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Pediatric Vision Screener 1: instrument design and operation

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Abstract. We develop the Pediatric Vision Screener (PVS) to automatically detect ocular misalignment (strabismus) and defocus in human subjects. The PVS utilizes binocular retinal birefringence scanning to determine when both eyes are aligned, with a theoretical accuracy of <1 deg. The device employs an autoconjugate, bull's-eye detector-based system to detect focus. The focus and alignment pathways are separated by both wavelength and data acquisition timing. Binocular focus and alignment are detected in rapid alternating sequence, measuring both parameters in both eyes in <0.5 sec. In this work, the theory and design of the PVS are described in detail. With objective, automated measurement of both alignment and focus, the PVS represents a new approach to screening children for treatable eye disease such as amblyopia.
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1 Introduction

In amblyopia, a structurally sound eye fails to develop good visual acuity either due to failure of the brain to receive input from one eye (deprivation) or due to active suppression of input from one eye by the brain (suppression). Amblyopia is a major public health problem due to the lack of an effective way to detect patients at risk for this treatable condition.[1,2]

Hunter et al.[3] have demonstrated that it is possible to accurately and noninvasively detect binocular alignment using binocular retinal birefringence scanning (BRBS). This technique utilized the method of retinal birefringence scanning (RBS), which detects foveal fixation by identifying the unique polarization signature created by the birefringence of the nerve fibers emanating from the fovea.[4–6] The previously described BRBS device[3] scanned both eyes in rapid alternating fashion, performing retinal birefringence scanning to detect foveal fixation in both eyes. In a pilot study, they found that they could distinguish binocular alignment from misalignment in subjects with good quality recordings; however, low-quality readings were obtained from 5/13 controls and 4/8 nonstrabismic subjects with myopia. The low quality of the readings was in part due to the time-based modulation utilized by that device, which created synchronization problems and incomplete noise subtraction.

The original BRBS device was not designed to detect ocular defocus, the other major amblyopia risk factor for amblyopia.[1] To characterize the focus of the eye using an automated, compact approach that could be incorporated into a hand-held instrument, we developed the focus detection system.[5,7] This technique uses a bull's-eye photodetector to characterize the quality of the retinal image by assessing the double-pass blur of a point light source. A high ratio of well focused light (imaged onto the central detector) to defocused light (imaged onto the annulus of the detector) indicates good focus of the eye.

The BRBS and focus detection approaches are automated, compact, and noninvasive. By combining them into a single hand-held device, it should be possible to screen for all major amblyopia risk factors. In this work, the design of this Pediatric Vision Screener (PVS) is described in detail. The enhanced design utilizes haploscopic design principles to eliminate the need for time-based modulation of the left and right channels. The performance of the PVS is then demonstrated in a control subject and in a strabismic subject to illustrate the potential feasibility of this approach.

2 Instrument Design

The design goals for development of the Pediatric Vision Screener included: 1. noninvasive measurement, 2. simultaneous assessment of alignment (using BRBS) and focus (using the focus detection system), 3. a data acquisition time of less than 5 sec, 4. multiple scans obtained during the acquisition time, 5. automated, threshold-based assessment, and 6. a hand-held, portable package allowing the device to be aimed

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at children seated on a parent's lap without head restraint. In this section, the device is described in terms of the optical and electronic designs of both the BRBS and focus detection channels, and the techniques for signal acquisition and processing.

2.1 *Optical Design: BRBS*

The concept of BRBS has been described previously.[3] Briefly, a spot of circularly polarized 830-nm laser light is scanned as an annulus on both retinas. For each eye, if the annulus surrounds the center of the fovea, the differential polarization signal of the returning light has a frequency twice the input scanning frequency. If the annulus does not surround the fovea, the differential polarization signal of the reflected light has a primary frequency equal to the input scanning frequency. For the PVS, the scanning frequency is 100 Hz, so that a predominantly 200-Hz signal from an eye indicates central fixation, while a 100-Hz signal indicates paracentral fixation. Thus, analysis of the frequency of the signals representing the right and left eyes can indicate whether a subject is fixating on the target with one eye, both eyes, or neither eye.

