A Telemedicine Program for Diabetic Retinopathy in a Veterans Affairs Medical Center—the Joslin Vision Network Eye Health Care Model

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RESEARCH TEAM

- PURPOSE: To extend access to diabetic eye care and characterize the extent of diabetic retinopathy {DR) and other ocular findings using the Joslin Vision Network (JVN).
- DESIGN: Retrospective observational cohort study.
- METHODS: Outpatients at the Togus VA Medical Center with diabetes mellitus, impaired fasting glucose, or impaired glucose tolerance underwent JVN protocol imaging. Images were transmitted to the Joslin Diabetes Center for grading and recommended treatment plan.
- RESULTS: The study included 1,219 patients (2,437 eyes); 1,536 eyes (63.0%) had no (DR), 389 (16.0%) had mild nonproliferative DR (NPDR), 105 (4.3%) moderate NPDR, 35 (1.4%) severe NPDR, 20 (0.8%) very severe NPDR, and 21 (0.9%) had proliferative DR (PDR). Regarding diabetic macular edema (DME), 1,907 eyes (78.3%) had no DME, 34 (1.4%) had early DME, and 16 (0.7%) had clinically significant macular edema

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(CSME). Of all patients, 354 (29.0%) had either no DR or mild NPDR in both eyes, no evidence of DME, and no significant nondiabetic findings; 679 (55.7%) had no DR in either eye, and 229 (18.8%) had mild NPDR in the more severe eye. Of the 908 patients (74.5%) with either no DR or mild NPDR in the more severe eye, 533 (58.7%) had at least one nondiabetic ocular finding necessitating referral. Finally, 320 eyes (13.1%) were ungradable for both DR and DME and 160 (6.6%) were ungradable for DME alone.

• CONCLUSION: In a non-ophthalmic setting, JVN identifies the severity of DR and nondiabetic ocular conditions, permitting appropriate triage for eye care. (Am J Ophthalmol 2005;139:597–604. © 2005 by Elsevier Inc. All rights reserved.)

IABETIC RETINOPATHY (DR) IS A LEADING CAUSE of acquired vision loss in the United States and other developed countries.¹ Despite demonstrated methods of reducing the risk of vision loss from diabetes mellitus (DM), approximately 40% of the U.S. diabetic population does not receive an eye examination according to American Diabetes Association guidelines, and only 60%^{2,3} of patients who would benefit from sight-saving laser surgery are accessed into patient care programs. Persons with DM too often fail to have eye care at recommended rates.

The Joslin Vision Network (JVN) is a validated, nonmydriatic digital-video retinal imaging telemedicine platform designed to facilitate access of patients with DM into a chronic disease management program involving eye care and diabetes care (Joslin Diabetes Eye Health Care Model).^{4–6} The JVN also has the potential to contribute to the overall diabetes education of the

TABLE 1. Clinical Level of Diabetic Retinopathy and Approximate ETDRS and International Classification Equivalent Levels

| Clinical Level of DR | ETDRS Level of DR (11) | International Classification of DR (21) |
|----------------------|------------------------|---|
| No apparent | Level 10: DR absent | No apparent DR |
| DR | | |
| Mild NPDR | Level 20; very mild | Mild NPDR |
| | NPDR | |
| Moderate | Levels 35, 43, 47; | Moderate NPDR |
| NPDR | moderate NPDR | |
| Severe | Levels 53A-D; | Severe NPDR |
| NPDR | severe to very | |
| | severe NPDR | |
| Very Severe | Level 53E; very | |
| NPDR | severe NPDR | |
| PDR | Levels 61, 65, 71, | PDR |
| | 75, 81, 85; PDR, | |
| | high-risk PDR, | |
| | very severe or | |
| | advanced PDR | |

DR = diabetic retinopathy; ETDRS = Early Treatment Diabetic Retinopathy Study; NPDR = nonproliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy.

patient. Diagnosis of clinical level of DR and appropriate referral to retinal specialist ophthalmologists based on grading of JVN images compares favorably with gradings using Early Treatment Diabetic Retinopathy Study (ETDRS) seven standard field 35-mm stereo color slides⁴ and retinal examination by retinal specialists through dilated pupils.⁷ Accurate determination of clinical level of DR (Table 1) provides the foundation of clinical eye care guidelines promulgated by the American Diabetes Association⁸ and other organizations, ^{9,10} and adherence to these guidelines substantially reduces the risk of vision loss.

