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The Impact of OCT on Diagnostic Accuracy of the Technology-Based Eye Care Services Protocol

Part II of the Technology-Based Eye Care Services Compare Trial

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Purpose: Ophthalmologic telemedicine programs help to address the growing demand for eye care and lessen healthcare disparities for patients. One example is Technology-Based Eye Care Services (TECS), implemented in the Veteran Affairs Healthcare System in 2015. Accuracy and quality data for TECS both have been reported, and data suggest that although the TECS examination is comparable with an in-person examination, sensitivity for glaucoma and glaucoma suspect detection is less than that for other diseases, such as macular degeneration. Several articles suggest that OCT can improve disease detection for glaucoma. Therefore, this study was undertaken to test the impact of OCT on the accuracy of the TECS protocol. This article reports the data from part II of the TECS Compare trial; results from part I are discussed in a previous article.

Design: Prospective comparison between the TECS protocol with OCT versus a face-to-face (FTF) examination for 256 patients.

Participants: An eligible patient was defined as a patient with no known ocular disease who desired a routine eye examination.

Methods: Patient underwent the TECS protocol workup and OCT nerve, OCT macula, and FTF examination on the same day.

Main Outcome Measures: Percent agreement, κ values, sensitivity, and specificity were calculated for nonexpert readers after OCT interpretation of the TECS protocol using the FTF examination as the clinical gold standard.

Results: OCT did not improve the diagnostic accuracy of the TECS protocol when compared with an FTF examination. In most cases, OCT had no impact, and in the case of reader 2, OCT actually reduced the κ value from moderate agreement to agreement equal to chance while lowering the percent agreement by 10%. OCT also did not impact inter- or intrareader variability parameters.

Conclusions: In this study, OCT did not seem to improve the accuracy of glaucoma or retinal disease detection when added to the standard TECS protocol. In one case, OCT worsened the agreement of the reader compared with the FTF. Further study is necessary to confirm these findings, and results may change if the readers are glaucoma or retina specialists instead of nonexpert OCT readers, comprehensive and anterior segment specialists. *Ophthalmology 2020;127:544-549 Published by Elsevier on behalf of the American Academy of Ophthalmology*

Telemedicine, providing care when the patient and provider are separated by distance, has been operational in many different areas of medicine since the 1970s. The development of the Internet and wide-ranging technological improvements has accelerated the use and adoption of telemedicine in the last 10 years, and ophthalmology is no exception. Ophthalmologic telemedicine primarily uses fundus images for disease detection, and several groups are now reporting on the use of another common ophthalmic imaging method for tele-eye programs: OCT. OCT can generate 3-dimensional models of intraocular structures at submicrometer resolution, so its potential to complement an image-based tele-eye screening program is worth exploring. Furthermore, in clinical decision making for several ophthalmic disorders, OCT may be the standard of care, but generally, it is used after a clinician has assessed the patient and determined that the suspicion for disease is high (e.g., increased cup-to-disc ratio). Literature for the use of OCT

 Published by Elsevier on behalf of the American Academy of Ophthalmology https://doi.org/10.1016/j.ophtha.2019.10.025
ISSN 0161-6420/19

on a screening population is less well defined, and because OCT is more expensive than a fundus camera, more information is necessary to determine whether the investment in OCT would lead to increased diagnostic accuracy and better patient care.

The Veterans Health Administration (VA) has used diabetic teleretinal screening since 2006, and in 2015, began Technology-Based Eye Care Services (TECS). Accuracy and quality-of-care data for TECS subsequently was published,[1,2] and areas that have been identified as targets for refinement include the detection of glaucoma suspect and glaucoma. Because glaucoma is a disease without clear visual pathognomonic features but has better clinical outcomes the earlier it is diagnosed and treated, OCT has been suggested to improve disease detection in a baseline screening telemedicine examination. The addition of OCT to TECS needs to be validated because use of this imaging method for screening purposes is not well documented and would require more time and resources to execute. Thus, part II of this prospective comparative study formally assessed the impact of OCT as a screening tool on the accuracy of the TECS protocol when compared with the standard clinical face-to-face (FTF) examination.

