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Original Article

Is Refraction with a Hand-Held Autorefractometer Useful in Addition to Visual Acuity Testing and Questionnaires in Preschool Vision Screening at 3.5 Years in Japan?

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The vision-screening program for 3.5-year-old children in Japan consists of 3 steps: questionnaires and home visual acuity testing, visual acuity testing by nurses and inspection by medical officers at regional Public Health Centers, and examinations by ophthalmologists. In this study, we tested refraction with a hand-held autorefractometer in addition to visual acuity testing and inspection to reveal whether or not autorefraction leads to better detection of eye problems. Autorefraction was performed in 6 consecutive sessions by a single examiner in 265 children at 3.5 years of age who all visited the same center. The children were sent to the third step of examinations by ophthalmologists based on refractive error criteria: >3 diopters myopia or >1 diopter hyperopia, and/or >2 diopters astigmatism in either eye, in addition to the current criteria: 1) failure in either eye for 0.5 visual acuity at the center, 2) eye-related symptoms revealed by the questionnaires, or 3) eye problems detected by medical officers. Notices to visit ophthalmologists were issued for 64 children (24%), and 37 of those (58%) made the visits, so that documents containing final diagnoses were sent back to the Public Health Office. Of the 64 children, 12 were sent to ophthalmologists based on the current criteria only, 10 based on both the current criteria and the refractive error criteria, and 42 based on the refractive error criteria only. Twelve of the 13 children visiting ophthalmologists by the current criteria had diagnoses such as amblyopia and strabismus. In contrast, 15 of 24 children visiting ophthalmologists by only the refractive error criteria had mainly diagnoses of refractive errors, with no serious problems. In conclusion, autorefraction in addition to visual acuity testing and inspection led to detection of only one additional case of an eye disease at 3.5 years, while tripling the number of children sending to the third-step examination by an ophthalmologist. Thus, from a cost-effectiveness standpoint, autorefraction is not recommended as an additional test when the current system is conducted as designed.

Key words: strabismus, amblyopia, refractive error, hand-held autorefractometer, preschool vision screening program

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According to the Maternal and Childhood Health Law in Japan, all children at the ages of 1.5 and 3.5 years have to undergo physical, mental, and

developmental checkups including urinalysis, dental, eye, and hearing examinations [1]. The examination at 3.5 years, including a dental checkup, was started in 1961, while that at 1.5 years was started in 1978, with the addition of a dental checkup starting in 1981. The vision and hearing examinations have been included as part of the checkups since 1991.

The eye examinations as vision-screening programs at 3. 5 years consist of 3 steps [1]. In the first step, family members fill out questionnaires asking about specific problems, such as squinting, and test the visual acuity of children with printed Landolt-C in two different sizes at home. In the second step, nurses at Public Health Centers measure uncorrected visual acuity in children who have either not taken or not passed the visual acuity test at home, and then pediatricians or medical officers (medical doctors) inspect eye problems such as eye alignment. Orthoptists' involvement in this second screening process is not the standard in this system. In the third step, children with suspected diseases are sent to ophthalmologists for detailed eye examinations. The final diagnoses are sent back to the City's Public Health Office.

The role of autorefraction in preschool vision screening has been discussed over the years [2–10], but until now no study has addressed whether autorefraction is superior or even equal to visual acuity testing. Furthermore, no study has shown the effectiveness of autorefraction in the current system of visual acuity testing at home and at the Public Health Centers. At present in Japan, some municipalities have abolished visual acuity testing as a screening method at the 3.5-year-old examination, replacing it with autorefraction. Here, we designed a prospective study to examine whether or not the addition of autorefraction to the current system including visual acuity testing would change the ability to detect eye diseases.

Materials and Methods

The population of Okayama City is about 700,000, and the Okayama City Government Public Health Centers consist of 6 facilities: the South, North, East, West, and Saidaiji Regional Public Health Centers and the Central Public Health Center. Once a month, the Central, North, and Saidaiji centers examine children who have recently reached 3.5 years of age; the other 3 centers have such examinations twice a month. We chose the East Regional Public Health Center for our study, and enrolled all 265 children who visited the Center on any of 6 examination days from November 2007 to February 2008. This study was approved by the Okayama City Government Public Health Office and Okayama University to be conducted as collaborative research. The aim of the study was explained in writing to families or guardians who brought the children to the Public Health Center, and informed consent was obtained from the families or guardians of all of the enrolled children.

