

Many studies were conducted over the course of the SureSight development to establish, refine, and validate its accuracy. To date, measurements from more than 3,200 eyes have been used for this purpose. More evaluations are currently under way using production units. Sensitivities (correct identification of those who should be referred) and specificities (correct identification of those within normal limits) for detection of important refractive errors have ranged from 78% to 100%. All results compared quite favorably to independent studies on the accuracy of other primary care screening techniques. These have shown sensitivity and specificity figures of 50%/50% or worse for the visual acuity (eye) chart, and 54%/67% or worse for photoscreeners when used for pre-school screening for refractive error. Testability for the SureSight has likewise been quite high, at or above 95% in all cases with preschoolers, which compares to values of 50% - 77% reported for visual acuity (eye chart) based screening methods in this age group.

Below is a summary of the published results to date:

Preschooler Screening (population with high astigmatism) ⁱ

166 Native American preschoolers (3 to 5 years old) were screened for high astigmatism, with results compared to those obtained by cycloplegic retinoscopy (the gold standard used by eye care) and the Nikon Retinomax (an autorefractor used by eye care that is 3X the SureSight's price). Testability with the SureSight was 95%, with 78% sensitivity, 100% specificity. This accuracy is comparable to the Retinomax and is significantly better than results obtained by the clinicians in this setting using a photoscreener (53% sensitivity/73% specificity when retakes [24% of patients] were excluded).ⁱⁱ

Comparison with the Eye Chart in Screening Settings ⁱⁱⁱ

Lay screeners who attended a four-hour course (on conducting visual acuity, stereoacuity, SureSight prototype, and Retinomax testing) screened 1,180 preschoolers (age range 39 to 62 months). 96.6% of the children's eyes were testable by the SureSight. Children who failed the screening were referred for a retinoscopic examination. On the 92 follow-ups with results, SureSight agreed 88% of the time with eye care findings for true positives, and had only ¼ of the false positives compared to the eye chart (18 vs. 66).

Repeatability of Measurements ^{iv}

Testing of 25 adults with a broad range of refractive errors was performed by Prevent Blindness America to assess testability and repeatability. Correlation between repeated measures was high (99% for sphere, 94% for cylinder), with good repeatability (mean difference 0.18 diopters sphere, 0.09 diopters cylinder). This is comparable to, or better than, results from studies of retinoscopic repeatability.

Comparisons to Retinoscopy

The readings from a SureSight prototype and the Retinomax across a sample of 167 adults and 88 children were compared to cycloplegic retinoscopy.^v It was found that the

SureSight's working distances reduced accommodative effects in non-cycloplegic children compared to the close working distance of the Retinomax.

Early testing of the technology was performed on a prototype and compared to cycloplegic retinoscopy of 44 children.^{vi} Results were sensitivity of 88% to 100%, and specificity of 88%.

Useful in developing and validating the product were the results from a number of other sites where Ophthalmologists and Optometrists collected data on the SureSight readings compared to retinoscopy. Sensitivity and specificity has typically remained in the ranges from other studies reported here.

Younger Patients

At another site, a SureSight prototype was used to screen children who averaged 9 months of age. For these 56 children (112 eyes), results were 71% sensitivity, 92% specificity using the Atkinson and Braddock referral criteria noted in our quick reference guide.

A recent survey of Pediatric Eye Specialists^{vii} found that ¾ of the respondents believed that refractive error screening by 24 months of age would be optimal, assuming that a validated device were available.

ⁱ Harvey E.M., Miller J.M., Dobson, V.. Preschool Vision Screening with a New Portable Vision Screener: Effectiveness in a Population with a High Prevalence of Astigmatism [ARVO Abstract]. 2000: S302 Abstract nr 1594.

ⁱⁱ Atodaria N.J., Harvey E.M., Miller J.M., Dobson V.. Preschool Vision Screening Using a New Photoscreener: Effectiveness in a Population with a High Prevalence of Astigmatism [ARVO Abstract]. 2000: S302 Abstract nr 1953.

ⁱⁱⁱ Robinson B.E., Bobier W.R.. Setting the Referral Criteria for Autorefractors Used in the Oxford County Preschool Vision Screening. *Optometry and Vision Science*, Issue 12S, Volume 76, # 26 1999.

