Original Article

Effective low-cost pediatric vision screening by naive nonophthalmic examiners using the 'Arclight' device

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Purpose: To explore whether a low-cost ophthalmoscope (Arclight) can be used by naive nonophthalmic examiners to effectively screen for pediatric eye disease. **Methods:** Fifty-four children (108 eyes) were examined by five medical students using an Arclight. Gold standard examination was performed by an ophthalmologist using a slit lamp and indirect ophthalmoscope. Examinations performed included ophthalmoscopy of the optic disc, estimation of the cup-to-disc ratio (CDR), corneal light reflex test (CRT), Bruckner's reflex test (BRT), and evaluation of refractive error. We determined the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the nonophthalmologist's Arclight exam compared to the gold standard findings of comprehensive evaluation by pediatric ophthalmologists. **Results:** Using the Arclight, the optic nerve exam was successfully completed in 65% of patients. CDRs above and below 0.5 could be determined with 66.7% sensitivity and 84.4% specificity. Arclight CRT measurements were significant ($P < .00001$) predictors of strabismus, with 80% sensitivity, 95.1%, specificity, 80% PPV, and 95.1% NPV. BRT was not a significant predictor of amblyopia, with a 34.6% sensitivity, 85.7% specificity, 69.2% PPV, and 58.5% NPV. Refractive error was estimated with a success rate of 81% for emmetropia, 38% for myopia, and 21% for hyperopia. The Arclight ease-of-use was rated on average as 4.4 (SD = 0.9) on a scale of 1 to 5, with 1 being the hardest and 5 being the easiest. **Conclusions:** Our study shows the Arclight as an affordable and effective alternative to the traditional ophthalmoscope for assessing eye disease in children. This device can improve eye health services in under-resourced regions.

Access this article online

Website: https://journals.lww.com/ijo

DOI: 10.4103/IJO.IJO_3027_23

Quick Response Code:

Key words: Arclight, naive nonophthalmic examiner, vision screening

Pediatric vision screening is an important step toward decreasing the burden of blindness worldwide.[1] It is estimated that over 600,000 children and adolescents in the United States and over 90 million worldwide have some form of vision loss.[2] Most of these cases are found in low- and middle-income countries (LMICs) where they are considered preventable or treatable if diagnosed early enough.[3] Although vision screening guidelines exist in many countries, countless children fall through the cracks of national efforts to catch and treat these populations due to a host of reasons, including prohibitive costs of both diagnostic tools and training, accessibility of consumables such as batteries and bulbs, health beliefs, and overburdened health care systems.[1] The gold standard for comprehensive eye examination typically involves the use of a direct and indirect ophthalmoscope and slit lamp. Because of the costs and skill involved in conducting these exams, these methods are only usually available in larger hospitals with dedicated eye care services. In countries with limited resources, the number of trained and equipped eye health professionals is disproportionately low.[3] Consequently, large numbers of patients are seen in rural or mobile clinics by primary and midlevel allied health personnel[4] with limited access to eye care equipment and training.

The Arclight is a low-cost portable solar-powered combination direct ophthalmoscope, loupe, and otoscope. St Andrews Medical Innovations Ltd, who is a subsidiary of the University of St Andrews, developed the device and is the sole supplier globally. The cost of the device varies depending on the World Bank classification of the purchasing country. The cost ranges from £12 to £60 per unit [Fig. 1].[5] It was developed for users in low-resource settings as a practical and cost-effective alternative to the more complex, bulky, and expensive traditional devices designed for use in wealthier settings. On one end of the device is a direct ophthalmoscope, with LED light sources providing three brightness levels and adjustable lenses with three different dioptric powers. On the other end is a magnifying loupe for anterior segment examination and a detachable speculum for ear examination. As a solar-powered compact device, the Arclight does not require consumables and

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Received: 15-Nov-2023 Revision: 19-Apr-2024
Accepted: 10-May-2024 Published: 11-Jul-2024

Cite this article as: Gore R, Wang JN, Yang CD, An M, Hunter SC, Shahraki K, *et al*. Effective low-cost pediatric vision screening by naive nonophthalmic examiners using the 'Arclight' device. Indian J Ophthalmol 0;0:0.

Figure 1: Arclight device

is highly portable, making it ideal for use in rural low-resource regions of the world.[6] Moreover, its simplified design makes it accessible to novices, such as medical students, nurses, and nonophthalmic healthcare workers. For these reasons, Arclight has the potential to overcome the challenges of accessibility, cost, and physician availability in global pediatric vision screening. Thus far, the device has been distributed to many LMICs around the world with over 35,000 devices being used globally.[6] Previous eye studies have so far demonstrated its efficacy in teaching ophthalmoscopy compared to traditional tools[7] and its comparative accuracy in screening for diabetic retinopathy, glaucoma, and 'red' reflex abnormalities.[8-10]

Our study aimed to assess whether the Arclight, in the hands of medical students, can effectively screen for the risk factors for amblyopia and identify common pediatric structural eye abnormalities in a clinic-based pediatric population.

