

## Research Article

# Comparison of a Cellphone-Based Fundoscope with Traditional Handheld Direct Fundoscope for Checking Red Reflex in Neonates

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### Abstract:

**Background:** Traditional handheld fundoscopes are expensive instruments and require training and expertise for their use to check red reflex in neonates. Cellphone based fundoscopes may prove to be a cheaper alternative to check red reflex for screening of congenital cataracts in neonates.

**Objective:** Evaluation of the diagnostic accuracy of a cellphone-based fundoscope OptiCard for screening of cataracts in neonates by checking pupillary red reflex.

**Methods:** An instrument validation study was conducted in the Neonatology Department of Services Hospital Lahore for 3 months from 1<sup>st</sup> August to 30<sup>th</sup> October 2021 to assess the diagnostic accuracy of cellphone-based fundoscope OptiCard for screening of cataracts in neonates using Wilson Score.

**Results:** Eyes of 110 neonates were examined for red reflex. Cellphone-based fundoscope OptiCard was found to have a sensitivity of 100% for diagnosing abnormal red reflex while its specificity was found to be 99.06% as compared to the traditional handheld direct fundoscope.

**Conclusion:** Cellphone-based fundoscope OptiCard has good diagnostic accuracy for detecting abnormal red reflex and it allows the images of pupillary glow to be stored for a photo follow-up.

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### Introduction:

Red reflex was described by Bruckner in 1962.<sup>1</sup> It is a red, red-orange, or orange glow seen symmetrically in both eyes.<sup>2,3</sup> Indirect ophthalmoscope utilizes a light source and a high power lens to visualize the eyes whereas, in a direct ophthalmoscope, light rays are collimated using a convex lens and reflected towards the patient's eyes using a mirror. As the light is shown on a normal eye from a distance of 45 cm (18 inches), it illuminates the retina through the pupils.<sup>4</sup> The red glow from the retinal blood vessels is reflected through the pupils of the eyes to the aperture of the direct

ophthalmoscope that is viewed by the observer as a red reflex.<sup>5</sup> Red reflex, is, therefore, a magnified view of the retinal blood vessels. The glow should be similar in intensity and homogenous in color bilaterally. If there is any abnormality in the pathway of the light, red reflex may be absent, asymmetrical in both eyes, white eye reflex (leukocoria), or unequal in intensity.<sup>6</sup> Red reflex was previously called a transillumination test by Bruckner who utilized it for checking squint in children. It is a non-invasive test to identify opacities in the visual axis of the eye such as corneal haziness, cataract in the lens, or abnormalities in the posterior chamber of the eye. It may be utilized for early detection of vision

abnormalities such as cataracts, retinoblastoma, squint, retinal abnormalities, or diseases with ocular manifestations such as galactosemia, and TORCH infections (Toxoplasma, Rubella, Cytomegalovirus, Herpes).<sup>4,7</sup> Various cell phone-based fundoscopes are available such as OptiCard<sup>8</sup>, Pan Retinal<sup>9</sup>, Peek Retina<sup>10</sup> and D-eye<sup>11</sup>. These devices attach to cell phone cameras and allow checking red reflex and performing a retinal examination on a cell phone display such that photographs may be taken for diagnosis, patient counseling, for record purposes, or a photo follow-up.<sup>8</sup> Russo et al used a cell phone-based fundoscope (D-Eye) and demonstrated that red reflex and retinal examination could be done easily<sup>11</sup>. Oluleye, Samuel, and Akinshola et. al utilized cellphone-based indirect funduscopy technique in resource-limited areas of Africa to screen preterm babies for retinopathy of prematurity with promising results.<sup>12</sup> Wintergerst, Petral, and Jeany et. al demonstrated that cell phone-based indirect fundus imaging may be utilized to stage and screen preterm babies for retinopathy of prematurity using a 40D lens and a cellphone camera.<sup>13</sup> American Academy of Pediatrics (AAP) recommends that neonates should undergo red reflex screening on every well-baby visit from age 0 to 6 months, and once between 6 to 12 months, 1 to 3 years, 4-5 years, and then at 6 years.<sup>14</sup> Examination of the eyes for red reflex using traditional handheld direct funduscopy requires training that is mostly lacking among primary health care workers and general practitioners. The World Health Organization (WHO) has, therefore, not included red reflex examination to rule out congenital cataracts in routine care of infants working in primary health care facilities since it requires expertise to use a direct or indirect fundoscope.<sup>15</sup> Moreover, traditional handheld ophthalmoscopes are expensive instruments as compared to cell phone-based ophthalmoscopes. ophthalmoscopes are, therefore, not available for routine screening of red reflex in the neonatal units in resource-limited countries. Cell-phone-based ophthalmoscopes are a cheaper alternative. Furahini G. Mndeme, Blandina T. Mmbaga, Min J. Kim, et al found that multiple cellphone based fundoscopes had sensitivities and specificities comparable with direct handheld fundoscope for the detection of cataract.<sup>16</sup> We aimed to compare the diagnostic accuracy of a