^{iv} Shoemaker, J.A.. Repeatability of Welch Allyn SureSight Autorefraction in Adults. [ARVO Abstract]. 2000: S301 Abstract nr. 1590

^v Bobier W.R., Cowan L., Machan C. etal. Autorefractors Preschool Screenings. *Optometry and Vision Science*, Issue 12S, Volume 76, # 113 1999.

^{vi} Ho C.S., Armstrong M., Bobier W. R., Screening for Refractive Errors in Children using the Welch Allyn DAV-1 Prototype. *Optometry and Vision Science*, Issue 12S, Volume 75, # 110 1998.

^{vii} Miller J.M., Hypermetropia Screening Recommendations of Pediatric Eye Specialists [ARVO Abstract] 2000: S302 Abstract nr. 1595.

Preschool Vision Screening with a New Portable Vision Screener: Effectiveness in a Population with a High Prevalence of Astigmatism. E.M. Harvey¹, J.M. Miller^{1,2}, V. Dobson^{1,3}. Ophthalmology¹, Optical Sciences², Psychology, University of Arizona, Tucson, AZ³.

Purpose: To compare the effectiveness of the Welch Allyn SureSight™ (SS) to the Nikon Retinomax K+ hand-held autorefractor (Rmax) in detecting high astigmatism in a sample of Native American preschoolers from a tribe with a high prevalence of astigmatism. **Methods:** We attempted to screen 166 preschool children enrolled in the Tohono O'odham Head Start Program with the SS and the Rmax without cycloplegia. Cycloplegic refraction (CR) was conducted to determine a best estimate of refractive error. Agreement between CR and each of the screening instruments was assessed in two ways: (1) the sensitivity and specificity for detection of high astigmatism (criteria were $\geq 2D$ for children under 4-years-old, and $\geq 1.5D$ for children 4-years or older), and (2) the mean difference (bias) between CR and screening measurements of sphere and cylinder. Results are presented for right eyes. **Results:** Of the 166 children examined, SS measurements were obtained from the right eye of 95% (157/166) of children (failures due to experimenter error/printing problems (3), lack of cooperation from child (5), and failure to obtain a measurement when the SS was aligned (1)). Rmax measurements were obtained from the right eye of 99% (164/166) of children (failures due to experimenter error (1) and lack of cooperation from child (1)). Sensitivity and specificity, respectively, for detection of high astigmatism were 78% and 100% for the SS, and 82% and 100% for the Rmax. The mean differences between CR and screening measures for sphere and cylinder, respectively, were +2.27D (SD 1.45) and +0.13D (SD 0.44) for the SS, and +1.29D (SD 0.87) and +0.15D (SD 0.32) for the Rmax. **Conclusions:** Results indicate that the success rates in obtaining measurements for both instruments were excellent in this sample of 3-5 year-olds. Both the SS and Rmax provided high sensitivity and specificity for detection of high astigmatism. However, the data suggest that without cycloplegia the SS and the Rmax overestimate myopia (underestimate hyperopia), and may be less effective for detection of high spherical refractive errors than for high astigmatic errors.
CR: C7 Support: NIH Grant EYO11155

Program Nr: 1593

Preschool Vision Screening Using a New Photoscreener: Effectiveness in a Population with a High Prevalence of Astigmatism. N.J. Atodaria¹, E.M. Harvey¹, J.M. Miller^{1,2}, V. Dobson¹. Departments of Ophthalmology¹, Optical Sciences, The University of Arizona, Tucson, AZ².

