Original Research

Prospective evaluation of optical coherence tomography for disease detection in the Casey mobile eye clinic

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Impact statement

This was a pilot study to use a low-cost SD-OCT unit to evaluate diabetic retinopathy, glaucoma, and narrow angle in an existing community outreach mobile program and compared it to clinical examination. Data was collected in the Casey Eye Community Outreach Program Mobile Clinic, which was designed to provide free eye screenings to underserved populations. This study showed that OCT detected additional cases in all three areas compared to clinical exam in a low-risk, medically underserved, ethnically diverse population, but OCT may not be sufficient as a stand-alone screening tool. OCT of the anterior segment detected more and the majority of cases of occludable angles than clinical exam and may be an ideal tool for narrow angle screening due to its non-invasive nature and ease of use.

Abstract

This study was designed to evaluate iVue Spectral-domain optical coherence tomography (SD-OCT) effectiveness in screening for eye disease compared to clinical examination. Subjects were recruited from the Casey Eye Community Outreach Program Mobile Clinic during its routinely scheduled outreach clinics to indigent, underserved populations throughout Oregon. Macular optical coherence tomography interpretation and automated optical coherence tomography analysis were compared to the clinical examination, with specific attention to findings indicative of retinal abnormalities, risks for glaucoma, and narrow angles. As a result, a total of 114 subjects were included in this study. In diabetics, optical coherence tomography and clinical exam were in fair agreement (kappa = 0.39), with 22% of eyes having abnormal findings on macular optical coherence tomography and 26% of eyes having diabetic retinopathy or diabetic macular edema on fundus exam. In non-diabetics, optical coherence tomography and clinical exam were in fair agreement (kappa = 0.28), with 11% of eyes having abnormal findings on macular optical coherence tomography and 9% on fundus exam. Using optical coherence tomography ganglion cell complex and retinal nerve fiber layer analysis, 18% of eyes were found to be glaucoma suspects, whereas clinical exam of cup-to-disc ratio detected 8% and intraocular pressure 5%. Agreements between optical coherence tomography and other methods were poor (kappa < 0.11) for glaucoma suspect. Anterior segment optical coherence tomography of the angle found 8% of eyes to have occludable angles, whereas slit lamp and gonioscopy found 5% of eyes to have narrow angles, with moderate agreement (kappa = 0.57). In summary, optical coherence tomography detected additional retinal abnormalities, glaucoma suspects, and narrow angles compared to clinical exam alone and may serve as a useful adjunct to the clinical exam in screening for eye disease in a low-risk, medically underserved, ethnically diverse population.

Keywords: Screen, optical coherence tomography, retinopathy, glaucoma, narrow angle, diabetes

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Introduction

The prevalence of blindness and visual impairment is projected to double by 2050 in the United States, but approximately 50% of those with vision-threatening diseases remain undiagnosed and untreated.[1,2] Community eye screening programs can detect common and potentially blinding eye diseases such as diabetic retinopathy, macular degeneration, and glaucoma, all of which benefit from early treatment. The Casey Eye Community Outreach Program Mobile Clinic is an ophthalmology clinic designed to provide free eye screenings to underserved populations throughout the state of Oregon. The program uses volunteer eye doctors to provide on-site eye exams in a van equipped with basic ophthalmic equipment including a slit lamp, tonometry, and an indirect ophthalmoscope, but

not machines for visual field testing or optical coherence tomography (OCT). Advancement in diagnostic testing beg the question whether testing modality such as OCT can be a useful adjunct to detect additional cases to prevent future visual impairment.

OCT has become one of the most commonly utilized imaging procedures in the diagnosis and management of eye diseases including macular degeneration, diabetic retinopathy, and glaucoma.[3] However, it has not been widely adapted for disease screening due to several factors. The machine can be large and not transportable. It may require skilled photographers to acquire good quality images. And its diagnostic utilities were often studied in patients with single diseases rather than in the primary screening setting where multiple eye diseases are being tested for. OCT has the potential as a screening tool for several reasons. The test is easy for patients to undergo, as it is non-invasive and quick. It is inexpensive, with Medicare reimbursement at about $50, making it financially feasible to perform the test on a large population. Recently, more portable and compact OCT models have been developed, and their ability to aid community screening programs for multiple eye diseases need to be studied. This study investigates the utility of OCT as a supplemental screening tool for diabetic retinopathy, diabetic macular edema, glaucoma, and narrow anterior-chamber angle.

