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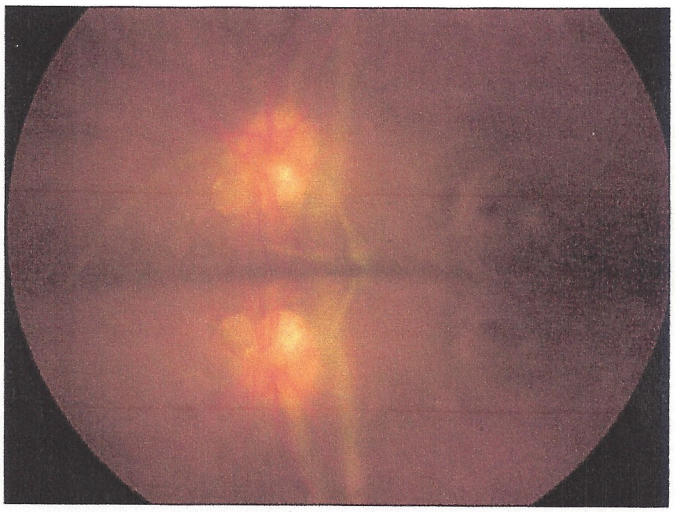

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Performance of Four New Photoscreeners on Pediatric Patients With High Risk Amblyopia

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ABSTRACT

Purpose: A new study by the American Academy of Pediatrics touts the benefits of photoscreening, especially in preverbal children who cannot yet perform monocular acuity screening. Emerging devices have not been compared in young and developmentally challenged children.

Methods: Consecutive patients in a pediatric eye practice had a comprehensive eye examination and four photoscreens: PlusoptiX (PlusoptiX, Nuremburg, Germany), SPOT (PediaVision, Lake Mary, FL), iScreen (iScreen, Memphis, TN), and the GoCheckKids application (Gobiquity, Aliso Viejo, CA) for the iPhone 4s (Apple, Cupertino, CA) with Delta Center Crescent interpretation. They were validated according to the 2003 American Association for Pediatric Ophthalmology and Strabismus uniform guidelines.

Results: One hundred eight children aged 1 to 12 years participated, with 56% having amblyopia risk factors and 10% having autism. For the four devices, sensitivity, specificity, and inconclusive results were as follows: PlusoptiX (83%, 86%, 23%), SPOT (80%, 85%, 4%), iScreen (75%, 88%, 13%) and iScreen (with Delta Center Crescent) (92%, 88%, 0%), and GoCheckKids (with Delta Center Crescent) (81%, 91%, 3%).

Conclusions: Even in high risk and young children, current instrument-based screeners can reliably screen for refractive and strabismic risk factors that lead to amblyopia. Some devices can reduce the proportion of inclusive results in challenging cases.

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INTRODUCTION

Amblyopia due to refractive error or strabismus is potentially curable if detected early and treated thoroughly in the first decade of life.[1] Photoscreening allows detection of refractive and strabismus risk factors for amblyopia as early as the first year of life[2] and can lead to better treatment acuity.[3] The American Academy of Pediatrics published an update on its photoscreening policy statement, encouraging objective screening until children are reliably able to participate in monocular visual acuity testing.[4] Although the American Academy of Pediatrics guidelines recommend a comprehensive eye examination for children with developmental delay, the timing of the examination is not defined. Developmentally delayed children may not be able to provide reliable acuity screening before amblyopia is no longer treatable and photoscreening may be particularly useful for them.[5]

A Current Procedural Terminology listing (code 99174) is available for photoscreening, easing the financial barriers for pediatricians to implement sophisticated instrument-based screening.

The original photoscreeners required an experienced interpretation to achieve valid results.[6,7] Several original photoscreeners, including the extensively validated Polaroid-film–based Medical Technology

From the Alaska Blind Child Discovery, Pediatric Ophthalmology and Strabismus, and Ophthalmic Associates, Anchorage, Alaska.

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The Alaska Blind Child Discovery received discount photoscreening technology from various vendors and received a grant from the Walmart Corporation in Alaska.

Dr. Arnold is a board member for Glacier Medical Software. Dr. Armitage has no financial or proprietary interest in the materials presented herein.

