Comparison between refraction measured by Spot Vision Screening™ and subjective clinical refractometry

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OBJECTIVE: The purpose of this study was to evaluate the accuracy of Spot Vision Screening™ as an autorefractor by comparing refraction measurements to subjective clinical refractometry results in children and adult patients.

METHODS: One-hundred and thirty-four eyes of 134 patients were submitted to refractometry by Spot and clinical refractometry under cycloplegia. Patients, students, physicians, staff and children of staff from the Hospital das Clínicas (School of Medicine, University of São Paulo) aged 7-50 years without signs of ocular disease were examined. Only right-eye refraction data were analyzed. The findings were converted in magnitude vectors for analysis.

RESULTS: The difference between Spot Vision Screening™ and subjective clinical refractometry expressed in spherical equivalents was $+0.66 \pm 0.56$ diopters (D), $+0.16 \pm 0.27$ D for the vector projected on the 90 axis and $+0.02 \pm 0.15$ D for the oblique vector.

CONCLUSIONS: Despite the statistical significance of the difference between the two methods, we consider the difference non-relevant in a clinical setting, supporting the use of Spot Vision Screening™ as an ancillary method for estimating refraction.

KEYWORDS: Refraction; Ocular; Equipment Design; Comparative Study.

■ INTRODUCTION

Uncorrected refractive errors are the main cause of visual impairment and the second cause of blindness worldwide (1). In 2011, the World Health Organization estimated that visual impairment affects 284 million people worldwide, among whom 43% have uncorrected refractive errors (2).

In preschool and school-aged children, refractive errors pose serious limitations (3,4) that can compromise intellectual and psychological development as well as academic performance (5-8), resulting in potentially life-long negative effects (9). Amblyopia and amblyopic factors, such as strabismus and refractive errors, are most commonly observed in children. Visual disorders should be detected as early as possible to increase the chances of effective treatment and minimize the burden on public health. In adults, screening for refractive errors provides an opportunity to identify conditions that may lead to blindness, including cataracts, glaucoma and diabetic retinopathy.

Currently, refractive error may also be detected using photo-screeners. The method is an attractive alternative for examining children with a risk for amblyopia or severe refractive errors, especially preschool, preverbal and mentally challenged children (10-15). In adults, photoscreeners may be used in refractive error screening campaigns, improving access to ocular health care services for socioeconomically disadvantaged populations (16).

Developed and marketed in October 2011 by PediaVision (Lake Mary, FL), Spot Vision Screening™ (SVS) technology was recently acquired by Welch Allyn (Skaneateles Falls, NY) (17). The SVS is a non-invasive, handheld, portable laser device that automatically captures vision data for both eyes concomitantly in children of all ages. The built-in software displays readings in a one-page summary and indicates whether the child should be referred to an ophthalmologist. Wi-Fi-enabled for easy data transfer and printing, the device is held at a distance of one meter from the face of the patient, much like a camera. The measuring range extends up to ± 7.50 diopters (D) for spherical errors and ± 3.50 D for cylindrical errors. The interpupillary distance, pupil diameter and ocular alignment may also be evaluated.

The purpose of this study was to evaluate the accuracy of SVS refraction measurements by comparing SVS readings to subjective clinical refractometry (SCR) results in volunteers consisting of children and adults.

■ METHODS

Following approval of the study protocol by the National Research Ethics Committee (CONEP), 134 healthy adult volunteers with no signs of ocular disease were submitted to refractometry at the ophthalmology out-patient service of Hospital das Clínicas (School of Medicine, University of São Paulo/USP).

The participants were aged 7-50 years and included patients, medical students (USP), physicians from the Hospital das Clínicas, staff and children of staff. All participants/caretakers were informed about the study objectives and procedures and provided their written consent.

Information was collected regarding age, date of birth, gender and ophthalmological findings. Subjects presenting a visual acuity <20/20 with correction in one eye and/or ocular disease were not eligible for inclusion in the study. Three patients were excluded because readings could not be obtained by SVS due to small pupil (n=1), pterygium (n=1) and signs of pigmentary glaucoma in one eye (n=1).

The ophthalmological measurements were obtained in the following sequence: i) visual acuity (Snellen chart at 5 m) without optical correction, ii) three static SVS refraction measurements under cycloplegia, iii) subjective clinical refractometry (SCR) under cycloplegia using a Greens refractor, iv) visual acuity with correction, and v) slit lamp biomicroscopy and fundoscopy.

The Spot Vision Screener used in this study was provided free of charge by Loktal Medical Electronics (São Paulo, Brazil).

Statistical analysis

Data were collected from the right eye only to avoid challenges associated with the interdependence of observations of eyes from the same individual.