fundoscope OptiCard that is developed as an adapter for cellphones with traditional handheld direct fundoscope for checking red reflex in neonates. Traditional handheld fundoscopes are expensive instruments, if the results of this study are favourable cellphone based fundoscope OptiCard may prove to be a cheaper alternative to check red reflex for screening of congenital cataracts in neonates.

### Methods:

Hospital-based instrument validation study was conducted in the Neonatology Department of Services Hospital Lahore for 3 months from 1<sup>st</sup> August to 30<sup>th</sup> October 2021 after taking ethical approval from Institutional Review Board (IRB). A sample size of 110 was estimated using the World Health Organization (WHO) sample size calculator considering the sensitivity of 90.2%, specificity 86.7%, precision 10%, and prevalence of red reflex of 59% with the confidence interval of 95%. Babies less than 30 days of life were included in the study using non-probability sampling. Any neonate having eye discharge or corneal haziness was excluded from the study. Pupils were not pharmacologically dilated and examination was done with ceiling lights turned off and daylight entering from the windows.

A red, red-orange, or orange glow from the pupil of the eye after shining light of the ophthalmoscope from a distance of 45 cm was considered a normal red reflex while an absent glow or white glow (leukocoria) from the pupil of the eye upon shining the light of a fundoscope was labeled as an abnormal red reflex. After taking consent from parents, red reflex was first observed using a traditional handheld fundoscope and the findings were then compared with those of OptiCard. Direct ophthalmoscope was set at 0 lens power and from a distance of 45 cm (approximately half an arm's Length) light was shown in the right eye and then in the left eye and glow was observed. OptiCard was attached to the cellphone with its camera turned on and was held at a distance of half an arm's length from the patient's eyes. The light was shown in both eyes separately and photographs of the findings were taken.

Findings were recorded in google forms and data were exported as an excel spreadsheet. Descriptive data such

as the age of neonate in days, gestational age at birth, and gender was analyzed in PSPP version 1.4 from Free Software Foundation while analysis for sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy was done in OpenEpi version 3.0.

### Results:

Out of 110 neonates enrolled in the study, 57 (51.8%) were male and 53 (48.2%) were female. Eighty six (78.2%) neonates were aged  $\leq 10$  days, 17 (15.5%) were aged 11 to 20 days and 7 (6.4%) were aged 21 to 30 days. Fifty (45.5%) neonates were full-term, 8 (7.3%) were early terms, 36 (32.7%) were late preterm, and 16 (14.5%) were very preterm as listed in Table 1.

**Table 1:** Characteristics of patients enrolled in the study

Patient Characteristics			
		Frequency (n=100)	Percentage (%)
Age (days)	$\leq 10$ days	86	78.2%
	11 to 20 days	17	15.5%
	21 to 30 days	7	6.4%
Gestational age at birth (weeks)	Very preterm (28 to 32+6/7 weeks)	16	14.5%
	Late preterm (32 to 37+6/7 weeks)	36	32.7%
	Early term (37 to 38+6/7 weeks)	8	7.3%
	Full term (39 to 40+6/7 weeks)	50	45.5%
	Gender	Male	57
	Female	53	48.2%

Out of 110 neonates included in the study, 4 patients had abnormal red reflex and were labeled “true positives”: 02 out of 4 had leukocoria (Figure 1) elicited on both handheld fundoscopic examination and cellphone-based fundoscopy, while the other 02 did not give any red or white reflex on examination by both devices due to normal pupillary constriction at the time of examination.