Materials and methods

Institutional Review Board

Institutional Review Board (IRB) approval was obtained through the Oregon Health & Science University IRB Committee, which included a waiver of consent. An information sheet for study participants containing the study protocol and its risks and benefits was submitted to the IRB and approved. This information sheet was provided to each study participant and reviewed with them.

Subjects

The Casey Eye Community Outreach Program Mobile Clinic is an ophthalmology clinic designed to provide free eye screenings to underserved populations throughout the state of Oregon. Study subjects were recruited from outreach program participants from January 2012 to October 2012, with no additional visits scheduled for this study. Self-reported information includes age, gender, history of diabetes (yes or no) and years since diagnosis, history of glaucoma (yes or no), prior ocular surgery (yes or no), and prior ocular trauma (yes or no). Each subject underwent a complete eye exam, including visual acuity, autorefraction, subjective refraction, confrontational visual fields, extraocular movements, intraocular pressure, pupil exam, slit lamp exam, and dilated fundus exam. The clinicians performing the anterior and posterior segment exams were volunteer ophthalmology faculty members and residents, not recruited for this study. Ophthalmologists were instructed to complete the exam and record their findings before reviewing any OCT images. They could use the OCT images for clinical management, but these real-time interpretations were not used for this study.

OCT and grading

A compact OCT unit, iVue spectral-domain OCT (Optovue, Fremont, CA), was chosen for screenings on the outreach van because of its portability, compact size, ease of use, and compatibility to be operated with a laptop computer. The iVue is FDA approved and capable of scanning both the anterior and posterior segments of the eye. It has a 26 kHz scan rate, a light source with a central wavelength of 840 nm, and 5-μm depth resolution. It was brought on the van and operated by a trained technician (Figure 1(a)). Anterior segment and dilated posterior segment macular and optic disc OCT scans were obtained for each eye. The macular OCT was obtained using the manufacturer's "iWellness" protocol (Figure 1(b)). The optic disc OCT was obtained using the manufacturer's "glaucoma scan" protocol (Figure 1(c)). The anterior segment angle scan is a single B-scan of the iridocorneal angle (Figure 1(d)). For all scan protocols, each type of scan was performed once, except for a repeat scan to replace the original if the signal strength index was lower than 40.

The iWellness OCT scans were read independently at a remote location by three retina specialists who were not given clinical information about the patients and did not examine the patients. The OCT provided a whole retinal thickness map and value with nine sectors (Figure 1(b)). The retinal thickness was considered abnormal if any sector was below 5% or above 95% of the manufacturer's normative database. The OCT also provided five high-definition cross-sectional images near the fovea (Figure 1 (b)). Using these images alone, the retina specialists were asked to comment on the presence or absence of the findings indicated in Table 1. If at least two out of the three retina specialists agreed, this was considered a true finding. Macular edema on OCT was decided when two or more readers agreed on the presence of retinal thickening, intraretinal fluid, cystoid macular edema, or subretinal fluid.

The glaucoma scans were analyzed using automated parameters previously described.[4] Three ganglion cell complex (GCC) variables from the iWellness macular scan (overall average, inferior hemisphere average, and superior hemisphere average thickness), and three retinal nerve fiber layer (RNFL) variables from the glaucoma optic nerve scan (overall average, inferior quadrant average, and superior quadrant average thickness) were analyzed. If any variable was below the 99th percentile of the normative database, the eye was considered a glaucoma suspect. By combining six variables, we expected to obtain 95% specificity.

