Screening of Children Study

THESIS

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By

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Abstract

PURPOSE:
SureSight Vision Screener and Retinomax Autorefractor have been shown to be effective screening tests for identification of significant refractive error in preschool children. The purpose of Screening of Children Study (SOCS) was to determine the effectiveness of the SureSight Vision Screener and Retinomax Autorefractor in identifying significant refractive error in school-aged children.

METHODS:
SureSight and Retinomax were used to measure non-cycloplegic refractive error in children aged five to thirteen undergoing comprehensive eye examination including cycloplegic autorefraction. Significant cycloplegic refractive error as measured using the Canon RK-3 autorefractor was defined as: hyperopia $\geq 2.75$ diopters (D) in any meridian, myopia $< -0.50$ D in any meridian, astigmatism $\geq 1.50$ D between principal meridians, and anisometropia $\geq 1.50$ D difference in spherical equivalent (SEQ). The ability of SureSight and Retinomax to identify each type of refractive error was summarized by the area under the receiver operating characteristic curve (AUC) using all possible cut points for defining failure. Detection of refractive error was based on the child’s worse eye using the following SureSight or Retinomax results: most positive meridian for
hyperopia, most negative meridian for myopia, cylinder for astigmatism, and difference in SEQ for anisometropia.

RESULTS:
One hundred and ninety-five subjects, mean age 9.35 ± 2.33 years, completed the study. Criteria for significant refractive error were met by 37 children for hyperopia, 87 for myopia, 52 for astigmatism, and 12 for anisometropia. Using SureSight, AUC was 0.89 (95% CI 0.84 – 0.95) for detection of hyperopia, 0.86 (0.81 – 0.91) for detection of myopia, 0.95 (0.91 – 0.99) for detection of astigmatism, and 0.82 (0.65 – 0.98) for detection of anisometropia. Using Retinomax, AUC was 0.96 (0.91 – 1.00) for detection of hyperopia, 0.85 (0.79 – 0.90) for detection of myopia, 0.95 (0.91 – 0.99) for detection of astigmatism, and 0.86 (0.73 – 0.99) for detection of anisometropia. Effectiveness of the two instruments was not statistically significantly different for detection of any type of significant refractive error.

CONCLUSION:
AUC was very good to excellent for detection of each type of significant refractive error using SureSight Vision Screener and Retinomax Autorefractor in school-aged children.
This document is dedicated to my family.
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Publications


Fields of Study

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Chapter 1: Introduction

Screening tests can be valuable when they are used to identify diseases which are prevalent, have long term negative effects, and are treatable. It is also important for screening tests to be effective and easy to administer to large numbers of those at risk for disease. The Vision in Preschoolers study identified Retinomax Autorefractor and SureSight Vision Screener as two of the most effective tests for detection of amblyopia, strabismus, and significant refractive error in preschool children. These are prevalent and treatable conditions that can have long term consequences if not identified, so they are valid targets for screening tests. Because these vision disorders can be treated successfully well into the teenage years, they should be screened for in school-aged children.

Vision Screening

The primary goals of individuals working in public health are to promote health and prevent disease.(1) As public health has developed, attention has been given to the natural history of disease in an effort to determine when effective intervention should occur. The course of disease can be broken into the pre-disease stage, or good health, the subclinical stage, in which the disease process has begun but does not cause symptoms or clinical signs, and the symptomatic stage, after which the patient will recover, become disabled, or die.(1) In the subclinical stage, healthcare providers may be able to detect the
development of a health condition even before the patient is aware of it, potentially stopping the disease process before it can have a negative effect on the patient’s lifestyle.

For this reason, early identification of disease and identification of those with risk factors for disease has become a major goal for healthcare providers. One of the important steps toward achieving this goal is implementation of public health screenings, which are tools that can aid in early identification of disease. (1) Although screenings should not take the place of comprehensive examination and cannot be used for disease diagnosis or treatment, they can be useful as a quick and easy method of detecting previously undiagnosed disease. In order for screenings to be most effective, they should be aimed at serious and chronic conditions with high prevalence that have a better prognosis when treated early. (1, 2) Because vision disorders meet all of these criteria, they are excellent candidates for public health screenings.

**Conditions Targeted By Vision Screenings**

There are several types of vision problems often targeted by screenings; one of the most significant of these is amblyopia. Amblyopia is a disorder of processing of visual information that manifests as a decrease in visual acuity that is not immediately correctable with glasses and is not attributable to structural or pathological anomalies. (3-5) It occurs due to a difference in refractive error between the two eyes, a problem with eye alignment, and/or an ocular condition that deprives the eye of stimulus. (3-7) These conditions, known as amblyogenic factors, must occur during the sensitive period, which many say is between birth and age seven, in order for amblyopia to develop. (3, 8)
Amblyopia is a serious condition because it leads to potentially permanent vision loss, which can affect a person’s functional abilities and/or choice of profession.(8, 9)

Screening for amblyopia is worthwhile because of its prevalence, its effect on society, and the effectiveness of amblyopia treatment. One to five percent of people in developed nations are affected by amblyopia, and amblyopia is the leading cause of monocular vision loss in adults aged 20 to 70.(3, 4, 6, 10, 11) People with amblyopia are also statistically more likely to lose vision in their non-amblyopic eye, which can be devastating to an individual and can place a significant burden on society.(3, 8, 12)

Thankfully, amblyopia is a treatable condition. Traditional methods of treatment include optical correction of any significant refractive error, patching of the non-amblyopic eye, or use of atropine in the non-amblyopic eye.(3, 6, 13) Studies have shown that significant improvement in visual acuity can occur with such treatment; in fact, in the Amblyopia Treatment Study, data from the first three trials showed that after only four to six months of treatment, 62 to 86% of subjects improved to an acuity of 20/30 or better in their amblyopic eye or improved from baseline by three or more lines of visual acuity.(6) Although treatment of amblyopia is most effective when initiated in young children, a study by the Pediatric Eye Disease Investigator Group showed that significant improvement can be seen in patients up to age 17.(3, 4, 13-16) Other studies show that improvement in binocularity and visual acuity in the amblyopic eye can be achieved into adulthood through treatment ranging from perceptual learning to binocular stimulation to refractive surgery.(17-20)
Amblyopia is most treatable when detected early, so much of the effort toward identification of amblyopia through screening has targeted preschool children. (2, 4) Screening for amblyogenic factors in school-aged children is also warranted because amblyopia can be effectively treated into the teenage years and beyond. (13, 14) In order to detect amblyopia, many screening programs use visual acuity determination, while others attempt to detect strabismus, and still others look at stereoacuity, which is often reduced or absent in individuals with amblyopia. (3) The Vision in Preschoolers (VIP) Study was established in order to identify the best tests for detecting significant vision problems in preschoolers, including amblyopia, strabismus, and significant refractive error. (2) The study found that some of the most effective screening tools for amblyopia measured refractive error. (3, 21)

Detection of significant refractive error is often targeted in vision screening due to its association with the development of amblyopia. (3, 6, 7, 16, 22) In addition, screenings often target identification of significant refractive error because it is one of the most common causes of decreased visual acuity in the world. (23-25) An estimated 153 million people, 12.8 million of them children aged five to fifteen, suffer from visual impairment due to uncorrected refractive error. (25) In a study of Brazilian children, refractive error was the cause of 77% of all visual impairment, and 52% of those who could achieve normal or near-normal vision did not have the necessary optical correction to do so. (26) Refractive error was the cause of 92% of all visual impairment in a study of Nepalese schoolchildren. (10)
Visual problems including uncorrected refractive error may hinder learning, and early correction of refractive error allows for better overall performance in school. (23, 24, 27, 28) When children with and without decreased visual acuity are compared, those with normal acuities are significantly more likely to achieve satisfactory academic performance. (23) In studies conducted by Roch-Levecq et al and Atkinson et al, children with emmetropia had significantly higher scores on standardized tests of visual-motor integration than their counterparts with significant uncorrected hyperopia. (28, 29) Studies by Shankar et al and Cornelissen et al suggest that vision disorders including significant uncorrected hyperopia and visual-perceptual problems can have an adverse effect on a child’s reading ability. (30, 31) In order to prevent a treatable condition like refractive error from having negative long-term effects on a child’s future, early detection is the key. (23, 25) Screening can play a critical role in identifying school-aged children with vision problems and helping them to receive treatment.

