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ORIGINAL ARTICLE

Evaluation of the SVOne Handheld Autorefractor in a Pediatric Population

Mark Rosenfield* and Kenneth J. Ciuffreda†

ABSTRACT

Purpose. The SVOne is a portable, Hartmann-Shack wavefront aberrometer, which can be attached to a smartphone to determine the refractive error of the eye objectively. Previous results have shown the device to provide measurements equivalent to those of standard clinical techniques in young, healthy adults. The aim of the present study was to compare the findings of the SVOne with retinoscopy, subjective refraction, and two commercially available autorefractors (Retinomax-3 and WAM-5500) in a pediatric population.

Method. The refractive error of the right eye was assessed both without and with cycloplegia in 40 visually normal children between 5 and 17 years of age (mean age = 11.3 years) using the five techniques described above. Further, to assess repeatability of the instruments, the entire procedure was repeated in a subgroup of five subjects. All data were analyzed in terms of power vectors (M, J_0, and J_{45}).

Results. No significant difference was observed between the mean values of M (spherical equivalent) for the different techniques. Retinoscopy showed the best agreement with subjective refraction, both without and with cycloplegia, followed by the open-field WAM-5500. The most repeatable procedures, when measured without and with cycloplegia, were the WAM-5500 and retinoscopy, respectively. Measurements with the SVOne showed a decline in repeatability under cycloplegia.

Conclusions. The results indicate that the SVOne provides measurements of refractive error in a normal, pediatric population that are not significantly different from other subjective and objective procedures. Accurate alignment along the visual axis, especially when measuring through a dilated pupil, is critical. This instrument is valuable for vision screenings, for examinations taking place outside the clinical office, and a starting point for the refractive assessment.
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Key Words: aberrometer, ametropia, astigmatism, autorefractor, refraction, refractive error, smartphone, SVOne

The SVOne (Smart Vision Labs, New York, NY) is a portable, Hartmann-Shack wavefront aberrometer,[1,2] which connects easily to a smartphone for alignment purposes, and for downloading and storage of data. The device converts Zernike defocus and astigmatism terms into the conventional sphere, cylinder, and axis format. In a previous publication, we compared the findings of the SVOne with retinoscopy, subjective refraction, and two commercially available autorefractors (Topcon KR-1W and Righton Retinomax-3), both with and without cycloplegia in 50 visually normal, young-adult subjects (mean age = 25 years).[3] No significant difference was observed between the mean values of spherical equivalent refractive error (M) for the different techniques. It was noted that this instrument could be valuable for vision screenings and to play a partial role in vision examinations taking place outside the clinical office. Further details of the instrument, together with photographs of the device, can be found in the earlier paper[3] and at the manufacturer's website (www.smartvisionlabs.com).

Given the interest in using this device as part of a vision screening test battery, it is essential to determine the efficacy of the instrument in children because they represent the target population in the majority of screenings. Indeed, the American Academy of Pediatrics and other ophthalmological organizations recommend the inclusion of handheld autorefraction as part of a screening for amblyogenic refractive error because "it is quick, requires minimal co-operation from the child, and is especially useful in the preverbal, preliterate, or developmentally delayed child."[4] Given that many vision screenings are performed by school nurses or other volunteers not trained to perform retinoscopy, handheld autorefraction is a valuable method for these individuals to assess refractive error in this type of setting.

However, the instrument also has useful applications for licensed eyecare practitioners, where such a device may be used as a starting point for the subjective refraction. In comparison with

*MCOptom, PhD, FAAO
†OD, PhD, FAAO
SUNY College of Optometry, New York, New York (both authors).

adults, children usually have larger pupils, a higher amplitude of accommodation, and more variable fixation. Therefore, the results obtained in an adult population may not be directly applicable to children. Accordingly, the aim of the present investigation was to compare the findings of the SVOne with retinoscopy, subjective refraction, and two other commercially available autorefractors, namely the open-field, Grand Seiko WAM-5500 (Grand Seiko, Hiroshima, Japan) and the Righton Retinomax-3 handheld autorefractor (Righton Ophthalmic Instruments, Tokyo, Japan), in a pediatric population (between 5 and 17 years of age). Assessment of refractive error was undertaken both before and after instillation of a cycloplegic agent.