Purpose: To evaluate a new photoscreening tool that utilizes a digital camera and objective computerized image analysis for detection of amblyogenic factors (refractive error, strabismus, media opacity) among a Native American preschool population with a high prevalence of astigmatism. **Methods:** 215 preschool children from the Tohono O'Odham Head Start Program participated in vision testing that included screening with the EyeDx digital photoscreening system and a complete cycloplegic eye exam conducted by a pediatric ophthalmologist who was masked to the EyeDx results. Once images were obtained, the computer software performed image analysis and yielded 1 of 3 results: (1) "Pass"-subject does not have an ocular condition that warrants referral, (2) "Refer"-subject has an ocular condition that warrants referral, or (3) "Retake"-image is deemed uninterpretable by the computer software. Two attempts to obtain EyeDx pass/fail results were permitted for each child. Results were compared to eye exam results, using the screening failure criteria listed in the EyeDx manual. Sensitivity and specificity were calculated: (1) including only pass and refer EyeDx results (retakes excluded), and (2) including all EyeDx results: pass and non-pass (refer+retake). **Results:** Data were obtained from 198 children. 14 were not screened due to computer failure unrelated to the EyeDx system, 3 refused to cooperate. EyeDx results were pass for 88 children, fail for 63, and retake for 47. Eye exam results were pass for 87, fail for 111 (primarily due to astigmatism). Sensitivity and specificity for the EyeDx were 53% and 73% when retakes were excluded, and 64% and 55% when retakes were scored as "refer". **Conclusions:** The screening effectiveness with the EyeDx camera was comparable to conventional photoscreening. Factors that may have limited effectiveness include a high prevalence of dark irides (making it difficult for software to identify pupil), study protocol limiting testing to 2 attempts, and variability in the lighting conditions. Effectiveness may improve with additional operator oversight of automated image selection.
CR: None Support: NIH Grant EYO11155

Further information on this and related documents can be found at

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Pediatric Optometry Poster

Sun. Dec. 12, 1999, Poster # 26, Hall 4C

SETTING THE REFERRAL CRITERIA FOR AUTOREFRACTORS USED IN THE OXFORD COUNTY PRESCHOOL VISION SCREENING

Barbara E. Robinson, William R. Bobier, *University of Waterloo, School of Optometry, Waterloo, ON, Canada*

PURPOSE. Noncycloplegic autorefraction of preschool children leads to uncertainty in the sphere measure due to their varying accommodative responses. This investigation defines referral criteria for 2 autorefractors, the Retinomax Plus (Nikon Co.) and a prototype DAV (Welch Allyn Co - to be marketed as the Suresight), used in a preschool vision screening study conducted by public health nurses. **METHOD.** Autorefractor measures were attempted on a total of 1180 children (mean age = 48.13 months) who were screened with tests of visual and stereo acuity. Pass/fail criteria remained as VA < 6/6 or stereoacuity < 100 sec. Failures were referred for a complete eye examination. Criteria for autorefractor failure were independently optimized for agreement with failure by visual acuity using kappa levels. **RESULTS.** The overall failure rate was 31.4% (369 out of 1176). Visual acuity, Retinomax and DAV measures were completed on 96.1%, 98.7%, and 96.6% of eyes respectively. The mean sphere readings for **DAV** were more hyperopic than those for the Retinomax. This resulted in the sphere value criterion for the DAV to be higher (>+3.00D) than that of the Retinomax ($\geq +1.00D$) while the cylinder criterion was similar (>1.12D and >1.00D) respectively. The overall percentage agreement between DAV and visual acuity is 78%; 43% for failures and 87% for passes (kappa = 0.30, P=0.00) and 76%; 36% for failures and 85% for passes (kappa = 0.21, P=0.00) for the Retinomax. Adoption of these criteria would have lead to an overall failure rate of 30.6% using the DAV and 26% using the Retinomax. Applying these criteria in comparisons with clinical results indicate that each instrument can discriminate between true and false positives. **CONCLUSION.** Kappa levels show fair agreement between both instruments and visual acuity values. However differing autorefractor designs appear to require individual referral criteria. Supported by Welch Allyn Co.

Program Nr: 1590

Repeatability of Welch Allyn SureSight Autorefractor in Adults. J.A. Shoemaker. Prevent Blindness America, Schaumburg, IL.

Purpose: The Welch Allyn SureSight is a new portable autorefractor marketed for screening use. Agreement between two repeated refractive measurements was assessed in adult subjects under ideal testing conditions.