The Landolt-C, sent to each family or guardian, was printed on sheets in 2 sizes: the large Landolt-C and the small Landolt-C were equivalent for visual acuity of 0.1 and 0.5, respectively, when tested at a distance of 2.5 m. The families were instructed to test the visual acuity of the children first with both eyes open using the 0.1-equivalent Landolt-C at 1 m. The visual acuity in both eyes open and then in each eye, with the other eye occluded by the examiner's hand, was tested with the 0.5-equivalent Landolt-C at a distance of 2.5 m. Four different directions of the Landolt-C (top, bottom, right, and left) were tested by rotating the print, and children were said to pass the test when they correctly recognized the figure in at least three directions [1].

The questionnaire sent to the families asked whether or not the visual acuity testing was done at home and whether or not the children understood the test and passed the 0.5-equivalent visual acuity testing in both eyes and in each eye. The presence or absence of eye-related conditions was also asked: convergent, divergent or vertical deviations, watching television at near distance, abnormal head postures (chin up or down, face turned, head tilted), winking at light, lid fissure narrowing, blepharoptosis, nystagmus, leukocoria, pupils of different sizes, and slower mobility in the dark. The families were also asked if an ophthalmologist had diagnosed the child with any eye disease [1].

At the Public Health Centers, nurses test visual acuity with the 0.1- and 0.5-equivalent Landolt-C cards at a distance of 5 m in each eye of children who had either failed or had not undergone visual acuity testing at home. The children were determined to pass the test when they correctly recognized the figure in at

least 3 directions of the Landolt-C. Refraction with a hand-held autorefractometer (Autorefractometer AR-20 type R, Nidek, Gamagori, Japan) was done in all children by a single, well-trained examiner (C.M.) who was masked to their visual acuity test results and questionnaire answers. Cycloplegics eye drops were not used, and the measurements were done first in the right eye and then in the left at a preset distance from the device. Five measurements for each eye in a quick mode were automatically processed to get representative values for spherical power, cylindrical power, and axis. Finally, all children were inspected systemically by medical officers (medical doctors) or pediatricians.

In parallel, families filled out questionnaires about hearing problems and tested the children's hearing at home by whispering 6 words, from a distance of 1 m, while the examiner's mouth was covered. Nurses at the regional Public Health Centers repeated the hearing test for children who did not pass the test at home.

The children who had problems revealed by the questionnaire, who had failed the visual acuity testing, or who were pointed out to have problems by pediatricians or medical officers were sent to ophthalmologists. In addition to these current criteria, children were sent to ophthalmologists with refractive error criteria based on the autorefraction results: greater than 3-diopter spherical power for myopia or greater than 1-diopter spherical power for hyperopia, and/or greater than 2-diopter cylindrical power for astigmatism. Failure to measure refractive errors due to the child's uncooperativeness was not considered a criterion for sending the child to the third step examination. The final diagnoses made by ophthalmologists and documents sent back to the Okayama City Government Public Health Office were reviewed with respect to the current criteria (visual acuity testing at home or by nurses, questionnaire, and doctors' inspection) versus the refractive error criteria.

Results

Of the 265 children enrolled, nurses tested the visual acuity of 48 children who either had not been given or had not passed visual acuity tests at home. Of these 48, 24 children passed with visual acuity of 0.5 in both eyes. The remaining 24 children did not pass and thus were scheduled to be sent to detailed examinations by ophthalmologists as the third step (Table 1).

Due mainly to uncooperativeness, in 15 children, refractive errors could not be measured by hand-held autorefraction in both eyes; in 2 other children, refractive errors could be measured in the left eye but not in the right. The distributions of spherical equivalents, spherical powers, cylindrical powers, and axes of refractive errors in 248 right eyes and 250 left eyes are shown in Fig. 1. The spherical powers of refractive errors were predominantly distributed in the range from −3.0 to +1.0 diopters in both eyes, while the cylindrical powers were predominantly distributed in the range from −2.0 to 0 diopters in both eyes. The ranges of twice the standard deviation around the mean spherical power were −4.9 to +1.5 diopters in the right eye and−4.6 to +1.2 diopters in the left. The ranges of twice the standard deviation around the mean cylindrical power were −2.2 to +0.7 diopters in the right eye and −2.1 to +0.7 diopters in the left. The cylindrical axes had peaks around 0, 90, and 180 degrees in both eyes, indicating the predominance of with-the-rule and against-the-rule astigmatism. A statistically significant correlation was noted between refractive errors of both eyes ($p<0.0001$ for spherical equivalents, $p<0.0001$ for spherical powers, $p<0.0001$ for cylindrical powers, and $p<0.0301$ for axes, Spearman correlation coefficient by rank, Fig. 2).