The Togus Veterans Affairs Medical Center (VAMC), the central medical facility for veteran services in Maine, provides comprehensive primary, specialty, and preventive care in an outpatient setting. The JVN program at Togus VAMC is designed to facilitate access to quality diabetes eye care that complies with VA guidelines for annual retinal examination for persons with DM and allows prioritization of patients for comprehensive eye evaluation.

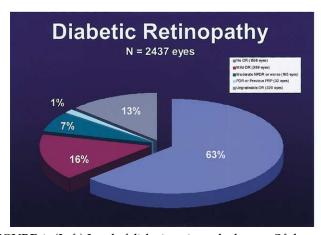
DESIGN

THIS REPORT IS A RETROSPECTIVE OBSERVATIONAL COhort study that presents a clinical diabetes eye care model using the Joslin Vision Network (JVN) digitalvideo retinal imaging telemedicine system within the Togus VAMC outpatient clinics to access patients into the VA diabetes eye care program and to provide appropriate standardized management and follow-up care. The JVN technology was used to characterize the level of diabetic eye disease and other pertinent nondiabetic ocular findings in the series of patients diagnosed with type 1 or type 2 DM or impaired glucose tolerance (IGT) or impaired fasting glucose (IFG).

METHODS

THE JVN DIGITAL-VIDEO RETINAL IMAGING SYSTEM IS THE enabling technology for the Joslin Diabetes Center Eve Health Care Treatment telemedicine program and has been described previously.6 As part of the Joslin, Department of Defense, and Department of Veterans Affairs Telemedicine Diabetes Detection and Care and Treatment Project (Cooperative Agreement DAMD 17-98-2-8017 for the Joslin/Department of Defense/Department of Veterans Affairs Program), the JVN was deployed in the outpatient clinic at the Togus, Maine, VAMC to access patients with DM in need of eye examination, assess the level of DR in these patients, and recommend a treatment plan and follow-up care. A series of 1,219 consecutive patients (2,437 eyes) diagnosed with DM, IFG, or IGT were examined according to the JVN protocol between March 2001 and April 2002. No enrolled patients were excluded, even if they had small pupils, media opacities, orbital or periorbital abnormalities, or preexisting ocular or systemic conditions. Patients were from dispersed geographic areas in Maine and scheduled for medical or other nonophthalmic appointments at the Togus VAMC. Most were overdue for their annual eye examination, and some had findings, symptoms, or complaints deemed by medical providers to warrant referral for eye examination. Based on the retrospective nature of this study, the number of patients referred to imaging based on patient history, symptoms, or examination findings is undetermined. Before arrival for scheduled nonophthalmic appointments, patients were contacted by the image acquisition specialist/ patient care coordinator who explained the imaging procedure and arranged a time for imaging before the scheduled medical appointment.

A certified JVN image acquisition specialist used a Topcon TRC-NW6S digital retinal camera to obtain nonmydriatic, nonsimultaneous stereoscopic retinal images of three 45-degree fields and an external image of each eye according to JVN protocol.^{4–6} This protocol allows readers to evaluate retinal disease posterior to the retinal equator, including the optic nerve head and the macula. Additional images or retinal fields were obtained if the imager observed a lesion outside of the defined JVN fields or felt that additional information would be of benefit to the image review specialists. Following imaging, basic education relating to causes



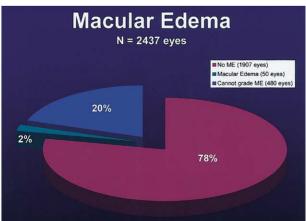


FIGURE 1. (Left) Level of diabetic retinopathy by eye. Of the total sample, 79% of eyes demonstrated no or mild nonproliferative diabetic retinopathy (NPDR) and would possibly be followed by Joslin Vision Network imaging annually; 8% of eyes had moderate or worse NPDR or proliferative diabetic retinopathy (PDR) and were identified as suggesting more prompt comprehensive eye evaluation; and 13% of eyes were ungradable for diabetic retinopathy and were also referred for prompt comprehensive retinal evaluation. (Right) Diabetic macular edema (ME) by eye. Of the total sample, 78% of eyes had no diabetic ME, suggesting possible deferral of comprehensive retinal evaluation, and 2% had diabetic ME, suggesting referral for comprehensive retinal evaluation; 20% of eyes were ungradable for diabetic ME and were also referred for prompt comprehensive retinal evaluation.

