

Effectiveness of the Welch Allyn SureSight Autorefractor as a Screening Tool in a Sample of Children Aged 3-69 Months

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Abstract

This study compares the Welch Allyn SureSight Autorefractor readings with conventional refractive findings of 93 children, whose ages ranged from 3 to 69 months. The Autorefractor's findings and the associated reliability number were recorded. If the findings had a low reliability (≤ 5), another measurement was attempted. At the conclusion, a pass/fail decision for each child was independently made using age dependent refractive criteria. The children who passed/failed the autorefraction screening were then compared to the children who passed/failed the refractive component of the optometric examination. The sample was divided into two subgroups; children age 3 months to 36 months and children 37 to 69 months. The analytical measures for the younger group were sensitivity 62.5% and specificity of 83.3%. False positives were 28.6%, while false negatives were 23.0%. In the older subgroup, sensitivity was 87.5% and specificity was 65.3%. False positives were 44.7% while false negatives were 8.6%. The high sensitivity and low false negative analytical measurement in our older age group indicate that using the SureSight Autorefractor as a screening tool for refractive conditions is more effective in the older age group. However, this is offset some by the lower specificity and high percentage of false

positives found in the older group, which could result in excessive referrals. In the younger subgroup there was less evidence as to the effectiveness of the SureSight autorefractor as a viable refractive screening instrument when compared with a more standard visual evaluation.

Key Words

astigmatism, false positive, false negative, hyperopia, infant, myopia, preschool children, retinoscopy, screening tool, sensitivity, specificity, Welch Allyn SureSight Autorefractor

Introduction

The purpose of this study was to evaluate the effectiveness of the Welch Allyn SureSight Autorefractor (Autorefractor) as a refractive screening tool in an infant-toddler and preschool population samples. The Autorefractor is an objective hand-held autorefractor (Figures 1, 2 and 3).¹ It is designed as a tool to detect myopia, hyperopia, astigmatism in $\frac{1}{4}$ diopter increments (can be changed to $\frac{1}{8}$ diopter), and axis. According to its manufacturer, the Autorefractor is an easy to use portable instrument that enables the examiner to test patients, including young children, in any environment.¹ The automatic objective refraction is measured from a test distance of 14 inches (35 cm). The child views a test pattern of peripheral blinking green lights and a central red light, which is seen when the instrument is aligned. These lights are accompanied by high and low



Figure 1. Autorefractor from the patient's view.



Figure 2. Autorefractor from doctor's view.



Figure 3. Autorefractor in action.

pitched chirping sounds, which serve as an indicator to the examiner of an appropriate testing distance. In conjunction with the auditory signal, the examiner places a cross mire onto the subject's pupil. The findings are automatically taken and read as sphere, cylinder and axis with an associated reliability number. The instrument has a child and an adult calibration setting. When used in the child mode, the instrument has a hyperopic accommodative lens compensation based on that of a three-year old. Thus, the child's mode refractive results will be relatively more hyperopic. An option of activating a screening referral indicator is also available.

Subjects and methods

State University of New York, State College of Optometry staff doctors, residents, and externs performed examinations on 114 children at their daycare center. The subjects' ages ranged from 3 to 69 months. The exam included; visual acuity (VA), distance and near cover test, extra-ocular motility, pupils, nearpoint of convergence, non-cycloplegic retinoscopy, color vision, stereopsis, and assessment of the anterior adnexia and posterior segment without dilation. Due to the age range and capabilities of our sample, some of the testing procedures were varied. Methods for assessing VA included Preferential Looking using Teller or Cardiff Cards,^a Lea Cards^b and Tumbling E. If the videotapes, which were used to control distant fixation, were not adequate during retinoscopy, the Mohindra method was employed. This procedure is conducted at 50 cm in a darkened room, while the child views the retinoscope.² The above procedures were performed on all children unless age and/or cooperation became a limiting factor. Using age dependent visual acuity and refractive criteria, a pass/fail decision for each child was independently made at the end of the examination. See Table 1. We decided not to include subjects with strabismus, ocular pathology or color vision deficits.

