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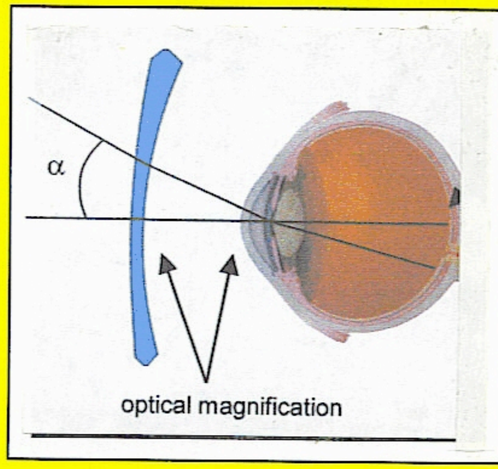

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Second Quarter, 2007

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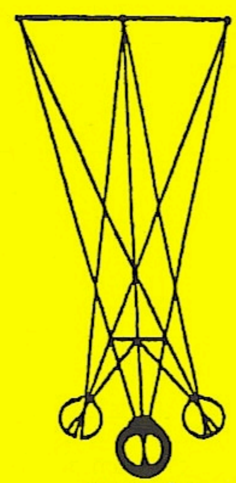

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Pediatric Eye/Vision Screening: Referral Criteria for PediaVisionPlusOptix S04 Photoscreener Compared to Visual Acuity & Digital Photoscreening:"Kindergarten Computer Photoscreening" M.M. Clausen, BA and R.W. Arnold, MD
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Original Scientific Article

Pediatric Eye/Vision Screening: Referral Criteria for the PediaVision PlusOptix S04 Photoscreener Compared to Visual Acuity & Digital Photoscreening: "Kindergarten Computer Photoscreening"

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ABSTRACT: ***Background and Purpose:*** Carefully interpreted photoscreen programs yield high predictive value and favorable sensitivity for amblyopia in pre-school children, but most require a long learning curve. The new PediaVision photoscreener appears to offer advantages and is evaluated in comparison with other established screening methods.

Methods: The PlusOptix S04 (PediaVision) computer-interpreted, infrared photoscreener was compared to digital physician-interpreted (Gateway DV-S20) photoscreening and patched Surround HOTV acuity testing in Kindergarten students.

Results: The estimated sensitivity and predictive value and speed of the objective photoscreeners exceeded visual acuity testing. The PediaVision photscreener, in addition, allowed a practical range of referral refractive criteria to be determined and utilized.

Conclusion: The PlusOptix allows user-chosen, age-related referral criteria, and a quick, child friendly photoscreening technique that should be ideal for many Kindergarten and preschool eye/vision screening programs.

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Financial Disclosure: The Alaska Blind Child Discovery (ABCD) has received discounted vision screen technology from various manufacturers including PlusOptix and Gateway.

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INTRODUCTION

American children truly deserve eye and vision screening for the early detection of amblyopia (1,2). Conventional vision screening has relied on visual acuity measurement in children old enough to identify optotypes. Objective screening for ocular risk factors for amblyopia can be performed in even younger children and may be substantially quicker than acuity screening (3). Unfortunately very few American children are photoscreened. Perhaps the ideal photoscreener has not yet been validated. The comments in a former publication (4) still have merit:

"The ideal photoscreener is portable, simple, and user-friendly for children and parents. It should be quick and inexpensive. It should focus on active children in reduced illumination. It should be capable of instantaneously demonstrating a good image, capable of obtaining orthogonal images and capable of storing and transmitting images for interpretation. The ideal photoscreener allows efficient and infallible identification of each child. The ideal photoscreener also provides rapid interpretation of the image so the parent can either a) be reassured of probable normality, or b) seek a confirmatory complete eye examination soon. Inconclusive interpretations due to inadequate photoscreen image quality or fixation are frustrating for parents". (4)

Another photoscreener has become commercially available since the Vision in Preschoolers Studies (5,6). We have acquired and investigated this upgrade of the PowerRefractor called the "PlusOptix S04" (PlusOptix Gbmh, Nurenberg, Germany, [marketed in the U.S. by PediaVision, LLC, 500 NE 2nd St., Pompano Beach, FL 33060, 1-888-514-73338, www.pediavision.com, or contact the designer, Christian Schmidt directly at c.schmidt@plusoptix.com.

The purpose of this study is to report, investigate and compare this pediatric photoscreener to digital physician-interpreted photoscreening and patched surround HOTV visual acuity testing in Kindergarten students.