Figure 1 details the light pathway for the BRBS channel. The divergent, linearly polarized output of an 830-nm laser diode is converted to collimated, circularly polarized light, converged through a clearance hole in a flat, 45-deg mirror, then further shaped to fill a concave, tilted, spinning mirror. The spinning mirror converts the stationary source to a circularly scanned point of light surrounding the hole in the 45-deg mirror, which is then directed toward the exit pupils by the 45-deg mirror. The scanned circle of light subtends an angle of approximately 3 deg at each eye of the subject. The projected images of the two patches of light falling on the spinning mirror create the exit pupils, located at the subject's eyes, 40 cm from the center of the 45-deg mirror.

Reflected light bundles from the retinas of both eyes follow the same paths back through the clearance hole until they are passed to detectors by a plate beamsplitter (the detector assembly has been rotated 90 deg about the optical axis for clarity of illustration). A knife-edge reflecting prism separates the spatially preserved signals from the right and left eyes. Polarizing beamsplitters separate the light bundles for each eye into orthogonal components of polarization (X and Y), which are separately converged onto two photodetectors conjugate to the retina to enable differential polarization detection, as described previously.[4] The laser outputs of 0.20 mW/cm^2 at the subjects' pupil are well below the established ANSI Z-136 safety standards of 0.56 mW/cm^2 for an indefinite period.

For data acquisition, subjects are seated at the location of the exit pupils, which are each 40 mm square and separated by 10 mm between the nasal edges. This geometry allows for the interpupillary separation of adults and children. Positioning of this hand-held instrument is facilitated by a triangulation, range-finding technique that utilizes two laser pointer modules projecting from above and below toward a point 1 cm anterior to the midpoint between the two exit pupils. The red laser spots were slightly separated horizontally to provide the needed direction clue for positioning forward and back relative to the subject.

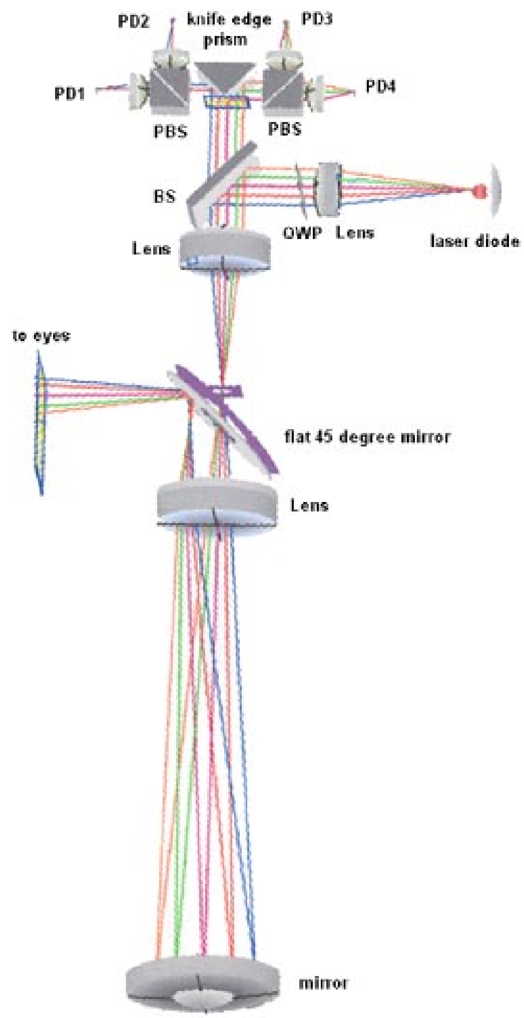

Fig. 1 Ray tracing diagram and physical layout of the BRBS device: PD=photodiode; PBS=polarizing beamsplitter; QWP=quarter wave plate; and BS=beamsplitter.