Methods

The Emory University Institutional Review Board and the VA Research and Development Committee approved this trial. This project complied with the Health Insurance Portability and Accountability Act and conformed to the tenets of the Declaration of Helsinki. All participants provided informed consent. The study was registered at ClinicalTrials.gov (identifier, NCT02558712). The Atlanta Clinical and Translational Science Institute partially funded this research; however, no conflict of interest exists for any of the authors.

Detailed methods are reported in another article.[3] Briefly, 256 participants were recruited from March 2015 through December 2017. Power calculations were based on the expected prevalence of glaucoma suspect and glaucoma in the veteran population. A sample size of 250 produced a 2-sided 95% confidence interval with widths equal to 0.127, 0.117, and 0.078 for κ statistics of 0.5, 0.7, and 0.9, respectively.

Study participants were recruited by mailing letters describing the study to patients who were already scheduled into the New Comprehensive Clinic at the Atlanta VA. These patients were either self-referred or sent by their primary care provider for a routine eye examination, had not been seen by the VA eye clinic in 2 years or more, and had no known ocular disease. Eligible patients were mailed information about the study, and they either called the research coordinator or were contacted by study staff 2 weeks after receiving the letter. On the day the patient arrived for the New Comprehensive Clinic eye assessment, they signed an informed consent and were enrolled in the trial. The participant underwent the full TECS screening protocol, performed by a trained ophthalmic technician, which included refraction, measurement of best-corrected visual acuity, pupil examination, anterior chamber depth by side illumination with a penlight, dilation, and fundus photographs. The veteran then underwent spectral-domain OCT macular cube, 5-line raster, and optic nerve protocols (cube, peripapillary retinal nerve fiber layer without ganglion cell layer analysis) performed on both eyes (Zeiss Cirrus OCT-4000; Carl Zeiss Meditech, Dublin CA). Finally, the patient underwent an FTF examination by one of the authors (A.Y.M.), a comprehensive ophthalmologist, who provided routine clinical care for the patient and never saw the OCT or fundus photographs. At the end of each participant's visit, the FTF physician completed a standardized report form indicating the presence or absence of surgical cataract, glaucoma suspect or glaucoma, age-related macular degeneration (AMD), or diabetic retinopathy (DR) if the patient was diabetic. Study patients' data were de-identified and all images, including OCT, were loaded into a secure research database, Research Electronic Data Capture (REDCap, Nashville, TN). OCT images viewed by the readers included OCT macula (the Zeiss 5-line raster of the macula including fovea) and OCT nerve (the Zeiss peripapillary retinal nerve fiber layer report) for both eyes. The de-identified information then was transmitted to the 2 readers (reader 1, R.J.; reader 2, X.L.) who individually reviewed the information and provided their interpretations. Neither reader was a glaucoma or retina specialist; one (R.J.) is a comprehensive ophthalmologist and the other (X.L.) is a cornea specialist. Both providers had experience as readers for the TECS program. Readers were blinded to the patient's name, medical record, the examining physician's findings, and each other's interpretations. The reading physicians first interpreted the participant's information without OCT and documented their findings on a REDCap case report form that was identical to the FTF physician's form. After this pre-OCT case report form was submitted, REDCap then allowed access to OCT images. Readers reinterpreted the patient case with OCT and submitted a post-OCT case report form. No changes could be made to the pre-OCT interpretations after the readers viewed the OCT images. After a 3-month washout period, 150 charts were selected randomly for a second read. Readers, blinded to their initial read, repeated the same procedure (reading before and after OCT) for those 150 patients and redocumented their findings on REDCap case report forms.

Data were analyzed using SAS statistical software (SAS Institute, Cary, NC). Diagnostic classification for 5 categories—surgical cataracts (best-corrected vision or glare worse than 20/40), glaucoma suspect or glaucoma, AMD, DR, and any condition resulting in referral—were reported for each participant as present or not present. We compared diagnoses obtained from the TECS protocol with OCT versus those obtained from FTF visits using percent agreement, Cohen's κ statistics, sensitivity, and specificity. To determine whether the incorporation of OCT images into the TECS protocol improved diagnostic accuracy, we calculated κ statistics to measure agreement between the FTF diagnostic classification and classification performed either before (before OCT) or after (after OCT) the TECS readers reviewed the OCT images. P values denoting the statistical significance of the observed differences in κ statistics were calculated from Z scores. All statistical tests were 2-sided and considered significant at an α level of 0.05. Finally, the Landis and Koch definition of κ was used for this analysis: $\kappa = 0.0 - 0.20$, none to slight agreement; $\kappa = 0.21 - 0.40$, fair agreement; $\kappa = 0.41 - 0.60$, moderate agreement; $\kappa = 0.61 - 0.80$, substantial agreement; and $\kappa > 0.80$, near perfect agreement.[4]