The refraction measures obtained using the two methods were averaged and compared. For the purpose of the refractive error analysis, the spherical component was expressed in spherical diopters, the cylindrical component in cylindrical diopters and the main axis of the cylinder in degrees.

To calculate average values and perform statistical analyses, readings were converted into a spherical equivalent (SE), which corresponded to the spherical value plus half the astigmatism value. In addition, the spherical and cylindrical components were converted into power vectors according to the Naeser equation (18): MV 90=m(sen$^2\alpha$-cos$^2\alpha$), where MV 90 is the magnitude vector on the 90° axis, m is astigmatism in diopters, and α is the meridian of astigmatism in degrees (vertical and horizontal refraction components). The equation MV 135=m(sen2(α-45)-cos2(α-45) allows the calculation of the difference between diopter components projected on the 135° axis and the 45° axis. To maintain the spherical equivalent format, the MV components were divided in half.

The statistical analysis was performed using the software R-project (19). The univariate analysis was conducted as follows. The difference in spherical equivalent (SE) values was calculated as the SVS spherical equivalent value minus the SCR spherical equivalent value. The same procedure was applied to MV90 and MV135, respectively. A positive difference indicated that SVS overestimated the corresponding value.

Comparisons between measurements were performed using a paired two-tailed Student's t-test. The level of statistical significance was set at 5% ($p < 0.05$).

■ RESULTS

The final sample consisted of 134 eyes of 134 subjects, among whom 54 (40.3%) were male and 80 (59.7%) were female. The average age was 29.7 years.

Table 1 shows the differences between the refraction values obtained by SVS and SCR, both under cycloplegia. The SVS produced the following mean ± SD: SE was +0.66 ± 0.56, MV90 was +0.16 ± 0.27 and MV135 was +0.02 ± 0.15. The data showed that SVS tended to overestimate both the Spherical and Cylindrical powers, although this difference was not large. The greatest difference was obtained for the spherical equivalent, which was slightly greater than half dioptry.

A bivariate analysis was performed to evaluate the influence of astigmatism on the differences between the refraction values obtained by SVS and SCR, both under cycloplegia (Figure 1).

In the trivariate analysis, a 3D plot was used to assess the relationship between the parameters SE, MV 90 and MV 135 and their influence on differences between the right-eye refraction values obtained under cycloplegia using SVS and SCR (Figure 2).

The conversion of refraction expressed in magnitude vectors to the conventional form revealed an average difference between SVS and SCR of +0.63 DE, with -0.33 DC on the 4 axis, for the right eye of each patient.

■ DISCUSSION

Photoscreening technology is gaining increasing popularity because of its range of advantages. Photoscreeners collect swift and binocular measurements, require minimal training, detect refractive errors, strabismus and risk factors for amblyopia and constitute a cost-efficient screening tool for populations with limited access to ocular health care.

In a recent study of 151 children submitted for photoscreening with SVS, Silbert and Matta (20) reported a sensitivity and specificity of 87% and 74%, respectively, for the detection of risk factors for amblyopia, according to the revised criteria of the American Association for Pediatric Ophthalmology and Strabismus. Using SVS, Arnold and Armitage (21) photoscreened 108 children aged 1-12 years and obtained a sensitivity and specificity of 80% and 85%, respectively; inconclusive results were collected in 4% of the

Table 1 - Univariate analysis of differences between right-eye refraction values obtained under cycloplegia by Spot Vision Screening™ and by subjective clinical refractometry in a sample of 134 healthy Brazilian volunteers.

	Variables	Average	SD[1]	p value
SVS-SCR*	SE[2]	+0.66	0.56	< 0.001
	MV 90[3]	+0.16	0.27	< 0.001
	MV 135[4]	+0.02	0.15	> 0.05

1) SD: standard deviation; 2) SE: spherical equivalent; 3) MV 90: magnitude vector on the 90° axis; 4) MV 135: difference between diopter components projected on the 135° axis and the 45° axis; *) SVS-SCR: difference between refraction values obtained by Spot Vision Screening™ and subjective clinical refractometry, both under cycloplegia.
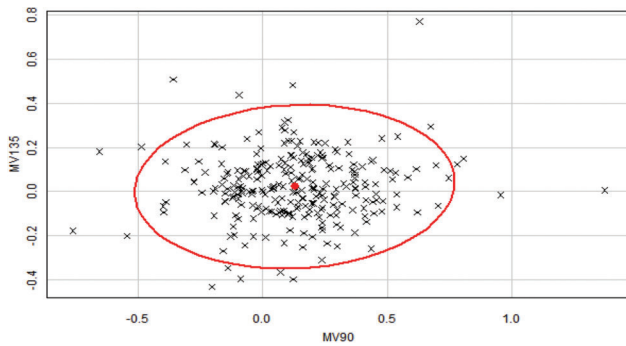
Figure 1 - Bivariate analysis of the influence of the parameters magnitude vector 90 and magnitude vector 135 on differences between right-eye refraction values obtained under cycloplegia by Spot Vision Screening™ and by subjective clinical refractometry in a sample of 134 healthy Brazilian volunteers. Magnitude vector 90: magnitude vector on the 90° axis; MV 135: difference between diopter components projected on the 135° axis and the 45° axis.