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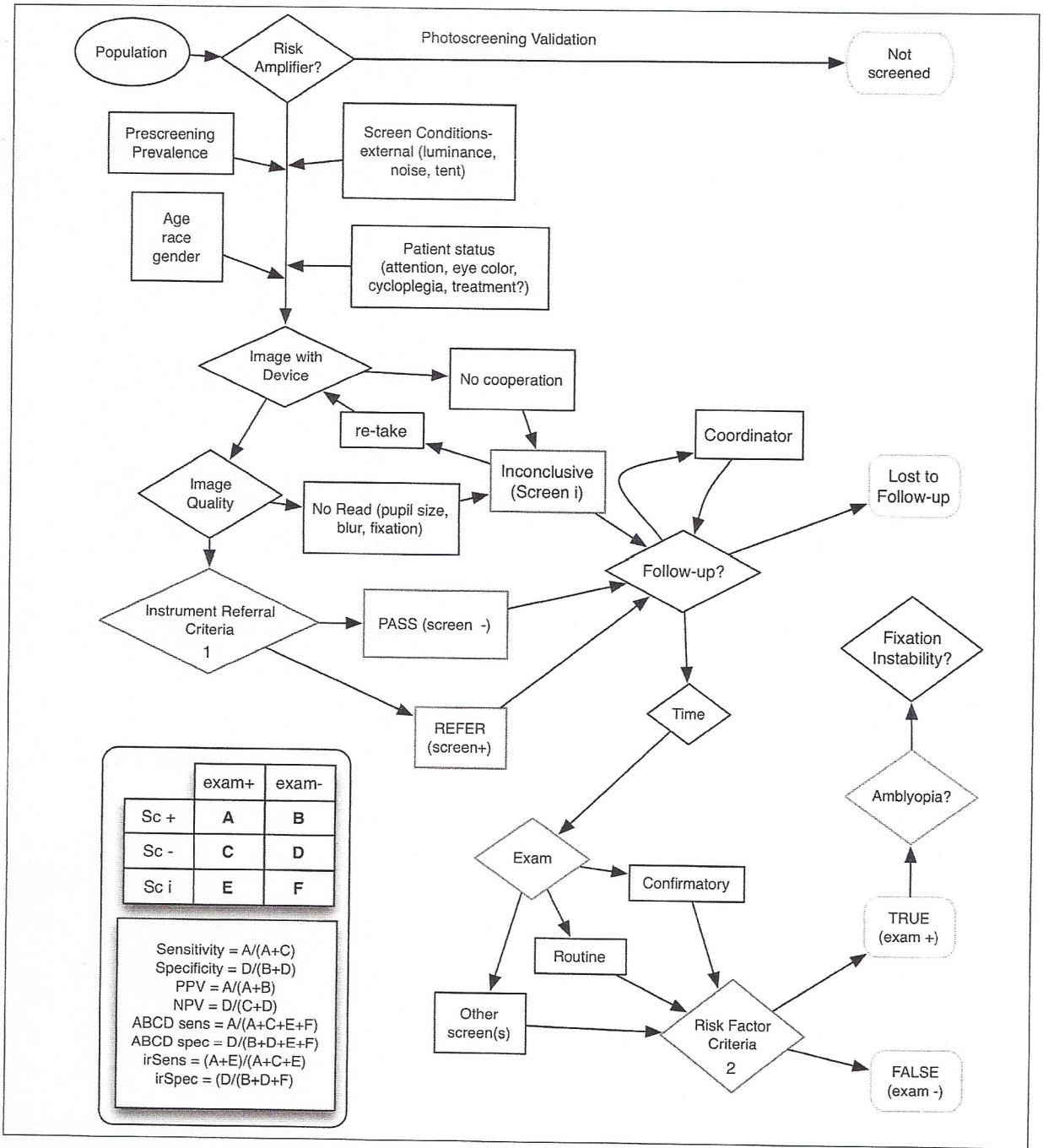

Figure 1. Flowchart of potential features for validation of a vision screening modality such as photoscreening. This study used a high prescreening probability as a result of the pediatric eye office environment and not excluding children with developmental delays. The Alaska Blind Child Discovery (ABCD) instrument and Delta Center referral criteria were used (diamond to the left) and the 2003 American Association for Pediatric Ophthalmology and Strabismus uniform guidelines (subsequent diamond to the right) were used to determine true and false risk factors.

