

A Smartphone-Based Near-Vision Testing System: Design, Accuracy, and Reproducibility Compared With Standard Clinical Measures

Do Gyun Kim, MD; Aaron D. Webel, MD, MBA; Mark S. Blumenkranz, MD; Yonguk Kim, MD; Ji Ho Yang, MD; Seung Young Yu, MD; Hyung Woo Kwak, MD; Daniel Palanker, PhD; Brian Toy, MD; and David Myung, MD, PhD

BACKGROUND AND OBJECTIVE: Ophthalmologic telemedicine has emerged during the COVID-19 pandemic. The objective of this study is to assess the accuracy and reproducibility of a smartphone-based home vision monitoring system (Sightbook) and to compare it with existing clinical standards.

PATIENTS AND METHODS: Near Snellen visual acuity (VA) was measured with Sightbook and compared with conventional measurements for distance and near VA at an academic medical center ophthalmology clinic in 200 patients with a variety of different specified preexisting ocular conditions. Measurements of contrast sensitivity were also compared by using an existing commercially available chart system in 15 normal patients and 15 patients with age-related macular degeneration.

RESULTS: Sightbook VA tests were reproducible (SD = ± 0.054 logMAR), and correlation with standard VA methods was significant ($R > 0.87$ and $P < .001$). Sightbook contrast sensitivity measurements were reproducible (SD/mean ratio, 0.02 to 0.04), yielding results similar to those of standard tests ($R^2 > 0.87$ and $P < .001$).

CONCLUSIONS: Smartphone-based VA and contrast sensitivity are highly correlated with standard charts and may be useful in augmenting limited in-office care.

[*Ophthalmic Surg Lasers Imaging Retina*. 2022;53:79-84.]

INTRODUCTION

COVID-19 has brought telemedicine and eHealth solutions to the leading edge of the patient care paradigm. In the field of ophthalmology, the success of telemedicine workflows depends on the acquisition of high-quality and actionable diagnostic data, which an eye care provider can effectively interpret from another location either synchronously or asynchronously. In the years before the pandemic, emerging solutions for remote monitoring of visual acuity (VA), other psychophysical parameters, and intraocular pressure demonstrated promise for earlier disease detection, including age-related macular degeneration (ARMD) and glaucoma, although many have not been critically evaluated against existing standards.^{1,2}

Strategies such as the paper Amsler grid have been used for many years to encourage patients to test their vision regularly at home. However, quantification of such home tests and patient compliance have been limited, as has communication of these results to physicians. More-recent efforts have included the home use of specialized electronic devices to mea-

From the Department of Ophthalmology, Myungji Hospital, Hanyang University, Goyang, Korea (DGK and JHY); Department of Ophthalmology, Byers Eye Institute, Stanford University, Stanford, California (ADW, MSB, DP, and DM); Department of Ophthalmology, Kyung Hee University, Seoul, Korea (YK, SYU, and HWK); and Department of Ophthalmology, Roski Eye Institute, University of Southern California, Los Angeles, California (BT).

Originally submitted June 12, 2020. Accepted for publication September 22, 2021.

Acknowledgement: ADW, DP, and DM were supported by departmental core grants from the National Eye Institute (P30-EY026877) and Research to Prevent Blindness to the Department of Ophthalmology at Stanford University School of Medicine.

Financial Disclosure: Mark S. Blumenkranz and Daniel Palanker are equity owners in Verana Health, which licensed the software technology used in this report from Stanford University. The remaining authors have no relevant financial relationships to disclose.

Address correspondence to David Myung, MD, PhD, Byers Eye Institute, Stanford University, 2452 Watson Court, 9 Palo Alto, CA 94303; email: djmyung@stanford.edu.