2.2 *Optical Design: Focus Detection System*

The concept of the monocular focus detection system has been described previously.[5,7] The critical component of the apparatus is a bull's-eye photodetector with two concentric active surfaces of equal area, a central circle and a surrounding annulus, positioned optically conjugate to a point light source. Using this configuration, sharply focused light falls only on the central area, while defocused light falls on both the central area and annulus, so that the ratio of center/annulus increases as the focus of the optical system improves.

The design of the binocular focus detection system is detailed in Fig. 2. A 785-nm laser diode produces monochromatic, diverging, linearly polarized light oriented vertically. A lens collimates the divergent light, which then passes into a polarizing beamsplitter. The beamsplitter is oriented to reflect essentially all of the vertically polarized light toward the subject. Light then passes through a quarter wave plate to produce circularly polarized light. A second lens converges the light to a point focus at the center of the hole in the flat 45-deg mirror (omitted from Fig. 2 for clarity; see Fig. 1). This places the 785-nm point source image 40 cm from the subject's eyes.

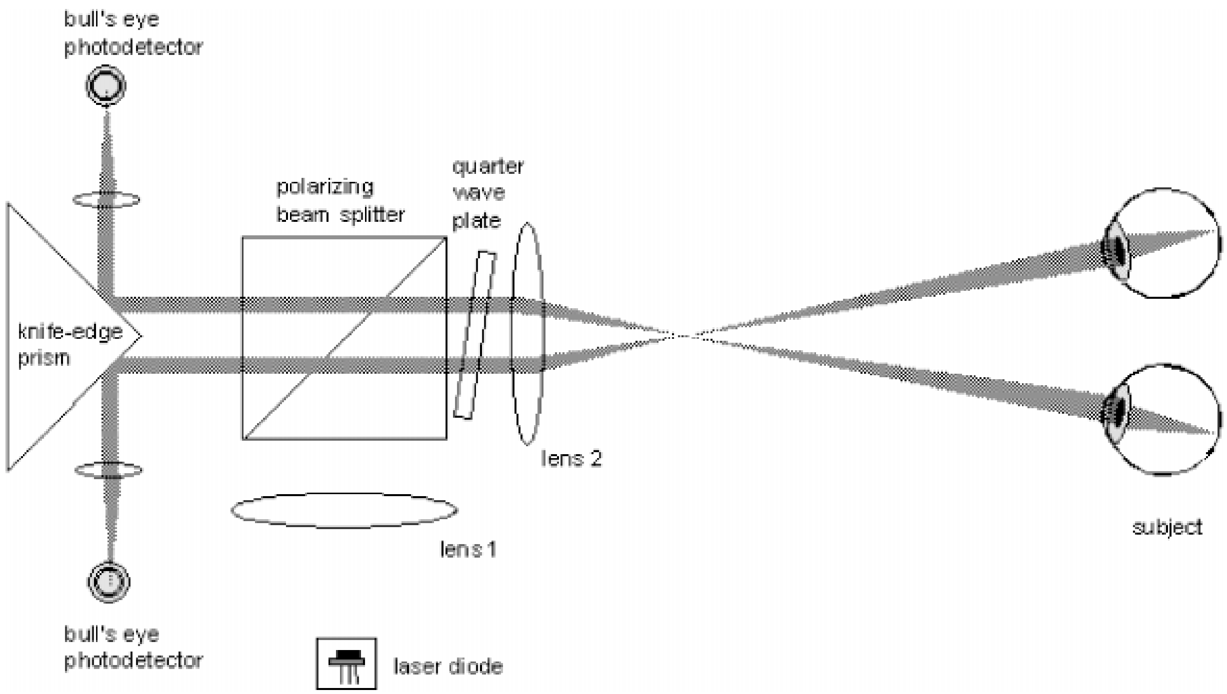

Fig. 2 Focus detection system (viewed from above): light emerges from the laser diode and travels toward the subject. The subject fixates on the image of the point source laser diode. Only the return light path is shown for clarity. Drawing not to scale.