One specific type of refractive error, hyperopia, is a particular target of vision screening. Hyperopia occurs when the eye is too short for its converging power; the retinal image may not be clear because rays of light converge to a point behind the retina. (32) The prevalence of hyperopia varies with age, peaking in childhood and old age. (33, 34) It also varies by race and ethnicity; studies of preschoolers in America found that Caucasian children and Hispanic children were more likely to be hyperopic than African American children. (35, 36) The reported prevalence of hyperopia for children aged five to 15 ranges from 0.4% to 18.3%, with the highest prevalence among Moroccan children and the lowest among those in Nepal. (10, 25, 33, 37-40)
Although blur associated with hyperopia can sometimes be overcome through accommodation, uncorrected hyperopia is still responsible for a portion of the world’s visual impairment. (32, 33) Also, the effort required to bring images into focus in children with hyperopia can cause strain on the child’s visual system; uncorrected hyperopia has been shown to have an adverse effect on a child’s ability to learn and achieve academically. (28, 29, 31, 41-43) In a review of studies looking at different types of refractive error and their effect on reading ability, Grisham et al found that hyperopia was most commonly associated with difficulty reading. (44)

Hyperopia is also a significant risk factor for development of amblyopia and strabismus. (3, 16, 45-47) Atkinson et al found that subjects whose significant hyperopia was corrected in infancy had lower rates of reduced visual acuity and strabismus by age four. (48) According to the American Association for Pediatric Ophthalmology and Strabismus (AAPOS) Vision Screening Committee, children with more than 3.50 diopters of hyperopia are at significant risk for developing strabismus, so they recommend that preschool vision screening target detection of hyperopia at this magnitude. (16) For school-aged children, it has been suggested that hyperopia of 1.50 diopters or more should be detected in screening. (49, 50)

Myopia is another type of refractive error targeted in vision screenings. Myopia results when the eye is too long for its magnitude of convergence; in this case rays of light converge and are in focus at a point in front of the retina, resulting in a blurry retinal image. (32) Although not as commonly associated with amblyopia as is hyperopia, some forms of myopia are considered amblyogenic factors. (3, 16) High myopia also increases a
child’s risk factors for complications including retinal detachment, choroidal neovascularization, and macular degeneration. (51) For preschoolers, the AAPOS Vision Screening Committee has recommended that screening programs seek to detect children with more than −3.00 diopters of myopia. (16) In school-aged children, it has been suggested that screening programs identify children with −0.50 diopters or more of myopia. (49, 50)

Myopia is even more prevalent than hyperopia. Prevalence varies with age; onset is often around the ages of seven and eight, and myopia then tends to progress until leveling off during the teenage years. (38, 51) Although myopia is present in all cultures, it does vary significantly by race and ethnicity. Studies of American preschoolers show that African American preschoolers are more likely to be myopic than their Caucasian and Hispanic counterparts. (34-36) Reported prevalence among school-aged children ranges from 3% to 51% with the lowest numbers found in children from Morocco and the highest in Indian schoolchildren. (10, 25, 33, 37-40, 51) Myopia is more common among Asian children than their European counterparts and tends to be more common in children raised in urban settings than those in rural settings. (51)

Symptoms associated with myopia, including distance blur, are often more overt than those associated with hyperopia. Unfortunately, uncorrected myopia is still a significant cause of vision impairment, in part because children often do not reliably report vision problems. (26) In one study of visual impairment, 24% of children with normal vision initially reported impairment, and 36% of those with impairment initially reported that their vision was normal. (23) Because myopia tends to progress during
childhood and adolescence and because children are often unable to reliably report vision changes, screenings for school-aged children typically target myopia.\(^{(38, 51)}\)

Screenings of school-aged children also target identification of astigmatism. This condition occurs when the optical system of the eye varies from meridian to meridian; in this case the eye is incapable of forming a single point image.\(^{(32)}\) Prevalence of astigmatism varies with race and ethnicity; studies of American preschoolers show that astigmatism is more prevalent in Hispanic children than their African American counterparts.\(^{(34)}\) In school-aged children, prevalence of astigmatism ranges from 2\% to 34\% with the largest percentages of those reported found in Native American children.\(^{(10, 25, 33, 40, 52)}\)

It is important to detect astigmatism early because uncorrected astigmatism can lead to meridional amblyopia.\(^{(3, 16, 53)}\) This visual disorder occurs because a child with uncorrected astigmatism will have focal planes of certain orientations that are consistently out of focus; input for these orientations is consistently degraded, so vision does not develop properly in these specific orientations.\(^{(53)}\) Early detection and correction of astigmatism is critical in order to prevent this type of vision reduction, so vision screenings target astigmatism as well.\(^{(53)}\) The AAPOS Vision Screening Committee suggests that screening should target astigmatism of more than 1.50 diopters when oriented at 90 or 180 degrees and of more than 1.00 diopters when oriented obliquely.\(^{(16)}\) When screening school-aged children, the Modified Clinical Technique recommends identifying those with astigmatism of 1.00 diopters or more.\(^{(49, 50)}\)
Anisometropia should be mentioned in conjunction with discussion of meridional amblyopia because its mechanism for degrading vision is similar. While astigmatism can cause amblyopia because focal planes of certain orientations are consistently out of focus, anisometropia can cause amblyopia because one eye is consistently out of focus. (3) Anisometropia occurs when the refractive error of the two eyes is significantly different; while there is some argument about the magnitude of difference that is significant, the AAPOS Vision Screening Committee suggests targeting anisometropia of greater than 1.50 diopters in preschool vision screenings, and the Modified Clinical Technique criteria for school-aged children is 1.00 diopters or more. (16, 49, 50)

If children with significant anisometropia go uncorrected, one eye will consistently receive a blurred image. (16) If this occurs over the long term, it will result in dysfunctional visual information processing and reduced visual acuity or amblyopia in the eye with the blurred image. (3) Although the prevalence of anisometropia has been found to be lower than that of other types of refractive error at 3-4%, detection of significant anisometropia is targeted in vision screening due to its association with amblyopia. (11, 40, 54)

**Determining Effectiveness of a Screening Method**

A screening test is effective if it is able to appropriately divide the population being screened into those who may have and those who probably do not have the condition for which they are being screened. (2) This can also be thought of in terms of sensitivity and specificity. (55) If the results of a screening test that classifies a child as pass or fail are compared with the results of a gold standard test that classifies a child as
pass or fail, the results can be summarized in a simple table. (56) (Table 1) This table can then be used to determine the sensitivity and specificity of the screening test. A test’s sensitivity is its ability to identify children with the disease; it is defined as the proportion of children with the disease who test positive, or \( A/(A+C) \) in Table 1. (2, 56) The specificity of a test is its ability to correctly determine subjects who do not have the disease; it is defined as the proportion of subjects without the disease who test negative, or \( D/(B+D) \) in Table 1. (2, 56)

This table can also be used to determine a test’s positive predictive value, which is the proportion of children testing positive who have the disease according to the gold standard test, or \( A/(A+B) \) in Table 1. (57, 58) Positive predictive value reflects the probability that a given patient who tests positive actually has the disease. While it is important for a test to have high positive predictive value, when evaluating an instrument’s effectiveness for use in a screening setting, sensitivity and specificity are more useful. (59) This is because sensitivity and specificity allow for evaluation of a test’s ability to discriminate between people with and without a condition, while positive predictive value determines the likelihood that a given individual has a disease based on the results of the test in question. (57, 59) Also, positive predictive value will vary with prevalence of a disease given a set specificity; it will be low if the prevalence of the disease in the population is low, and it will be high if the disease has high prevalence in the population tested. (57, 58) It is possible to have high positive predictive value for a disease with lower prevalence, but in this case specificity must be very high, and high specificity comes at the cost of sensitivity. On the other hand, sensitivity and specificity
of a test are intrinsic values that should be the same regardless of the prevalence of the
disease in the population screened. (57, 58)

<table>
<thead>
<tr>
<th>Screening Test</th>
<th>Gold Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Positive</td>
<td>Disease</td>
</tr>
<tr>
<td>A</td>
<td>true positive</td>
</tr>
<tr>
<td>B</td>
<td>false positive</td>
</tr>
<tr>
<td>Test Negative</td>
<td>C</td>
</tr>
<tr>
<td>false negative</td>
<td>true negative</td>
</tr>
</tbody>
</table>

Table 1. 2X2 Table Showing Test Results

The effectiveness of a screening test can be determined using receiver operating
characteristic (ROC) curves. (60) In an ROC curve, sensitivity and specificity are
determined for all possible cut points (potential referral criteria) in a test. Sensitivity is
graphed on the Y axis versus 1–specificity on the X axis. (56, 60) The area under the
ROC curve can be used to summarize the accuracy of a test. If the test is perfect and so
identifies all true positives and no false positives, the area under the curve will be 1.00. If
the test is no better than chance, the area under the curve will be 0.50, meaning that the
rate of true positives is equal to the rate of false positives for any potential referral
criteria. (56)

In addition to determining the effectiveness of a screening test, the ROC curve
analysis can also be used to set referral criteria. These criteria can be selected to
maximize either sensitivity or specificity depending on the nature of the condition for which subjects are being screened. (2, 16, 21, 56, 60) For a serious condition in which testing to confirm screening results is not too invasive, sensitivity should be maximized. Here it would be most important to find all individuals with the condition in spite of the fact that a few people without the condition might be incorrectly classified as disease-positive. If the condition screened for is less serious and the confirmation testing is expensive or invasive, specificity might be more important. (16) In this case, it would be more important to avoid subjecting a false positive to such testing in spite of the fact that a few people with the condition might be incorrectly identified as disease-negative. There is debate over whether sensitivity or specificity should be maximized in the case of vision screening tests. (16) While many argue that in the case of vision screenings, sensitivity should be maximized in order to identify and treat as many children with vision disorders as possible, others argue that the cost associated with examining false-positive patients could be better spent elsewhere. (61)

**Evaluation of SureSight and Retinomax When Used in Screening**

There has been previous research evaluating the effectiveness of SureSight and Retinomax in identifying children with significant vision disorders. SureSight Vision Screener is a handheld autorefractor able to measure a patient’s spherical and cylindrical power readings in about three seconds per eye. (62) It has a working distance of 35 cm and does not have to make contact with the patient’s face to take a reading, so it is considered by many to be an ideal test for use on children. (62-64) Retinomax is a handheld autorefractor that measures a patient’s sphere, cylinder, and axis in about 5
It has a working distance of six centimeters and a forehead rest that makes contact with the subject’s face in order to stabilize the instrument during measurement. Because the subject’s chin is free and the instrument is smaller in size, it is often less intimidating to young children than traditional tabletop autorefractors.