and Innovations (MTI) Photoscreener, are no longer commercially available. Some current models with uniform computer or Internet interpretation compare favorably with the MTI Photoscreener.[8,9]

Photoscreeners rely on a short flash-to-lens location and a screening distance from the patient sufficient to yield a flash-eye-lens angle of approximately 1°. Consumer digital cameras matching this description can provide clinically useful photoscreen images.[10] The iPhone (Apple, Cupertino, CA) has a short flash-to-lens distance and can provide adequate photoscreen images, the quality of which are reduced by the mandatory "red eye redux" preflash.[11] GoCheckKids (previously called iCheckKids; Gobiquity, Ali-

TABLE 1

AAPOS 2003 GSE Confirmatory Criteria[a]

GSE	Parameter
From age	24 months
To age	59 months
Anisometropia	> 1.50
Hyperopia	> 3.50
Astigmatism	> 1.50 axial, > 1.00 oblique
Myopia	> 3.00
Alignment	Manifest strabismus

AAPOS = American Association for Pediatric Ophthalmology and Strabismus; GSE = Gold Standard Examination
[a]The findings from confirmatory GSE for preschoolers with threshold diopters of cycloplegic refractive error and ocular alignment that constitute a true amblyopia risk factor. Axial + cylinder astigmatism defined as within 10° of vertical axis, whereas oblique was more than 10° from vertical.

so Viejo, CA) has developed an iPhone application (app) to provide instant flash with an on-screen facial mask for proper focusing distance to the patient.

The purpose of this study was to apply the GoCheckKids and three other commercial photoscreeners (the iScreen [iScreen, Memphis, TN], PlusoptiX [PlusoptiX, Nuremburg, Germany], and SPOT [PediaVision, Lake Mary, FL]) to young patients and developmentally challenged patients in a pediatric eye practice with the intent of better informing pediatricians interested in implementing photoscreening in well child visits.

PATIENTS AND METHODS

The Alaska Blind Child Discovery (ABCD) is a Health Insurance Portability and Accountability Act compliant study of pediatric vision screening (**Figure 1**) with institutional review board approval from Providence Alaska Hospital, Anchorage, Alaska. Parents of consecutive new, young patients in a pediatric eye practice consented to having four photoscreens at the time of a comprehensive eye examination. Patients with developmental delay and autism were intentionally included. Some of the young patients were directly referred by local pediatric photoscreening (PlusoptiX S09, iScreen, or Gateway DV-S20 [Gateway, Irvine, CA]).

Each photoscreener was non-cycloplegic, without spectacles, and in random order by the orthoptist and the pediatric ophthalmologist. The orthoptist attempted to obtain an optotype acuity (surround HOTV) and motility with cover testing. The confirmatory examinations were then performed by the pediatric ophthalmologist, who included motility confirmation, anterior segment examination, and retinal indirect examination. Cycloplegic refractions were performed using a mixture of cyclopentolate 1% and neosynephrine 2.5% instilled 30 minutes before retinoscopy. The study complied with American Association for Pediatric Ophthalmology and Strabismus guidelines (**Table 1**) for uniform comparison of vision screening technology.[12] Additional validation statistics were added to deal with inconclusive or incomplete screening results; the "ABCD-sensitivity" and the "ABCD-specificity" add inconclusive interpretations to the denominator and therefore favor techniques with few inconclusive results.[13] The "ir-sensitivity" and "ir-specificity" assume inconclusive results were treated as referrals (**Table 2**).

Images from two photoscreeners (iScreen and GoCheckKids) were available for expert interpretation using the Delta Center Crescent method.[14] By this interpretation method, the referral threshold was when the light crescent in the red reflex approached 1 mm of the center of the pupil.

GoCheckKids

GoCheckKids was uploaded into an iPhone 4s (Apple). This app was released in late 2012 to override the mandatory pre-flash and facilitate vertical and horizontal photoscreen images. We used software for the iPhone 4s. Although versions of the software could be used on a low-reslution iPod Touch (Apple), subsequent versions work even better with higher-resolution cameras on the iPhone 5s. Demographic data were entered on the phone (name, birth date, and patient unique ID code) before multiple images could be acquired with a face-outline mask on the iPhone screen to assist with proper camera-to-patient distances (half meter). Images can then be securely uploaded to a user account on the GoCheckKids website for storage and rudimentary interpretation using some online tools. The latest version of the app has a method to initiate a child-friendly animal noise to facilitate fixation attention. This 5.0 version of the app did not yet have an auditory fixation-prompting signal, so patients were encouraged to view the cell phone camera. Focusing distance of a half meter was achieved by overlapping the patient's face with the distance-screen mask on the iPhone screen.