children. To our knowledge, the performance of SVS in adults has not been assessed.

Before widespread adoption, new screening methods must be validated against the gold standard for diagnosis. To some authors, a difference of ± 1.00 D SE between methods is relevant. Therefore, we adopted this value as a failure criterion (22,23). In the present study, we analyzed the performance of Spot Vision Screening™ as a refractor against subjective clinical refractometry under cycloplegia and observed significant quantitative differences between the methods with regard to SE ($+0.66$) and MV 90 ($+0.16$). However, this difference may be considered of minor relevance in the clinical setting. The difference with regard to MV 135 was negligible ($+0.02$) and non-significant.

The bivariate analysis (Figure 2) revealed astigmatism had little influence (greater for MV 90 than for MV 135) on the results. Naeser obtained similar results in a study that demonstrated greater differences for the vertical and horizontal components than for the oblique component, from which the
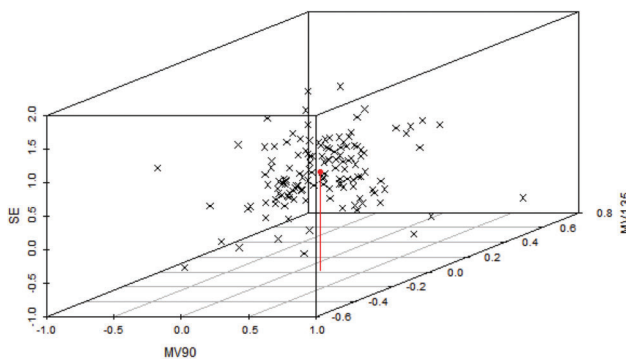
author inferred that the vertical component was more susceptible to eyelid tone and the blink mechanism (19).

Demirci et al. compared photoscreening (Plusoptix S08) to retinoscopy. The methods differed with regard to average SE (0.46 ± 0.35; $p=0.007$) but presented comparable astigmatism values. The authors concluded that the device is a feasible alternative for patients in whom conventional autorefractors cannot be employed (24).

In a similar study, Lang et al. compared dynamic and static subjective refractometry readings obtained using the autorefractor Topcon RM8800 and the Near-Eye Tool for Refractive Assessment (NETRA), a new method based on smartphones. The study subjects (n=33; 38 eyes) were aged 14-61 years (34.2 ± 13.0) and had a visual acuity $\geqslant 20/40$. Under cycloplegia, the methods did not differ significantly with regard to diopters in SE (absolute average difference: 0.94 ± 0.7 D; $p=0.99$), but in the absence of cycloplegia, the difference was significant (SE 2.88 ± 1.8 D; $p=0.02$). In conclusion, the authors demonstrated a good agreement between NETRA and autorefractometry (difference < 1D in SE) in patients under cycloplegia (23).

In this study, Spot Vision Screening (SVS) was found to be a simple and quick refractometry method. From the clinical perspective, comparable measurements were obtained by SVS and subjective clinical refractometry. This finding validated the use of SVS as an ancillary method for estimating refraction, especially in cases in which conventional clinical examinations are difficult to perform.

■ FUNDING INSTITUTION

■ AUTHOR CONTRIBUTIONS

Jesus DL and Villela FF examined the patients, analyzed the results and wrote the manuscript. Orlandin LF and Eiji FN examined the patients, reviewed the literature and wrote the manuscript. Dantas DO reviewed the literature, performed the statistical analysis and wrote the article. Alves MR directed the study design and participated in manuscript writing.

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Figure 2 - Trivariate analysis showing the influence of the parameters spherical equivalent, magnitude vector 90 and magnitude vector 135 on differences between right-eye refraction values obtained under cycloplegia by Spot Vision Screening™ and by subjective clinical refractometry) in a sample of 134 healthy Brazilian volunteers. SE: spherical equivalent; MV 90: magnitude vector on the 90° axis, magnitude vector 135: difference between diopter components projected on the 135° axis and the 45° axis.

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