undilated pupil. Pupillary dilation is associated with a very small risk of angle-closure glaucoma, an acute and severe elevation of the intraocular pressure resulting from obstruction of the outflow angle of the eye. The risk of inducing angle-closure glaucoma with pupillary dilation using only 0.5% tropicamide, as was used in this study, is minimal with no reported cases in a large meta-analysis of published data.²² In this study of nearly 3000 patients, there were no reported cases of angle-closure glaucoma because of pupillary dilation for DigiScope imaging. Nevertheless, the primary care physician and staff in whose office the DigiScope is being used must be familiar with the symptoms of angle-closure glaucoma and know to refer patients with such symptoms for immediate

treatment. Part of the staff training prior to implementation of the DigiScope in a PCP's office includes verbal instruction and written material on recognition of the signs and symptoms of angle-closure glaucoma.

The advantages of the DigiScope imaging system are ease of use (minimal training required), convenience (located in PCP's office), and the ability to detect diabetic retinopathy at a level requiring referral to an ophthalmologist. While cost effectiveness was not a part of this study, this telemedicine diabetic retinopathy assessment system appears to be economically viable when imaging as few as one patient with diabetes per day in each office because the business model is based on placing the instrument in PCP's offices for nominal set-up and maintenance fees rather than actual hardware acquisition by the PCP. One of the most important outcomes of the implementation study is the fact that 70% of the patients with diabetes screened did not require referral. Because these patients were screened with the DigiScope indicates that the patients in this cohort had not been seen by an ophthalmologist in the past year. With the DigiScope, an overall increase in the number of patients with diabetes being screened for diabetic retinopathy may be achieved with the goal of reducing rates of vision loss. This study was not designed to determine whether patients for whom referral or urgent referral was recommended actually underwent an evaluation by an ophthalmologist. However, a report indicating the presence of diabetic retinopathy or other ocular pathology may be a strong incentive for patients to seek ophthalmic care. This study also did not evaluate whether DigiScope implementation in a primary care setting results in the unwanted consequence that patients receiving the recommended eye care would elect to have a DigiScope evaluation in lieu of returning to their ophthalmologist. Additional follow-up studies are necessary and are planned in order to evaluate the DigiScope fully as a diabetic retinopathy assessment tool and to address these issues.

The DigiScope has been successfully integrated into numerous primary care sites as a means to increase compliance with recommendations for diabetic retinopathy screening and

a large number of patients have been screened. This study demonstrates that the validated DigiScope protocol provides a useful telemedicine tool to triage patients with diabetes into an appropriate eye care program.

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Under an agreement between EyeTel Imaging and the Johns Hopkins University, Dr. Zeimer is entitled to a share of sales royalty received by the University from EyeTel Imaging. Dr. Zeimer and the University own EyeTel Imaging stock, which under University policy, cannot be traded until 2 years after the first sale of FDA-approved products related to the research described in this manuscript. The terms of this agreement have been reviewed and approved by the University in accordance with its conflict of interest policies.

Dr. Ingrid Zimmer-Galler is a consultant and member of the Scientific Advisory Board for EyeTel Imaging.

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