PlusoptiX S09

This extensively validated, multi-radial, infrared photoscreener is a Linux-based computer-interpreted photoscreener that has evolved from the Photorefrac-

TABLE 2

Raw Data and Validation Statistics for 108 Children Undergoing 4 Different Photoscreens and Eye Examinations by 2003 AAPOS Guidelines[a]

2003 AAPOS Guidelines	Plusoptix	SPOT	iScreen	iScreen DCC	GoCheckKids
A	34	45	40	55	47
B	5	7	5	6	4
C	7	11	13	5	11
D	37	41	36	42	43
E	19	4	7	0	2
F	6	0	7	0	1
Sensitivity = A/(A+C)	83%	80%	75%	92%	81%
Specificity = D/(B+D)	88%	85%	88%	88%	91%
PPV = A/(A+B)	87%	87%	89%	90%	92%
NPV = (D/C+D)	84%	79%	73%	89%	80%
ABCD-sensitivity = D/(B+D+E+F)	52%	75%	60%	92%	77%
ABCD-specificity = A/(A+C+E+F	55%	79%	65%	88%	86%
irSens = (A+E)/(A+C+E)	88%	82%	78%	92%	82%
irSpec = D/(B+D+F)	77%	85%	75%	88%	90%

	Exam +	Exam -
Sc+	A	B
Sc-	C	D
Sci	E	F

AAPOS = American Association for Pediatric Ophthalmology and Strabismus; DCC = Delta Center Crescent; PPV = positive predictive value; NPV = negative predictive value; ABCD = Alaska Blind Child Discovery

[a]Additional statistics favor screenings with fewer inconclusive results (ABCD-sensitivity and ABCD-specificity) or incorporate inconclusive results as if they were all referred (irSens and irSpec). The 2 × 6 matrix in the lower right identifies referrals (Sc+), passes results (Sc-), and inconclusive results (no image and/or no interpretation; Sci). Prescreen probability = (A+C)/(A+B+C+D); false positive = B/(A+B); false negative = C/(C+D); Sc+ = screening refer; Sc- = screening pass; Sci = inconclusive screening

The PlusoptiX is manufactured by PlusoptiX, Nuremburg, Germany, the Spot is manufactured by Pediavision, Lake Mary, FL, the iScreen is manufactured by iScreen, Memphis, TN, and GoCheckKids is manufactured by Gobiquity, Aliso Viejo, CA.

tor II and the Windows/Firewire based PlusoptiX S04 and S08. The hand-held camera connected by cable to a small computer and a monitor. Alignment and focal distance were guided by a video image on the monitor. The child fixated on a light-emitting diode in the camera. The age-based criteria by which the PlusoptiX software referred a patient relative to refractive error, ocular alignment, and pupil size was manufacturer supplied, but could also be user defined to modify for desired specificity and sensitivity. We employed the current ABCD age-based referral criteria (**Table 3**).

SPOT

Released in late 2011, version 1.0.3, software 1.1.51, this self-contained, hand-held, battery-powered unit has a pressure-sensitive screen for data entry and monitoring of alignment and proper focus distance. The SPOT performed an estimation of pupil size, interpupillary distance, ocular alignment, and refractive error. From these, an age-based decision "pass" or "refer" was shown on the screen and incorporated in a printable report if a local printer was available by Wi-Fi transfer. It was also possible to export a database of screening variables for each patient or input user-defined referral criteria by USB flash drive.

iScreen 3000

The iScreen 3000 (iScreen) was released in late 2011 as a battery-operated, hand-held version of the original, tabletop iScreen. The iScreen 3000 has a keyboard for data entry, a monitor, and an ethernet port for data export and import. Focus and alignment with the new iScreen were similar to the MTI with triangulated red laser beams to be aimed between the eyebrows. The iScreen has a single shutter button that exposes rapid (0.1 second) sequential horizontal and

TABLE 3

Instrument Referral Criteria[a]