and prevention of diabetes-related eye complications and vision loss was provided to each patient. The imager performed initial triage while photographing each patient. If a potentially urgent condition was noted during imaging, the JVN reading center in Boston, Massachusetts, was contacted for immediate image review before dismissing the patient. The patient was referred immediately to the Togus eye clinic or other service for an evaluation if the JVN reader considered the retinal findings urgent.

The images from all studies were transmitted electronically to the JVN Reading Center at the Beetham Eye Institute (BEI) of the Joslin Diabetes Center in Boston. Certified image review specialists (readers) graded all case studies. The reader promptly contacted the imager on detection of any unexpected urgent ocular or systemic findings. All images were reviewed by the end of the next business day. Reader-generated reports that included diagnosis of level of DR and diabetic macular edema, identification of nondiabetic ocular disorders, and treatment plan based on these findings, patient history, and interval since last eye evaluation were electronically transmitted to the imager/patient care coordinator at Togus VAMC. These reports were then forwarded to each patient's referring physician or other provider, and patients were prioritized into the Togus VAMC eye or medical care program. If the distribution of retinopathy suggested systemic disease other than DM, the primary care provider was alerted immediately to the results via electronic transmission, telephone, or a hard copy of the report.

The JVN images were graded stereoscopically for clinical level of DR and diabetic macular edema (DME) according to standardized JVN guidelines.^{4–6} Other

ocular, retinal, and choroidal disorders were also recorded. Images were deemed ungradable for level of DR if photographic quality, obscuration from cataract, vitreous hemorrhage (VH), or other abnormality made it impossible to determine the presence or degree of a lesion. In accordance with the JVN protocol, if at least three disk areas of a retinal quadrant were visible in a photographic field and the area was free of a lesion, the lesion was graded absent rather than ungradable. Cataract was determined by observation of the pupillary red reflex, decreased clarity of retinal images without suspicion of other causes of media opacity such as VH or corneal opacification, or both. After detailed review of each retinal image, readers populated the JVN clinical

| TABLE 2. Togus VA Patient Demographic Information | 1 |
|---|---|
| (N = 1.219) | |

| Women/Men | 13/1,206 |
|-----------------------------------|-----------------|
| Average age | 63.2 years |
| Median age | 64.0 years |
| Age range | 28-87 years |
| Patients with DM | 1,162 |
| Type 1 DM*/type 2 DM | 45/1,117 |
| Average duration of diagnosed DM | 7.9 years |
| Median duration of diagnosed DM | 6.0 years |
| Range of duration of diagnosed DM | 1 week-46 years |
| Patients with IGT/IFG | 57 |

 ${\sf DM}={\sf diabetes}$ mellitus; ${\sf IGT}={\sf impaired}$ glucose tolerance; ${\sf IFG}={\sf impaired}$ fasting glucose; ${\sf VA}={\sf Veterans}$ Affairs.

*Using onset of DM at or before age 40 years and insulin use as an operative definition for type 1 DM.

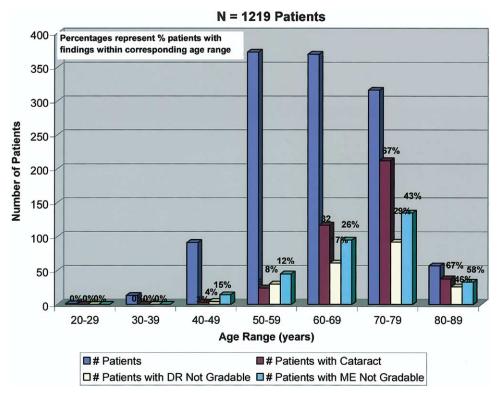


FIGURE 2. Percentage of patients in each age group and percentage of each age group with ungradable diabetic retinopathy (DR) and ungradable macular edema (ME) with presence of cataract. The largest percentage of patients with ungradable images are in the 50- to 80-year-old range. Images ungradable for level of diabetic retinopathy and diabetic macular edema were likely when there was associated cataract.

findings template and computer-generated algorithms calculated the level of DR and DME based on a modified ETDRS classification¹¹ (Table 1).