doi: 10.3928/23258160-20220121-05

TABLE 1
Levels of Contrast Sensitivity in the App

Step	Calculated contrast, %	Listed in the app, %	Log
1	100.00	100	0.00
2	70.71	71	-0.15
3	50.00	50	-0.30
4	35.36	35	-0.45
5	25.00	25	-0.60
6	17.68	18	-0.75
7	12.50	13	-0.90
8	8.84	8.8	-1.05
9	6.25	6.3	-1.20
10	4.42	4.4	-1.35
11	3.13	3.1	-1.51
12	2.21	2.2	-1.66
13	1.56	1.6	-1.81
14	1.10	1.1	-1.96

sure metamorphopsia with preferential hyperacuity perimetry.³ This method quantifies the image distortion due to retinal deformation that is associated with conversion from nonexudative to exudative disease, although its benefit in assessing disease progression and regression in patients already receiving treatment of exudative disease has not been conclusively established. A portable device for quantitative detection of image distortion has also been described.⁴ Although potentially improvements on traditional Amsler grid testing, these methods have the requirement of grading at a centralized reading center and are not specifically correlated with in-office traditional VA measurements.

A telecommunications-enabled software-based mobile monitoring system (Sightbook) for iOS-based devices was developed, which allows patients to test and track their vision. Sightbook was previously validated in the clinical setting, with strong agreement between the Sightbook VA and Amsler testing and reference clinical testing.⁵ It includes a series of tests, including Snellen VA, contrast sensitivity, low-light Snellen VA, and metamorphopsia. The tests were designed to be taken on a recent-generation iPhone, iPad, or iPod touch device while holding the device at approximately 14 inches (36 cm) from the face and matching a series of randomly displayed letters of precise font size, contrast, and background lighting that automatically increase or decrease in size depend-

ing on whether they are correctly identified by the patients via a software-enabled, easy-to-see keypad. The test continues with successively smaller and/or larger letters until the smallest-sized letter that can be consistently identified by the patient is reliably determined and takes less than 5 minutes to self-administer for most patients. Vision test data are then both stored on the phone and transmitted and stored on a secure website that is compliant with the Health Insurance Portability and Accountability Act. Although not currently enabled or tested in this study, additional software could enable patients and their designated physicians to access these data in a secure fashion, including algorithmically driven VA change alerts. With these features, Sightbook may prove useful as a clinical decision support tool for patient triage by physicians attempting to care for patients with the requirement for acute or ongoing treatment of various ophthalmic conditions—including ARMD, diabetic retinopathy, and retinal vein occlusion—that require periodic anti-vascular endothelial growth factor injections. Here, we describe the design and results of initial clinical testing of the accuracy and reproducibility of Sightbook. We compare it with the standard clinical charts for measurement of near and distance VA and contrast sensitivity in an office environment.

PATIENTS AND METHODS

DESCRIPTION OF THE TESTING ALGORITHM

A typical human eye can resolve 1 arc minute of visual angle, which at 20 feet (6 m) corresponds to line spacing of about 1.75 mm. The 20/20 letters in the Snellen and Early Treatment Diabetic Retinopathy Study (ETDRS) charts used by most clinicians to measure distance VA are sized such that the separation of the lines that make up those letters corresponds to a visual angle of 1 arc minute. For testing of near vision, the chart is held 14 inches (36 cm) from the eyes, and line spacing corresponding to 20/20 vision is approximately 0.1 mm. The numerator 20 (or 6) refers to the distance in feet (or meters) between the subject and the chart. A 20/20 (or 6/6 in metric units) VA is considered nominal performance for human vision. The 20/40 (or 6/12) vision corresponds to letters twice larger in size and is considered half the normal acuity. Unlike the Snellen method, which determines the line in which most letters can be correctly identified, the ETDRS system determines the number of correctly identified letters (five per line), which provides for greater precision. In the decimal system, the acuity is defined as the reciprocal value of the size of the gap (measured in arc minutes) of the smallest Landolt C that can be reliably identified.

TABLE 2
VA Measured in Various Categories of Patients by Using the App, Good-Lite, and S-ETDRS Charts