One screening study, performed by Kemper et al, aimed to compare results of screening with SureSight Vision Screener with those of a comprehensive eye examination. The study enrolled 170 children aged zero to five years who presented to a pediatric ophthalmology clinic as new patients. Subjects were refracted using the SureSight Vision Screener and then underwent comprehensive eye examination including cycloplegic refraction. Subjects were classified based on their comprehensive eye examination as having significant refractive error, strabismus, decreased visual acuity, ptosis, and/or media opacity. Data was analyzed using correlation coefficients and receiver operating characteristic curves. The study showed that SureSight was effective at identifying cases of visual impairment in subjects aged three to five, although it generated a significant number of false-positive results. Results were not as good when children under age three were screened.

Rowatt et al also studied the performance of SureSight. In this study, trained adult volunteers did screenings at day care centers, preschools, and Mother’s Day Out programs. Volunteers screened 2052 children aged zero to six years, and those identified as screening failures (n=251) were referred for comprehensive eye examination including cycloplegic retinoscopy by local optometrists and ophthalmologists. Of the children referred, 144 had examinations deemed adequate
by study personnel, and the results of these examinations were used to determine if the referrals were false-positive or true-positive based on criteria for amblyogenic factors. (68) (Table 2) The study concluded that SureSight could be used successfully for preschool screening. (68)

Silverstein et al did a larger study using subjects taken from the same population base as that of Rowatt et al. (5) (Table 2) In this study, trained adult volunteers used Welch Allyn SureSight at preschools, day care centers, Mother’s Day Out programs, and other locations to screen 15,749 children aged one to five. (5) The 1,154 children who did not meet screening criteria were referred for comprehensive eye examination including cycloplegic retinoscopy. (5) In this study, 533 children received examinations deemed adequate by study personnel, and the results of these examinations were used to determine positive predictive value (PPV) of different referral criteria for SureSight (PPV=correct referrals/all referrals). (5) This study concluded that while SureSight may not be useful in screenings in which specificity is considered paramount, it provides an acceptable referral rate and positive predictive value for most large screening programs. (5)

Cordonnier et al performed several studies evaluating the performance of the Retinomax autorefractor when used on children aged nine to 36 months presenting for screening at a University Hospital in Brussels, Belgium. (7, 67, 69) (Table 3) Screening was advertised in pediatricians’ offices and preschools, and all those who expressed interest were screened. (7, 67, 69) The screening included near cover test and Retinomax, and any child with abnormal refraction or strabismus whose parents consented underwent
cycloplegic refraction during the same session. (7, 67, 69) To establish controls, a consecutive group of children with normal screening results whose parents consented also underwent cycloplegic refraction. (7, 67, 69) The non-cycloplegic Retinomax results were compared with cycloplegic refraction performed during the same session in data analysis. After participating in the study, children with abnormal manifest or cycloplegic refraction or with strabismus were then referred for comprehensive eye examination with an ophthalmologist. (7, 67, 69)

One of these studies by Cordonnier et al worked to determine the performance of Retinomax for detection of hyperopia. (7) In this study, 897 children aged six months to five years were screened. (7) (Table 3) Of the 202 who exhibited abnormal refraction or strabismus, 72 underwent cycloplegic refraction with Retinomax, as did 148 controls with normal screening refraction. (7) Results were analyzed using receiver operating characteristic curves, and researchers determined that Retinomax was a useful tool for identifying significant levels of hyperopia in preschool children under non-cycloplegic conditions. (7)

Another study by Cordonnier et al sought to determine the effectiveness of Retinomax when used to measure astigmatism in non-cycloplegic conditions. (67) Retinomax was used to screen 1205 subjects aged six months to 48 months, and 302 children had repeated testing under cycloplegic conditions. (67) The selection of these 302 children was based solely on parental consent for cycloplegia; 43% were screened positive and 57% were screened negative. (67) In this study, Cordonnier et al calculated
predictive values for three different thresholds of manifest astigmatism and found that Retinomax is effective at identifying children with significant astigmatism. (67)

A third study by Cordonnier et al evaluated performance of Retinomax in screening for significant levels of hyperopia, myopia, astigmatism, and anisometropia under non-cycloplegic conditions. (69) This study included 1218 children aged six months to 68 months, all of whom underwent near cover testing and screening with Retinomax under non-cycloplegic conditions. (69) Of those screened, 239 exhibited abnormal refraction or strabismus. (69) 302 subjects underwent cycloplegia and were re-tested with the Retinomax; 116 had screened positive for significant refractive error and 186 had screened negative and served as controls. (69) After analysis of sensitivity, specificity, and positive predictive value of the instrument, researchers concluded that Retinomax was useful for detection of myopia, astigmatism, and hyperopia. (69) Analysis showed that Retinomax did not perform as well for identification of anisometropia. (69)

Cordonnier et al also conducted a study that evaluated the effectiveness of both SureSight and Retinomax when used as screening devices. (70) (Tables 2-3) This study enrolled 98 healthy children ranging in age from six months to 16.5 years who presented to an eye clinic in Brussels, Belgium, for checkup or screening. (70) Subjects were screened with Retinomax and SureSight and then underwent cycloplegia and were refracted with either a Topcon RMA 6000 tabletop autorefractor (n=85) or cycloplegic retinoscopy (n=12). (70) Results were analyzed using receiver operating characteristic curves. (70) Child mode, a function of the SureSight Vision Screener which is recommended to compensate for accommodation, was used on subjects age six and
younger, and a separate analysis of the instrument's effectiveness at detecting significant levels of hyperopia was performed for these subjects. The results of the analyses showed that both devices were effective when used to screen for significant refractive error.

The Vision in Preschoolers (VIP) Study, a multicenter, multidisciplinary, prospective study in which eleven different preschool screening tests were evaluated, also looked at the effectiveness of SureSight and Retinomax. (2, 21, 71, 72) The VIP study compared the results of 11 screening tests to find which were most effective at identifying children with targeted vision conditions (amblyopia, strabismus, significant refractive error, and unexplained decreased visual acuity). (2, 21, 71, 72) Subjects were 2588 children between the ages of three and five enrolled in Head Start programs. (2, 21, 71, 72) In the course of the study, children were tested using Lea Symbols distance visual acuity, HOTV distance visual acuity, Random Dot “E” stereacuity, Stereo Smile II stereacuity, cover-uncover test, and non-cycloplegic retinoscopy and were screened with Retinomax Autorefractor, SureSight Vision Screener, MTI Photoscreener, Power Refractor II, and iScreen Photoscreener. (2, 21)

The study was conducted in two phases. In Phase I, screening tests were performed by eye care professionals in a controlled environment, and sensitivities of tests were compared when specificity was set at 90 and 94%. (2, 21, 72) In the second phase of the study, tests which performed best in Phase I were evaluated in the hands of trained nurse and/or lay screeners in a more realistic screening environment, namely a Head Start center. (72) Sensitivities of tests were compared when specificity was set at 90%. (72) All
subjects underwent gold standard eye examinations including monocular distance visual acuity testing, cover testing, evaluation of anterior segment, binocular indirect ophthalmoscopy, color vision testing, non-cycloplegic retinoscopy, stereoacuity, ductions and versions testing, and cycloplegic retinoscopy. (2) The results of this testing were used to determine if the subject had any of the targeted conditions listed above or normal vision. (2)

Targeted conditions were classified by severity of condition, with group one conditions considered the most critical to diagnose and treat early. (2, 21, 71, 73) Group one conditions included children with the most severe signs of amblyopia (presumed unilateral amblyopia with visual acuity less than 20/64 in the worse eye or suspected bilateral amblyopia), children with constant strabismus, and children with severe refractive error (anisometropia with interocular difference greater than 2.00 diopters for hyperopia, 3.00 diopters for astigmatism, and 6.00 diopters for myopia; hyperopia of 5.00 diopters or greater; myopia of 6.00 diopters or greater; and astigmatism of 2.50 diopters or greater). (2, 21) Group two conditions were considered important to detect early and included amblyopia (suspected unilateral or presumed unilateral with acuity in the worse eye better than 20/64), intermittent strabismus, and less severe refractive error (anisometropia but not severe, hyperopia between 3.25 and 5.00 diopters with interocular difference in spherical equivalent of 0.50 diopters or greater, astigmatism between 1.50 and 2.50 diopters, and myopia from 4.00 diopters to less than 6.00 diopters). (2, 21) Group three conditions included reduced visual acuity (unilateral or bilateral) and refractive error (hyperopia between 3.25 diopters and 5.00 diopters with interocular
difference in spherical equivalent of less than 0.50 diopters and myopia between 2.00
diopters and 4.00 diopters). (2, 21)