METHODS

The study was performed on 40 subjects (20 female, 20 male) between 5 and 17 years of age (mean age = 11.3 years; SEM = 0.50 years). They were drawn from pediatric patients at the SUNY University Eye Center, and relatives of staff and faculty at the SUNY College of Optometry. All had corrected visual acuity of at least 6/6 (20/20) in each eye, and a pupil diameter between 3 and 8 mm under the testing conditions adopted (subdued clinic room lighting). Any subject with contraindications to the use of cycloplegia, such as a diagnosis of glaucoma or ocular hypertension or any suspicion of such a diagnosis, an intraocular pressure greater than 24 mm Hg, or taking any topical or systemic medication that may interact adversely with the cycloplegic agent, was excluded from the study. Intraocular pressure was measured by non-contact tonometry, or for those children where non-contact tonometry was not deemed possible, assessed by digital palpation through the eyelids. The methodology followed the tenets of the Declaration of Helsinki. Informed consent was obtained from the subject's parent or guardian (with assent being obtained, where possible, from the child) after an explanation of the nature and possible consequences of the study. The protocol was approved by the Institutional Review Board at the SUNY State College of Optometry. The study was conducted by licensed optometrists in the Clinical Vision Research Center at the College.

Before all measurements, corrected monocular and binocular distance visual acuity, tonometry (if possible—using a Marco Nidek NT-2000 automatic non-contact tonometer; Nidek Co. Ltd., Aichi, Japan), pupil diameter (using the Neuroptics VIP-200 Pupillometer; NeurOptics, Inc., Irvine, CA), and assessment of the posterior pole with a direct ophthalmoscope (undilated) were carried out to ensure subjects satisfied both the inclusion and exclusion criteria described above. Subsequently, the refractive error of the subject's right eye was assessed using the following techniques: (1) streak retinoscopy, (2) subjective refraction, (3) objective autorefraction using the SmartVision SVOne (first generation with software version 2.3), (4) objective autorefraction using the WAM-5500 autorefractor, and (5) objective autorefraction using the Retinomax3 autorefractor. To minimize the possibility of experimenter bias from knowledge of the autorefractor findings, retinoscopy was always performed first (with the left eye fogged during the procedure), followed by subjective refraction using the Jackson cross-cylinder (if possible) and sphere refinement, to achieve an endpoint of maximum plus (or minimum minus) for best visual acuity.[5] The retinoscopy finding was used as the starting point for the subjective refraction. Although performing retinoscopy before the subjective refraction is the conventional clinical protocol, one could argue that knowledge of the retinoscopy result could have influenced the subjective findings.[5] During both procedures, subjects viewed a projected, calibrated Snellen visual acuity chart at a distance of 5 m. The targets comprised either Snellen letters, Tumbling Es, numbers, or picture optotypes as considered age-appropriate by the examiner. After subjective refraction, the refractive error was quantified using each of the three automated devices. The order of testing of these instruments was counterbalanced across subjects to minimize order effects. Subjects were instructed to fixate a single optotype within the 20/25 line of the distance visual acuity chart, and five readings were recorded for each device and subsequently averaged. The left eye remained open and unfogged during the autorefractor procedures.

After the pre-cycloplegic measurements of refractive error were completed, cycloplegia was induced by instilling one drop of the topical anesthetic proparacaine hydrochloride (0.5%), followed 5 minutes later by one drop of tropicamide (1%) into each eye. However, for children under 8 years of age, proparacaine was not used to avoid the potential difficulty of having to instill two drops into the eye. Adequate cycloplegia was defined as having a subjective amplitude of accommodation of less than 2D.[6] This was assessed by measuring the push-up amplitude of accommodation,[7] with a supplementary +2.00D lens added to the distance refractive correction. The endpoint for the push-up procedure was

TABLE 1.