The iridocorneal angle was measured by OCT using a previously described method.[5] The distance from Schwalbe's line (the termination of the corneal endothelium) to the iris, that is perpendicular to the line between Schwalbe's line and scleral spur, was measured by the technician. If this distance was less than 290 μm, it was considered occludable with specificity as high as 87%.[5]

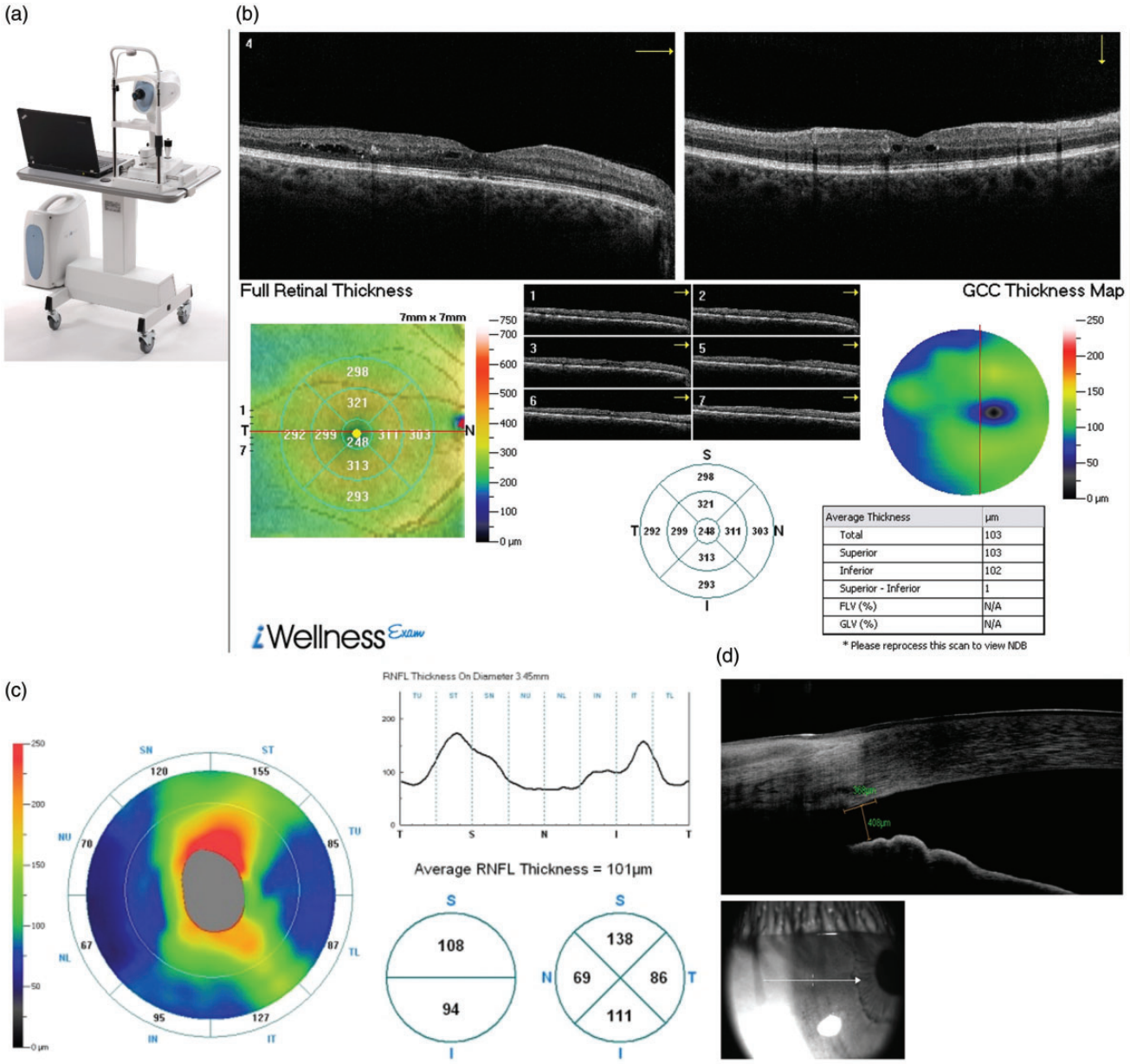

Figure 1. OCT system and scan patterns (a) the iVue spectral-domain OCT unit mounted on a wheel platform and operated using a laptop. (b) the iVue iWellness macular 6 × 6 mm scan includes macular ganglion cell complex thickness map, whole retinal thickness map, as well as superior and inferior average thickness and focal loss volume (FLV) and global loss volume (GLV). (c) the iVue glaucoma scan pattern is a 4.9 mm composite scan centered on the optic disc; it includes 13 concentric ring scans and radial scans. Its output includes average total, hemispheric, and sectoral RNFL thickness. (d) Cornea angle includes angle structure and no automatic measurements.