Data were analyzed to quantify the number of eyes with each clinical level of DR and DME. Additionally, a level of DR was assigned to each patient based on the more severe level of DR and DME when comparing the two eyes, and recommended follow-up was based on the more severe level (Figure 1), For purposes of patient referral and data analysis, an ungradable field was considered a more severe finding than an eye with no DR, mild nonproliferative diabetic retinopathy (NPDR), moderate NPDR, or evidence of prior scatter (panretinal) laser photocoagulation with quiescent proliferative diabetic retinopathy (PDR). Inability to grade images is considered a pertinent positive finding because a high level of pathology has been identified in ungradable JVN images in previous reports.7 In contrast, severe NPDR, very severe NPDR, or PDR was considered a more severe finding than an ungradable field. A diagnosis of DME or clinically significant macular edema (CSME) was considered a more severe finding than an inability to grade macular thickening. Additionally, the presence of significant, referable nondiabetic ocular findings correlated with each level of DR.

RESULTS

BETWEEN MARCH 2001 AND APRIL 2002, 1,219 TOGUS VAMC patients participated in JVN imaging. Patient characteristics are summarized in Table 2. As anticipated, because of the age and nature of the veteran population, participants were predominantly men (98.9%) and had type 2 DM (91.6%) using as an operative definition of onset of DM after 40 years of age.

Of a total of 2,437 eyes evaluated for retinopathy (one prosthetic eye was excluded), 1,536 eyes (63.0%) had no evidence of DR, 389 (16.0%) had mild NPDR, 105 (4.3%) had moderate NPDR, 35 (1.4%) had severe NPDR, 20 (0.8%) had very severe NPDR, and 21 (0.9%) had PDR (Figure 2). There was no evidence of DME in 1,907 eyes (78.3%), whereas 34 (1.4%) had early DME, and 16 (0.7%) had clinically significant ME. Ungradable images occurred in 320 eyes (13.1%) for both levels of DR and DME, and an additional 160 eyes (6.6%) were ungradable for DME only. Cataract was observed in 179 (55.9%) of the 320 eyes ungradable for DR and DME.

Of a total of 1,219 patients evaluated, 679 patients (55.7%) had no evidence of DR in either eye, and 229 (18.8%) had mild NPDR as the most severe level of DR in either eye (Tables 3 and 4). The more severe eye in 51

TABLE 3. Level of DR, DME, and Nondiabetic Ocular Findings by Patient (N = 1,219 Patients)

| DR | Patients* (n) | Total Patients (%) | Patients* With Nondiabetic Findings (n) | Patients With Corresponding Level of DR (%) |
|-------------------------------|------------------|-----------------------|---|---|
| No DR (level 10) | 679 | 55.7 | 392 ^{†,‡} | 57.7 (392/679) |
| Mild NPDR (level 20-35) | 229 | 18.8 | 141 ^{§,∥} | 61.6 |
| Moderate NPDR (level 43-45) | 51 | 4.2 | 37 | 72.5 |
| Severe NPDR (level 53 a-d) | 21 | 1.7 | 9 | 42.9 |
| Very Severe NPDR (level 53 e) | 12 | 1.0 | 9 | 75.0 |
| PDR (level 61-71) | 14 | 1.1 | 11 | 78.6 |
| Previous PRP | 6 | 0.5 | 5 | 83.3 |
| Ungradable DR | 207 | 17.0 | 151 | 72.9 |
| ME | | | | |
| No ME | 866 | 71.0 | 497 | 57.4 |
| DME | 28 | 2.3 | 17 | 60.7 |
| CSME | 11 | 0.9 | 8 | 72.7 |
| Ungradable ME | 314 | 25.8 | 251 | 79.9 |
| | | | | |

CSME = clinically significant macular edema; DME = early diabetic macular edema, not clinically significant; DR = diabetic retinopathy; ME = macular edema; NPDR = nonproliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy; PRP = scatter (panretinal) laser photocoagulation.