Mean values of M, J_0, and J_{45} vectors (D) measured both before and after instillation of a cycloplegic agent using each of the five measurement techniques

	Pre-cycloplegia	Pre-cycloplegia	Pre-cycloplegia	Post-cycloplegia	Post-cycloplegia	Post-cycloplegia
	M	J_0	J_{45}	M	J_0	J_{45}
Retinoscopy	−0.90 (0.27)	0.14 (0.05)	0.02 (0.02)	−0.68 (0.27)	0.12 (0.06)	−0.01 (0.03)
Subjective	−0.80 (0.25)	0.10 (0.04)	−0.04 (0.03)	−0.66 (0.26)	0.06 (0.05)	−0.03 (0.02)
SV1	−0.90 (0.27)	0.18 (0.06)	−0.05 (0.04)	−0.46 (0.29)	0.14 (0.06)	0.01 (0.04)
WAM	−0.81 (0.24)	0.12 (0.05)	0.07 (0.03)	−0.63 (0.25)	0.11 (0.05)	0.04 (0.03)
Retinomax	−1.46 (0.24)	0.05 (0.05)	−0.06 (0.02)	−0.95 (0.27)	0.08 (0.05)	−0.05 (0.02)
p value	0.31	0.48	0.004	0.78	0.84	0.18

Numbers in parentheses indicate 1 SEM.

SV1, SmartVision SVOne; WAM, WAM-5500; Retinomax, Righton Retinomax-3.

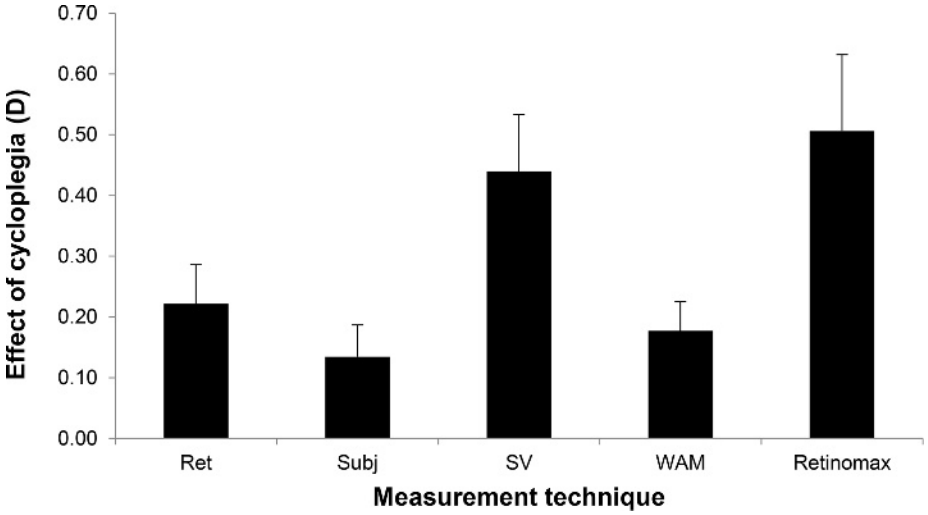

FIGURE 1.

Mean change in spherical equivalent refractive error (M) following the instillation of cycloplegic agent (tropicamide 1%) in 40 pediatric subjects using 5 measurement techniques. Ret, retinoscopy; Subj, subjective refraction; SV, SmartVision SVOne; WAM, WAM-5500; Retinomax, Righton Retinomax-3. Error bars indicate 1 SEM.

taken as the report of first, slight, sustained blur.[7] Once adequate cycloplegia had been achieved (i.e. amplitude of accommodation less than 2D), then the refractive measurements were repeated using the methodology described above.