Results

The demographic data are reported in Table 1 of the TECS Compare Trial part I publication.[3] In summary, 256 total patients were recruited in the 2-year period. The average age of the participants was 60 years, and 86.7% of patients were men. Most of the patients were black (60.3%), 38.3% were white, and 0.4% were Asian. Table 1 presents the percent agreement, κ statistics, sensitivity, and specificity of the TECS protocol with OCT between the 2 readers and the FTF examination for the 5

Table 1. Agreement, Sensitivity, and Specificity for Diagnoses Obtained from In-Person Examinations Compared with Those Obtained Using the Technology-Based Eye Care Services Protocol with OCT (n = 256)*

Diagnosis	Face-to-Face Examination, No. (%)	Technology-Based Eye Care Services OCT, No. (%)	Percent Agreement	κ Value (95% Confidence Interval)	Sensitivity (95% Confidence Interval)	Specificity (95% Confidence Interval)
Reader 1 compared with FTF examination						
Cataracts referred for surgery	10 (3.9)	16 (6.3)	97.7	0.76 (0.57–0.94)	1.00 (0.69–1.00)	0.98 (0.95–0.99)
Glaucoma and glaucoma suspect	68 (26.6)	81 (31.6)	80.9	0.54 (0.42–0.65)	0.74 (0.61–0.84)	0.84 (0.77–0.89)
Macular degeneration	6 (2.3)	5 (2.0)	98.1	0.54 (0.18–0.90)	0.50 (0.12–0.88)	0.99 (0.97–1.00)
Diabetic retinopathy	8 (3.1)	9 (3.5)	98.1	0.70 (0.44–0.95)	0.75 (0.35–0.97)	0.99 (0.97–1.00)
Any diagnosis resulting in referral	112 (43.8)	131 (51.2)	73.1	0.46 (0.36–0.57)	0.78 (0.69–0.85)	0.69 (0.61–0.77)
Reader 2 compared with FTF examination						
Cataracts referred for surgery	10 (3.9)	14 (5.5)	97.7	0.74 (0.54–0.94)	0.90 (0.56–1.00)	0.98 (0.95–0.99)
Glaucoma and glaucoma suspect	68 (26.6)	58 (22.7)	70.3	0.20 (0.07–0.33)	0.37 (0.25–0.49)	0.82 (0.76–0.88)
Macular degeneration	6 (2.3)	17 (6.6)	94.1	0.32 (0.07–0.57)	0.67 (0.22–0.96)	0.95 (0.91–0.97)
Diabetic retinopathy	8 (3.1)	7 (2.7)	98.1	0.66 (0.38–0.94)	0.63 (0.24–0.91)	0.99 (0.97–1.00)
Any diagnosis resulting in referral	112 (43.8)	163 (63.7)	65.2	0.33 (0.22–0.43)	0.83 (0.75–0.89)	0.51 (0.43–0.60)

FTF = face-to-face.
*A single FTF examination was carried out with Technology-Based Eye Care Services reader 1 and Technology-Based Eye Care Services reader 2 being compared with the single FTF examination results.

diagnostic categories. According to the FTF examinations, the prevalence of surgical cataracts in the study population was 3.9%, the prevalence of glaucoma and glaucoma suspect was 26.6%, the prevalence of AMD was 2.3%, and the prevalence of DR was 3.1%. The presence of any diagnosis resulting in referral was noted in 43.8% of study participants. Under the TECS OCT protocol, more patients were diagnosed with cataracts (5.5% and 6.3% for readers 1 and 2, respectively) and with any condition resulting in referral (51.2% and 63.7% for readers 1 and 2, respectively). The percent of patients with matched diagnoses from FTF visits and the TECS OCT protocol ranged from 65.2% to 98.1%, with the highest rates observed for DR. The κ statistics for the 5 diagnostic categories above were slightly higher for reader 1 (κ = 0.46–0.76) compared with reader 2 (κ = 0.20–0.74). Specificity measures for cataracts, glaucoma, AMD, and DR fell between 0.84 and 0.99 for both readers, whereas specificity estimates for any diagnosis resulting in referral were 0.51 and 0.69 for reader 1 and reader 2, respectively. The sensitivity measures displayed greater variability, ranging from 0.50 to 1.00 for reader 1 and from 0.37 to 0.90 for reader 2.