*Patients with corresponding level of DR as the more severe finding when comparing two eyes. In data analysis comparing two eyes of each patient, ungradable DR is considered a more severe finding than no DR, mild NPDR, moderate NPDR, and previous PRP. Severe NPDR, very severe NPDR, and PDR are considered more severe findings than ungradable DR, DME or CSME is considered more severe findings than ungradable ME (Table 4).

[†]175 patients had cataract in at least one eye, and 100 patients had cup/disk asymmetry.

Of the 88 patients with mild DR and no other significant nondiabetic findings, 3 had DME and 6 had ungradable ME.

patients (4.2%) had moderate NPDR, in 21 patients (1.7%) had severe NPDR, in 12 patients (1.0%) had very severe NPDR, in 14 patients (1.1%) had PDR, and in 6 patients (0.5%) had evidence of previous panretinal photocoagulation

TABLE 4. Follow-up Recommendations Based on JVN Findings

| 4-12 MONTHS | 1-4 WEEKS | 1-7 DAYS |
|---------------|----------------|------------------|
| No DR | Ungradable DR | Severe NPDR |
| Mild NPDR | | Very severe NPDR |
| Moderate NPDR | | PDR |
| S/P PRP with | | |
| quiescent | | |
| PDR | | |
| No DME | Ungradable DME | DME |
| | | CSME |

Patient follow-up determined by shortest interval based on JVN diagnosis. Referable Findings Follow-up determined by severity of condition. CSME = clinically significant macular edema; DME = diabetic macular edema less than clinically significant macular edema; DR = diabetic retinopathy; NPDR = nonproliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy; PRP = panretinal photocoagulation; S/P = status post.

(PRP), presumably for PDR that was now quiescent (Tables 3 and 4; Figure 1). There was no evidence of DME in either eye in 866 patients (71.0%), whereas 28 patients (2.3%) had early DME in one or both eyes, and 11 patients (0.9%) had CSME in at least one eye. Two hundred and seven patients (17.0%) had an ungradable level of DR as the most significant finding in either eye (Table 3); of these patients, 151 (72.9%) also had at least one referable nondiabetic finding, resulting in no more than 4.6% of the overall patient population being referred without a definitive finding.

A variety of ocular disorders other than DR were observed in the Togus VAMC population (Table 5). Readers identified findings with urgent medical implications, including 23 eyes (0.9%) in 21 asymptomatic patients with suspected retinal emboli, 32 eyes (1.3%) in 20 patients with suspected renal disease or hypertension, and 7 eyes (0.3%) in 6 patients with either branch or central retinal vein occlusion.

Forty-six eyes (1.9%) in 26 patients were presumed to have a referable level of macular degeneration, 136 eyes (5.6%) in 96 patients had macular pigmentary changes or drusen, and glaucoma was suspected in 152 patients (12.5%) with cup-to-disk asymmetry and in 233 eyes (9.6%) in 135 patients with large or suspicious optic disk cupping. Twenty-nine patients (2.4%) had both cup-to-

[‡]68 patients had cataract in at least one eye, and 25 patients had cup/disk asymmetry.

[§]Of the 287 patients with no DR and no other significant nondiabetic findings, there were no cases of macular edema; 12 had ungradable MF

TABLE 5. Nondiabetic Ocular Findings in Togus Veterans Affairs Patients (N = 1,219 Patients, 2,437 Eyes*)

| | Eyes [†] | | Patients [‡] | |
|---|-------------------|------|-----------------------|------|
| Finding/Diagnosis | n | % | n | % |
| Urgent medical conditions | | | | |
| Renal/hypertensive retinopathy | 32 | 1.3 | 20 | 1.6 |
| Retinal emboli | 23 | 0.9 | 21 | 1.7 |
| Urgent ocular conditions | | | | |
| Age-related macular degeneration | 46 | 1.9 | 26 | 2.1 |
| Retinal vein occlusion | 7 | 0.3 | 6 | 0.5 |
| Preretinal hemorrhage | 2 | 0.1 | 2 | 0.2 |
| Vitreous hemorrhage | 1 | 0.04 | 1 | 0.1 |
| Traction retinal detachment | 1 | 0.04 | 1 | 0.1 |
| Additional ocular conditions | | | | |
| Cataract | 749 | 30.7 | 395 | 32.4 |
| Large/suspicious optic disk cupping | 233 | 9.6 | 135 | 11.1 |
| Cup/disk asymmetry (rule out glaucoma) | _ | _ | 152 | 12.5 |
| Macular drusen/RPE changes | 136 | 5.6 | 96 | 7.9 |
| Intraocular lens implant | 109 | 4.5 | 64 | 5.3 |
| Choroidal nevus/lesion | 107 | 4.4 | 104 | 8.5 |
| Lid lesion | 39 | 1.6 | 37 | 3.0 |
| Epiretinal membrane | 35 | 1.4 | 32 | 2.6 |
| Asteroid hyalosis | 18 | 0.7 | 17 | 1.4 |
| Miscellaneous retinal and choroidal disorders | 16 | 0.7 | 15 | 1.2 |
| Chorioretinal scar/atrophy | 14 | 0.6 | 14 | 1.1 |
| Pterygium | 13 | 0.5 | 12 | 1.0 |
| Single/isolated nerve fiber layer hemorrhage(s) | 10 | 0.4 | 10 | 0.8 |
| Optic disk hemorrhage | 7 | 0.3 | 7 | 0.6 |