Additionally, to assess repeatability of the instruments, the entire procedure was repeated in a subgroup of five subjects, with the second session being scheduled between 3 and 14 days after their initial testing. This subgroup comprised the first five subjects examined who were willing to return for a second trial. All results were converted into power vectors (M, J_0, and J_{45}) as described by Thibos et al.[8] Statistical analysis was performed using StatistiXL software (www.statistixl.com; Broadway-Nedlands, Western Australia).

RESULTS

Based on the cycloplegic subjective refraction results, the mean spherical equivalent refractive error was −0.66D (SEM = ±0.26; range +1.25 to −6.25D). Mean astigmatism was −0.46D (SEM = ±0.09; range 0–2.75D). Mean values of M, J_0, and J_{45} for the five methods of measurement are shown in Table 1. A one-way analysis of variance indicated that the only significant difference between the techniques was for the pre-cycloplegic, J_{45} parameter ($F = 3.95$; $df = 4, 199$; $p = 0.004$). Post hoc analysis using the Tukey test revealed that the J_{45} finding for the WAM was significantly higher than the values for subjective refraction ($p = 0.046$), the SVOne ($p = 0.015$), and the Retinomax instrument ($p = 0.008$). None of the other post hoc comparisons for this parameter were significant ($p > 0.05$).

The mean differences between M findings obtained with and without cycloplegia for each technique are shown in Fig. 1. Analysis of variance revealed that the effect of measurement technique was significant ($F = 4.10$; $df = 4, 199$; $p = 0.003$). Post hoc testing (Tukey test) indicated that this difference when measured with the Retinomax was significantly higher than found using either subjective refraction ($p = 0.01$) or the WAM ($p = 0.04$). Nonsignificant trends were observed when comparing the SVOne results with subjective refraction ($p = 0.07$) and the Retinomax findings with retinoscopy ($p = 0.10$).

To compare the difference between each of the findings and subjective refraction, the 95% limits of agreement (LOA) was quantified using the technique described by Bland and Altman.[9] Here, the difference between each vector measurement with respect to the subjective finding was determined, and the LOA calculated as 1.96 multiplied by the standard deviation of the differences. These values are shown in Table 2, with lower values representing better agreement. The difference between the SVOne and the subjective refraction findings (in terms of M, J_0, and J_{45}), with respect to the mean of these two values, is shown in Fig. 2, with good agreement being observed. A similar comparison between the SVOne findings and retinoscopy is shown in Fig. 3.

TABLE 2.

95% limits of agreement (D) between each technique and subjective refraction (calculated as 1.96 multiplied by the standard deviation of the differences)

	Pre-cycloplegia	Pre-cycloplegia	Pre-cycloplegia	Post-cycloplegia	Post-cycloplegia	Post-cycloplegia
	M	J_0	J_{45}	M	J_0	J_{45}
Retinoscopy	0.61	0.30	0.33	0.40	0.26	0.15
SV1	0.89	0.38	0.30	1.06	0.50	0.38
WAM	0.63	0.35	0.33	0.60	0.36	0.25
Retinomax	1.47	0.32	0.24	1.03	0.32	0.23