Table 2 illustrates the effect of OCT on κ values for comparing agreement between the FTF provider and the readers. For both readers, the addition of OCT to the TECS protocol did not statistically significantly change the observed agreement for most diagnostic categories. OCT affected reader 2 significantly in only 1 category, glaucoma suspect or glaucoma ($P < 0.01$). For these diagnoses, OCT actually reduced the level of agreement between the FTF examination and reader 2. Tables 3 and 4 illustrate the impact of OCT on interreader and intrareader variability, respectively. Apart from a significant decline in interreader agreement for glaucoma ($P = 0.02$), adding OCT produced no statistically significant changes (neither improved nor worsened) in either interreader or intrareader variability.

Discussion

Although OCT technology is not new,[5] its potential use as a screening tool is more novel. OCT provides in-depth visualization of retina and nerve structures and potentially could improve disease detection if carried out on every participant. Several studies have suggested that OCT enhances retina[6–9] and glaucoma[10,11] disease detection. However, Bussel et al[12] questioned the use of OCT of the peripapillary nerve fiber layer as a screening tool. The results of part II of the TECS study aligns with the findings of Bussel et al. Adding OCT macula and peripapillary retinal nerve fiber layer to the standard TECS protocol did not impact positively reader percent agreement, κ values, or interreader or intrareader variability when comparing them with an FTF examination. In fact, OCT of the nerve actually reduced the κ value of reader 2 by a statistically significant amount ($P = 0.0001$; Table 2) such that the κ value was only slightly more than what would be expected by chance alone. In addition, the presence of OCT of the nerve reduced the interreader percent agreement by 10%, from 87.5% (κ = 0.62) to 77.0% (κ = 0.42) for glaucoma. Several potential explanations may substantiate these surprising results, especially given that OCT has a high area under the receiver operating characteristic curve for glaucoma detection.[13] Based on the data, it seemed

Table 2. Comparison of Agreement between Diagnoses Obtained from In-Person Examinations and Technology-Based Eye Care Services Protocols Either with OCT Review (after OCT) or without OCT Review (before OCT; n = 256)

Diagnosis	κ Value* (Standard Error)		Difference (After Minus Before)	*P* Value†
	Before OCT	*After OCT*		
Reader 1				
Cataracts referred for surgery	0.77 (0.10)	0.76 (0.10)	−0.01	1.00
Glaucoma and glaucoma suspect	0.65 (0.06)	0.54 (0.06)	−0.11	0.18
Macular degeneration	0.54 (0.18)	0.54 (0.18)	0.00	1.00
Diabetic retinopathy	0.74 (0.12)	0.70 (0.13)	−0.04	0.80
Any diagnosis resulting in referral	0.51 (0.05)	0.46 (0.06)	−0.05	0.58
Reader 2				
Cataracts referred for surgery	0.71 (0.11)	0.74 (0.10)	0.03	0.83
Glaucoma and glaucoma suspect	0.52 (0.06)	0.20 (0.07)	−0.32	<0.01
Macular degeneration	0.34 (0.13)	0.32 (0.13)	-0.02	0.93
Diabetic retinopathy	0.61 (0.15)	0.66 (0.14)	0.05	0.83
Any diagnosis resulting in referral	0.38 (0.06)	0.33 (0.05)	−0.05	0.50

*Measures agreement between diagnoses obtained from in-person examinations and Technology-Based Eye Care Services protocols.
†Z scores comparing κ statistics.

that OCT had an impact in both directions on the agreement between the nonexpert readers and the FTF examiner. OCT falsely reassured reader 2 (so-called green disease) regarding 13 patients who were identified correctly as having glaucoma or suspected glaucoma before OCT and no longer were identified as having glaucoma or suspected glaucoma after OCT. Also, some evidence of false-positive referrals exists, potentially for so-called red disease. Reader 1 considered 17 patients and reader 2 considered 29 patients did not have glaucoma or suspected glaucoma before OCT and who then changed to suspicious after OCT when the FTF examiner had not identified the patients as having glaucoma or suspected glaucoma.