Photoscreener	From Age (mo)	To Age (mo)	Anisometropia (D)	Hyperopia (D)	Astigmatism (D)	Myopia (D)	Alignment
PlusoptiX S09/ A09, ABCD 2011	0	8	1.50	3.00	2.50	3.00	10
	9	72	1.00	2.50	2.25	2.25	10
	73	120	1.25	2.00	1.50	1.50	10
SPOT V 1.0.3, Software 1.1.51	6	12	1.50	3.50	2.25	2.00	8
	12	36	1.00	3.00	2.00	2.00	8
	36	72	1.00	2.50	1.75	1.25	8
	72	240	1.00	2.50	1.50	0.75	8
iScreen V 3.5.3, 2011	Central reading center , computer, then expert reader, Delta Center Crescent						
GoCheckKids iPhone 4s, V 5	Delta Center Crescent						

D = diopters; ABCD = Alaska Blind Child Discovery

[a]Age-based referral criteria in photoscreener software (version shown) for ranges of age in months and instrument estimates of refractive error (diopters) and instrument-specific ocular alignment estimates (not specifically prism diopters or degrees).

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vertical flash images. The screener views an image of the pupils to determine if satisfactory with an option to rescreen before saving the image. The images can be sent via ethernet to a central iScreen interpretation center immediately or after a period of screening without turning the unit off (or running out of battery).

RESULTS

One hundred eight (54 female) children from 9 to 146 months old (average: 47 months) participated. Forty-three were 9 to 30 months old, 18 were 31 to 48 months old, and 26 were 49 to 72 months old. The prescreening probability of American Association for Pediatric Ophthalmology and Strabismus amblyopia risk factors[12] was 56%. Eleven patients had developmental delay and/or autism. Eleven had constant strabismus and one had nystagmus. Refractive error averaged +0.5 sphere plus 1 diopter (D) cylinder; spherical equivalent ranged from -22 to +6 D sphere. Ten patients had anisometropia greater than 2.0 D with a maximum spherical equivalent anisometropia of 6.25 D.

Validation statistics derived from a 2 × 3 table are presented in **Table 2**. Conventional values of sensitivity and specificity discard inconclusive interpretations. Note the impact of including inconclusives in the denominator (ABCD-sensitivity and ABCD-specificity) and of considering each inconclusive as a referral (ir-sensitivity and ir-specificity). **Table 4** gives screening results for two subgroups for whom monocular acuity screening was difficult: the 62 children younger than 4 years and the 11 children with autism of other developmental delays (average age: 78 months). The sensitivity and specificity for these new photoscreeners averaged 80% and 88%, respectively.

Of the 27 patients who passed all photoscreens, 9 had intermittent strabismus from 10 to 30 prism diopters.

One patient had isolated small (1 mm) cataract and had inconclusive PlusoptiX, passed SPOT, but was referred by iScreen and GoCheckKids.

DISCUSSION

In this context of challenging young pediatric eye patients with high prescreening probability of amblyopia risk factors, each of these photoscreeners was capable of providing images for effective photoscreening sensitivity and specificity. Photoscreening can be particularly useful in developmentally delayed patients,[5] even though the American Academy of Pediatrics suggests such patients receive at least one comprehensive eye examination at some time during childhood.[15]

Each of these photoscreening instruments has advantages and disadvantages. The PlusoptiX yields a report of refractive error, ocular alignment, pupil size, and interpupillary distance and has extensive validation and calibration experience, emanating from current

TABLE 4

Screening Results for Four Photoscreeners of Children Younger Than 4 Years Old and Children With Autism of Other Developmental Delays

Photoscreener	No.	Sensitivity	Specificity	PPV	Inconclusives[a]
Plusoptix (all children)	108	83%	88%	87%	23%
Preschool[b]	62	74%	92%	89%	21%
Delays[c]	11	67%	100%	100%	27%
SPOT (all children)	108	80%	85%	87%	4%
Preschool[b]	62	69%	87%	83%	5%
Delays[c]	11	80%	83%	80%	0%
iScreen (all children)	108	75%	88%	89%	13%
Preschool[b]	62	58%	88%	83%	19%
Delays[c]	11	75%	100%	100%	9%
GoCheckKids DCC	108	81%	91%	92%	3%
Preschool[b]	62	74%	90%	88%	3%
Delays[c]	11	80%	100%	100%	0%

PPV = positive predictive value; DCC = delta center crescent

[a]Inconclusives were all children for whom the screening failed to yield a "refer" or "pass" result, due either to inability to image or no reading from the device or interpretation.