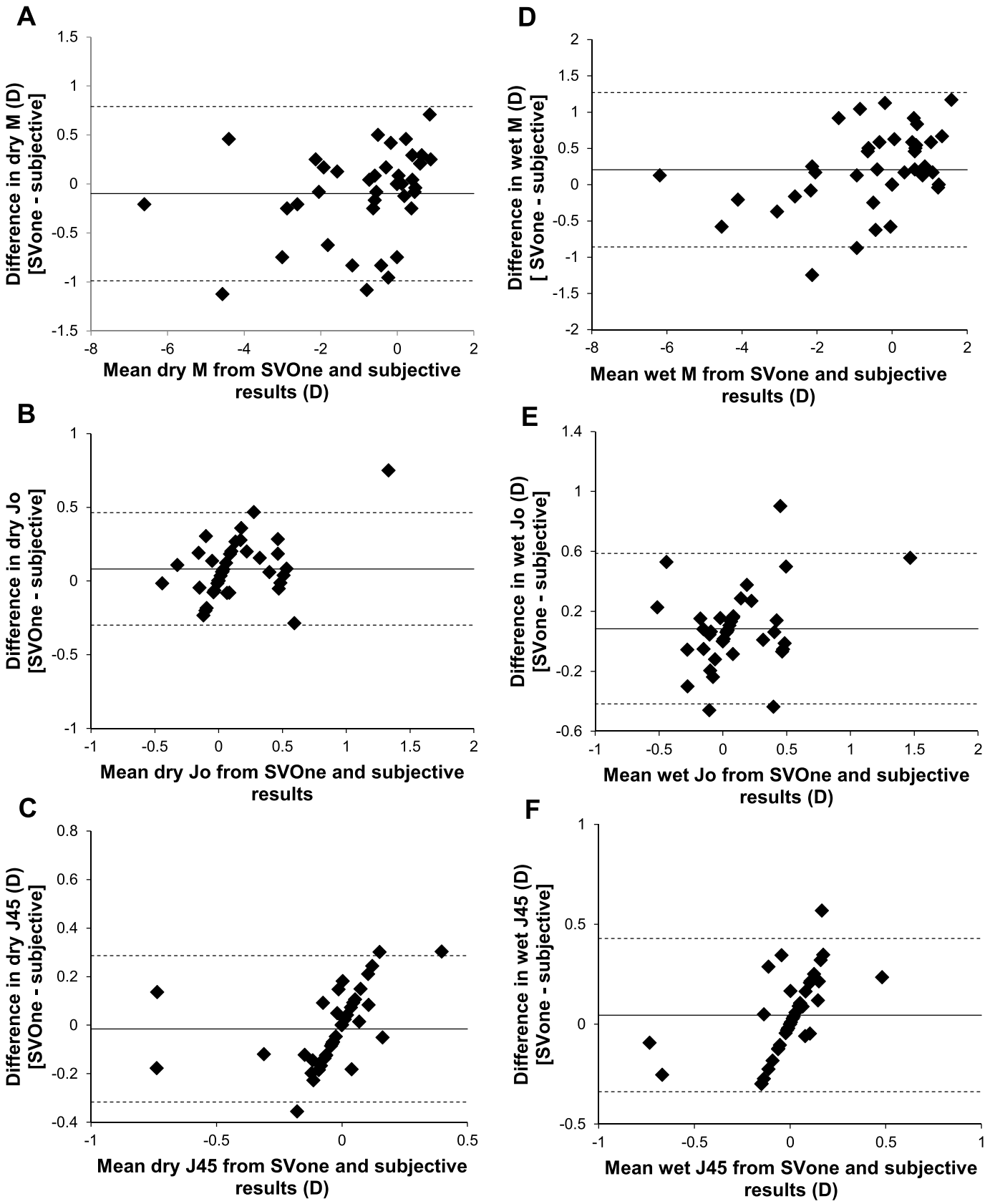

FIGURE 2.

Plots showing the difference between the SVOne and subjective refraction findings, with respect to the mean of these 2 results for 40 subjects. A, B, and C: Findings for M, J_0, and J_{45}, respectively, without cycloplegia. D, E, and F: Findings for M, J_0, and J_{45}, respectively, under cycloplegia. In all figures, the solid horizontal line represents the mean difference, whereas the upper and lower dashed lines indicate the 95% limits of agreement (calculated as 1.96 times the standard deviation of the differences).