	All Patients	Normal	ARMD	Cataract	DR
Number of eyes	200	69	41	35	55
Age, mean ± SD, years	59.9 ± 15.4	50.7 ± 19.0	70.2 ± 8.5	67.1 ± 9.3	59.1 ± 9.6
Female sex, n (%)	102 (51)	35 (51)	13 (32)	23 (66)	31 (56)
VA on app, mean ± SD, logMAR	0.40 ± 0.30	0.25 ± 0.29	0.52 ± 0.29	0.47 ± 0.24	0.46 ± 0.27
Range of VA on app, logMAR	0.0 to 1.3	0.0 to 1.3	0.1 to 1.0	0.1 to 1.3	0.0 to 1.3
Reproducibility, SD	±0.054	±0.051	±0.058	±0.062	±0.044
VA on Good-Lite, mean ± SD, logMAR	0.38 ± 0.26	0.25 ± 0.27	0.49 ± 0.22	0.45 ± 0.23	0.40 ± 0.25
VA on S-ETDRS, mean ± SD, logMAR	0.35 ± 0.28	0.24 ± 0.28	0.34 ± 0.26	0.48 ± 0.25	0.41 ± 0.27

ARMD = age-related macular degeneration; DR = diabetic retinopathy; S-ETDRS, standard Early Treatment for Diabetic Retinopathy Study; VA = visual acuity.

A value of 1.0 corresponds to VA of 20/20, and 0.1 corresponds to acuity of 20/200. LogMAR is another commonly used scale, expressed as the decadic (also known as decimal or common) logarithm of the minimum angle of resolution. Normal VA (20/20) corresponds to logMAR = 0.0, and 20/200 corresponds to logMAR = 1.0. Sightbook VA test begins with a letter size in the middle of the Snellen visual range (20/70) and decreases by one step after each correct response or increases by one step after an incorrect response. The test stops at the level where two correct responses have been obtained and two incorrect responses have been obtained at one level smaller. Alternatively, the test stops when the minimum font size (20/20) has been identified correctly twice or the maximum font sizes (20/400) have not been read correctly twice. In the latter case, the result displayed is $\leq 20/400$. The test is structured with lines corresponding to a standard Snellen chart. For the standard visual portion of this study, the results were displayed in units (English, metric, decimal, logMAR, or ETDRS letters).

For the contrast sensitivity test portion of this study, the contrast of the letters displayed varies according to the Pelli-Robson contrast scale, and with each step, the contrast (level of black in the gray) decreases by approximately 20.5 and is digitized according to the screen brightness levels. Therefore, the contrast C after N successive steps can be calcu-

lated as follows: $C (\%) = 100 \times 2^{(1-N)/2}$. The contrast in this test ranges from 100% (black letters on white background) to 1.1% (faint gray letters on white background), as listed in **Table 1**.

The test begins in the middle of the range (at 25% contrast), and the contrast decreases after each correct response or increases after an incorrect response. The test stops at the level where two correct responses have been obtained and two incorrect responses have been obtained at one level harder. Alternatively, the test stops when the minimum contrast (1.1%) has been identified correctly twice or the maximum contrast (100%) has not been identified correctly twice. The button “Not Sure” becomes brighter 5 seconds after the letter is presented. Contrast is plotted with a negative sign to indicate that higher values represent poorer contrast sensitivity. An inverse contrast test is similar to the standard contrast sensitivity test, except that it uses light letters displayed on a black background instead of dark letters displayed on a white background. In this case, the font color is determined as the amount of white in the gray. White letters represent 100% contrast.

COMPARISON WITH THE STANDARD CHARTS OF VA AND CONTRAST SENSITIVITY

All tests were performed in the Department of Ophthalmology at Kyung Hee University after in-

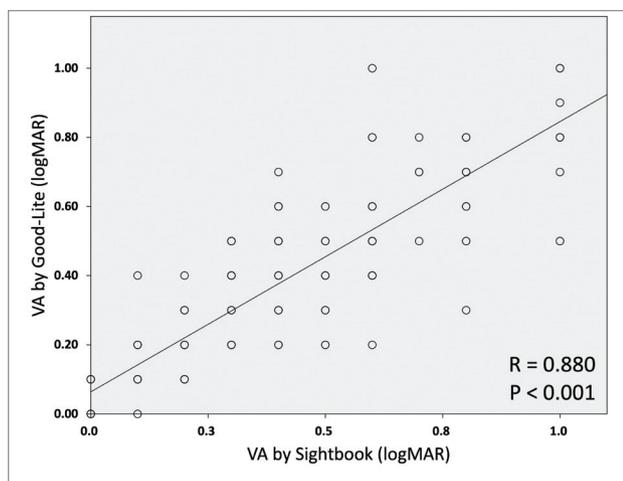


Figure 1. Correlation between VA measured by Sightbook and by Good-Lite chart. VA = visual acuity.