Methods

Examiners

Four medical students were recruited to participate in the study and serve as naïve nonophthalmic examiners (NNOEs). They were given a 1-hour group training session. Thirty minutes consisted of didactic learning to familiarize them with interpreting the physical exam findings of the Bruckner's red reflex test (BRT), corneal light reflex test (CRT), estimation of the cup-to-disc ratio (CDR), and general appearance of healthy and abnormal eyes. Another 30 minutes consisted of hands-on training to familiarize them with how to use the Arclight device and the technique of direct ophthalmoscopy and to practice the BRT, corneal light reflex test, and examination of the fundus on each other.

Patients and methods

Fifty-four patients under 18 years of age who presented to the pediatric ophthalmology clinic for their scheduled appointments were recruited for an Arclight examination. A total of 108 eyes were examined. No follow-up visits were required. The NNOE performed eye examinations using the Arclight in dim lighting and recorded their interpretations of the BRT, CRT, optic disc findings (including the CDR), and any other structural abnormalities. They also recorded their perceived ease of use (EOU) in performing eye examinations with the Arclight. Twenty-five of the 54 patients had their pupils dilated before the Arclight exam was conducted. A pediatric ophthalmologist masked to the NNOE's findings and then proceeded to perform a gold standard eye examination including retinoscopy, motility testing, slit lamp examination, and binocular indirect ophthalmoscopy. The gold standard exam recorded the measurement of refractive error as a sphere, cylinder, and axis. The spherical equivalents (SEs) of these measurements were categorized into three groups for comparison as follows: SE > -0.5D and < 0.5D = emmetropia; SE ≥ 0.5D = hyperopia; SE ≤ -0.5D = myopia. Demographic data were extracted from the electronic medical record without any identifying information. The study was approved by the University of California Irvine IRB committee with approval number IRB: #677.

Statistical analysis

Arclight exam results were compared to the gold standard examination by calculating sensitivity, specificity, and positive and negative predictive values (PPVs and NPVs) of various components of the exam. Fisher's exact test was used to evaluate the association between examiner interpretation and gold standard diagnosis.

Results

Of the 54 subjects (108 eyes) examined, each had at least one component of the eye examination successfully completed. There were 29 (53.7%) males and 25 (46.3%) females. The mean age was 7.5 ± 4 years, ranging 1–17 years. Ethnicity groups were Hispanic (13), Asian (12), Caucasian (10), and Other (11). All patients had pre-existing ophthalmological concerns, ranging from dry eye to amblyopia and refractive errors.

Optic nerve exam and cup-to-disc ratio assessment

On fundus examination with the Arclight device, NNOEs were able to observe the optic nerve and assess the CDR in 35/54 subjects or 70/108 eyes (65% success rate). Ethnicity, gender, and dilation status did not significantly affect the success of the optic nerve exam. However, there was a statistically higher success rate for examining children 3 years and older compared to those who were younger ($P = 0.03$).

NNOE CDRs were obtained by observing the optic nerve using the Arclight. Gold standard CDR values were determined using an indirect ophthalmoscope or slit lamp biomicroscopy. The mean CDR value obtained by NNOEs using the Arclight device was 0.35 ± 0.15 (range: 0.2–0.8), whereas the mean CDR value obtained with the gold standard exam was 0.26 ± 0.1 (range: 0.1–0.5). Paired *t*-test revealed that NNOE and gold standard CDR values were significantly different ($P < 0.05$). When compared to the gold standard, the NNOEs using the Arclight device were able to distinguish between CDRs above and below 0.5 with 66.7% sensitivity and 84.4% specificity [Fig. 2].

Detection of strabismus

The CRT was performed using the Arclight to screen for the presence of strabismus. Deviation >=5 pd was taken as strabismus.