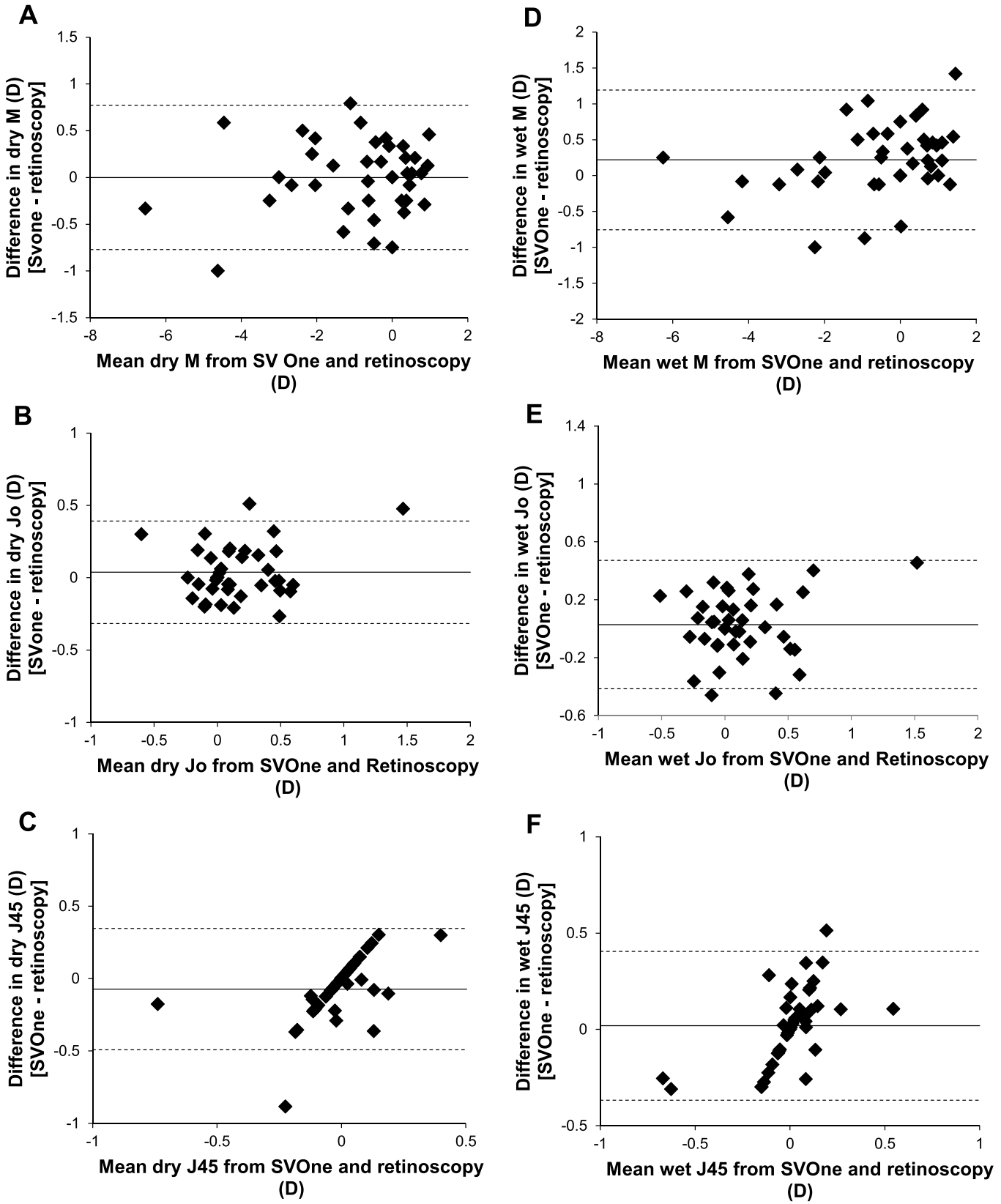

FIGURE 3.

Plots showing the difference between the SVOne and retinoscopy findings, with respect to the mean of these 2 results for 40 subjects. A, B, and C: Findings for M, J0, and J45, respectively, without cycloplegia. D, E, and F: Findings for M, J0, and J45, respectively, under cycloplegia. In all figures, the solid horizontal line represents the mean difference, whereas the upper and lower dashed lines indicate the 95% limits of agreement (calculated as 1.96 times the standard deviation of the differences).