As the third step, notices to visit ophthalmologists for detailed examinations were issued to 64 (24%) of

Table 1 Results of visual acuity testing by nurses in 48 of 265 children at the regional Public Health Center

Visual acuity testing results	The number of children
0.5 in both eyes	24
0.5 in the right eye, 0.1 in the left eye	7
0.1 in the right eye, 0.5 in the left eye	1
0.1 in both eyes	7
Un-measurable in both eyes	8
0.5 in the right eye, un-measurable in the left eye	1
In total	48

Children who did not achieve 0.5 visual acuity in both eyes were sent to detailed examinations by ophthalmologists as a third step. Visual acuity was tested with Landolt-C cards and expressed in decimals.

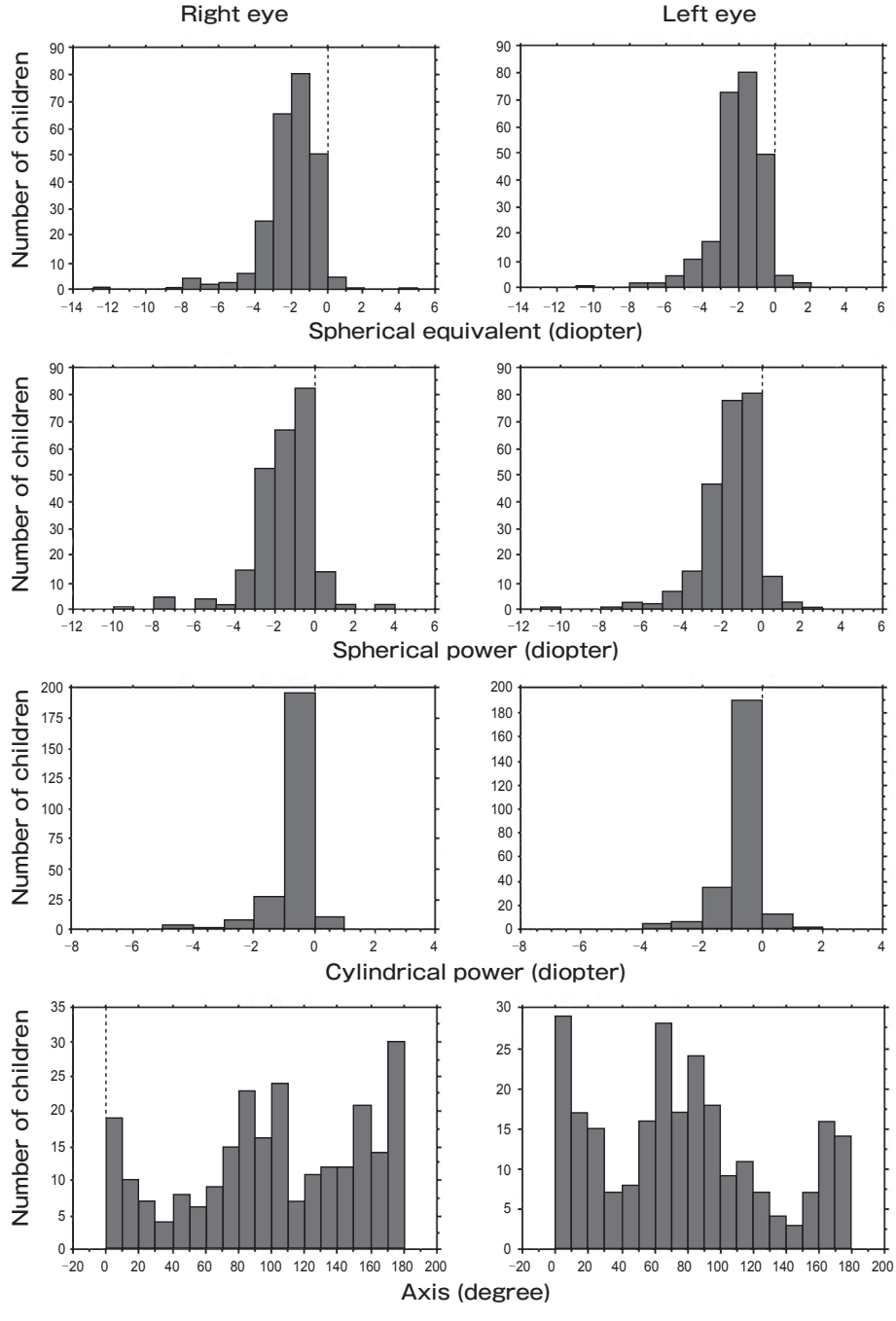

Fig. 1 Distributions of spherical equivalents, spherical powers, cylindrical powers and axes of autorefraction in 248 right eyes and 250 left eyes out of 265 