The VIP study group calculated the sensitivity of each test for detecting children
with one or more targeted conditions and for detecting conditions grouped into the three
levels of severity described above. Researchers found that when specificity was set at
90% or 94% and tests were conducted by eye care professionals, non-cycloplegic
retinoscopy, Retinomax Autorefractor, SureSight Vision Screener, and Lea Symbols VA
had the highest sensitivity for children with amblyopia, the most severe conditions (group
one), and children with one or more targeted conditions. (21, 71) Trained nurse and lay
screeners using Retinomax and SureSight achieved similar sensitivities for detecting
preschool children with one or more targeted conditions. (21) When SureSight and
Retinomax performance for detecting any targeted condition and group one conditions
was compared to that of non-cycloplegic retinoscopy, the three methods had similar
efficacy. (73) The VIP study also determined the referral criteria that maximize sensitivity
at 90% and 94% specificities for SureSight and Retinomax when used on preschoolers. (2,
21, 71, 72, 74)
<table>
<thead>
<tr>
<th>Study</th>
<th>n / Subject Age (years)</th>
<th>Definition of Significant RE (D)</th>
<th>Area Under the Curve</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Recommended Referral Criteria (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kemper et al(4)*</td>
<td>170 0 – 5</td>
<td>H &gt; 3.50 M &lt; −3.00 C &gt; 1.50 D ≥ 1.50</td>
<td>RE 0.79</td>
<td>RE 85</td>
<td>RE 52</td>
<td>H ≥ 2.00 M ≤ −1.00 C ≥ 1.00 D ≥ 1.00</td>
</tr>
<tr>
<td>Rowatt et al(68)*</td>
<td>2052 1 – 6</td>
<td>H &gt; 3.50 M &lt; −3.00 C &gt; 1.50 D ≥ 1.00</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>H ≥ 4.25 M ≤ −1.00 C ≥ 2.20 D ≥ 3.00</td>
</tr>
<tr>
<td>Silverstein et al(5)*</td>
<td>15,749 1 – 6</td>
<td>H &gt; 3.50 M &lt; −3.00 C &gt; 1.00/1.50 D &gt; 1.00</td>
<td>NA</td>
<td>RE 59</td>
<td>RE 96</td>
<td>H ≥ 4.20 M ≤ −1.00 C ≥ 2.20 D ≥ 3.00</td>
</tr>
<tr>
<td>VIP(2, 72, 75)*</td>
<td>2588 3 – 5</td>
<td>H &gt; 3.25 M &lt; −2.00 C &gt; 1.50 D &gt; 1.00 H, ≤−3.00 M, &gt;1.50 C</td>
<td>RE 0.92 – 0.93</td>
<td>RE 69 – 75</td>
<td>RE 63</td>
<td>H ≥ 4.00 – ≥ 4.50 M* ≤ −1.00 C* ≥ 1.50 – ≥ 1.75 D+ ≥ 2.25 – ≥ 3.00</td>
</tr>
<tr>
<td>Cordonnier et al(70)</td>
<td>98 0.5 – 16.5</td>
<td>H &gt; 3.50 M &lt; −3.00 C ≥ 2.00</td>
<td>H 0.77*, 0.91 M 0.99 – 1.00 C 0.85 – 0.92</td>
<td>H 71 – 72 M 100 C 67 – 71</td>
<td>H 83 – 87 M 99 – 100 C 90</td>
<td>H &gt; 2.25 M &lt; −2.00 C &gt; 1.75</td>
</tr>
</tbody>
</table>

H=hyperopia, M=myopia, C=astigmatism, D=anisometropia, RE=significant refractive error. If two definitions for C, 1\textsuperscript{st} is for oblique findings. *Indicates Child Mode was used on all subjects during screening. +Referral criteria based on 90% specificity.

Table 2. Results from SureSight Screening Studies
<table>
<thead>
<tr>
<th>Study</th>
<th>n / Subject Age (years)</th>
<th>Definition of Significant RE (D)</th>
<th>Area Under the Curve</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Recommended Referral Criteria (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cordonnier et al (7)</td>
<td>897 0.5 – 5</td>
<td>H &gt; 3.50</td>
<td>H 0.79 – 0.82</td>
<td>H 70</td>
<td>H 95</td>
<td>H &gt; 1.50</td>
</tr>
<tr>
<td>Cordonnier et al (67)</td>
<td>1205 0.5 – 5</td>
<td>C ≥ 2.00</td>
<td>NA</td>
<td>C 51 – 54</td>
<td>C 98</td>
<td>C ≥ 2.00</td>
</tr>
</tbody>
</table>
| Cordonnier et al (69)  | 1218 0.5 – 5            | H > 3.50  
M < −3.00  
C ≥ 2.00  
D ≥ 1.50 | NA                   | H 46  
M 87  
C 37  
D 66 | H 97  
M 99  
C 99  
D 93 | H > 1.50  
M < −3.00  
C ≥ 2.00  
D ≥ 1.50 |
| VIP (2, 72, 75)        | 2588 3 – 5              | H > 3.25  
M < −2.00  
C > 1.50  
D > 1.00 H, < −3.00  
M, > 1.50 C | RE 0.92 – 0.93 | RE 71 – 78  
RE 63 – 66 | RE 90  
RE 94 | H^+ ≥1.50  
M^+ ≤ −2.75 – ≤ −3.25  
C^+ ≥ 1.50 – ≥ 1.75  
D^+ ≥ 1.75 – ≥ 2.75 |
| Cordonnier et al (70)  | 98 0.5 – 16.5           | H > 3.50  
M < −3.00  
C ≥ 2.00 | H 0.87 – 0.91  
M 0.98  
C 0.94 – 0.95 | H 67 – 73  
M 100  
C 81 | H 95 – 98  
M 96  
C 94 – 98 | H > 1.50  
M < −2.50  
C > 1.75 |

H=hyperopia, M=myopia, C=astigmatism, D=anisometropia, RE=significant refractive error. ^Referral criteria based on 90% specificity.

Table 3. Results from Retinomax Screening Studies
Evaluation of the Accuracy of SureSight Vision Screener

While the studies mentioned above evaluated the effectiveness of SureSight as a vision screening device, several other studies have been conducted that look at the accuracy of the readings generated by SureSight.(63, 76-78) For instance, Steele et al and Schimitshek et al evaluated the performance of SureSight and found that SureSight readings (spherical equivalent and cylinder power) taken under cycloplegic conditions correlated significantly with those of cycloplegic retinoscopy.(64, 78)

Because SureSight was designed primarily as a rapid screening device, it would not commonly be used on subjects who are cyclopleged. Screening tests are meant to be rapid and easy to administer to large numbers of people, and examination under cycloplegia is not desirable because administration of cycloplegic agents takes time and may deter some people from participation.(79) Accommodation is clearly of significance when determining refractive error in young children; for this reason, SureSight Vision Screener has a child mode recommended for use up to age six that is designed to correct for the accommodative response in non-cyclopleged children.(62, 63) The exact formula used for compensation is proprietary, although there are reports that a constant value, possibly +2.50 diopters, is added to the spherical result for compensation.(63, 68, 78, 80) The value may have been chosen because the manufacturers predicted that children would accommodate to the autorefractor, located at a distance of 35 cm.(62, 78) Performance indicates that child mode is largely ineffective.(63, 70, 78) A study by Cordonnier et al did separate analysis for detection of significant hyperopia in subjects on whom child mode was used and reported that these results showed more bias and spread.
than those for subjects on whom adult mode was used. (70) Cordonnier suggests that this problem could occur because a constant value is being added to compensate for accommodation when accommodation in young children is typically quite variable. (70)

Results from studies investigating the use of SureSight for measurement of spherical refractive error under non-cycloplegic conditions are mixed. While studies by Iuorno et al, Buchner et al, and Schimitzek et al found that SureSight tends to overestimate myopia and underestimate hyperopia, others including those by Suryakumar et al and Cordonnier et al found that SureSight had a slight hyperopic bias. (63, 70, 76, 78, 81) This difference in findings could be due to the variation in age of subject, which ranged from six months to 81 years across the studies, and so in implementation of child mode. (63, 70, 76, 78, 81)

On the other hand, Iuorno et al, Buchner et al, Schimitzek et al, Suryakumar et al, and Cordonnier et al concluded that SureSight determination of cylinder power is consistent with that of other more established tests, including cycloplegic retinoscopy, cycloplegic autorefraction, and cycloplegic refraction. (63, 70, 76, 78, 81) Harvey et al, however, reported that SureSight tends to overestimate astigmatism values. (77) While results of the study by Harvey et al showed that quantitative astigmatism values were inconsistent between non-cycloplegic SureSight and their gold standard measurement, cycloplegic Retinomax K+ readings, Harvey et al reported that SureSight could accurately categorize the amount of astigmatism as 2.00 DC or less, greater than 2.00 DC, and greater than 3.00 DC. (77)
Evaluation of the Accuracy of Retinomax Autorefractor