Examiner MV used the Autorefractor to screen all subjects who met the above criteria. At approximately 35 cm, the SureSight was directed toward the child's eye to be measured and a series of beeping tones allowed for fine adjustment of the test distance. The unit has flashing lights and sounds that assist in engaging the

| Age | Hyperopia | Myopia | Astigmatism |
|-----------------|---|--|--|
| 0 to 24 months | Anisometropia > 1.00 D Isoametropia >2.50 D | Anisometropia >2.00 D Isoametropia > 0.75 D | Anisometropia > 1.50 D Isoametropia > 1.50D |
| 25 to 69 months | Anisometropia > 1.00 D Isoametropia > 2.00 D | Anisometropia >2.00 D Isoametropia > 0.75 D | Anisometropia > 1.25 D Isoametropia > 1.25D |

| Analytic Measure | Age 0- 36 months | Age 37-69 months |
|------------------|------------------|------------------|
| Sensitivity | 62.5% | 87.5% |
| Specificity | 83.3% | 65.3% |
| False Positives | 28.6% | 44.7% |
| False Negatives | 23.0% | 8.6% |

child throughout the procedure.¹ A "ta-dah" sound indicates that the instrument has successfully taken a measurement. With each reading the SureSight calculated and displayed the sphere, cylinder, axis and reliability number. The reliability number indicates the number of good readings and their consistency on a scale from 1 to 9, with ≥ 6 being acceptable, 5 indicating a marginal reading, and ≤ 4 being poor. If the reliability value was less than 6, the measurement was repeated. Subjects were excluded from the analytical calculation, if on repeated measurement attempts the minimum reliability value of 6 was not obtained. At the conclusion, again a pass/fail decision was made using visual acuity and age dependent refractive criteria as applied for standard or Mohindra retinoscopy (Table 1).

Results

Initially there were 32 subjects in the 3-36 months group. Two of these children were not included because of strabismus. In the initial 82 subjects in the 37-69 months group, two subjects were not included because of strabismus and two were not included because of a color vision deficit. Further exclusions from the results are as follows: In the younger group, six subjects did not meet the validity criterion, and we could not obtain results on four others on the Autorefractor. In the older group, two did not meet the validity criterion and we could not obtain results on three others on the Autorefractor. Thus, the results of comparing the Autorefractor with conventional retinoscopy are for 20 children in the younger group and 73 in the older group.

A failure list was independently generated from the results of the conventional

refraction and a separate failure list was generated from the results of the Autorefractor. Thirty-three (33) children failed the visual acuity and/or refractive aspect of the optometric evaluation (nine in the younger group and 24 in the older group). Forty-four (44) children failed the Autorefractor (six in the younger group and 38 in the older group). Twenty-six (26) children were common to both groups.

The analytical measures of sensitivity, specificity, false positives and false negatives were calculated (Table 2).³ Sensitivity is a measure of the probability that the screening test will be positive when an abnormality actually exists, i.e., test being positive and the patient requiring referral. This measure indicates how good a test is at identifying the children needing referral. Specificity is the probability that the screening test will be negative when an abnormality actually is not present, i.e., test is negative and the patient does not need a referral. This measure indicates how good a test is at identifying the children who don't need to be referred. A false positive is when the test is positive but the patient does not need a referral and false negative is when the test is negative but the patient does need a referral. The best diagnostic tests are those with few false positives and false negatives.³

Discussion

A valid and efficient vision-screening tool should be quick and easy to administer. The instrument and method used should be able to identify the most prevalent and sight threatening visual disorders, which can be remedied or treated. In the present study, the Autorefractor was used to evaluate the refractive status in children who were divided into two subgroups: in-

infant and toddler (3-36 months) and preschool (37-69 months). The first group was comprised of 20 qualifying subjects, and 73 qualifying subjects were in the second group. In our sample, different age based referral refractive criteria were used. Refractive error referral criteria were based on type, magnitude and potential implication, such as refractive amblyopia (Table 1).