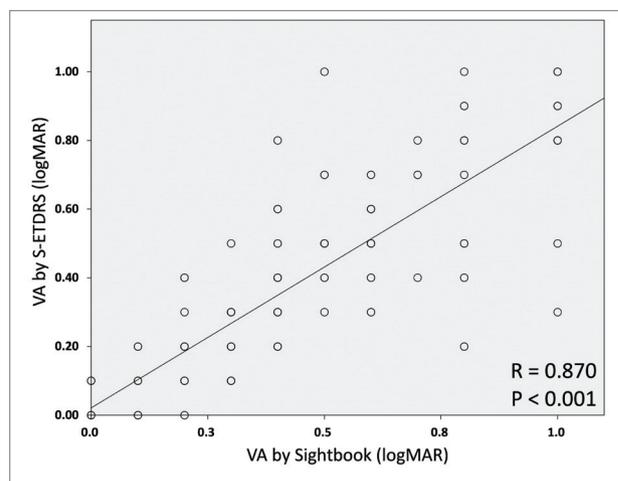


Figure 2. Correlation between VA measured by Sightbook and by ETDRS chart. ETDRS = Early Treatment Diabetic Retinopathy Study; VA = visual acuity.

formed consent and approval from the institutional review board were obtained. To assess correlation between VA measurements obtained with Sightbook and those obtained with standard printed charts, near VA with habitual near correction was measured at approximately 35 cm with Sightbook in the office, with a technician providing instructions and overseeing the patient measuring process, and was compared with the Good-Lite near-vision chart and with best-corrected distance acuity measured by using an S-ETDRS chart, which were administered by a trained ophthalmic technician under standard well-controlled lighting and distance conditions of 6 m. A total of 200 eyes were tested, including 69 from healthy volunteers, 41 from patients with ARMD, 35 with cataract, and 55 with diabetic retinopathy. The corresponding ages in each group are listed in **Table 2**. To assess the reproducibility of the results, each measurement with Sightbook was performed twice—before and after the measurements with standard printed charts.

Contrast sensitivity was measured in 15 healthy eyes (average age, 31 years) and 15 eyes with dry and wet ARMD (average age, 70 years) by using three methods: (1) Sightbook, (2) Functional Acuity Contrast Test (FACT), and (3) Contrast Sensitivity Testing System CSV-1000 (VectorVision). Again, for the assessment of reproducibility, each measurement on Sightbook was performed twice.

RESULTS

The results of the VA measurements with Sightbook were highly reproducible in all the groups, with the average SD of ± 0.05 logMAR, as shown in **Table 2**.

The intraclass correlation coefficient of the repeated measurements exceeded 0.86 in all cases. The 95% limits of agreement were in the range of -0.189 to $+0.204$ for all patients.

Comparison of the VA measured by using Sightbook, the Good-Lite near-vision chart, and the ETDRS chart among different populations is summarized in **Table 2**. There were no statistically significant differences between tests using Sightbook and the two standard methods in any of the tested patient populations. Further analysis of the correlation of the various levels of acuity between Sightbook and the two standard charts is shown in **Figures 1** and **2**. In both cases, correlation was significant ($P < .001$ and $R > 0.87$).

Measurements of contrast sensitivity with Sightbook were also found to be reproducible: in both normal and ARMD populations, the ratio of SD/mean was in the range of 0.02 to 0.04, as shown in **Table 3**. Contrast sensitivity measured with Sightbook yielded results similar to those of the standard CSV-1000 chart and the FACT chart in both normal participants and in patients with ARMD, as shown in **Table 3**. Linear regression between the contrast sensitivity measurements with Sightbook and with the CSV-1000 chart, shown in **Figure 3**, demonstrates significant correlation ($P < .001$ and $R^2 > 0.87$).