The accuracy of Retinomax Autorefractor has also been the subject of several studies. (64, 65, 81-85) Although the majority of research was conducted on young children, studies have included subjects ranging in age from five months to 29 years. (64, 65, 81-85) In particular, the performance of Retinomax when used on subjects under cycloplegia has been investigated extensively. (64, 65, 81-85) Harvey et al and Steele et al report that cycloplegic autorefraction with Retinomax is both reliable and valid as compared with cycloplegic retinoscopy. (64, 84) Other investigators agree that when used under cycloplegia, Retinomax results for sphere, cylinder, and axis compare closely to those of cycloplegic retinoscopy as well as table-top autorefractors. (65, 81-83, 85)

For testing patients without cycloplegia, Retinomax attempts to prevent accommodation using a fogging system; this is employed during normal mode and disabled during quick mode to allow for rapid readings on difficult subjects. (65, 67, 81, 83) Wesemann et al and Cordonnier et al each found no difference between measurements when normal mode and quick mode were enabled. (7, 67, 83) For this reason, these authors endorse the use of quick mode on all subjects. (7, 67, 83) Cordonnier et al describe the significant overminusing that sometimes occurs due to a child’s accommodation as “instrument myopia.” (7, 69) They report that the effect is most significant early in the measurement process; as Retinomax takes a succession of measurements, they recommend waiting for results that are more positive and stable before stopping measurement capture. (7, 69)
When looking at the results of non-cycloplegic Retinomax as compared to those of cycloplegic retinoscopy or cycloplegic evaluation with a tabletop autorefractor, Harvey et al, el-Defrawy et al, Wesemann et al, and Suryakumar et al agreed that Retinomax readings tend to bias toward lower, or more myopic, sphere findings.\(^{81-84}\) Wesemann et al report that in 24% of children, non-cycloplegic Retinomax readings were more than 2.00 diopters more myopic than those of cycloplegic retinoscopy.\(^{83}\) When comparing results of non-cycloplegic Retinomax with non-cycloplegic tabletop autorefraction, Liang et al report an average bias of 0.59 diopters toward more negative sphere values.\(^{65}\) Some suggest that this is due to the instrument’s short working distance, which could induce proximal accommodation.\(^{81}\)

In addition to this general tendency to overminus, it has also been reported that Retinomax returns a more significant minus overcorrection in a small number of children; Wesemann et al report a minus overcorrection of 10 diopters in one subject.\(^{82, 83}\) Although it is difficult to predict on which subjects the Retinomax will perform poorly, Wesemann et al report that in their study, which included 67 children ranging in age from two to 12 and 50 adults ranging in age from 24 to 29, the problem occurred more commonly in children.\(^{83}\) Harvey et al suggest that this could be due to greater cooperation among older subjects.\(^{84}\) This problem occurs rarely, however; investigators report that the majority of Retinomax readings fall within an acceptable range.\(^{65, 69, 83-85}\)

Retinomax had better performance when measuring cylinder in non-cyclopleged patients than when measuring spherical refractive error in non-cyclopleged patients.\(^{65,\,}
Many studies found no significant difference between cylinder values reported by non-cycloplegic Retinomax and those found with cycloplegic retinoscopy or cycloplegic use of a tabletop autorefractor. (65, 81-84) One of the largest mean differences in cylinder value, 0.34 diopters cylinder, was found by Harvey et al, and one of the smallest, 0.19 diopters cylinder, was measured by Suryakumar. (81, 84) Each of these two studies compared non-cycloplegic Retinomax to cycloplegic retinoscopy. (81, 84)

**Characteristics Critical to an Effective Screening Test**

An effective screening test has several important characteristics; it should be easy to administer, have high testability, and be effective at identifying the targeted conditions. The Modified Clinical Technique (MCT), established in 1959, has long been considered the gold standard for vision screening of school-aged children. (86, 87) MCT includes distance visual acuity testing with a Snellen acuity chart, assessment of refractive error by retinoscopy, cover testing at distance and near to detect strabismus, external observation of the eyes, and direct ophthalmoscopy. (49, 86, 87) There have been several arguments against the effectiveness of MCT: its reported 98% sensitivity and 99% specificity could not be replicated when carried out by optometry students, its high sensitivity and specificity suggest that under-referral may have occurred, and its use of case discussions to determine pass-refer criteria for questionable cases cannot be practically applied at most screenings. (86) The most important concern when evaluating the MCT as a viable screening method centers around the expertise needed to conduct the tests themselves; most require an optometrist or ophthalmologist to perform so cannot be implemented by
nurses or lay people. (49, 50, 86) Therefore, MCT cannot be administered quickly and easily on a large number of children. (1, 86)

Tests that are effective and can be rapidly administered among school-aged children are clearly needed. SureSight Vision Screener and Retinomax Autorefractor have been shown to be effective at identifying significant vision disorders in preschool children in the hands of eye care professionals, nurses, and lay screeners, but previous research has not evaluated their effectiveness at identifying significant refractive error in school-aged children. (21) In addition, referral criteria for use among school-aged children have not been identified. The purpose of this study is to evaluate the effectiveness of Retinomax and SureSight for detection of significant refractive error in school-aged children. In addition, preliminary investigation of the referral criteria that maximize sensitivity and specificity in school-aged children will be performed.
Chapter 2: Methods

Subjects

The study protocol was reviewed and approved by The Ohio State University Institutional Review Board. The protocol met all requirements of the declaration of Helsinki. Children aged 5 to 13 years who presented to The Ohio State University College of Optometry Pediatric Service for comprehensive eye examination were invited to participate in the study. Consent was obtained from each participating child and her/his accompanying parent(s) or guardian(s). All children who presented and consented to participate were included in the study. This was designed as a pilot study to gather preliminary data; the sample size took the prevalence of targeted conditions in children into consideration (range of approximately 3 to 35%).(25, 34-36, 71)

Definitions of Significant Refractive Error

Definitions of significant refractive error, based on cycloplegic autorefraction, were formed after a review of established screening recommendations and definitions of significant refractive error in other studies using Retinomax and SureSight.(4, 5, 7, 16, 21, 63, 68, 85, 87-89) (Table 4) Hyperopia was defined as greater than or equal to 2.75 diopters of hyperopia in any meridian; this was a compromise between criteria established by the Modified Clinical Technique as determined by the Orinda Study (≥ +1.50 diopters) and recommendations of the American Association for Pediatric
Ophthalmology and Strabismus (AAPOS) Vision Screening Committee (> +3.50 diopters).(16, 49, 50) The selected definition was slightly lower than the magnitude of hyperopia that Lyons et al found a majority of optometrists and almost half of ophthalmologists reported they would consider prescribing for in four year olds (> +3.00 diopters).(89) Myopia was defined as greater than 0.50 diopters of myopia in any meridian; this definition was modified slightly from that established in the Modified Clinical Technique (≤ -0.50 diopters).(49, 50) Astigmatism was defined as greater than or equal to 1.50 diopters cylinder between meridians, and anisometropia was defined as greater than or equal to 1.50 diopters difference in spherical equivalent. These two definitions were modified slightly from the recommendations of the AAPOS Vision Screening Committee (astigmatism ≥ 1.50 diopters or ≥ 1.00 diopters in the oblique axis, anisometropia > 1.50 diopters).(16)

<table>
<thead>
<tr>
<th><strong>Targeted Disorder</strong></th>
<th><strong>Definition</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperopia</td>
<td>≥ 2.75 D in any meridian</td>
</tr>
<tr>
<td>Myopia</td>
<td>-0.50 D or more in any meridian</td>
</tr>
<tr>
<td>Astigmatism</td>
<td>≥ 1.50 D between meridians</td>
</tr>
<tr>
<td>Anisometropia</td>
<td>≥ 1.50 D difference in spherical equivalent</td>
</tr>
</tbody>
</table>

Table 4. Definitions of Significant Refractive Error
Procedures

Comprehensive eye examination was performed at The Ohio State University College of Optometry Pediatric Service. Data from the child’s comprehensive examination, including diagnosis, age, correction status, best corrected visual acuities and method, cycloplegic agent used, and results of unilateral and alternate cover testing, manifest refraction, and cycloplegic retinoscopy were entered into a data collection form using an ID code for each child. Visual acuity testing was performed by fourth year optometry students, and cover test and retinoscopy were performed by clinical faculty. Testing using the SureSight Vision Screener and Retinomax Autorefractor as well as cycloplegic autorefraction using the Canon RK-3 Autorefractor was performed by the first author, and results were recorded for each child.