The small amount of light reflected by the fundus maintains most of its circular polarization but changes handedness on reflection before exiting the eye and returning to the quarter wave plate. The reflected light emerges from the quarter wave plate horizontally polarized and is passed toward the photodetectors by the polarizing beamsplitter.

A near-infrared wavelength was selected to minimize reflex pupillary constriction and thus loss of signal power.[8] To separate the optical pathways of the focus detection system (785 nm) from the BRBS (830 nm), appropriate bandpass filters were inserted before the respective detectors, and the optics were coated with appropriate antireflection coatings. To electronically filter the desired focus detection reflected signal from background noise, a driver modulated the laser diode to produce a square wave at 400 Hz.

The circular polarization system was designed to detect maximum light reflected from the fundus while removing half of the depolarized light (produced by facial reflections and other diffuse reflections) from the signal. As long as a substantial fraction of the circularly polarized light reflected from the retina retains its polarization, this optical arrangement maximizes the light returning to the bull's-eye detector.[9]

The detectors and laser diode were aligned using parallax to locate them in conjugate planes and were then visibly centered under high magnification. Exact optical conjugacy of the point source and detector was essential for proper performance, ensuring that as long as the eye was focused, the retina remained optically conjugate to both.

2.3 *Electronics and Signal Acquisition*

The signals were acquired, processed, analyzed, and stored in near-real time in a custom virtual instrument environment developed using Lab Windows software (National Instruments, Austin, Texas). For each subject, a preliminary scan was obtained with eyes closed, and this background scan was then digitally subtracted from all subsequent data scans, improving the signal-to-noise ratio.

The focus detection laser light flashed on and off at 7 Hz to attract the subject's attention. The background-subtracted output of the bull's-eye photodetectors was displayed as calculated power spectra of the center (C) and annulus (A) signals. To adjust for potential differences in overall reflectivity of the eye, the ratio C/A was calculated, producing a minimum value of $C/A=1$ for a defocused eye. This ratio allowed focus detection system readings to be compared among subjects with varying reflectivity. As the value of A approached zero, the ratio C/A approached infinity. Therefore, the normalized ratio $(C-A)/(C+A)$ was also calculated and stored. This ratio produced a predictable range of the focus detection system (FDS) output from 0 for a defocused eye to 1 for an ideally focused eye.

BRBS data were collected only during the "off" portions of the focus detector duty cycle to minimize interference. The software computed the percentage of power at 100 and 200 Hz, and characterized a reading as central fixation (200 Hz $>$100 Hz) or paracentral fixation (200 Hz$<$100 Hz). A reading was characterized as bilateral (both eyes with central fixation), unilateral (one eye with central fixation), or no reading (neither eye with central fixation).

2.4 *Device Operation*

The prototype portable BRBS is shown in Fig. 3. The scanning laser beams exited the instrument toward the eyes through the exit hole in the face of the device [Fig. 3(b)]. Cables (not shown) connected power and data lines from the scanner to a "lunch box" data acquisition computer. The sub-

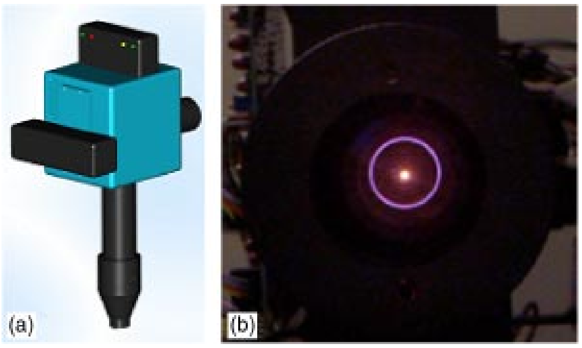

Fig. 3 Prototype Pediatric Vision Screening device. (a) Illustration of device from operator's side. (b) Subject's view of fixation target (focus detection system) surrounded by faint ring (the scanned BRBS laser). The intensity of the ring is artificially enhanced in this photograph.

ject was seated across from the examiner, without head restraint. Room lights were dimmed to enhance interest in the fixation target. A blinking fixation target, the focus detection laser diode, was presented in combination with a synchronized beeping tone to draw the subject's interest to the instrument [Fig. 3(b)]. A single reading was obtained in <0.5 sec. The software was configured to obtain a rapid sequence of 0.5-sec readings over 5 to 10 sec.

