Refractive And Ocular Indices In Kindergarten Israeli Children

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<u>Declarations</u>	26
• The authors have no relevant financial or non-financial interests to disclose.	27
• The authors have no conflicts of interest to declare that are relevant to the content of this article.	28
• All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.	29
• The authors have no financial or proprietary interests in any material discussed in this article.	30
• This is a retrospective cross-sectional study. The Israeli Ministry of Health, as well as local ethical committees have confirmed that no ethical approval is required, because the results obtained using the PlusoptiX S12 device do not include the name or ID number of the participants in it, so the results are completely anonymous.	31
• Informed consent was gained from the parents of all participants.	32
• All data stored contains no patient-identifiable data.	33
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<u>Abstract</u>	51
Purpose: To report normative data on paediatric refractive and ocular indices in kindergarten Israeli children.	52 53
Methods: Retrospective cross-sectional study of 101,417 Israeli children from 4-5 years old, obtained from 2013-2018. Data was collected using the PlusoptiX S12. We studied the number of referrals made for hyperopia, myopia, astigmatism and anisometropia.	54 55 56 57
Results: Mean sphere value was $0.83D \pm 0.73$ for the right eye and $0.85D \pm 0.73$ for the left eye. Mean SE was $0.56D \pm 0.66$ for the right eye and $0.59D \pm 0.67$ for the left eye. Mean cylinder value was $-0.53D \pm 0.48$ for the right eye and was the same, $-0.53D \pm 0.47$, for the left eye. Mean axis values for the right and left eyes were $80.85^\circ \pm 55.57$ and $80.42^\circ \pm 56.60$ respectively. Mean pupil size was $5.83\text{mm} \pm 0.87$ for the right eye, and $5.82\text{mm} \pm 0.88$ for the left eye. 13.26% had anisocoria $\geq 0.4\text{mm}$; of these, 0.66% had anisocoria $> 1.0\text{mm}$. There was no difference in pupil size between sexes or different cities. Mean IPD was $49.58\text{mm} \pm 3.50$, and mean gaze vector value was 2.64 ± 1.66 . According to the Vision Screening Guidelines, 0.8% of children had hyperopia and 0.17% had myopia. 6.22% of children had astigmatism and 10.85% had anisometropia.	58 59 60 61 62 63 64 65 66 67
Conclusion: Amblyopia is the most common cause of unilateral vision loss in childhood. The earlier the diagnosis, the better the outcome, hence the importance of investigating the causative indices leading to amblyopia in kindergarten. After searching the literature, this is the largest study population for this topic to our knowledge.	68 69 70 71 72 73
<u>Key words:</u> Amblyopia, Refractive, Ocular Indices, Paediatric.	74 75 76

<u>Introduction</u>	77
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Amblyopia has an incidence of 1-4% (1–4) and is the leading cause of unilateral vision	79
loss in children (5). Childhood is the critical period for diagnosis and management for	80
the best prognosis. Amblyopia risk factors are strabismus, anisometropia and media	81
opacity. The aim was to report normative data on paediatric refractive and ocular	82
indices in Kindergarten Israeli children.	83
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<u>Methods</u>	86
	87
In this retrospective cross-sectional study, data were collected by <i>Lions Clubs Israel</i>	88
volunteers during a screening programme to detect amblyogenic risk factors in children.	89
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Semi-darkened, minimally illuminated examination rooms were uniformly set up	91
across kindergartens in Israeli cities. Children were positioned one metre from the	92
device and instructed to fixate their eyes on a <i>smiling face</i> drawing. Pupils were not	93
dilated, and bilateral eye measurements were taken simultaneously. Measurements	94
were saved in the device, allowing retrospective retrieval of data.	95
	96
<i>Subjects</i>	97
101,417 Israeli children from 4 to 5 years old in kindergartens in major Israeli cities	98
were included. Data were collected from 2013 to 2018, and 50.3% of our subjects were	99
female. Exclusion criteria were those wearing glasses, and those without parental	100
consent.	101