TABLE 3.

Square of the linear correlation coefficient (r^2) between each technique and subjective refraction

	Pre-cycloplegia	Pre-cycloplegia	Pre-cycloplegia	Post-cycloplegia	Post-cycloplegia	Post-cycloplegia
	M	J_0	J_{45}	M	J_0	J_{45}
Retinoscopy	0.97	0.79	0.20	0.99	0.86	0.78
SV1	0.93	0.72	0.59	0.92	0.58	0.47
WAM	0.96	0.72	0.43	0.97	0.69	0.53
Retinomax	0.78	0.73	0.54	0.91	0.75	0.52

In all cases, the correlations were statistically significant (all $p < 0.01$).

Additionally, linear regression analysis was used to compare each of the parameters with the findings from subjective refraction. Correlation coefficients are listed in Table 3, and all were statistically significant.

Repeatability measurements for the subgroup of five subjects are shown in Table 4. The best repeatability of M (smallest LOA) for the pre- and post-cycloplegic measurements was found using the WAM autorefractor and retinoscopy, respectively.

DISCUSSION

The results of the present study are very similar to those of our previous investigation on young adults.[3] In both studies, no significant difference was found between the spherical equivalent refractive error (M) for any of the instruments tested, both with and without cycloplegia. This confirms the validity of the SVOne device in children, either as a starting point for the refractive sequence or as part of a vision screening paradigm.

A recent study by Durr et al. compared a custom-developed, handheld, wavefront autorefractor with both subjective refraction and the Grand Seiko WAM-5100K autorefractor (without cycloplegia) in a group of 41 subjects between 18 and 64 years of age.[10] The latter device is similar to the WAM-5500 instrument used in the present investigation. In comparing the SVOne and the custom device used by Durr et al.,[10] similar levels of agreement were found despite the different-aged populations. These mean differences and the 95% limits of agreement are shown in Table 5.

However, a limitation of both the present study and our previous investigation[3] was the small number of subjects having large amounts of astigmatism. Here, 29 out of the 40 subjects (72.5%) had less than 0.75D of astigmatism. Similarly, in the young-adult study,[3] 64% of the subjects had less than 0.75D of astigmatism. Examination of the J_{45} data shown in Figs. 2c, 2f, 3c, and 3f suggests differences in cylindrical findings between the different methods of measurement. However, given the very small mean values recorded for the J_{45} parameter (see Table 1), it is difficult to draw any conclusions regarding the accuracy and repeatability of the cylindrical component as measured with the SVOne from the present findings. Future work should be directed to examining subjects with larger amounts of astigmatism, where obtaining precise measurements of the cylinder axis and power is more critical.

In comparing the 95% LOA between subjective refraction and the other measurement techniques for values of M, retinoscopy showed the best agreement, both with and without cycloplegia, with the table-mounted, open-field WAM autorefractor exhibiting the second best agreement. This confirms the value of retinoscopy in the hands of a skilled operator, especially when examining pediatric patients. However, as noted previously, many vision screenings are performed by school nurses and other non-optometric personnel without training in retinoscopy. For these individuals, the handheld, SVOne device will provide valuable data when screening children.

When examining the difference between cycloplegic and non-cycloplegic measurements of spherical equivalent refractive error (see Fig. 1), significant variations were observed depending on the measurement technique adopted. However, for all procedures, less myopia was observed under cycloplegia. This is consistent with the findings of Manny et al.,[11] who noted that after the instillation of 2 drops of tropicamide (1%) in 469 myopic children, the vast majority of subjects exhibited up to 0.50D less myopia. Because the Retinomax instrument was the only device tested here that required subjects to fixate an internal target, it is not surprising that this showed the biggest change with cycloplegia. Both the internal target (even if imaged at optical infinity) and the proximity of the device are likely to provide significant cues to proximally induced accommodation.[12] When examining the larger difference between cycloplegic and non-cycloplegic findings in the

TABLE 4.