Autorefractors

*Welch Allyn SureSight Vision Screener* (Version 2.12) by Welch Allyn, Inc., Skaneateles Falls, NY was evaluated. This autorefractor is hand-held, lightweight (2.0 lbs), and easily transported. (77, 80) (Figure 1) It has a working distance of 35 cm and provides auditory cues to aid the tester in aligning the instrument properly to allow for measurement. (62, 63, 80) (Figure 2-3) The instrument uses visual cues of a circle of flashing green lights with a central red laser light on the front of the instrument to help the subject to fixate. (77, 78)
SureSight is the first autorefractor based on wave front analysis, which allows for determination of refractive error based solely on imaging and calculations. The SureSight instrument sends an infrared beam from a laser diode through a beam splitter into the patient’s eye. This beam can actually be seen as it exits the instrument; it is the previously described central red laser that is used as a fixation target. As the beam...
has a small diameter, it has a large depth of focus when imaged on the retina. The beam reflects from the retina back into the autorefractor. There it passes a beam-splitter and reaches the Hartmann-Shack sensor, which is made up of a matrix of small lenses arranged in a grid. The lenses project small light spots onto the surface of a charged-couple-device (CCD) matrix camera.

The position of the light spots allows for calculation of the subject’s refractive error. Light will leave an emmetropic eye in parallel rays and produce uniformly spaced light spots on the CCD camera. Light spots will also be uniformly spaced in cases of simple myopia or hyperopia, but the spot pattern will be expanded or contracted because the light rays reflected from the retina will be divergent or convergent. Patients with an astigmatic component to their refractive error will produce light spots that are not uniformly spaced, because the light bundle that leaves the eye will not be rotationally symmetrical. The exact algorithm used for calculation is proprietary information controlled by Welch Allyn, Inc.

As the above description demonstrates, SureSight Vision Screener can be used to measure spherical refractive error, cylindrical refractive error, and anisometropia. It has a Child Mode, which was designed for use on children aged six and younger in order to compensate for their accommodation response. The exact formula used for compensation is proprietary, although different studies suggest that a constant value, possibly +2.50 diopters, is added to the spherical result for compensation. After each measurement, the instrument panel displays values for sphere (S) and cylinder (C). Difference in mean spherical power between the two eyes (D) is also displayed.
(Figure 3) The results shown are an average of five to eight readings. A reliability number ranging from zero to ten is also displayed; this is based on the number of good readings that are obtained and their consistency. (62) The higher the number displayed, the more reliable the reading. Welch Allyn suggests that testing should be repeated when the reliability number is below six, but subsequent studies have shown that repeated testing does not increase the sensitivity or specificity of screening with SureSight Vision Screener. (62, 77, 80)

![SureSight Results Screen](image)

**Figure 3. SureSight Results Screen**

SureSight Vision Screener has a spherical measurement range of $+5.50$ to $-4.50$ diopters and a cylindrical measurement range of $\pm 3.00$ diopters. (62) A result that is out of measurement range is indicated by $+9.99$ or $-9.99$ diopters. (62) When the instrument is used in Child Mode, an asterisk will appear beside readings that are outside the set referral criteria to aid lay screeners in determining which children should be referred as screening failures. (62) If the instrument is purchased from School Health, it comes set with an approximation of the referral criteria determined by the VIP study, namely $\geq +4.25$ diopters hyperopia, $\leq -1.00$ diopters myopia, $\geq 1.75$ diopters cylinder, and $\geq 3.50$ diopters astigmatism.
diopters anisometropia. (2, 71, 72) If the instrument is purchased through Welch Allyn, it comes set with manufacturer’s criteria.

When measurement using the SureSight Vision Screener is complete, results can be printed through use of electronic transfer to a small printer. (Figure 4) Calibration of SureSight Vision Screener is performed by the Welch Allyn Technical Service Department. Welch Allyn recommends that SureSight be calibrated yearly; a warning symbol will appear when the instrument has gone 18 months without calibration. (62)

Figure 4. Thermal Printer

*Nikon Retinomax K+ (Nikon Inc, Tokyo)* hand-held autorefractor also was evaluated. It is light-weight (just over 2 lbs) and easily transported. (66, 82) (Figure 5) It has a working distance of 6 cm and uses a tree with green grass and a blue sky background as the fixation target. (65, 67) (Figure 6) The minimum required pupillary diameter for use is 2.7 mm. (7) Because Retinomax has no chin rest, it is easier to use on children than a standard tabletop autorefractor. (7, 82)
Retinomax uses infrared light in detection of refractive error. (7) The principle of retinoscopy is used for the illumination system and the Scheiner principle for the detection system. (7) Instead of neutralizing the retinoscopy reflex, the instrument sweeps through 360 degrees very quickly and determines the speed of the reflex in each meridian in order to establish refractive error. (7, 65) The instrument can be used in normal mode,
in which the instrument fogs the fixation target to minimize the accommodative response as soon as alignment is achieved, or the quick mode, in which the instrument disables the fogging system so that measurement can be taken immediately. (65, 81-83) The quick mode is useful when children are moving too much to achieve measurement in normal mode but can give inaccurate values if the eye is not fixating properly. (7, 83)

Retinomax can be used to determine spherical refractive error, cylindrical refractive error, axis values, and anisometropia. (65, 66) The person operating the instrument can see the subject’s eye on a screen through aid of an infrared light-sensitive camera, and she uses the reflected light from the subject’s cornea to align the instrument. (7) Retinomax takes a series of readings of the patient’s refractive error and prints out a maximum of eight measurements. (65, 66) It also provides a single representative value reached through a proprietary algorithm. As described by Cordonnier, the instrument takes a certain number of measurements and then uses a formula to select the reading closest to the median value of the patient’s sphere, cylinder, and axis measurements. (7)

Along with values for refractive error, the instrument provides a confidence number that indicates the reliability of the reading. (65, 66) This value can range from E to 10, with higher numbers indicating greater reliability. (83) The manufacturer recommends that the reading be repeated if the confidence number is less than 8. (66) The Vision in Preschoolers group conducted a study to determine if such repetition resulted in higher confidence numbers and if readings with higher confidence numbers resulted in better sensitivity and specificity. (66) They found that repeated screening allowed for
achievement of the manufacturer’s recommended confidence number 87% of the time and the higher confidence number significantly increased the specificity of screenings.(66)

Retinomax has a spherical measurement range of −18.00 diopters to +22.00 diopters and a cylindrical range of 8.00 diopters.(7, 77) The VIP study group protocol states that instrument calibration should be checked using a model eye each day before use.(2) Once measurements are taken, results can be electronically transferred to a printer.

Procedures for Non-Cycloplegic Autorefraction

Subjects presented for comprehensive eye examination and were screened using SureSight Vision Screener and Retinomax Autorefractor before cycloplegic agents were instilled. Non-cycloplegic results of SureSight Vision Screener and Retinomax Autorefractor were compared to cycloplegic autorefraction, the gold standard.

SureSight Vision Screener

The child stood during examination. Child mode was used on children aged six and younger and adult mode was used on all other children per manufacturer recommendation. (62) The screener sat on a chair approximately 50 cm from the child and instructed the child to fixate on the red lights at the front of the instrument during testing. The screener looked through the viewfinder and centered the crosshair on the pupil of the child’s right eye. The screener adjusted her distance from the child based on auditory cues provided by the instrument and moved the instrument slowly in a circle around the child’s pupil until a reading was captured, at which point the instrument
signaled completion via an auditory cue. The screener repeated the procedure for the child’s left eye, and then printed the refractive error and reliability values for each eye.

If the reliability rating was less than six, the screener repeated the measurement a maximum of two times in order to achieve a higher rating. If a rating of six was not achieved for a given eye after these repetitions, the refractive error value with the highest reliability rating of those collected was used for analysis. If the instrument timed out without obtaining a reading on a given eye, measurement of that eye was attempted a maximum of two additional times. If no refractive error measurement was secured for a given eye, that child was treated as a screening failure.

*Retinomax Autorefractor*

The child stood during examination. The instrument was used in normal mode for all data capture. The instrument’s headrest was placed against the child’s forehead, and the child was instructed to look into the instrument at the fixation target. The screener then focused the mires in the center of the subject’s right pupil while the instrument captured readings automatically. The procedure was repeated for the child’s left eye. If the reliability reading for a given eye was less than eight, per the manufacturer’s recommendations, the measurement was repeated. Measurements were repeated a maximum of two times; at that point, if the reliability reading was still less than the desired eight, the measurement with the highest reliability reading was selected for use in analysis.
Cycloplegic Autorefraction

After testing with Retinomax Autorefractor and SureSight Vision Screener, the child continued with comprehensive examination, receiving cycloplegic drops as per the attending clinician’s standard of care. Cyclopentolate and/or tropicamide were used for cycloplegia/dilation during the comprehensive eye examinations at The Ohio State University Pediatric Service. Phenylephrine 2.5% was also used in combination with cyclopentolate or tropicamide in some instances. Additional drops were added if cycloplegia was determined inadequate by the intern or attending optometrist conducting the comprehensive examination. Upon completion of the comprehensive examination (30 to 60 minutes after drop instillation), cycloplegic autorefraction was performed using the Canon RK-3 Autorefractor.

Data Analysis

PASW Statistics 18 was used to run descriptive statistics on the patient population. Based on the results of cycloplegic autorefraction using the Canon RK-3 Autorefractor, previously listed criteria were used to determine if each child was classified as having significant hyperopia, myopia, astigmatism, and/or anisometropia. (Table 4) Most positive meridian was used for hyperopia, most negative meridian was used for myopia, absolute value of the cylinder power was used for astigmatism, and the absolute difference in spherical equivalent between the two eyes was used for anisometropia.