Previously, other autorefractors have been evaluated with conflicting results.⁴⁻⁹ Barry and Konig used the hand held Nikon Retinomax as a non-cycloplegic screening instrument in 3-year-old kindergarten children.⁴ This study had a screening sensitivity of 80% and specificity of 58%, which were slightly lower than the analytical measures of our older age group. Barry et al concluded that the Retinomax's reliability was too low to be used as an effective refractive screening tool. Cordonnier et al, using cycloplegia to control accommodation, compared the Retinomax to retinoscopy and on-table, i.e., not hand held autorefractor.⁵ They concluded the instrument was accurate in measuring spherical equivalent refraction when compared to the other methods used in the study. When the instrument was compared to a non-cycloplegic refraction, the authors concluded that the Retinomax, as a screening device, had definite usefulness and reasonable accuracy.⁶ Wesemann and Dick echoed the need for cycloplegia to obtain accurate autorefractor results when using the Nikon Retinomax.⁷ Isenberg et al, investigated the reliability, accuracy, and repeatability of the HARK 599 Autorefractor and drew similar conclusions.⁸

Using a group of young children Harvey studied three different hand held autorefractors: SureSight, Retinomax, and Nidek.⁹ Although Harvey felt the SureSight provided the easiest and quickest results, this instrument had the greatest variability of results and some differed significantly with those previously obtained by the other means. This study concluded that the SureSight is the most effective tool for refractive screening purposes, but for assessing refractive error by an automated objective method, the Nikon and Nidek fared better.⁷ Thus, the literature has a fair amount of disagreement as to the accuracy and effectiveness of various autorefractors as screening instruments.

We acknowledge that there are limitations to our data, including using non-cycloplegic retinoscopy and a different doctors or interns performing retinoscopy on subsequent screening days. Further, while permission for the exam was obtained from the parent/legal guardian by written consent, most children were examined in the absence of their parents with little to no history being available. Additionally, two methods of retinoscopy, the standard static and the Mohindra method were used. Finally, in determining pass or fail, a clinical judgment was made in that we considered both visual acuity and refractive status in the visual examination data.

Conclusion

The Welch Allyn SureSight Autorefractor is designed as tool to detect myopia, hyperopia, astigmatism in ¼ diopter increments and axis. However, the instrument does not test for strabismus, pathology, or more subtle ocular problems hence, does not replace the need for a comprehensive eye examination. The low sensitivity and high false positives and negatives do not constitute analytical measures of a good screening instrument in the 3-36 month population. Additionally in this age group, there was a high percentage of low validity measurements (6 of 30 subjects) or instances where no results were obtainable (4 of 30 subjects). In situations where a comprehensive eye examination is not feasible, the unit has higher sensitivity for the older age group (37-69 months) but also has a high false positive which may result in a large number of children being over-referred.

An earlier version of this research was presented as a poster at the 2002 annual meeting of the American Optometric Association in New Orleans, LA.

None of the authors has financial or other interest in the Welch Allyn SureSight Autorefractor.

Sources

- a. Vistech Consultants Inc.
4162 Little York Road
Dayton, OH 45414
- b. Precision Vision
944 First Street
LaSalle, IL 61301
Richmond Products, Inc.
1021 South Rogers Circle #6
Boca Raton, FL 33487

References

1. Welch Allyn SureSight Autorefractor Manual. Skaneateles Falls, NY.
2. Mohindra I. Comparison of near retinoscopy and subjective refraction in adults. *Am J Optom Physiol Opt.* 1977;54:319-22.
3. Hulley SB, Cummings SR. *Designing Clinical Research.* Baltimore, Williams & Wilkins. 1988.
4. Barry JC, Konig HH. Non-cycloplegic screening for amblyopia via refractive findings with the Nikon Retinomax hand held autorefractor in 3-year-old kindergarten children. *Br J Ophthalmology* 2001 Oct; 85(10): 1179-82.
5. Cordonnier M, Dramaix M, Kallay O, de Bideran M. How accurate is the hand held refractor Retinomax in measuring cycloplegic refraction: a further evaluation. *Strabismus* 1998 Sep; 6(3): 133-142.
6. Cordonnier M, Kallay O. Non-cycloplegic screening for refractive errors in children with the hand-held autorefractor Retinomax: final results and comparison with non-cycloplegic photo screening. *Strabismus* 2001 Jun; 9(2): 59-70.
7. Wesemann W, Dick B. Accuracy and accommodation capability of a handheld autorefractor. *J Cataract Refract Surg* 2000 Jan; 26(1): 62-70.
8. Isenberg SJ, Del Signore M, Madani-Becker G. Use of the HARK autorefractor in children. *Am J Ophthalmol* 2001 Apr; 131 (4): 438-41.
9. Harvey B. Hand held autorefractors A comparative trial of their use in paediatric screening. *Optician* Aug 24/01; 222(5815): 20-22, 24.

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Date accepted for publication:
June 7, 2002