**Figure 1:** Leukocoria as seen using a cellphone based fundoscope OptiCard

01 patient was “false positive” since the patient had normal red reflex elicited by traditional handheld fundoscope while neither red nor white reflex could be elicited by cellphone-based fundoscope.

105 patients were “true negatives” since a normal red reflex could be elicited by both of the devices used for fundoscopy (Figure 2, 3, and 4). Figure 4 illustrates the



**Figure 2:** Normal red reflexes as seen using a cellphone-based fundoscope OptiCard

red reflex when the light was shown simultaneously in both eyes (Bruckner's test).

Keeping a confidence interval of 95%, OptiCard was found to have a sensitivity of 100% for diagnosing abnormal red reflex while its specificity was found to be 99.06% as compared to the traditional handheld direct fundoscope as shown in Table 2.



**Figure 3:** Normal red reflexes as seen using a cellphone-based fundoscope OptiCard



**Figure 4:** Bruckner test elicited using the cellphone-based fundoscope OptiCard

**Table 2:** Results of cellphone-based fundoscope (OptiCard) as a screening tool for detection of cataracts in neonates

		Direct Fundoscope			Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Diagnostic Accuracy
		+	-	Total					
<b>OptiCard</b>	+	4	1	5	100%	99.06%	80%	100%	99.09%
	-	0	105	105					
	Total	4	106	110					

CI = Confidence interval, PPV = Positive predictive value, NPV = Negative predictive value

### Discussion:

Examination of the pupils for the red reflex to screen for congenital cataracts is included in the newborn examination as recommended by the American Academy of Pediatrics (AAP).<sup>14</sup> Screening for leukocoria should be done at every well-baby visit.<sup>15</sup> The World Health Organization (WHO), However, has not included the screening of congenital cataracts in newborns in primary healthcare facilities.<sup>16</sup> Hand-held direct ophthalmoscopes involve complex optics and are, therefore, expensive instruments. The usage of direct ophthalmoscope requires training to view red reflex and perform retinal examination, and few clinicians perform it due to lack of confidence.<sup>17</sup>

Cellphone-based fundoscopes are less expensive as compared to the traditional handheld direct ophtha-

lmoscopes and are more portable. These may be carried easily in pocket and healthcare personnels may find these easy to use.

Multiple studies have shown that cellphone-based ophthalmoscopes have high sensitivity and specificity for diagnosing cataract as compared to handheld direct ophthalmoscopes. Furahini G. Mndeme, Blandina T. Mmbaga, Min J. Kim et al found similar results as our study that cell phone-based ophthalmoscopes had high sensitivities and specificities for detection of abnormal red reflex.<sup>18</sup>

Sunil Mamotra, Maria Teresa et al had concluded that cellphone-based fundoscope D-eye improves the accuracy of fundal examination by non-ophthalmologists as compared to traditional direct ophthalmoscope.<sup>19</sup>

Primary healthcare workers may be trained for the usage of cell phone-based ophthalmoscopes such as OptiCard so that community-based screening of cataracts may be done that is the leading treatable cause of blindness.<sup>20</sup> Red reflex screening should be included in the expanded program of immunization (EPI) card and checkboxes may be given for screening at birth, 6 months, 1 year, 5 years, and lastly, at 6 years, as recommended by the American Academy of Pediatrics (AAP).

There are certain limitations of the study such as the study was conducted only on neonatal age group, and red reflex in older age groups was not seen using Opticard. Moreover, comparison of OptiCard with traditional direct handheld ophthalmoscope was done for viewing red reflex only, and retinal examination was not done.

A cell phone-based application of the EPI vaccination card is being developed for the vaccination record of every child in Pakistan and photos of the red reflex may be uploaded in the application. The photos may be evaluated by ophthalmologists who may then decide if any baby requires formal evaluation. The images of normal red reflexes and leukocoria may be used to train algorithms in data science to detect cataracts, retinoblastoma, etc without the need for evaluation by a physician.

### Conclusion:

Cellphone-based fundoscope OptiCard has good diagnostic accuracy for detecting abnormal red reflex and it allows the images of pupillary glow to be stored for a photo follow-up.

**Ethical Approval:** Given

**Conflict of Interest:** The authors declare no conflict of interest.

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