DISCUSSION

During limitations on physical interaction, it is important that ophthalmology patients continue to receive standard of care, which can include virtual clinics, telemedicine consultations, and remote interpretation of diagnostics.⁶ The US Food and Drug

TABLE 3

Contrast Sensitivity Measured in Various Categories of Patients by Using the App, FACT, and CSV-1000 Charts

	Normal	ARMD
Number of eyes	15	15
Age, mean \pm SD, years	31.3 \pm 5.6	70.5 \pm 9.4
App, mean \pm SD, log	1.91 \pm 0.09	1.51 \pm 0.20
Reproducibility, SD	\pm 0.080	\pm 0.031
FACT, mean \pm SD, log	1.91 \pm 0.07	1.53 \pm 0.20
CSV-1000, mean \pm SD, log	1.96 \pm 0.08	1.55 \pm 0.25

ARMD = age-related macular degeneration; FACT = Functional Acuity Contrast Test.

Administration has issued guidance that during the COVID-19 public health emergency, there is a temporary reduction in the regular requirements for class 1 remote ophthalmic assessment and monitoring devices.⁷ A variety of reports have documented the potential utility of various devices for out-of-office measurement of visual functions in the management of ophthalmic disease. These include at-home measurements of metamorphopsia, VA, intraocular pressure, and visual fields, but these tools require validation and reliability data. A recent review of 42 available remote tools for monitoring VA found that only one tool was validated against standard measures and no tools provided reliability data.¹ In contrast, Sightbook was found to be reproducible and was validated against standard near and distance VA measures and contrast sensitivity measures.

There are reports of computer screen-based home measurements of the VA and detection of metamorphopsia using Amsler grid patterns for patients undergoing anti-vascular endothelial growth factor and steroid injections⁸ and a home monitoring system based on hyperacuity measurements for the early detection of choroidal neovascularization.⁹ A handheld mobile device for mapping hyperacuity has also been tested for usability in an elderly population,⁴ in which patients older than 75 years achieved 85% compliance.¹⁰ In another published study, a smartphone-based near VA test employing the Sightbook software algorithm used in this study demonstrated good correlation with clinical Snellen test ($\rho = 0.91$) in a screening program of 50 consecutive patients with diabetes.¹¹ In other work, a smartphone-based medical game evaluating near VA was evalu-

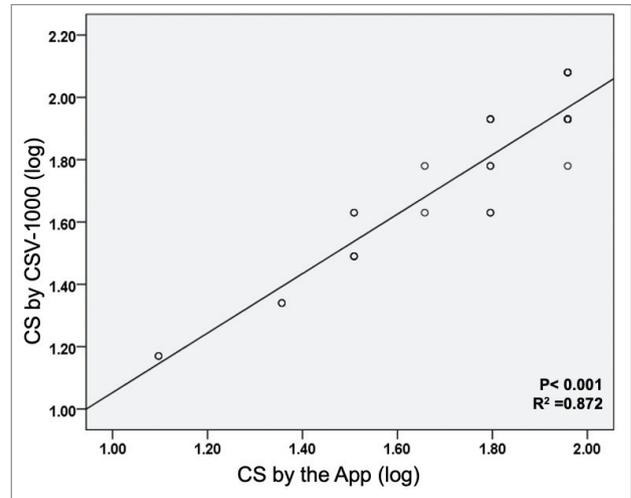


Figure 3. Correlation between CS measured by Sightbook and by CSV-1000. CS = contrast sensitivity.

ated in a heterogeneous group of 120 eyes with varied ocular conditions and resulted in 90% of eyes having a difference of fewer than nine letters compared with Sloan ETDRS chart at 40 cm.¹²

Broad use of smartphones by patients enables a convenient platform for home monitoring of various aspects of visual function. The Sightbook app described in this study uses touch-enabled responses and a cloud-based secure database from which the test results can be accessed by treating physicians with patient consent, allowing for remote assessment of vision, which can limit in-office contact. Verbal responses on Sightbook may prove useful as an adjunct in future iterations, especially for patients with worse VA. Sightbook also lends itself to enhanced automated analysis of the changes in visual functions compared with the infrequent measurements currently used with office visits alone. Frequent monitoring of VA at home and easy access to the data may allow physicians to optimize the treatment regimen for each patient, preventing both vision loss due to undertreatment and unnecessary office visits. It may also allow physicians to more safely assess the need for patients to be seen urgently for acute or chronic treatment visits.