In anticipation that the PVS will be used as a screening tool, the software illuminated an array of four light emitting diodes (LEDs) mounted on the instrument [Fig. 3(a)]. The LEDs indicated right-eye alignment, right-eye focus, left-eye focus, and left-eye alignment, respectively. Each LED indicated green for a pass measurement, red for a refer measurement, or dim for an inconclusive reading, with thresholds set in software as described later. A single red indicator at the end of a series of measurements would, in practice, indicate the need for a comprehensive eye examination, while any dim indicator would indicate a need to repeat the screening. Four green LEDs would indicate the desired state, namely bilateral, simultaneous foveal fixation with bilateral simultaneous focus.

The front panel of the custom-programmed Lab Windows panel is shown in Fig. 4. The software displayed the results of the data analysis in both graphical form on the computer screen and also by illuminating the array of four LEDs described earlier. The fast Fourier transform (FFT) power spectrum of the BRBS signals was displayed as separate plots for the right and left eyes, and the FFT power spectrum of the focus detection signals was displayed as a pair of peaks for each eye—one representing the center (C) of the bull's-eye photodetector, the other the annulus. Red and green lights in the upper right-hand corner of the RBS and focus detection

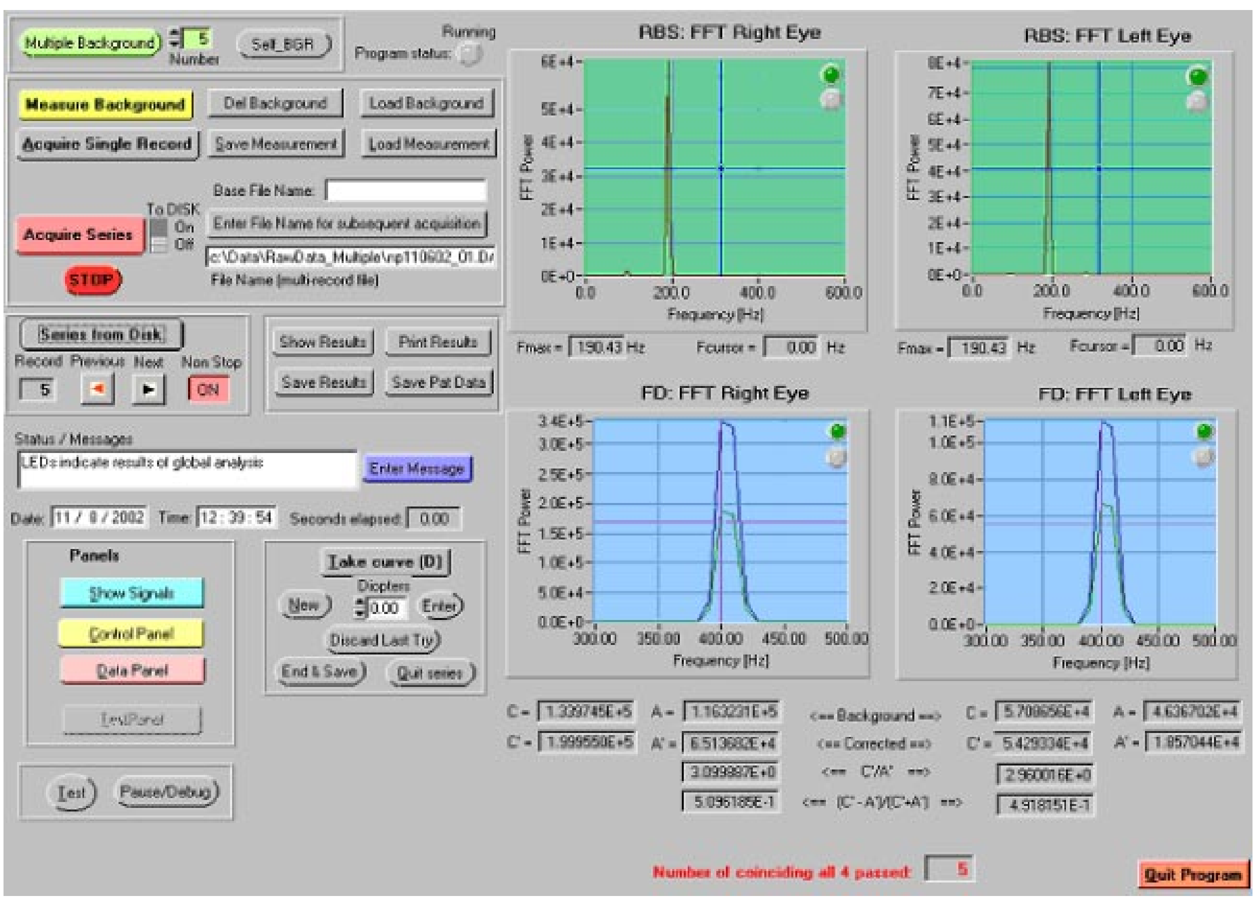

Fig. 4 Pediatric Vision Screener software, main panel. Left side shows acquisition and control parameters. Panels show RBS (upper) and focus detection (lower) output. Upper light within each panel indicates passing measurement. In this case the subject demonstrated bilateral foveal fixation and bilateral focus.

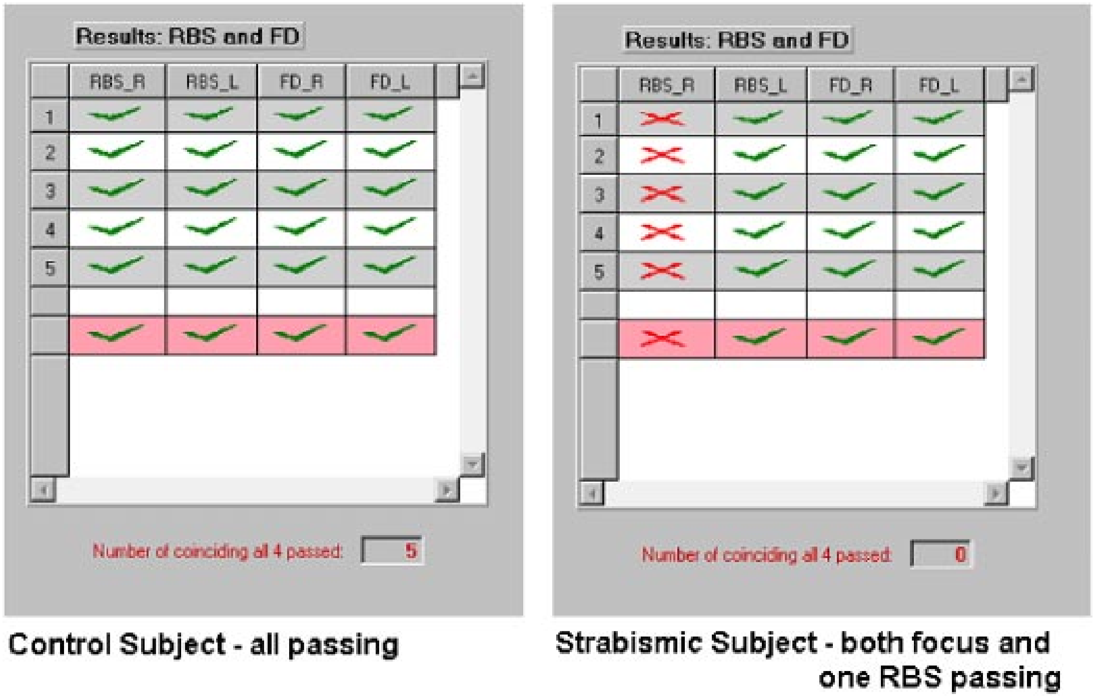

Fig. 5 Output of two Pediatric Vision Screener sessions. Five readings shown, with summary at bottom. **RBS_R**=right RBS channel; **RBS_L**=left RBS channel; **FD_R**=right focus channel; **FD_L**=left focus channel.