Table 1. Macular abnormality findings on OCT.

	Number of eyes		
Finding on macular OCT	**Diabetic eyes $n = 114$ Number of eyes (%)**	**Non-diabetic eyes $n = 114$ Number of eyes (%)**	**Total $n = 228$ Number of eyes (%)**
Retinal thickening or thinning	12 (11)	4 (4)	16 (7)
Irregular RPE	5 (4)	4 (4)	9 (4)
Intraretinal fluid	5 (4)	1 (1)	6 (3)
Hyper-reflective spots in retina	5 (4)	0	5 (2)
Photoreceptor damage	2 (2)	2 (2)	4 (2)
ERM	2 (2)	2 (2)	4 (2)
Pigment epithelial detachment	1 (1)	1 (1)	2 (1)
Ganglion cell complex thinning	0	1 (1)	1 (<0.5)
Drusen	1 (1)	0	1 (<0.5)
Vitreomacular adhesion with traction	1 (1)	0	1 (<0.5)
Preretinal hemorrhage	0	0	0
Macular hole	0	0	0
Subretinal fluid	0	0	0
Subretinal tissue	0	0	0
Total findings	34	15	49
Total number of eyes with findings	25 (22)	13 (11)	38 (17)

RPE: retinal pigment epithelium; OCT: optical coherence tomography; ERM: epiretinal membrane.

Clinic exam

Chart review was performed to record diagnosis and exam findings of diabetic eye disease (mild, moderate, to severe diabetic retinopathy with the presence or absence of macular edema), glaucoma suspect, and narrow angles. We recorded diabetic retinopathy as proliferative or non-proliferative. Glaucoma suspect was diagnosed based on notching of the disc rim, increased cup-to-disc ratio (>0.5) on fundus exam, or ocular hypertension (OHT) if intraocular pressure was greater than 21 mmHg. Narrow angles were primarily evaluated by Van Herick method at the slit lamp, as gonioscopy was performed on only three patients at the clinician's discretion. No standard angle grading method was utilized. The mobile clinic was not equipped with any other testing modalities such as fundus photo and visual field machines.

Statistics

The OCT results (combining automated analysis and specialist grading) and clinic exams were compared for agreement using Venn diagrams plus kappa,[6] McNemar test,[7] and F1-score. Given a 2×2 table with cells of true positive (TP), true negative (TN), false positive (FP), and false negative (FN), the kappa used all four cells, including both the agreement and disagreement cells; the McNemar test only used the disagreement cells, FP and FN; the F1-score measures of a model's accuracy, uses TP, FN, and FP. The three agreement measurements are related, but may have different trend depending on the balance of cells and classes. We gave all three of them; thus clinician may choose based on the cost and importance of each cell in real life. We characterized kappa values < 0 as indicating no agreement and 0–0.20 as slight, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1 as almost perfect agreement.[8] McNemar $p < 0.05$ means one method is significantly sensitive than other methods. F1-score close to 1 means good agreement. The statistical analysis was done with Matlab (MathWorks, Natick, MA).

Results

Of the 118 subjects enrolled in the study, four were excluded from incomplete clinical exams, and two from incomplete or poor-quality OCT imaging. The remaining 114 subjects had the following demographics: the average age of the 114 subjects was 45.5±12.0 years, with 36% being female and 74% being male. The race/ethnicity of the subjects was as follows: 40% white, 36% Hispanic or Latino, 8% black or African American, 6% American Indian or Alaskan Native, 3% Asian, and 3% more than one race, and 5% no response/declined to answer. Fifty-seven participants (50%) reported a history of diabetes, with an average disease duration of 8.0±7.1 years. The average logMAR visual acuity (VA) in the better-seeing eye was 0.12±0.22, equivalent to Snellen VA of 20/26. In the worse-seeing eye, the average logMAR VA was 0.20±0.27, equal to Snellen VA of 20/32.