95% limits of agreement (D) calculated as 1.96 multiplied by the standard deviation of the differences when each procedure was repeated on a subgroup of five subjects

	Pre-cycloplegia	Pre-cycloplegia	Pre-cycloplegia	Post-cycloplegia	Post-cycloplegia	Post-cycloplegia
	M	J_0	J_{45}	M	J_0	J_{45}
Retinoscopy	0.41	0.27	0.20	0.27	0.24	0.20
Subjective	0.47	0.36	0.20	0.53	0.54	0.24
SV1	0.29	0.18	0.12	0.61	0.54	0.26
WAM	0.26	0.26	0.14	0.37	0.27	0.30
Retinomax	2.00	0.38	0.06	0.84	0.30	0.06

TABLE 5.

Mean difference in diopters ±95% limits of agreement when comparing values of M, J_0, and J_{45} measured using a Grand Seiko autorefractor with either the SVOne device from the present study or a custom-made instrument described by Durr et al.[10]

	SVOne	Data from Durr et al.[10]
M	−0.09 ± 0.99	−0.20 ± 0.84
J_0	−0.06 ± 0.37	−0.15 ± 0.31
J_{45}	0.13 ± 0.33	0.06 ± 0.25

SVOne, in comparison with subjective refraction (see Fig. 1), this variation narrowly failed to reach statistical significance ($p = 0.07$).

In considering the change in spherical equivalent refractive error (M) observed when using the SVOne after instillation of a cycloplegic agent, this may be caused by greater awareness of instrument proximity stimulating proximal accommodation[13,14] because the device is in direct contact with the area of the face immediately adjacent to the eye, unlike retinoscopy and the open-field, WAM autorefractor. Another explanation is due to the measurements being recorded through a dilated pupil. Atchison pointed out that because of ocular aberrations, the refractive power may vary across the pupil.[15] Therefore, it is important that refractive measurements are taken as close to the visual axis as possible. Examination of Table 4 shows that the 95% LOA for the SVOne before and after cycloplegia (for M) were 0.29 and 0.61D, respectively. Interestingly, examination of this same parameter in our previous study on young adults found equivalent findings of 0.51 and 0.89D, respectively.[3] In both cases, the SVOne was *less* repeatable under cycloplegia, with an approximate doubling of the LOA. In none of the other procedures was a comparable change observed. The increased variability noted when measuring with the SVOne through a dilated pupil may occur because different parts of the pupil were being assessed. This model of instrument does not allow the pupil to be visualized while measurements are being recorded. Accordingly, it is hard to assess whether the device was actually centered in the subject's pupil. Differences in positioning relative to the visual axis could explain the increased variability found with the SVOne when measuring through a dilated pupil. This is particularly important when examining children because they tend to have larger pupils (even without the use of mydriatics), and they are the group most frequently undergoing cycloplegic examinations. However, the manufacturers of the SVOne (SmartVision Labs) have indicated that a new model will be available in the Spring of 2016, which does allow visualization of the patient's pupil, which should improve centration.

In conclusion, it is apparent that the SVOne provides measurements of spherical equivalent refractive error (M) in both children and adults that are not significantly different from those of other standard clinical procedures. Although retinoscopy, in the hands of a skilled operator, showed the closest agreement with subjective refraction, newer technologies can be valuable as a preliminary step in the refractive examination. However, none of these automated devices should be considered a substitute for a comprehensive eye examination by a licensed practitioner, comprising a full evaluation of the patient's refractive and binocular status, and an assessment of the health of the ocular and visual system.

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Mark Rosenfield
SUNY College of Optometry
33 West 42nd Street
New York, NY 10036
e-mail: rosenfield@sunyopt.edu