Methods: Autorefractor was attempted in 21 adults (16 female, 5 male; mean age = 46.4) until two successful measurements had been taken in each eye. Testing was performed in dim lighting in a quiet room free of distractions. The testing procedure was that recommended by the manufacturer. All subjects had been tested previously with the SureSight and were highly cooperative. Results: The procedure was completed successfully on the first attempt (less than 30 seconds per eye) in all but one subject who required four attempts for the first eye and three for the second. Two subjects were found to have refractive errors outside the measurement range of the instrument and were excluded from analysis. The refractive error measurements in the remaining 38 eyes ranged from +2.6 to -4.5 diopters of sphere (mean = -0.71; SD = 1.55) and 0.1 to 2.2 diopters of cylinder (mean = 0.59; SD = 0.41). Differences between the repeated measures ranged from 0.0 to 0.7 diopters of sphere (mean = 0.18; SD = 0.18) and from 0.0 to 0.5 diopters of cylinder (mean = 0.09; SD = 0.11). The correlation coefficients between the repeated measures were 0.99 for sphere and 0.94 for cylinder. Conclusions: Under ideal conditions with cooperative adult subjects, the SureSight produces highly repeatable measures. It remains to be seen if such repeatability can be achieved under less ideal circumstances in more realistic screening conditions (e.g. with young children in preschool classrooms), although the present results suggest the instrument may be fundamentally reliable. Validity of the refractive measurements also remains to be assessed.

CR: None Support: Instrument provided on loan by Welch Allyn, Inc.

Further information on this and related documents can be found at

The American Academy of Optometry

<http://www.aaopt.org/DB/DB.html>

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Optics & Refraction Poster

Sun. Dec. 12, 1999, Poster # 113, Hall 4C

AUTOREFRACTORS IN PRESCHOOL SCREENINGS

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PURPOSE. Autorefractors have been considered as a means to provide a rapid estimation of the (non-cycloplegic) refractive errors of preschool children. However, while such instrumentation may be accurate in adult populations, the instrumentation must be able to relax the child's accommodation and be robust in its alignment otherwise variations will be introduced in both the sphere and cylinder measures. Two types of autorefractors, the Retinomax Plus (Nikon Co) and two DAV prototypes (SureSight, Welch Allyn Co) were tested both on a preschool and adult population. **METHOD.** Autorefractors were introduced into a preschool screening of 1180 children (Mean age=48.13mo.) To date, clinical retinoscopic measures were available for 88 of the children referred by the screening. The Retinomax and DAV2 were also tested on 167 adults attending an optometric clinic. **ANALYSIS.** Refractive measures for the right eye were transposed into three independent variables M (equivalent sphere), J0 and J45 (cylinder components). Differences between retinoscopy and autorefractive measures were computed for each variable. **RESULTS.** The Retinomax showed a significantly more myopic M value (-0.73D; $p=0.0001$) compared with clinical retinoscopic findings. Cylinder components however were not significantly different. The adults however, showed a more hyperopic M value (0.39D), $p=0.0001$). Compared with retinoscopy, the M value of DAV2 was consistently more hyperopic for preschoolers and adults (1.39D; 1.27D respectively); but, showed significant differences in the J0 component. **CONCLUSIONS.** These results suggest the close working distance of the Retinomax induces over-accommodation in non-cyclopleged preschool children. This **effect** is reduced by the 40cm working distance of the DAV prototypes. However, the Retinomax provides a robust measure of astigmatism in preschool children. We acknowledge the support of Welch Allyn Co.

Poster #109

(PO-120)

Poster # 110

(PO-128)

THE COMBINED INCIDENCE OF HEARING AND VISION PROBLEMS IN A FIRST GRADE POPULATION Tracy Schroeder Swartz, OD, MS, Bill Rainey, OD, Doug Horner, OD, PhD, Andrya Lowther, MS, David Goss, OD, PhD, *Indiana University, School of Optometry, Bloomington, IN*; David Eddins, PhD, *Department of Speech and Hearing Sciences -- not school of optometry.*

PURPOSE Early screening results collected as part of the Benton Project, a longitudinal epidemiological study of predictors of academic failure, will be reported. While discussion continues regarding the value of screening vision and hearing in school-aged children continues, the comorbidity of vision and hearing problems in this population has rarely been reported in the literature. An increased incidence of vision problems is commonly accepted within our profession, although mainly small studies of selected populations, such as juvenile detention centers or learning disabled programs, have been reported. **METHODS** 462 first graders were screened for vision and hearing problems over three years as part of the Benton Project, a multi-disciplinary study of predictors of academic failure. Vision screening included evaluation of visual acuity, refractive error, accommodation, angle of deviation, and ocular health. Auditory evaluation included otoscopic examination, pure-tone audiometry, speech reception threshold, word recognition in quiet, tympanometry screening, and a central auditory testing battery. For the purposes of this report, only hearing problems found on the otoscopic exam and pure-tone audiometry are considered. To examine the relationship of socio-economic levels to referral rates, poverty levels were obtained from each elementary school, based on the percentage of children receiving free lunches. **RESULTS** 14.3% of all first graders had vision problems requiring referrals. 16.5% of all students had ear health or hearing problems. 2.2% of the children were referred to both hearing and vision specialists. Correlation between poverty level and referrals made was relatively strong: $r = +0.78$. **CONCLUSION** This study supports the value of vision and auditory screening, especially in lower socio-economic areas.