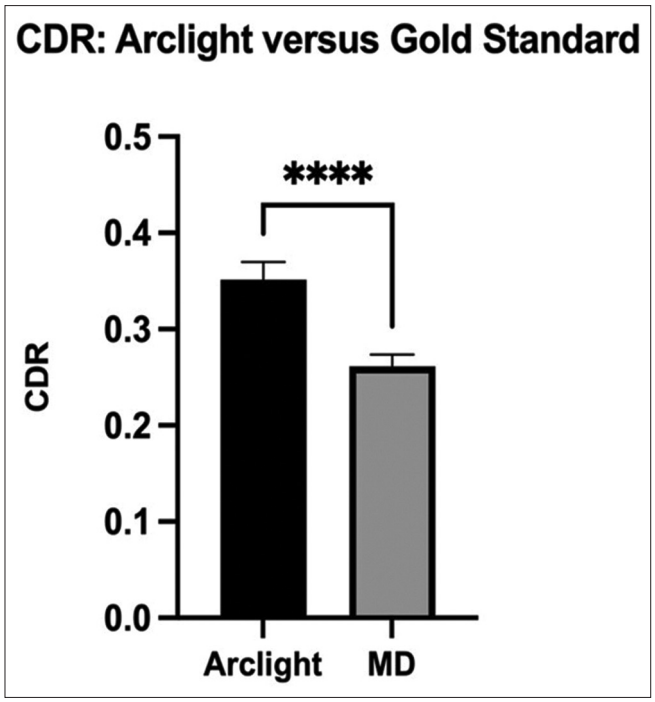

Figure 2: A histogram of the CDR for the NNOE examination with the Arclight versus the gold standard

This test had a sensitivity of 80% (95% CI, 44.4%–97.5%) and a specificity of 95.1% (95% CI, 83.5%–99.4%). The PPV of this test was 80% (95% CI, 50%–94.1%), and the NPV was 95.1% (95% CI, 84.9%–98.5%). We performed Fisher's exact test to examine the association between an abnormal CRT result and the presence of strabismus, and it was found to be statistically significant ($P < 0.00001$).

Detection of amblyopia risk

The BRT was performed by examiners and recorded as a "symmetric/negative" or "asymmetric/positive". Whether the patient had any amblyogenic risk factors was determined from the Gold standard exam using AAPOS 2021 criteria for pediatric vision screening.[11] Based on the gold standard eye examination, 15 children had bilateral visually significant refractive error, 7 had anisometropia, and 12 had strabismus. Of these, eight children had two of three AAPOS amblyogenic risk factors. Positive BRTs showed 34.6% (95% CI, 17.2%–55.7%) sensitivity and 85.7% (95% CI, 67.3%–95.9%) specificity in picking up risk factors for amblyopia. The PPV of this test was 69.2% (95% CI, 44%–86.5%), and the NPV was 58.5% (95% CI, 50.7%–66%). Fisher's exact test was conducted to examine the association between a positive BRT and the presence of amblyogenic risk factor (s), and it was found to be statistically insignificant ($P = 0.11$).

Refractive error estimation

The NNOEs were able to determine the type of refractive error based on BRT in 92 eyes, recorded as emmetropia, hyperopia,