METHODS

This ongoing vision screening study has received institutional review from Providence Hospital and from the Anchorage School District and Grace Christian School Board. Details of the ABCD (Alaska Blind Child Discovery) program can be viewed on www.abcd-vision.org.

Objective and subjective methods of vision screening were offered to younger elementary students and validated in Anchorage during Spring 2004 (7). This study, done during the Fall of 2006, compared patched, surround HOTV acuity testing, digital photoscreening with subsequent physician interpretation and PlusOptix S04 (PediaVision) infrared photoscreening in the same tent facility.

Testing Environment:

Parents gave consent with brief ocular history on standard ABCD paperwork. Lists of names with birthdates of each Kindergarten and pre-K student were transmitted from each school nurse to the primary vision screener (author MMC) and entered into the PlusOptix software database. On the morning of each scheduled screening, a PVC pipe and dark cloth examination tent (dimensions 2.5 m x 1.0 m x 1.3m) was erected near the classrooms; the tent prevented distractions and excess luminance allowing better pupil dilation for photoscreening.

HOTV Visual Acuity Cards:

Children were tested at a chart distance of 10-feet (~3 meters) using a modified surround HOTV card set (Precision Vision, Lasalle, IL, Cat number 2021). First they were familiarized with the optotypes on the flip cards and the matching card. Then the non-tested eye was patched with child-friendly, ABCD "No-Peeking" eye patches (Ad Tape and Label, Wisconsin). From 3 meters, the critical line first optotypes were presented in random order (20/40 size for Kindergarten and younger, 20/32 older than Kindergarten). If the child was unable to pass two of four of the critical lines, then larger logMAR options are shown until the child either achieves a successful line (smallest optotypes child is able to pass 3 of four optotypes). A child unable to pass the critical line was then offered the chance to pass using the integral pinhole "spectacles" built into the matching card. A child failing the pinhole can attempt the critical line on the built-in child surround HOTV near card. For the children who pass the critical line (three of four correct), then smaller optotypes are shown until a threshold smallest optotypes is achieved for that eye.

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After the first (right eye) is tested, the patch is carefully transferred to the other eye and the sequence repeated. Children were tested with their spectacles if available.

Digital physician-interpreted photoscreening
Gateway DV-S20:

The Gateway DV-S20 is a simple digital flash 2 Megapixel camera with fixed optical lens (No optical zoom), automatic flash in low luminance without "red eye reduction." The short flash-to-lens distance, mimizing the eccentricity of the light source, make it an efficient, inexpensive photoscreener. Children are given a large nametag taped to the upper torso, and then seated in a decreased luminance tent at a distance of 2 meters from the camera. The camera is set to fine resolution. A 120V A/C adapter is preferred over the AA battery option. The camera has the possibility of generating a blue LED flash for more remote portraits. However, we have found valid photoscreening just by urging the child to "look at the camera" held directly in front of the screener's face. At least two flash images are taken; one with camera held vertically and one with the camera rotated 90 degrees.

Although the Gateway DV-S20 can record up to 40 MB on its internal memory, we instead use an SD flash memory card of at least 256 MB capacity. Images are downloaded to a computer imaging program (Apple I-Photo® preferred, Cupertino, Calif), cropped and then physician interpreted using the "Delta Center Crescent" method (8).

Infrared Refractometer Photoscreener
PlusOptix S04: (see Figure 1, right ->)

The PlusOptix S04 is a portable, hand held infrared photorefractor system with accompanying Windows-based database and interpretation capacity. The unit and computer run on A/C power and can output to a printer or label printer. A major difference and advantage for this device is that interpretation threshold criteria can be entered for a wide range of patient ages. Patient identification can be entered at the time of screening, or well in advance of a busy clinic. The camera hand piece is activated with a single trigger, and aimed and focused while viewing the camera image on the computer screen. The child's attention is captivated by age-appropriate audio and their fixation / accommodation directed by a series of flashing LEDs. The PlusOptix interprets each image and outputs refractive estimates (full sphere, cylinder and axis OU), pupil size and dot-graph and measurement of fixation / alignment of each eye, and binocular alignment..

The Gateway DV-S20 digital camera and the PlusOptix S04 with software on a portable Windows-based portable computer were placed in one end of the examination tent with the student seated at the other. Visual acuity testing was performed next to the tent. The order of acuity testing versus the objective testing varied for these kindergarten children.