children. The mean and standard deviation are: −2.1 and 1.6 diopters in spherical equivalents in the right eye, −2.1 and 1.5 diopters in spherical equivalents in the left eye, −1.7 and 1.6 diopters in spherical power in the right eye, −1.7 and 1.5 diopters in spherical power of the left eye, −0.8 and 0.7 diopters in cylindrical power in the right eye, and −0.7 and 0.7 diopters in cylindrical power in the left eye.

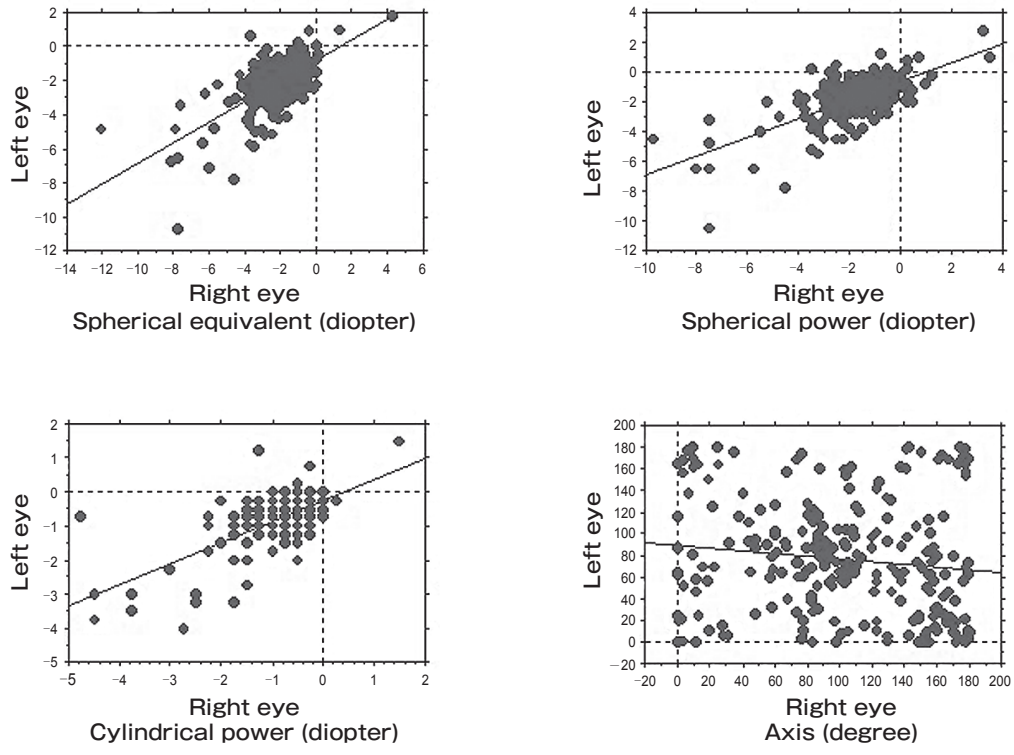

Fig. 2 Correlation between spherical equivalents, spherical powers, cylindrical powers and axes of autorefraction in the right eye and in the left eye of 248 children who had both eyes measured. Statistically significant correlations are noted between both eyes ($p < 0.0001$ for spherical equivalents, $p < 0.0001$ for spherical powers, $p < 0.0001$ for cylindrical powers, and $p < 0.0301$ for axes; Spearman correlation coefficient by rank).