RPE = retinal pigment epithelium.

disk asymmetry and large or suspicious optic disk cupping. Presumed epiretinal membrane was detected in 35 eyes (1.4%) in 32 patients. One hundred and seven eyes (4.4%) of 104 patients had a choroidal nevus. Consistent with the median age (64 years) of the patient sample, 749 eyes (30.7%) in 395 patients were observed to have cataract^{12,13} (Table 5). Other, less frequently observed retinal and choroidal disorders referred for further evaluation included retinoschisis, possible choroidal neovascular membrane, ocular histoplasmosis, and suspicious elevated pigmented choroidal lesions. Referable conditions were identified on external images in 39 eyes (1.6%) in 37 patients with lid lesions requiring further evaluation to rule out neoplasia and 13 eyes (0.5%) in 12 patients with pterygium.

Of 679 patients identified with no DR in either eye, 392 (57.7%) had at least one referable nondiabetic ocular finding (Table 3). Similarly, of 229 patients with mild NPDR as the most severe level of DR in either eye, 141 (61.6%) had at least one significant nondiabetic ocular finding. Accordingly, in the 908 patients (74.5%) with either no DR or mild NPDR as the more severe level of DR in either eye, 375 patients (41.3%) had no other signifi-

cant abnormality, whereas 58.7% had at least one nondiabetic ocular finding of a severity necessitating referral.

DISCUSSION

DIGITAL-VIDEO RETINAL IMAGING IS THE ENABLING TELE-medicine technology for the Joslin Diabetes Center Eye Health Care Model. Within this cohort of patients in a VAMC health care setting, JVN imaging served as a tool to access patients with DM into an eye care program; assess level of DR, DME, and other nondiabetic findings; determine retinal examination and associated medical care follow-up; and prioritize referral to optometrists, ophthalmologists, and other health care providers.

There are multiple benefits associated with the nonmydriatic retinal imaging program employed with JVN imaging. Obviating the need for pupil dilation is convenient for the patient, potentially safer, and allows for brief image acquisition time. Patients can be accessed spontaneously or before a nonophthalmic medical appointment. The immediate availability of digital-video images also allows the

^{*}Excludes one eye with ocular prosthesis.

[†]Some eyes had more than one finding.

[‡]Some patients had more than one finding in one or both eyes.

imager to perform initial triage and to contact the readers promptly when there are suspicious findings, while the patient is still present at the health care facility. Patient education is enhanced because a component of the JVN model includes individual image demonstration and patient education regarding the importance of timely and appropriate eye examination and optimal glycemic control. Further study is required to determine whether JVN imaging and patient education result in increased patient awareness of diabetes complications and ongoing improvement in glycemic control.

Analyses of these data reveal that, in this predominantly older male population with type 2 DM, 74.5% of patients have no DR or mild NPDR as their most severe ocular finding, of which only 41.3% also have no other significant nondiabetic ocular findings. JVN might possibly aid in deferring a comprehensive annual eye examination in this subset, thus allowing patients with more significant findings to be scheduled for timelier comprehensive eye examination and treatment.14 Studies are currently underway to determine the safety and efficacy of using JVN evaluation to defer annual examination when retinopathy and other findings are minimal or nonexistent. Similar programs involving retinal imaging by other groups using several proprietary and nonproprietary approaches are underway. Some of these studies suggest that digital mydriatic¹⁵ and nonmydriatic¹⁶ imaging techniques likewise are useful in detecting DR.