Ability of SureSight and Retinomax to discriminate children with significant refractive error from normal children was analyzed using Receiver Operating
Characteristic (ROC) Curves, which are generated by plotting sensitivity (true positives) on the Y axis and 1-specificity (false positives) on the X axis of the graph.(7, 56) Sensitivity is the probability that a given child will test positive in the presence of significant refractive error \((\text{true positives}/(\text{true positives} + \text{false negatives}))\).(56) Specificity is the probability that a given child will test negative in the absence of significant refractive error \((\text{true negatives}/(\text{true negatives} + \text{false positives}))\).(56)

Sensitivity and 1-specificity of SureSight Vision Screener and Retinomax Autorefractor were calculated using all possible cut points for each refractive error category: hyperopia, myopia, astigmatism, and anisometropia. The most positive meridian reported by SureSight and Retinomax was used for detecting hyperopia, most negative meridian for myopia, absolute value of cylinder for astigmatism, and absolute difference in the spherical equivalent for anisometropia.

Eyes for which SureSight returned values that were out of range of the instrument \((\pm 9.99 \text{ diopters sphere or } +9.99 \text{ diopters cylinder})\) were considered to have been classified by SureSight as having significant refractive error. Eyes that were classified as +9.99 diopters sphere were considered to be hyperopic, eyes that were classified as \(-9.99 \text{ diopters sphere}\) were considered to be myopic, and eyes that were classified as +9.99 diopters cylinder were considered to have significant astigmatism. In order to perform data analysis for other types of refractive error in eyes with these readings, the out of range 9.99 value was replaced with a conservative estimate based on SureSight’s measurement range. Specifically, readings of \(-9.99 \text{ and } +9.99 \text{ diopters sphere}\) were replaced with \(-4.75 \text{ and } +5.75 \text{ diopters sphere}\) respectively, as SureSight’s spherical
measurement range is −4.50 to +5.50 diopters sphere. Readings of +9.99 diopters cylinder were replaced with +3.25 diopters cylinder based on SureSight’s cylinder measurement range (±3.00 diopters cylinder). Eyes on which SureSight failed to capture a reading were treated as screening failures.

The area under the ROC curve can be used to summarize the discriminating power of each screening test, and so to determine the potential usefulness of the test being studied.(56) If a test is perfect, it will have 100% sensitivity and 100% specificity; all subjects will be appropriately classified as being with or without disease. In this event, the area under the ROC curve would be 1.0. If the area under an ROC curve is 0.5, this means that the test performs similar to chance and for any given cut off value the rate of true positives will be equal to the rate of false positives.(56) The closer the area under the curve is to 1.0, the better the sensitivity and specificity of the test.(7)

For the current analysis, an area under the ROC curve of equal to or greater than 0.9 is considered excellent discrimination, where an area under the curve of greater than or equal to 0.8 but less than 0.9 is considered very good.(90) An area under the curve greater than or equal to 0.7 but less than 0.8 is considered good, and an area under the curve greater than or equal to 0.6 but less than 0.7 is considered average.(90) An area under the curve of less than 0.6 is considered poor.(90) (Table 5)
<table>
<thead>
<tr>
<th>Area Under the ROC Curve</th>
<th>Classification (90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 0.90</td>
<td>Excellent</td>
</tr>
<tr>
<td>≥ 0.80</td>
<td>Very Good</td>
</tr>
<tr>
<td>≥ 0.70</td>
<td>Good</td>
</tr>
<tr>
<td>≥ 0.60</td>
<td>Average</td>
</tr>
<tr>
<td>&lt; 0.60</td>
<td>Poor</td>
</tr>
</tbody>
</table>

Table 5. Classification of Area Under the ROC Curve

The area under the ROC curve was calculated for each instrument for each refractive error category using nonparametric ROC analysis and then compared between SureSight and Retinomax. (91, 92) All ROC analyses were performed using STAT 10.0 (Statacorp, College Station, TX). Finally, data from the ROC curves was used to determine the dioptric value of the cut point (referral criteria) that simultaneously maximized sensitivity and specificity for detecting each type of significant refractive error for each instrument. The cut points generated are specific to the instruments when used in this study on this specific subject population.
Chapter 3: Results

Descriptive Statistics

Consent was obtained for 198 children, all of whom were screened with SureSight Vision Screener and Retinomax Autorefractor. Of these, two children did not undergo cycloplegia during the course of comprehensive examination and one was not screened using the Canon RK-3 Autorefractor, so 195 children completed comprehensive vision examination and cycloplegic autorefraction. The age of the subjects ranged from five years and zero months to 13 years and 11 months with a mean age of 9.35 ± 2.33 years. Of the subjects enrolled, 110 had been previously prescribed glasses. Based on cycloplegic results from the Canon RK-3 Autorefractor, the mean spherical equivalent refractive error for the 390 eyes of the 195 subjects was +0.12 diopters (range −15.06 diopters to +8.69 diopters). (Table 7) Among those who completed the study, 37 children were classified as hyperopes (19.0%), 87 were classified as myopes (44.6%), 52 were found to have significant astigmatism (26.7%), and 12 were found to be anisometropes (6.2%). (Table 4, 6)
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Number of Children (n=195)*</th>
<th>Percentage (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant Refractive Error</td>
<td>128</td>
<td>65.6</td>
</tr>
<tr>
<td>Hyperopia (≥ 2.75 D)</td>
<td>37</td>
<td>19.0</td>
</tr>
<tr>
<td>Myopia (&lt; −0.50 D)</td>
<td>87</td>
<td>44.6</td>
</tr>
<tr>
<td>Astigmatism (≥ 1.50 D)</td>
<td>52</td>
<td>26.7</td>
</tr>
<tr>
<td>Anisometropia (≥ 1.50 D)</td>
<td>12</td>
<td>6.2</td>
</tr>
<tr>
<td>No Significant Refractive Error</td>
<td>67</td>
<td>34.4</td>
</tr>
</tbody>
</table>

*Some subjects fell into multiple categories

Table 6. Characteristics of Study Population Based on Cycloplegic Autorefraction
### Table 7. Distribution of Refractive Error Measured by Cycloplegic Autorefraction

<table>
<thead>
<tr>
<th>Range of Refractive Error (SEQ)</th>
<th>Number of Eyes (n=390)*</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>more than −4.00</td>
<td>10</td>
<td>2.6</td>
</tr>
<tr>
<td>−4.00 to &lt; −2.00</td>
<td>50</td>
<td>12.8</td>
</tr>
<tr>
<td>−2.00 to &lt; −0.50</td>
<td>77</td>
<td>19.7</td>
</tr>
<tr>
<td>−0.50 to &lt; +0.50</td>
<td>86</td>
<td>22.1</td>
</tr>
<tr>
<td>+0.50 to +1.00</td>
<td>58</td>
<td>14.9</td>
</tr>
<tr>
<td>&gt;+1.00 to +2.00</td>
<td>50</td>
<td>12.8</td>
</tr>
<tr>
<td>&gt;+2.00 to +3.25</td>
<td>24</td>
<td>6.2</td>
</tr>
<tr>
<td>&gt;+3.25 to +5.00</td>
<td>13</td>
<td>3.3</td>
</tr>
<tr>
<td>&gt; +5.00</td>
<td>22</td>
<td>5.6</td>
</tr>
</tbody>
</table>

| Mean (SD) (SEQ) | +0.12 (2.72) |
| Median (Range) (SEQ) | +0.25 (−15.06 to +8.69) |

*From 195 subjects, SEQ = spherical equivalent in diopters

Testability of SureSight and Retinomax

The proportion of eyes that were testable by SureSight Vision Screener was 379 of 390 (97.18%). All untestables occurred due to the instrument timing out before taking a reading. All eyes (100%) were testable using Retinomax Autorefractor.
SureSight and Retinomax Performance Analysis

SureSight Vision Screener

When using non-parametric ROC analysis to evaluate performance of SureSight Vision Screener, the area under the ROC curve for significant hyperopia was 0.89 (95% confidence interval 0.84 – 0.95). (Table 8, Figure 7) Area under the curve was 0.86 (0.81 – 0.91) for myopia, 0.95 (0.91 – 0.99) for astigmatism, and 0.82 (0.65 – 0.98) for anisometropia. (Figures 8-10, respectively)

Retinomax Autorefractor

When non-parametric ROC analysis was used to evaluate performance of Retinomax Autorefractor, the area under the ROC curve when determining significant hyperopia was 0.96 (95% confidence interval 0.91 – 1.00). (Table 8, Figure 7) Area under the curve was 0.85 (0.79 – 0.90) for myopia, 0.95 (0.91 – 0.99) for astigmatism, and 0.86 (0.73 – 0.99) for anisometropia. (Figures 8-10)