Figure 1 *(Clausen and Arnold): PediaVision PlusOptix SO4 pediatric eye/vision infrared photoscreener with computer. Note the camera image on the computer screen of the child'seyes and their red reflexes. Illustration taken fromthe US distributor's brochure. For further info, view the website: www. PediaVision.com.*

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RESULTS

ASD-ABCD 2006 (this study) screened 624 early elementary school children: 8 first grade, 90 3rd grade leaving 424 Kindergarten subjects. The breakdown of interpretation status for the three vision screening tests for these children with 'True" and "False" confirmatory exams by AAPOS standards (9) is shown in Table 1, below.

For these 73 limited followups, we can estimate that the Positive Predictive Values (PPV) for Gateway are 89%, for PlusOptix 84% and for patched HOTV acuity 75%. The estimated sensitivity / specificity for Gateway DV-S20 would be 100%/94%, for PlusOptix 67% / 94% and for HOTV acuity 25% / 96%.

The newer PlusOptix was then compared to our established Gateway DV-S20 in an attempt to determine referral criteria (Table 2). These are derived from the receiver-operator Characteristic curve that was generated for various permutations of referral criteria for anisometropia, hyperopia and astigmatism (See Figure 2, Top next page).

Table 1: RESULTS : Available Confirmatory Exam Validations (73 F or T)

Comparison for Gateway DV-S20, PlusOptix (ABCD preferred interpretation) and HOTV patched acuity testing in Kindergarten (n= 424).

T = True Positive by AAPOS guidelines[9]
F = AAPOS normal exams.

Gateway	PlusOptix+	Acuity	total	F	T
refer	refer	refer	21	1	6
refer	refer	pass	26	2	10
refer	pass	refer	0		
refer	pass	pass	29	0	8
pass	refer	refer	0		
pass	refer	pass	6	1	
pass	pass	refer	13	1	
pass	pass	pass	329	44	0
			424		

Table 2: RESULTS: Referral criteria in the kindergarten age range for the PlusOptix S04 derived from ADBC physician-interpreted photoscreening[8].

Referral Intent	Anisometropia	Hyperopia	Astigmatism	Myopia
Sensitive	≥ 1.00 D	≥ 2.00 D	≥ 1.25 D	> 2 D
Specific	≥ 2.00	≥ 3.00 D	≥ 2.00 D	≥ 3 D
ABCD-preferred	≥ 1.00 D	> 2.50 D	> 1.50 D	> 2.00

CONCLUSION

As of January 2007, photoscreening for amblyopia has not yet received definitive endorsement from the Vision Screening Authorities of the American Academy of Pediatrics (AAP) (10) On the other hand, photoscreeners and remote auto-refractors had sensitivities comparable to patched

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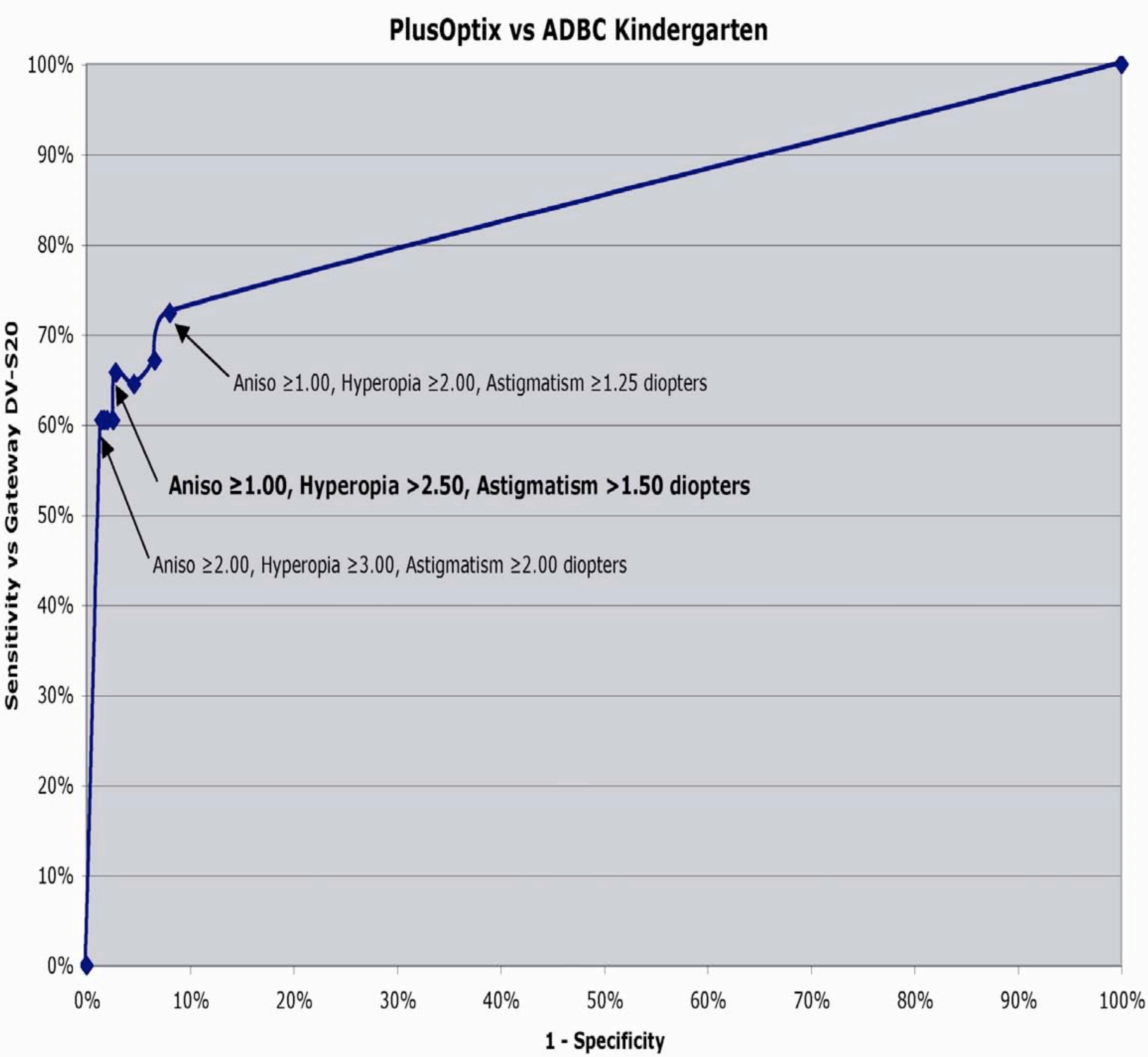