[b]Children younger than 4 years of age (n = 62).

[c]Children with autism or other developmental delays (n = 11).

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and prior similar models. The current PlusoptiX model (we used S09 before S12 was released) required cables connected to a computer with monitor and was less portable than the other instruments. The PlusoptiX often did not yield a result (estimation of refractive error and alignment) for children with high refractive error, or those unable to sustain fixation; instead it persisted with the screening audio signal much slower (range: 2 to 3 minutes) than typical, simple PlusoptiX screening of a normal patient (less than 5 seconds).

The iScreen had a quick, simple alignment and focus mechanism of triangulated light beams similar to the MTI Photoscreener, and took near-instantaneous orthogonal images. The iScreen central interpretation was prompt but not immediate onsite, and results did not estimate refractive error. Our Delta Center Crescent interpretation combined with 100% image capture with iScreen resulted in excellent ABCD statistics and ir-sensitivity. SPOT required at least 2 seconds of attentive fixation similar to the PlusoptiX, but yielded extensive eye examination information, including refractive error, pupil size, interpupillary distance, and an estimate of ocular alignment.

The GoCheckKids app markedly improved the iPhone's ability to retrieve photoscreen images with a fairly simple interface. Because the light source was not actually an instant flash but instead a momentary light-emitting diode, patient and screener steadiness was critical to image quality. There was no fixation stimulus-light on the iPhone. The manufacturer suggests using an iPhone case with a child-friendly image instead. There is not an internal interpretation program at this time, but images can be uploaded to the GoCheckKids website, from which the user can apply templates to estimate ocular alignment and red reflex crescent dimensions. All four instruments had the capacity to elicit child-friendly sounds to encourage attentive fixation.

Practical photoscreening combines a flash camera with predetermined referral criteria. Over time, screening programs can adjust the referral criteria to favor inversely related sensitivity and specificity (low false-positives) over the Receiver-Operator Characteristic Curve. ABCD has adjusted PlusoptiX referral criteria to exclude most cases of presumed small-angle strabismus[16] because we believe new cases of amblyopia due solely to isolated small-angle strabismus are extraordinarily rare. Instrument fea-

tures and refinements in referral criteria for refractive error and strabismus risk factors are expected to improve with more widespread clinical use.

The limitations of this study included the context of pediatric eye patients, and enhanced population, that does not usually represent similarly aged typical patients in a pediatrician's practice. The interpreter of the images was not completely blinded to the patient identities. The authors just acquired the GoCheckKids app and were initially more experienced screening with the other instruments. Some patients were older than preschool age, and some had developmental delays sufficient to warrant a pediatric eye referral independent of photoscreen results.

Objective pediatric vision screeners have been compared in various environments with different prescreening probabilities (**Figure 1**). Developmentally delayed children are often excluded even though objective screening can be particularly useful for children not yet capable of giving a reliable visual acuity. In the hallmark National Institutes of Health funded Vision in Preschoolers Study in child care educational centers using non-American Association for Pediatric Ophthalmology and Strabismus validation criteria, photoscreeners (MTI, iScreen, and PlusoptiX precursor) had suboptimal performance compared to optometric examination (sensitivity 37% and specificity 94%). In pediatric eye practices with high prescreening probability, the MTI Photoscreener and PlusoptiX had similarly good performance (sensitivity 84% vs 99%, specificity 91% vs 96%, respectively).[8] Our results resemble this latter comparison study and exceed photoscreening results from the Vision in Preschoolers Study.

The prevalence of amblyopia risk factors (21%), including some cases of intermittent strabismus and moderately high levels of hyperopia and astigmatism, differs substantially from the prevalence of amblyopia (acuity < 20/40; 2.5%).[17] Our study highlights this; 9 of the 27 photoscreen-passed patients had intermittent strabismus. The photoscreener identifies patients who are unable to align eyes or are unable to accommodate sufficiently.

All four of these photoscreening instruments can yield good screening accuracy and are valuable in identifying treatable vision impairment early enough for amblyopia therapy to succeed. Some (particularly the iScreen) stimulate fixation and have a fast shutter that allows image capture in children with diminished attentiveness.

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