265 children. Of the 64, 37 children (58%) attended such examinations, and documents containing final diagnoses were sent back to the Public Health Office. Of the 64 children, 12 were sent to ophthalmologists based on the current criteria only, 10 based on both the current criteria and the refractive error criteria, and 42 based on the refractive error criteria only (Table 2). The rates of children who visited ophthalmologists and had their final diagnoses sent back to the Public Health Office were 50% (6 of 12 children) under the current criteria only, 70% (7 of 10 children) under both the current criteria and the refractive error criteria, and 57% (24 of 42 children) under the refractive error criteria only. The rates were not significantly different among the 3 groups ($p = 0.6322$, chi-square test).

Twelve of the 13 children visiting ophthalmologists under the current criteria had diagnoses such as amblyopia and strabismus: 1 child with esotropia, 3 children with intermittent exotropia, 1 child with ametropic amblyopia, and 1 child with congenital blepharoptosis (Table 2). In contrast, 15 of 24 children visiting ophthalmologists by only the refractive error criteria had mainly diagnoses of refractive errors with no serious problems. However, it should be noted that 1 child with ametropic amblyopia was detected by the refractive error criteria only. The rate of children with abnormalities was higher under the current criteria ($12/13 = 92\%$) than under the refractive error criteria only ($15/24 = 63\%$), but the difference between the 2 groups was not statistically significant ($p = 0.0655$, Fisher's exact probability test).

Discussion

Until now, there has been no evidence to support the benefit of autorefraction in preschool vision-screening programs [11–14]. We designed a prospective study to elucidate whether or not the addition of

Table 2 Among a total of 265 children examined, the number of children sent to ophthalmologists' examinations and their diagnoses, based on the current criteria and/or the refractive error criteria

Criteria	The number of children recommended for ophthalmologists' examination	The number of children visiting ophthalmologists and with final diagnoses sent back to Public Health Office	The number of children diagnosed as abnormal	The number of children with diagnoses
The current criteria only	12	6	5	Myopia/myopic astigmatism 3 Intermittent exotropia 1 Esotropia 1
The current criteria plus refractive error criteria	10	7	7	Hyperopic astigmatism 1 Mixed astigmatism 2 Intermittent exotropia 2 Ametropic amblyopia 1 Congenital blepharoptosis 1
The current criteria in total	22	13	12	
Refractive error criteria only	42	24	15	Myopia 9 Hyperopia 1 Mixed astigmatism 1 Exophoria 2 Ametropic amblyopia 1 Poor visual acuity 1
Grand total	64 (24% of 265 children)	37 (14% of 265 children)	27 (10% of 265 children)	

The current criteria: visual acuity testing at home or at the Public Health Center, questionnaire, and medical officers' or pediatricians' examinations.
The refractive error criteria: greater than 3-diopter spherical power for myopia or greater than 1-diopter spherical power for hyperopia, and/or greater than 2-diopter cylindrical power for astigmatism.
"The current criteria only" indicates children detected by the current criteria but not detected by the refractive error criteria.
"The current criteria plus refractive error criteria" indicates children detected by the current criteria and also by the refractive error criteria.
"Refractive error criteria only" indicates children detected by refractive error criteria but not by the current criteria.

autorefraction in the current system would improve the detection of eye problems in preschool vision-screening programs for Japanese children at the age of 3.5 years. In Japan, vision-screening programs for children and students are conducted as part of physical, mental, and developmental checkups, together with dental checkups and hearing-screening programs. Children are examined at 1.5 and 3.5 years, and at 5 years just before entering elementary school. Students at each grade of elementary school, junior high school, and high school, that is, from 6 to 18 years of age, have visual acuity testing every year at school [15, 16].

The addition of autorefraction requires at least 1 examiner and takes a certain amount of time in the whole examination process at 3.5 years: nurses do urinalysis, check questionnaires, and interview families about medical history, vaccinations, and daily life (sleeping and eating) habits; dentists perform their examinations; and medical officers or pediatricians conduct physical, mental, and developmental examinations. In addition, nurses do visual acuity tests and hearing tests for children who failed or did not undergo these tests at home.