SCREENING FOR REFRACTIVE ERRORS IN CHILDREN USING THE WELCH ALLYN DAV-1 PROTOTYPE Cindy S. Ho, Margeret Armstrong, William R. Bobier, OD, PhD, *University of Waterloo, School of Optometry, Waterloo, ON, Canada.*

INTRODUCTION. There is a need to develop instrumentation and procedures for rapid screening of refractive errors in young children. We have been testing a prototype instrument, the Welch Allyn DAV-1, which uses a 40cm working distance. Refractive measures are obtained using waveform analysis of a collimated IR laser beam reflected from the subject's eye. Investigations of the working range of the instrument suggested that hyperopic errors would be optimally detected using a 2-step approach by repeating refractive measures through +2D spectacle lenses. **METHOD.** Refractive and binocular motor status of 33 children (3 to 11 years) was assessed at the Eye Care Center of the University of Waterloo. Prevalence of refractive errors was 45%. Subjects were later screened for refractive errors with the DAV-1 using the 2-step approach. Testers were blind to the child's refractive status. **ANALYSIS.** Screening criteria was based on those defined by the American Optometric Association. Screening failures were defined as myopia $\geq 1D$ and/or cylinder $\geq 1D$ in one or both eyes for measures without spectacles. In cases of hyperopia, failure was defined as a measured spherical refractive error $\geq +0.25D$ for measures through +2D spectacles. Data from 2 subjects was discarded due to poor image quality. **RESULTS.** The sensitivity of the instrument was increased from 77% to 100% when a second measure was taken through +2D spectacles while the specificity remained unchanged at 89%. These values compared well to those taken, without +2D lenses, using the Retinomax K-plus (Nikon) (sensitivity = 79% and specificity = 89%). **CONCLUSIONS.** Investigation with a small population of young children found the DAV-1 prototype to be effective in providing a rapid screening of children's refractive errors using a 2-step approach. This research is supported by a grant from Welch Allyn, Inc.

Program Nr: 1595

Hypermetropia Screening Recommendations of Pediatric Eye Specialists. J.M. Miller, on behalf of the Pediatric Eye Screening Study Group. Ophthalmology, University of Arizona, Tucson, AZ.

Purpose: Referral guidelines are needed for commercially available screening devices that detect refractive error (photorefractors and autorefractors). We report the recommendations of the members of two pediatric eye care provider organizations regarding the optimal age to screen and level of hypermetropia that should be referred.

Methods: A two-question survey was sent to members of the American Association for Pediatric Ophthalmology and Strabismus (AAPOS) and the College of Optometrists in Vision Development (COVD). Respondents listed the level of hypermetropia considered "worrisome" in an asymptomatic child from birth to 48 months of age, and their opinion on the optimal 6 month age range for screening, assuming that a validated device were available.

Results: Response rates were 61% for AAPOS members, and 27% for COVD members. Median "worrisome" hypermetropia decreased with age for both groups. AAPOS members were concerned with 5D of hypermetropia from birth to 6 months, and 4D thereafter to 48 mos (median level), while COVD median "worrisome" hypermetropia declined from 3.5D (birth to 6 mos), 3D (from 6 to 24 mos), 2.5D (24 - 30 mos) and 2D thereafter to 48 months. Screening by 18 months of age was recommended by more than half of respondents, and by 24 months by three quarters of the respondents of both organizations.

Conclusions: If a reliable screening device were available, both AAPOS and COVD respondents agreed that screening should be done by 24 months. Despite commercial availability of objective screening instruments their use in federally mandated screening programs is unwarranted until better validation in smaller settings has occurred. A comprehensive evaluation of objective screening methods for children less than 24 months is needed, to determine if their use provides any advantage over traditional visual acuity based screening efforts in the older child.

CR: None Support: NIH/NEI EYO11155