Retinal abnormality

Thirty-nine (34.2%) diabetic eyes and 19 (16.7%) non-diabetic eyes had abnormal retinal findings based on either clinical exams or OCT. Among patients with diabetes, 28 eyes (16 patients) had diabetic retinopathy based on clinical exam, and 25 eyes (14 patients) had retinal abnormality based on OCT images; 11 eyes were diagnosed by OCT alone without clinical exam confirmation, and 14 eyes were diagnosed on the clinical exam alone without OCT findings (Figure 2(a)). The most common abnormality on OCT was retinal thickening and thinning among diabetic patients (Table 1). The agreement between the OCT and clinical findings was fair (Table 2, kappa = 0.39). Among the 11 diabetic patients who had findings on OCT only, nine had macular edema that was not identified on clinical

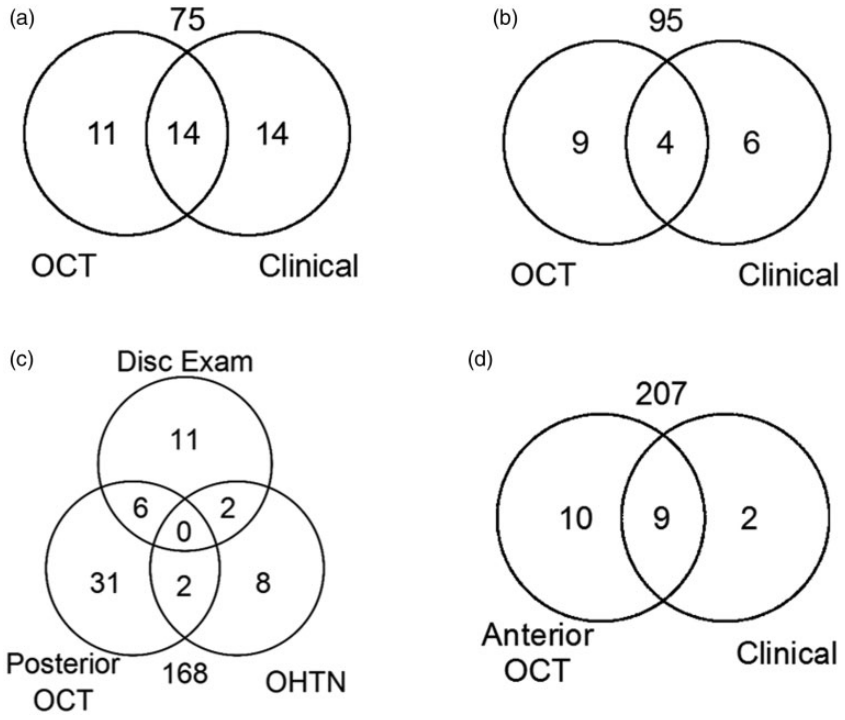

Figure 2. Rates of diagnoses between OCT and clinical exam for (a) diabetic eye disease (including diabetic retinopathy and diabetic macular edema), (b) retinal abnormality in non-diabetic patients, (c) glaucoma suspect, and (d) narrow angle. OHTN: ocular hypertension.

Table 2. Agreement test between clinical exam and OCT.

Abnormality	Kappa	McNemar Test p-Value	F1-Score
Retinal abnormality in DR eyes	0.35	0.85	0.52
Retinal abnormality in non-DR Eyes	0.28	0.61	0.35
Retinal abnormality in all eyes	0.35	0.76	0.47
Glaucoma abnormality in all eyes (OCT vs. disc exam + ocular hypertension)	0.10	0.21	0.24
Glaucoma abnormality in all eyes (OCT vs. disc exam)	<0.01	<0.01	0.08
Glaucoma abnormality in all eyes (OCT vs. ocular hypertension)	0.11	<0.01	0.21
Narrow angle abnormality in all eyes	0.57	0.04	0.60

DR: Diabetic retinopahty; OCT: optical coherence tomography.