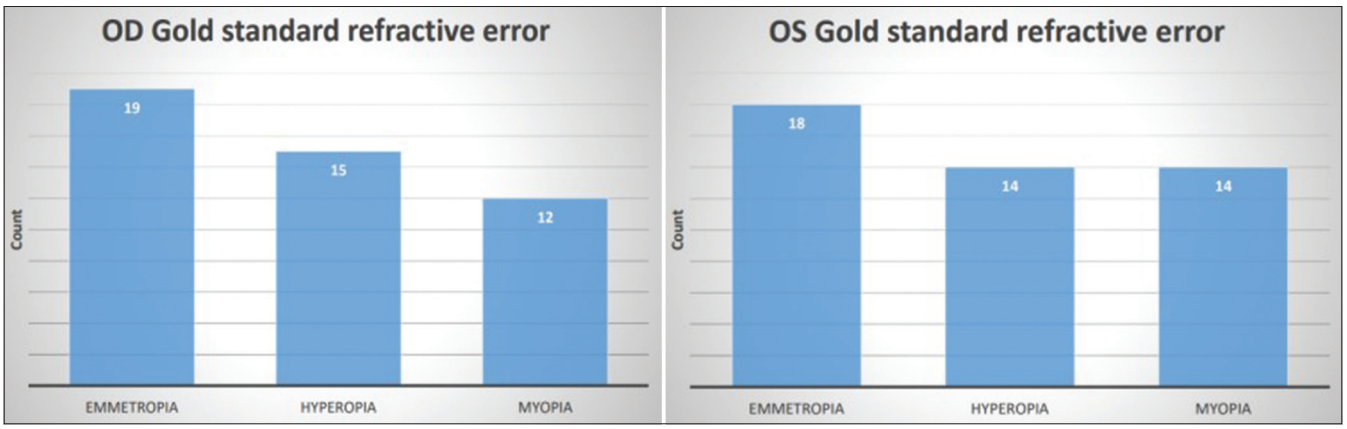

Figure 3: Right and left eye NNOE exam results

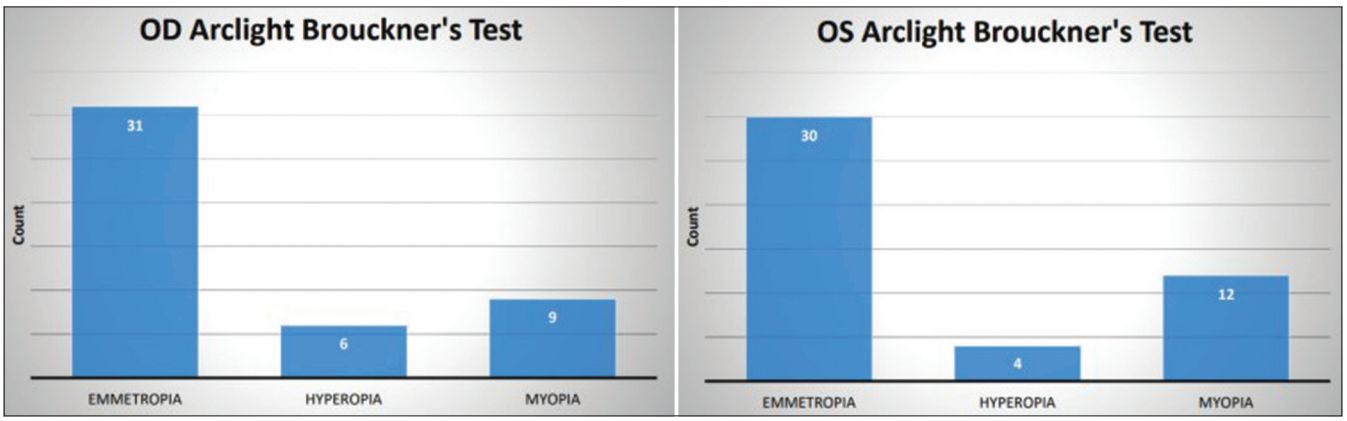

Figure 4: Right and left eye gold standard exam results

and myopia. They were unable to classify 16 eyes, which were excluded from this analysis. NNOEs were best able to identify emmetropia as they correctly identified 30 out of 37 emmetropic eyes versus only 6 out of 29 hyperopic and 10 out of 26 myopic eyes. Examiners tended to overcall emmetropia as they labeled 61/92 eyes as emmetropic [Fig. 3], when only 37/92 were actually emmetropic [Fig. 4].

Ease of use

The mean EOU score was 4.4 ± 0.9 on a scale of 1 to 5, with 1 being the hardest and 5 being the easiest. There was no statistically significant difference when comparing eye exams on dilated versus nondilated eyes.

Discussion

Eye examinations are pivotal in determining those in need of further systemic and neurological evaluations.[1] Central to this evaluation is the optic disc, a structure discernible during ophthalmoscopy. Notably, pediatric optic nerve issues, ranging from hypoplasia to disc edema, often correlate with systemic illnesses.[12] Despite the noted statistical difference in CDR values when using Arclight versus the gold standard (0.35 vs 0.26), such a variance is within a clinically acceptable range. The utility of Arclight in this context is even more pronounced when considering its potential as an early detection tool, especially in resource-scarce regions, even though our study sample had limited optic nerve anomalies.

Amblyopia, a developmental vision disorder, is commonly linked with conditions like high refractive errors or strabismus.[13] Convenient screening methods exist for these disorders. For instance, the CRT, though not entirely precise, serves as a rapid screening measure. Our results reaffirm its utility, especially when combined with the multifaceted Arclight device. Such tools become invaluable in locales where specialist eye care professionals are sparse. Furthermore, although Bruckner's test has shown varied sensitivity in previous studies when wielded by optometrists or pediatricians,[14-17] our results, using NNOE, highlighted the need for enhanced training for accurate pediatric vision screenings using the Arclight.

Intriguingly, even without specialized eye training, our examiners found Arclight user-friendly. Arclight's design attributes, including its ergonomic build, solar-power source, and LED illumination, make it not only user-friendly but also economical and sustainable, particularly when juxtaposed with battery-dependent counterparts. In settings with limited resources, this tool, when coupled with proper instruction, offers a promising avenue for reliable pediatric eye screening by nonspecialist healthcare professionals.

Acknowledging the WHO's push for inclusive eye health, especially in resource-constrained regions, it is imperative to explore the outcomes of broad-scale Arclight deployment among primary healthcare workers in these areas, focusing on its potential to mitigate blindness.

Conclusions

The Arclight stands out as a cost-efficient, user-friendly alternative to traditional ophthalmoscopes. Its potential as a screening tool for pediatric visual disorders is evident, especially for regions grappling with limited resources. Widespread application could have profound implications for global eye health, underscoring the importance of further investigations into its community and national-level impacts. The lack of adequately trained and equipped eye health care workers in LMICs amplifies the need for tools like Arclight. Investing in such innovations aligns with the WHO's strategy to bolster Primary Eye Care and promote Inclusive Eye Health, aiming for a world with fewer visual impairments.

Financial support and sponsorship: Nil.

Conflicts of interest: There are no conflicts of interest.

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