Comparison of Performance of SureSight and Retinomax

When results of non-parametric ROC analysis for the two instruments were compared, SureSight Vision Screener and Retinomax Autorefractor were not significantly different in their ability to identify significant levels of hyperopia, myopia, astigmatism, or anisometropia. (Table 8) Using a threshold p-value of 0.05, Retinomax and SureSight values for area under the curve were not statistically significantly different for detection of children with any type of significant refractive error, but approached significance for superior detection of hyperopia by Retinomax (p = 0.07).
<table>
<thead>
<tr>
<th></th>
<th>SureSight Vision Screener</th>
<th>Retinomax Autorefractor</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperopia (n=37)</td>
<td>0.89 (0.84 – 0.95)</td>
<td>0.96 (0.91 – 1.00)</td>
<td>0.07</td>
</tr>
<tr>
<td>Myopia (n=87)</td>
<td>0.86 (0.81 – 0.91)</td>
<td>0.85 (0.79 – 0.90)</td>
<td>0.76</td>
</tr>
<tr>
<td>Astigmatism (n=52)</td>
<td>0.95 (0.91 – 0.99)</td>
<td>0.95 (0.91 – 0.99)</td>
<td>0.98</td>
</tr>
<tr>
<td>Anisometropia (n=12)</td>
<td>0.82 (0.65 – 0.98)</td>
<td>0.86 (0.73 – 0.99)</td>
<td>0.70</td>
</tr>
</tbody>
</table>

Table 8. Results of ROC Analysis for SureSight and Retinomax
Figure 7. SureSight and Retinomax ROC Curves for Hyperopia
Figure 8. SureSight and Retinomax ROC Curves for Myopia
Figure 9. SureSight and Retinomax ROC Curves for Astigmatism
Figure 10. SureSight and Retinomax ROC Curves for Anisometropia

**Referral Criteria for SureSight and Retinomax When Used on a School-Aged Population**

ROC curve findings were analyzed to determine the failure criteria that maximize sensitivity and specificity for each type of refractive error. (Tables 9-10) For SureSight Vision Screener, sensitivity values ranged from 69.4 for detection of significant myopia.
to 90.4 for detection of significant levels of astigmatism, and specificity values ranged from 84.2 for detection of significant levels hyperopia to 88.8 for detection of significant levels of astigmatism. For Retinomax Autorefractor, sensitivity values ranged from 72.2 for detection of significant levels of myopia to 91.7 for detection of significant levels of anisometropia, and the specificity values ranged from 77.6 for detection of anisometropia to 93.0 for detection of significant levels of astigmatism.

<table>
<thead>
<tr>
<th></th>
<th>SOCS Definition of Significant RE* (D)</th>
<th>SureSight Failure Criteria (D)</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperopia</td>
<td>≥ 2.75</td>
<td>1.50</td>
<td>86.5</td>
<td>84.2</td>
</tr>
<tr>
<td>Myopia</td>
<td>-0.50 or more</td>
<td>-1.30</td>
<td>69.4</td>
<td>87.4</td>
</tr>
<tr>
<td>Astigmatism</td>
<td>≥ 1.50</td>
<td>1.20</td>
<td>90.4</td>
<td>88.8</td>
</tr>
<tr>
<td>Anisometropia</td>
<td>≥ 1.50</td>
<td>1.75</td>
<td>75.0</td>
<td>88.5</td>
</tr>
</tbody>
</table>

*RE=refractive error

Table 9. Failure Criteria for SureSight with Sensitivity and Specificity Maximized
<table>
<thead>
<tr>
<th>Condition</th>
<th>SOCS Definition of Significant RE* (D)</th>
<th>Retinomax Failure Criteria (D)</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperopia</td>
<td>≥ 2.75</td>
<td>0.50</td>
<td>89.2</td>
<td>90.5</td>
</tr>
<tr>
<td>Myopia</td>
<td>-0.50 or more</td>
<td>-1.25</td>
<td>72.2</td>
<td>90.8</td>
</tr>
<tr>
<td>Astigmatism</td>
<td>≥ 1.50</td>
<td>1.00</td>
<td>86.5</td>
<td>93.0</td>
</tr>
<tr>
<td>Anisometropia</td>
<td>≥ 1.50</td>
<td>0.75</td>
<td>91.7</td>
<td>77.6</td>
</tr>
</tbody>
</table>

*RE=refractive error

Table 10. Failure Criteria for Retinomax with Sensitivity and Specificity Maximized
This study evaluated the performance of SureSight and Retinomax in identifying school-aged children with significant refractive error; instrument effectiveness was determined by area under the receiver operating characteristic curve. The study showed that both instruments had excellent results for identification of astigmatism and very good results for identification of myopia and anisometropia. The two instruments were characterized differently in their effectiveness at identifying significant levels of hyperopia; Retinomax had excellent performance here while SureSight was very good. The performance of the two instruments was not statistically significantly different for detection of any type of significant refractive error but approached significance for superior detection of hyperopia by Retinomax.

While this study supports prior findings showing that Retinomax and SureSight are effective for detection of significant refractive error, the results from the Screening of Children Study are not directly comparable to prior studies evaluating the effectiveness of Retinomax and SureSight in a screening setting due to differences in study population and methodology. Specifically, the majority of prior research has focused on detection of potentially amblyogenic levels of refractive error in children preschool age or younger, while the purpose of the current study was to evaluate detection of significant refractive error in school-aged children. This
difference has meaningful implications for the definitions of significant refractive error. (88)

When considering glasses for preschoolers, doctors are concerned with potentially amblyogenic factors, while when prescribing for school-aged children, optimizing visual acuity becomes the more important goal. (16, 93) In a study performed by Miller and Harvey, members of the American Association for Pediatric Ophthalmology and Strabismus were surveyed about their glasses prescribing standards. (88) The results showed that doctors were more likely to prescribe for lower amounts of hyperopia, myopia, and astigmatism in children aged four to seven than in those less than four years old. (88) Because SOCS is working to identify problems in school-aged children, definitions of significant refractive error, particularly for hyperopia and myopia, were set to identify children with smaller amounts of refractive error.

The age of subjects enrolled in the studies also prevents comparison because of differences in the application of SureSight’s Child Mode. The manufacturer recommends that this mode be employed when screening all children aged six and younger in order to compensate for their accommodative response. (62) Because of the age of subjects enrolled, this mode was used on all subjects in the VIP study and studies by Kemper et al, Rowatt et al, and Silverstein et al, while it was used on only 42 of the 195 subjects enrolled in this study (22%). (4, 5, 21, 68)

Another important difference that prevents comparison between SOCS and other screening studies has to do with the conditions targeted in the screening. SOCS attempts to identify only significant hyperopia, myopia, astigmatism, and anisometropia.
Researchers in several other studies sought to identify children with significant refractive error as well as amblyopia, strabismus, decreased visual acuity, ptosis, and media opacity. (4, 5, 7, 21, 67, 68) This difference could affect both the area under the curve and the referral criteria suggested in each study.

Finally, SOCS is not comparable to several of the other screening studies because of differences in data collection and analysis. (5, 7, 67-69) The current study compared non-cycloplegic Retinomax or SureSight results for each subject to those of cycloplegic autorefraction and determined receiver operating characteristic curves for each instrument. Several of the other screening studies, however, estimated the area under the curve based upon the examination results of a sample of children or used positive predictive value instead of sensitivity and specificity because all children screened in these studies did not undergo subsequent cycloplegic evaluation. (5, 7, 67-69) Another study generated ROC curves using a few selected referral criteria, where SOCS generated the ROC curve using all possible cut points for failure. (4)

**Strengths and Limitations**

A strength of this study is the fact that all children enrolled underwent cycloplegic autorefraction, so sensitivity and specificity values could be calculated for each instrument. Limitations to this study include the small sample size, which did not allow for evaluation of the effectiveness of SureSight and Retinomax in identification of subjects with one or more types of significant refractive error. Small sample size was also a factor in evaluating the instruments’ performance on anisometropia. In spite of recruiting subjects from a population with a high prevalence of refractive error, only 12
children who had refractive error categorized as anisometropia by the parameters of this study were enrolled. This means that although the area under the ROC curve for anisometropia was very good for both SureSight and Retinomax, it is difficult to draw strong conclusions about the instruments’ ability to identify children with anisometropia based on such a small sample.\(^{(90)}\) Another possible limitation relates to the study methodology. Although in SOCS all subjects were screened by a single examiner in a controlled setting, it is expected that the results would be similar in a more typical screening environment given the similar performance of Retinomax and SureSight in VIP Phases I (testing by licensed eye professionals in a mobile medical unit) and II (testing by trained nurse and lay screeners in Head Start centers).\(^{(21)}\)

**Future Directions**

While this study begins to answer an important question about the use of SureSight and Retinomax on a school-aged population, more work in this area is needed. Screening of Children Study results reveal that both instruments hold promise for identifying children with significant refractive error in this age group, but a larger study with more subjects having each type of refractive error, particularly anisometropia, would be beneficial.

**Conclusion**

Both SureSight and Retinomax had excellent results for identification of astigmatism and very good results for identification of myopia and anisometropia. For detection of hyperopia, Retinomax had excellent performance, while SureSight was very
good. Both instruments were effective in detecting significant refractive errors in school-aged children.
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15. Cordonnier M, de Maertelaer V. Screening for amblyogenic factors in preschool children with the retinomax hand-held refractor: do positive children have amblyopia and is treatment efficacious? Strabismus. 2005 Mar;13(1):27-32.