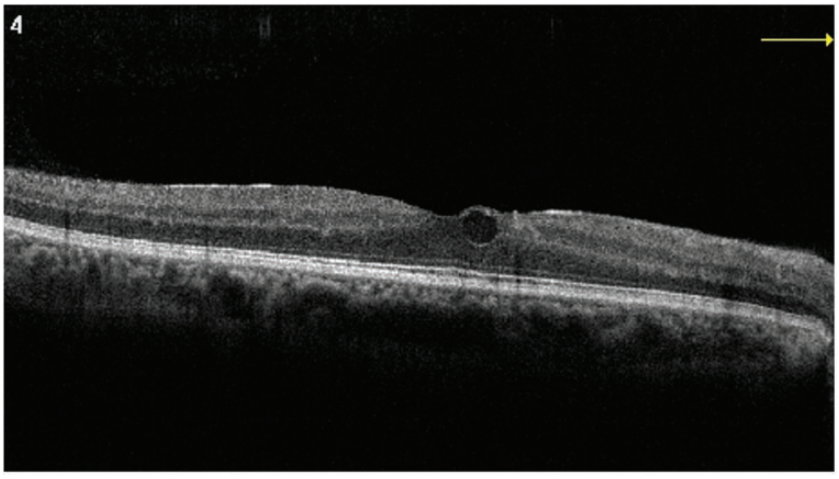

Figure 3. An example of diabetic macular edema found only on OCT and not on clinical exam. The OCT shows loss of the foveal contour and the presence of a single intraretinal cyst. Clinical exam revealed moderate to severe non-proliferative diabetic retinopathy without clinically significant macular edema. Best-corrected visual acuity was 20/25.

exam. Figure 3 demonstrates an example of subclinical macular edema found on OCT and not on clinical exam. Among the 14 eyes with only diabetic retinopathy findings on clinical eye examination but not on OCT, all except one had mild non-proliferative diabetic retinopathy or background diabetic retinopathy.

Among patients without diabetes, 10 eyes (six patients) had abnormal retinal finding based on clinical exam, and 13 eyes (10 patients) had retinal abnormality based on OCT finding; nine eyes were diagnosed by OCT alone without clinical exam confirmation, and six eyes were diagnosed on the clinical exam alone without OCT confirmation (Figure 2 (b)). The most common finding on OCT was retinal thickening/thinning and irregular RPE, while the most common findings on clinical exam were chorioretinal scars, epiretinal membrane, and early macular degeneration (Table 1). The agreement between OCT and clinical exam was fair (Table 2, kappa = 0.28). For the macular OCT reading for all eyes, the agreement among the three retinal specialists ranged from fair to moderate (kappa =0.31–0.54).

Glaucoma suspect. A total of 60 eyes (26.3%) were diagnosed as glaucoma suspects: 19 by disc exam, 12 by intraocular pressure, and 39 by OCT. Thirty-one eyes were diagnosed by OCT alone, 11 by disc exam alone, and 9 by ocular hypertension alone (Figure 2(c)). No eyes were diagnosed as glaucoma suspect by all three methods. Agreement between OCT and disc exam was very poor (Table 2, kappa < 0.01). OCT detects significantly more cases than either OHT or disc exam alone (McNemar, $p < 0.01$) but not the combination of disc exam and OHT (McNemar, $p = 0.21$).

Narrow angles. A total of 21 eyes (10.9%) were diagnosed with narrow angle, with 11 by clinical exam and 19 by anterior segment OCT (Figure 2(d)). Among the 11 eyes with narrow angle by clinical exam, nine were by Van Herick method on slit lamp exams and two were by gonioscopy at the clinicians' discretion. Nine eyes were diagnosed by both clinical exam and anterior OCT, but 10 eyes were diagnosed by only OCT and not clinical exam, while only two eyes were diagnosed by clinical exams (Van Herick method) and not OCT (Figure 2(d)). Agreement between OCT and disc exam was moderate (Table 2, kappa = 0.57). OCT detected significantly more eyes with narrow angles than clinical exam (McNemar, $p = 0.04$).