Hand-held autorefractometers have been available for years and have been proven useful and accurate for measuring noncycloplegic refraction in children [2–10]. Astigmatism can be measured correctly, but myopic shifts takes place under noncycloplegic conditions. Based on the results of previous studies [4, 5, 7], we set thresholds for myopia as spherical power greater than 3 diopters, hyperopia as spherical power greater than 1 diopter, and astigmatism as cylindrical power greater than 2 diopters. The distributions of spherical powers and cylindrical powers of autorefraction in 250 children gave a rationale for using cutoff values of −3.0 diopters for myopia and −2.0 diopters for astigmatism in this study. The threshold for myopia might be shifted to a higher value to limit the number of children sent to ophthalmologists. Based on the distribution of spherical powers of both eyes in this study, a cutoff value for spherical powers may be placed at −4.5 to −5.0 diopters, corresponding to the lower end of twice the standard deviation around the

mean. However, a presumptive cutoff value for spherical powers placed at −4.5 diopters leads to no meaningful divide between the normal and the abnormal in this study.

The present results could be interpreted in two opposite ways. As a positive interpretation, the addition of the refractive error criteria only did lead to the detection of one child with ametropic amblyopia, and thus raised the rate of detection of strabismus and amblyopia at the earlier age. As a negative interpretation, on the other hand, the addition of the refractive error criteria led to a threefold increase in the number of children sent to ophthalmologists and yet led to the detection of only one additional case requiring treatment, that is, the child with ametropic amblyopia.

The number of 3.5-year-old children in Okayama City, with a population of about 700,000 is around 6500, about 80% of whom are examined annually [1]. Therefore, the sample of the present study (265 children) is 5% of the entire population. From this sample, the one child with ametropic amblyopia detected by the refractive error criteria only would lead us to estimate roughly 20 children with ametropic ampbyopia in the entire population of children. Since these children would pass the visual acuity of 0.5 in both eyes at home or at office, their levels of amblyopia would not be deep. These children would have a chance of being detected again in preschool vision-screening at 5 years of age before entry to elementary school.

All the costs of examining the 3.5-year-olds, including the cost of the third step examination by ophthalmologists, are paid by the Public Health Office and thus are funded by taxpayer money. The threefold increase in the number of children sent to ophthalmologists suggests a threefold increase in cost. Furthermore, at least 1 examiner for autorefraction is required in addition to the current examination staffs, leading to additional personnel costs. Against such increases in cost, the effectiveness is the detection of only 1 child with ametropic amblyopia among the present 265 children.

In this study, refraction with a hand-held autorefractometer was conducted by a single examiner who was well trained beforehand and was blinded to the results of acuity testing and the questionnaire answers during the examination. The masking was adopted as a method in this prospective study, but in the real-world setting, the autorefraction examiner should pay attention to questionnaire answers and acuity test results. By integrating autorefractive measurements with visual acuity testing results and questionnaire answers, the number of children sent to the third-step examination might be reduced to an appropriate level. Orthoptists are thus recommended to be involved in vision-screening programs from the standpoint of understanding eye diseases [17–20].

The present study also revealed a unique fact concerning the testing procedure. Visual acuity and autorefraction were tested first in the right eye and then in the left. Seven children showed visual acuity of 0.5 in the right eye and 0.1 in the left eye, whereas only 1 child showed the opposite result: visual acuity of 0.1 in the right eye and 0.5 in the left. This predominance of better visual acuity in the right eye might be related to the sequence of testing from the right eye to the left eye, as a child might lose attention after testing in the right eye. In contrast, the spherical and cylindrical powers of refractive errors measured by autorefraction showed basically the same distributions and a significant correlation between the right and left eyes. Outliers of the correlation of spherical powers or spherical equivalents between both eyes could be candidates for screening anisometropic amblyopia.

A major drawback of this study is that the rate of children who were examined by ophthalmologists remained at about 60% of those who were recommended for it. The rates of this third-step visit were not different between the children referred under the current criteria and those referred under the refractive error criteria only. To reach public health service goals, further effort is necessary to increase the rate of children who go to these third-step visits when referred.

In conclusion, the present study is the first to address the role of autorefraction in the current vision-screening program for 3.5-year-old Japanese children as part of systemic examinations including physical, mental, developmental, dental, hearing, and vision checkups. Autorefraction in addition to the questionnaire, visual acuity testing at home or at the Center, and medical officers' or pediatricians' examinations in the current standard system, led to about a threefold increase in the number of children sent to

third-step examinations with ophthalmologists. Of these, only one additional child was diagnosed with a vision problem requiring treatment, in this case, ametropic amblyopia. Autorefraction is not recommended as an additional test from a cost-effectiveness standpoint, as long as the current system is conducted as designed.

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