The current TECS protocol does not incorporate OCT, and therefore, there are no specific OCT guidelines for interpretation. The lack of specific interpretation guidelines and no training on OCT reading leads to inconsistent OCT interpretation, which may help to explain the results and why OCT had an impact on the readers in both directions: green and red disease. Furthermore, although good OCT interpretation guidelines are available, newer developments such as ganglion cell layer analysis or OCT angiography also need to be taken into consideration. In addition, the reading pool in this study was small, and neither reader was a glaucoma specialist. It is conceivable that results may be different if all readers are glaucoma specialists who are well versed on interpreting OCT nerve reports. The results also may change if readers had OCT guidelines available before interpreting those images and were given specific OCT interpretation training.

Finally, this study had several limitations. First, the patient population was predominantly men and included a high proportion of black persons. The study cohort thus does not mirror the demographics of the United States population, and therefore, our results may not be as generalizable to other groups. However, because TECS is implemented currently only in the VA, the study cohort is representative of the veteran population, and therefore, results are probably more likely to be applicable for the VA healthcare system. It is worth noting that this study was conducted in the southeastern United States, where minority populations are high and other regions of the VA (e.g., the northwestern United States) may not have the same demographic features, and therefore, these results may not be as applicable in a different VA geographic area. Second, the study cohort is a screening population, and therefore, not a high number of patients showed retinal pathologic features such as AMD and DR, where OCT may have been more helpful with

Table 3. Comparison of Interreader Agreement, Either with OCT (after OCT) or without OCT (before OCT; n = 256)

Diagnosis	κ Value* (Standard Error)		Difference (After Minus Before)	*P* Value†
	Before OCT	*After OCT*		
Cataracts referred for surgery	0.83 (0.68–0.98)	0.86 (0.72–1.00)	0.03	0.64
Glaucoma and glaucoma suspect	0.62 (0.50–0.73)	0.42 (0.30–0.54)	−0.20	0.02
Macular degeneration	0.46 (0.20–0.72)	0.44 (0.18–0.69)	−0.02	0.91
Diabetic retinopathy	0.61 (0.33–0.90)	0.61 (0.33–0.90)	0.00	0.81
Any diagnosis resulting in referral	0.33 (0.22–0.45)	0.36 (0.24–0.47)	0.03	0.45

*Agreement between diagnoses obtained from reader 1 and reader 2.
†Z scores comparing κ statistics.

Table 4. Comparison of Intrareader Agreement, Either with OCT (after OCT) or without OCT (before OCT; n = 150)

Diagnosis	κ Value* (Standard Error)		Difference (After Minus Before)	P Value†
	Before OCT	*After OCT*		
Reader 1				
Cataracts referred for surgery	0.70 (0.14)	0.60 (0.16)	−0.10	0.64
Glaucoma and glaucoma suspect	0.70 (0.07)	0.72 (0.06)	0.02	0.86
Macular degeneration	‡	‡	‡	‡
Diabetic retinopathy	0.56 (0.23)	0.49 (0.22)	−0.07	0.81
Any diagnosis resulting in referral	0.39 (0.07)	0.47 (0.07)	0.08	0.45
Reader 2				
Cataracts referred for surgery	0.87 (0.08)	0.93 (0.05)	0.06	0.52
Glaucoma and glaucoma suspect	0.67 (0.08)	0.67 (0.07)	−0.01	0.96
Macular degeneration	0.59 (0.19)	0.72 (0.16)	0.13	0.59
Diabetic retinopathy	0.66 (0.20)	0.80 (0.15)	0.14	0.58
Any diagnosis resulting in referral	0.69 (0.06)	0.53 (0.07)	−0.16	0.09

*Agreement between diagnoses obtained from readers at day 0 and at day 90.
†Z scores comparing κ statistics.
‡Unable to calculate because reader did not diagnose any cases of age-related macular degeneration.