Discussion

This study evaluated the rate of disease detection of three types of ocular conditions using iVue SD-OCT system compared with the clinical exam in a community outreach screening program. The program found a high prevalence of retinal abnormality among diabetic patients and glaucoma suspects (27.3% and 26.3%), followed by retinal abnormalities in non-diabetic subjects (16.7%) and narrow angle (10.9%). The prevalence in our study was higher than the national average, likely due to the at-risk screening population. Adding OCT testing detected additional glaucoma suspect, narrow angle, and retinopathies among diabetic and non-diabetic subjects that were not picked up by clinical exams. In fact, OCT alone detected half of the glaucoma suspect not caught by disc exams or tonometry. OCT also detected narrow angles in all but two cases diagnosed on clinical exam. This is the first study using this model of compact OCT system to screen for retinopathy, glaucoma, and narrow angles.

In retinopathy screening, OCT and clinical exam detected equal number of eyes with abnormality in diabetic patients, with about 1/3 by OCT alone, 1/3 by clinical exam alone, and 1/3 with both modalities. OCT was better at detecting diabetic macular edema and retinal thickening. The clinical exam was better at detecting intraretinal hemorrhage, microaneurysms, venous beading, and intraretinal microvascular abnormalities. The clinical exam was also better at examining the peripheral retina and detecting findings outside the area scanned by OCT. While retinal abnormalities found on OCT alone may have subclinical visual significance at the time of screening, it provides evidence of retinopathy that may allow an opportunity for early intervention before visual impairment occurs. OCT and clinical exam likely complement each other and are both needed to detect retinal abnormalities.

For glaucoma suspect, OCT alone detected 65% (39 eyes) of the cases, and OCT detected an additional 31 eyes that were not picked up by clinical exam or intraocular pressure. Studies have found that glaucoma screening using intraocular pressure missed 50% of the cases,[1,9–11] and optic nerve exam by glaucoma specialists have poor agreements.[12] Previous study has found the iVue SD-OCT model to have high sensitivity (0.96) and specificity (0.90) for glaucoma and can be performed by non-expert personnel in undialed eyes.[13] Another study comparing detection between frequency doubling technologies (FDT) visual field testing and iVue OCT found that OCT performed significantly better than FDT.[14] In an outreach screening program without the equipment or capacity for fundus photography or visual field testing, OCT is likely to detect glaucoma not otherwise apparent on clinical exam.

Anatomical narrow angle is a risk factor for angle closure glaucoma, which has found to be more severe and visual impairing than the more common primary open angle glaucoma. Gonioscopy, the gold standard exam for narrow angle, requires a skilled ophthalmologist to perform, and screening efforts using gonioscopy are impractical. Our study showed the highest moderate agreement between OCT and clinical exam in the detection for narrow angle. OCT detected the majority of narrow angle cases found on clinical slit lamp exam, and OCT diagnosed an additional 10 eyes not caught on clinical exams. However, we did not perform the gold-standard gonioscopy to confirm the diagnosis. Van Herick test of <25% was found to have similar sensitivities but higher specificity than anterior segment OCT from a Cochrane review.[15] However, in our outreach program, the van Herick test grading was not standardized and did not describe the percentage of narrowing. Prior studies have found high reproducibility of the angle assessment using iVue OCT as well as between different OCT machines.[16] OCT evaluation of the angle could be a useful screening tool because it does not require a skilled

ophthalmologist to perform the gonioscopy exam and its non-contact nature improves patient acceptance and comfort. It can be beneficial in populations with a higher prevalence of angle closure where screening for occludable angles and subsequent referral for treatment such as laser peripheral iridotomy could effectively prevent blindness.