(FD) plots indicated the status of the red and green LEDs on the instrument.

2.5 *Volunteer Testing*

To determine whether the PVS could identify strabismus and/or poor focus, measurements were obtained from one control and one strabismic volunteer. An orthoptist performed a "gold standard" examination, measuring best-corrected visual acuity, refractive error, binocular vision, and ocular motility. Residual refractive error was measured with vision correction in place if worn. The study was approved by the appropriate institutional review boards, and informed consent was obtained from all subjects.

The control subject was female, age 32, with hazel eye color and uncorrected visual acuity measured as 20/15 right eye (RE) and 20/15 left eye (LE). The strabismic subject was also female, age 35, with brown eyes and refraction RE: $-3.25+0.75\times180$, LE: $-4.50+1.50\times002$. With contact lenses there was no residual refractive error, and corrected visual acuity measured 20/60 in the amblyopic right eye and 20/25 in the left eye.

Subjects were asked to fixate centrally with both eyes, then centrally with each eye separately as the untested eye was covered with a clinical occluder. Subjects were then asked to fixate centrally and in four ordinal directions on the ring of laser light alternately (1.5 deg from the center). This protocol allowed testing for repeatability, detection of cross talk between channels, and identification of false positive responses. Five readings were obtained for each direction of fixation.

3 Results

The graphical output produced by the PVS is shown in Fig. 5; in addition, a detailed quantitative text output of all measurement parameters was provided by the software. The control subject depicted in Fig. 5 (left) passed fixation and focus in both eyes for all five readings. In contrast, the strabismic subject passed focus with both eyes but failed fixation in the right eye for all five measurements (Fig. 5, right).

Bilateral simultaneous foveal fixation was detected in the control subject, while only unilateral fixation was detected in the subject with strabismus. Central fixation was never detected during paracentral fixation in four ordinal directions, and cross talk (detection of fixation in an occluded eye while the other eye focused on the fixation target) never occurred.

4 Discussion

The PVS shows potential as a sensitive and specific detector of binocular alignment. The overall performance was superior to that of the previous BRBS device, probably due to the elimination of time-based multiplexing. In the feasibility test, the angle of strabismus tested was 35 prism diopters. However, the device actually detected 1.5 deg (3 prism diopters) of misalignment of individual eyes, because during paracentral fixation, subjects were instructed to fixate on the red ring, located 1.5 deg away from the central fixation target, and this amount of misalignment was always detected. This is consistent with the theoretical threshold of 0.75 deg (1 prism diopter), considering the accuracy of RBS for detection of fixation.[4] Studies of subjects with small angle strabismus are ongoing in our laboratory to determine the minimum ocular misalignment detectable with the PVS.

Currently available static and video photoscreeners detect strabismus only via highly insensitive, subjective analysis of the corneal light reflex. The PowerRefractor[10] automates this corneal light reflex analysis and may possibly be able to detect moderate to large angles of strabismus, but its performance has not yet been fully characterized. The PowerRefractor's use of the corneal light reflex to detect strabismus is likely to produce false positive and false negative results in subjects with pseudostrabismus secondary to abnormal angle lambda.[11] It would also allow false negative results in patients with retinal abnormalities to pass, whereas the PVS depends on an intact architecture of the delicate nerve fibers surrounding the fovea to detect alignment of each eye.

The PVS represents a new strategy for screening pediatric patients for eye disease because it relies on simultaneous objective measurement of alignment and focus. Future studies will determine the performance of the device in cooperative adult controls and patients with well-characterized strabismus, followed by clinical trials involving large numbers of pediatric patients. A sensitive and specific device that automatically identifies patients at risk for amblyopia will allow earlier detection and treatment of this preventable cause of vision loss.

Acknowledgments

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