Although 74.5% of all patients in this cohort had either no DR or mild NPDR as the most severe level of DR in either eye, 58.7% of these individuals had at least one nondiabetic ocular finding of a severity necessitating referral. An additional 25.5% of patients had at least one eye with moderate NPDR or worse. Therefore, JVN imaging provides the critical function of detecting significant retinopathy as well as identifying other retinal disorders, thus reducing the number of patients that might otherwise be inappropriately deferred based solely on retinopathy findings. Further validation studies are required to determine the sensitivity and specificity of JVN imaging to detect this diverse array of nondiabetic ocular abnormalities.

Media opacities and small pupil size were commonly cited factors resulting in suboptimal image clarity. Patient discomfort or inaccurate fixation during imaging, ptosis, dermatochalasis, and strabismus were also reported. It should be noted that image quality insufficient for grading of DR or DME should be viewed as a finding indicative of the potential for significant ocular disease, as reported previously.^{4,7} The median age of this patient cohort was 64.0 years. Because ocular disease is more prevalent in an older population, it follows that significant ocular findings would be more likely in our patient cohort. It is also anticipated that the average pupil size will be smaller in an aging population,¹⁷ and it has previously been observed that pupil size is significantly smaller in diabetic vs non-diabetic patients in the dark-adapted state.¹⁸ Because both

the camera flash and the proximity of the camera lens to the eye can stimulate pupil constriction, some images may not be of optimal quality in this patient population. Figure 2 illustrates that the number of ungradable JVN images increased with patient age as did the incidence of cataract. Only 141 eyes (5.78% of total) were ungradable for level of DR for reasons other than cataract such as small pupil size, corneal opacity, lid abnormalities, vitreous opacity, or strabismus. Only 27.1% (86) of eyes ungradable for level of DR had no other significant nondiabetic ocular disease. Thus, referable ocular disease was found in nearly 73% of ungradable images, clearly reinforcing the notion that ungradable images are a marker for significant ocular disease and warrant referral for comprehensive eye examination. The JVN can therefore be effective in both accurate retinal evaluation for level of DR and patient triage to ophthalmic care for diabetic and nondiabetic ocular lesions.

Although independent confirmation of findings and diagnoses based on JVN readings was not conducted in this study, previous reports demonstrate the high concordance between management decisions based on IVN imaging, clinical examination, and fundus photography.^{4,7} JVN image analysis actually tends to diagnose level of DR that is ultimately found to be less severe. Referring patients who have ungradable images or the presence of nondiabetic eye disease further reduces the likelihood that patients with sight-threatening retinopathy will fail to receive an appropriate ocular examination. The American Telemedicine Association in its Guidelines for Ocular Telehealth for Telehealth for DR19 defines four categories of imaging ability, referenced to 35-mm seven standard field stereo photography as the accepted standard. These categories are as follows: ability to distinguish between no DR and any DR (category 1), sight-threatening DR vs no or non-sightthreatening DR (category 2), level of DR matching clinical examination (category 3), and the ability to match or surpass 35-mm seven standard field stereo photography for detailed ETDRS-style grading (category 4). The JVN imaging system provides a category 3 assessment.

In addition to DR characterization, JVN imaging identifies nondiabetic ocular findings with agreement ranging from 91.3% to 100% compared with subsequent clinical examination.²⁰

These data were obtained retrospectively and the cohort includes mostly patients overdue for eye examinations but also those directly referred for potential eye findings. Thus, some degree of ascertainment bias is possible, and how applicable these data will be to other populations including more women, people with type 1 DM, more diverse or different ethnic groups, and varying age distribution remains to be evaluated. Additional study is also required to determine the sensitivity and specificity of the JVN imaging in identifying nondiabetic ocular disease.

Nevertheless, based on these photographic findings, it is apparent that substantial ocular pathology suggest-

ing further ophthalmologic evaluation was present even in the absence of extensive DR. Thus, these data support the use of the JVN Eye Health Care Model to prioritize patients into traditional eye care programs in conjunction with appropriately timed comprehensive eye examination.

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