The agreement of OCT retinal findings between the three retinal specialists was at best moderate. This level of agreement may suggest that OCT interpretation remotely without clinical context or associated fundus exam can be challenging. Previous studies have shown a higher correlation between multiple remote OCT readers.[17,18] Training and standardization for OCT interpretation may improve the inter-observer agreement. This study has several limitations. First, this study was not a clinical trial specifically designed to evaluate the diagnostic powers of OCT. Instead, it assessed the additional case detection found by a compact OCT system in an existing community outreach program run by volunteer ophthalmologists. The volunteer ophthalmologists' different levels of training, varied subspecialties, and the lack of standardized exam and recording protocols likely contributed to inconsistency in the clinical exam findings. Second, we did not confirm diagnosis after the referrals were made to obtain the sensitivity and specificity of each diagnostic modality. The doctors on the outreach van provided referral for follow-up care if needed. Still, the results from full assessment by a specialist or comprehensive eye provider was not available to us. Therefore, it is unknown if the additional OCT testing indeed increased diagnostic sensitivity or merely increased the FP rate. Thirdly, the OCT testing and data analysis was done in 2012–2013, and there have been significant advancements in OCT technology since then. The original iVue model has a scanning speed of 26,000 Hz. Most current OCT machines across different manufacturers have scan speeds between 50,000 and 100,000 Hz. It is generally accepted that higher speed OCT reduces testing time and is better tolerated by patients. It also makes high density 3D volumetric scan possible, which enhances the detection of anatomic abnormalities. Newer high-speed platforms also incorporate OCT angiography, which greatly improves the detection of vascular abnormalities.[19–24] Image segmentation and quantification algorithms have generally improved over the years. However, there is still a need to develop artificial intelligence algorithms to detect and classify pathologies on OCT images to perform referral decisions in real-time without expensive human clinicians on site.

Portability of the OCT system is critical in screening with OCT. For example, the OCT system in this study was considered because it was compact enough to set into the van. Besides portability, it is also crucial for screening OCT to have the availability of automated acquisition software to assist operators with relatively low levels of training. Several low-cost portable OCT machines have been developed, but the lack of automated scanning and software programs for disease detection makes them challenging to perform eye screening in a population setting. Several commercially available, relatively compact OCT models (i.e. iScan from Optovue, USA, and Maestro2 from Topcon, Japan) are equipped with fully automated scanning and verified diagnostic software. Studies using these OCT machines are needed to determine their utility in eye screening programs.

Comprehensive eye screening studies on OCT have been surprisingly sparse in the literature, as studies tend to evaluate diseases separately. In diabetic retinopathy, OCT is thought to improve diagnostic accuracy, particularly in macular edema while reducing cost,[25–27] although a study found no additional benefit by adding a portable OCT (Maestro, Topcon, Japan) to fundus photo in an Aboriginal screening program.[28] In glaucoma, studies showed that a newer iVue model and a fully automated OCT-I Maestro (Topcon Corp., Tokyo, Japan) were able to achieve higher sensitivities and specificities,[13,29] but the findings have not been confirmed in populational screening. Studies on angle assessment using OCT are limited, and no screening studies have been found using OCT from a literature review.

In conclusion, remote OCT reading can detect additional retina pathologies, glaucoma suspect, and narrow angle beyond clinical exams in a community outreach screening program, but it is not a sufficient standalone tool for screening. Further work is necessary for assessing OCT as a screening tool for eye disease.

AUTHORS' CONTRIBUTIONS

OT, YL, DH, and MFC designed the study. OT, AC, and DH wrote the article and all coauthors critically commented and/or edited the article. DH supervised the project. SB, TH, and AL did the OCT reading on retina. YL did the OCT reading on anterior chamber.

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DECLARATION OF CONFLICTING INTERESTS

Oregon Health & Science University (OHSU), Dr. Huang, Dr. Tan and Dr. Li have significant financial interests in Optovue, a company that may have a commercial interest in the results of this research and technology. These potential conflicts of interest have been reviewed and managed by OHSU.

ETHICAL APPROVAL

IRB approval (IRB00008038) was obtained through the Oregon Heath & Science University IRB Committee, which included a waiver of consent. An information sheet for study participants containing the study protocol and its risks and benefits was submitted to the IRB and approved. This information sheet was provided to each study participant and reviewed with them.

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