diagnosis. The low numbers of patients with AMD also impacted interpretation of the results and led to wide confidence intervals. Third, for early glaucoma detection, another limitation was the type of OCT study that was performed on the patients. Macular ganglion cell layer analysis may be helpful at detecting early glaucoma,[14] and this image analysis was not performed in this study because the OCT machine that was used (Cirrus 4000 Zeiss) did not have that capability. A fourth major limitation is that, during this trial, the FTF examiner was purposefully blinded to the OCT and fundus images. The authors desired the gold standard of this study to approximate closely what truly occurs during a routine FTF examination, and generally, OCT and fundus imaging are not ordered unless actual suspicion of disease exists. If the FTF examiner had an opportunity to review OCT images after the patient was examined, the results might have been different. Moreover, as noted in the companion article, the authors assumed that an FTF examination was the gold standard for disease diagnosis, but this may not always be the case. In fact, it is highly likely that in cases of glaucoma suspect, preperimetric glaucoma, or mild macular edema, an OCT image would be more accurate than an FTF examination. For example, an OCT can identify physiologic cupping versus true glaucomatous damage correctly. Results may change if each patient suspected of nerve disease was adjudicated to establish so-called ground truth for the patient using FTF examination, photographs, and OCT images.

Future work can clarify the value of OCT in a screening population using telemedicine techniques. Implementing rigorous evidence-based OCT interpretation guidelines may improve κ values, sensitivity, and specificity. Having the study data and OCTs read by subspecialists such as glaucoma or retina specialists may better answer the question about the impact of OCT on the diagnostic detection of glaucoma by the TECS protocol. Avenues of further research include qualitatively evaluating which diagnostic changes occurred after OCT, for instance, whether patients read as having normal results before the OCT more likely to be referred for evaluation after the OCT. Another avenue of exploration would be to measure the effect on reading accuracy of training comprehensive readers with specific OCT guidelines. Moreover, having all discrepancies between readers and FTF providers adjudicated or using the patient's ultimate clinical outcome as the gold standard would allow for a more in-depth analysis of the impact of OCT on a telemedicine screening protocol.

The TECS protocol currently lacks well-established OCT reading guidelines, and adding routine OCT to every screening visit would increase the cost of the program. Thus, screening patients with OCT does not seem to be an effective use of resources at the present time. An OCT also requires more clinical time, more imager technical skill, and increased reader interpretation time. Based on these trial data, the investment of time and cost for OCT to be added to routine TECS screening does not seem to improve disease detection. However, more studies in this area are required to validate or refute these preliminary findings. These results also stress how emerging teleophthalmology programs need to consider the goals of their individual telemedicine program carefully and tailor the equipment as well as the screening to the populations at greatest risk.

Acknowledgments

The authors thank the Atlanta Veterans Health Administration ophthalmology chief, the Atlanta Veterans Health Administration eye clinic staff, the reading physicians, the medical students, and the ophthalmic technicians for their support, especially the project's research coordinator, whose hard work and commitment to the project were truly invaluable to the study's success.

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Footnotes and Financial Disclosures

Originally received: May 23, 2019.
Final revision: October 16, 2019.
Accepted: October 23, 2019.
Available online: October 30, 2019. Manuscript no. 2019-472.

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Financial Disclosure(s):
The author(s) have no proprietary or commercial interest in any materials discussed in this article.

Supported in part by the Atlanta Clinical and Translational Institute (translational research grant). The funding source had no role in the design or conduct of this study.

HUMAN SUBJECTS: Human subjects were included in this study. The human ethics committees at Emory University and the Veterans Health Administration approved the study. All research complied with the Health Insurance Portability and Accountability (HIPAA) Act of 1996 and adhered to the tenets of the Declaration of Helsinki. All participants provided informed consent.

No animal subjects were included in this study.

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Obtained funding: N/A

Overall responsibility: Maa, McCord, Lu, Janjua, Howell, Hunt, Medert, Giangiacomo, Lynch

Abbreviations and Acronyms:
AMD = age-related macular degeneration; **DR** = diabetic retinopathy; **FTF** = face-to-face; **REDCap** = Research Electronic Data Capture; **TECS** = Technology-Based Eye Care Services; **VA** = Veterans Health Administration.

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