Figure 2 (Clausen and Arnold): RESULTS: The Receiver-Operator Characteristic Curve for the PlusOptix S04 compared with ADBC Physician-Interpreted photoscreen in Kindergarten children.

acuity testing in the Vision in Preschoolers Studies (VIPS)(5,6). Since amblyopia is an evolving process for many children throughout the critical first decade, AAP does NOT recommend a single age-based vision screen or comprehensive examination, but rather an age-appropriate series of vision screening tests (2). Just like the investigators in VIPS modified referral criteria to improve sensitivity for remote autorefractors, photoscreen programs can alter the referral criteria based on photoscreen crescent location, pupil size and ocular alignment. Programs with a series of fairly sensitive tests with sufficient specificity to yield high positive predictive value are probably better accepted by community eye doctors, pediatricians and parents than overly sensitive tests with too high a false positive rate (11).

While many different types of photoscreeners can show an optical alteration in the pupil reflex (8), variable interpretation of these has dampened interest in photoscreening (12) and resulted in prolonged learning curves (11) and in variable referral rates between regional programs (13). Photoscreeners such as the MTI (Medical Technology Incorporated, Cedar Falls, Iowa) record pupil reflex images that must be carefully interpreted or ideally sent to an experienced reading center with delayed (non-ideal) notification of parents. The I-Screen system utilizes a central reading center in Memphis, Tennessee for prompt internet-transferred images (14). The EyeDx system (SanDiego, California) utilizes a digital camera with serial cable connection to a computer with software interpretation of red reflex (4 15.

The PlusOptix S04 and the Gateway DV-S20 differ in the character of fixation target; the Gateway was just a handheld digital camera in a dim tent whereas the PlusOptix emits child-friendly sounds and prompts fixation and probably accommodation with a group of flashing LEDs. The difference in prompting accommodation by the cameras when validated with AAPOS guideline refractive errors, may explain the seemingly less sensitive PlusOptix. Many children with supra-validation threshold hyperopia are capable of sufficient accommodation to yield a "false negative" result (16).

In our experience, both objective tests outperformed acuity testing in Kindergarten children. VIPS on the other hand, showed modified LEA and HOTV acuity testing to outperform externally interpreted photoscreening in preschoolers (5,6). Photoscreening can outperform deliberate conventional acuity testing in pediatrician's office preschool screening (17). While ABCD was happy with ADBC (amblyopia detection by camera) as an intermediate, portable digital step to follow Polaroid photoscreening, the rapid computer interpretation with age-based, user definable referral criteria makes the PlusOptix S04 a most potent weapons against amblyopia for any program that can obtain them.

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