Validation of these measurements of visual functions across a range of VAs will be necessary to ensure that remote monitoring of eye health does not compromise quality of care, but the accuracy and reproducibility of the system we describe in this study provide a reassuring foundation for such tools. The importance of at-home digital health tools has become apparent during the COVID-19 pandemic, and they have the potential to drive new paradigms of eye

care moving forward as patients and physicians reassess the modes by which safe and effective medical therapy can be delivered.

REFERENCES

1. Yeung WK, Dawes P, Pye A, et al. eHealth tools for the self-testing of visual acuity: a scoping review. *NPJ Digit Med.* 2019 Aug 22;2:82. doi: 10.1038/s41746-019-0154-5. Erratum in: *NPJ Digit Med.* 2019 Nov 26;2:117. PMID: 31453377; PMCID: PMC6706420.
2. Hark LA, Katz LJ, Myers JS, et al. Philadelphia Telemedicine glaucoma detection and follow-up study: methods and screening results. *Am J Ophthalmol.* 2017;181:114-124. <https://doi.org/10.1016/j.ajo.2017.06.024> PMID:28673747
3. Faes L, Bodmer NS, Bachmann LM, Thiel MA, Schmid MK. Diagnostic accuracy of the Amsler grid and the preferential hyperacuity perimetry in the screening of patients with age-related macular degeneration: systematic review and meta-analysis. *Eye (Lond).* 2014;28:788-796. <https://doi.org/10.1038/eye.2014.104> PMID:24788016
4. Wang YZ, He YG, Mitzel G, Zhang S, Bartlett M. Handheld shape discrimination hyperacuity test on a mobile device for remote monitoring of visual function in maculopathy. *Invest Ophthalmol Vis Sci.* 2013;54:5497-5505. <https://doi.org/10.1167/iovs.13-12037> PMID:23860761
5. Khurana RN, Hoang C, Khanani AM, Steklov N, Singerman LJ. A smart mobile application to monitor visual function in diabetic retinopathy and age-related macular degeneration: the CLEAR study. *Am J Ophthalmol.* 2021;227:222-230. <https://doi.org/10.1016/j.ajo.2021.03.033> PMID:33831342
6. Ting DSW, Carin L, Dzau V, Wong TY. Digital technology and COVID-19. *Nat Med.* 2020;26:459-461. <https://doi.org/10.1038/s41591-020-0824-5> PMID:32284618
7. Enforcement policy for remote ophthalmic assessment and monitoring devices during the coronavirus disease 2019 (COVID-19) public health emergency. Guidance for industry and Food and Drug Administration staff. US Food and Drug Administration. April 2020. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-ophthalmic-assessment-and-monitoring-devices-during-coronavirus-disease>.
8. Meyer CH, Lapolice DJ. Computer-based visual evaluation as a screening tool after intravitreal injections of vascular endothelial growth factor inhibitors. *Ophthalmologica.* 2008;222:364-368. <https://doi.org/10.1159/000151246> PMID:18698145
9. Chew EY, Clemons TE, Bressler SB, et al; AREDS2-HOME Study Research Group. Randomized trial of a home monitoring system for early detection of choroidal neovascularization home monitoring of the Eye (HOME) study. *Ophthalmology.* 2014;121:535-544. <https://doi.org/10.1016/j.ophtha.2013.10.027> PMID:24211172
10. Kaiser PK, Wang YZ, He YG, Weisberger A, Wolf S, Smith CH. Feasibility of a novel remote daily monitoring system for age-related macular degeneration using mobile handheld devices: results of a pilot study. *Retina.* 2013;33:1863-1870. <https://doi.org/10.1097/IAE.0b013e3182899258> PMID:23609122
11. Toy BC, Myung DJ, He L, et al. Smartphone-based dilated fundus photography and near visual acuity testing as inexpensive screening tools to detect referral warranted diabetic eye disease. *Retina.* 2016;36:1000-1008. <https://doi.org/10.1097/IAE.0000000000000955> PMID:26807627
12. Brucker J, Bhatia V, Sahel JA, Girmens JF, Mohand-Said S. Odysight: a mobile medical application designed for remote monitoring-a prospective study comparison with standard clinical eye tests. *Ophthalmol Ther.* 2019;8:461-476. <https://doi.org/10.1007/s40123-019-0203-9>