	102
<i>Variables</i>	103
Using the PlusoptiX S12, we collected data on sphere, cylinder and axis. Spherical	104
equivalent (SE) was calculated from sphere and cylinder. Measurements were taken on	105
pupil size, gaze vector value, and interpupillary distance (IPD). We studied the number	106
of referrals made for hyperopia, myopia, astigmatism and anisometropia. We chose the	107
PlusoptiX S12 as it has high sensitivity and specificity (6) and its results correlate with	108
the refractive results from retinoscopy, the gold standard (7).	109
	110
<i>Ethical issues</i>	111
The Israeli Ministry of Health, as well as local ethical committees (The Helsinki	112
Committee of Baruch Padeh Medical Center, and Bar-Ilan University Azrieli Faculty	113
of Medicine), confirmed that no ethical approval is required and approved the	114
examinations and data collection, because the results obtained using the PlusoptiX S12	115
device do not include the name or ID number of the participants in it, so the results are	116
completely anonymous and all data stored contains no patient-identifiable data. All	117
experiments were performed in accordance with relevant guidelines and regulations.	118
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<u>Results</u>	121
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The following data, including table 1 and table 2, were obtained from 101,417 children	123
from 2013 to 2018.	124
Table 1:	125

<i>Parameter</i>	OD	OS
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<i>Mean sphere</i>	0.83 D $\pm$ 0.73	0.85 D $\pm$ 0.73
<i>Mean spherical equivalent</i>	0.56 D $\pm$ 0.66	0.59 D $\pm$ 0.67
<i>Mean cylinder</i>	-0.53 D $\pm$ 0.48	-0.53 D $\pm$ 0.47
<i>Mean axis</i>	80.85° $\pm$ 55.57	80.42° $\pm$ 56.60
<i>Mean pupil size</i>	5.83mm $\pm$ 0.87	5.82mm $\pm$ 0.88
<i>Mean interpupillary distance</i>	49.58mm $\pm$ 3.50	
<i>Mean gaze vector</i>	2.64 $\pm$ 1.66	

Table 1: Mean values of refractive and ocular indices in 4 to 5-year-old kindergarten 126

Israeli children. 127

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Table 2: 129

<i>Anomalies</i>	
<i>Anisocoria ≥ 0.4 mm</i>	13,448 children (13.26%)
<i>Anisocoria 0.5 – 0.9 mm</i>	6,314 children (6.23%)
<i>Anisocoria > 1.0 mm</i>	669 children (0.66%)
<i>Hyperopia</i>	807 children (0.80%)
<i>Myopia</i>	171 children (0.17%)
<i>Astigmatism</i>	6,307 children (6.22%)
<i>Anisometropia</i>	11,008 children (10.85%)

Table 2: Number of children with anomalies detected out of 101,417 kindergarten 130

Israeli children. 131

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Discussion

Amblyopia is the most common cause of unilateral vision loss in childhood, with an incidence of 3-5% (5,8). It is susceptible to diagnosis and treatment until 10 years of age (9), and the earlier the diagnosis, the better the outcome (10), hence the importance of investigating the causative indices leading to amblyopia in kindergarten.

Larsson et al. (11) found a mean spherical equivalent (SE) of $0.64 \text{ D} \pm 0.70$ for the right eye and $0.67 \text{ D} \pm 0.80$ for the left in 10-year-old Swedish children, similar to our data of $0.56 \text{ D} \pm 0.66$ for the right eye and $0.59 \text{ D} \pm 0.67$ for the left. Sandfeld et al. (12) studied 445 Danish children from 4.5 to 7 years old, finding $1.75 \text{ D} \pm 0.97$ and $1.72 \text{ D} \pm 0.96$ for right and left eye, respectively. Mayer et al. (13) found a mean SE of $1.13 \text{ D} \pm 0.85$ for both eyes in 2-year-old US children. The difference of these two studies compared to our findings could be due to the non-standardised lighting conditions, and the fact that we used non-cycloplegic refraction, so we could not eliminate accommodation as a confounding variable. Hence, our results likely underestimated the refraction, mainly in hyperopes. A previous study from our group (7) found the differences between cycloplegic refraction and PlusoptiX photoscreening to be $0.68 \text{ D} \pm 2.63$ and $0.25 \text{ D} \pm 1.31$ respectively for mean SE.

Larsson et al. (11) reported a mean cylinder value of $-0.43 \text{ D} \pm 0.26$ for the right eye and $-0.44 \text{ D} \pm 0.28$ for the left eye, similar to our findings of $-0.53 \text{ D} \pm 0.48$ for the right eye and $-0.53 \text{ D} \pm 0.47$ for the left eye. They found with-the-rule astigmatism to equal against-the-rule, whereas Sandfeld et al. (12) found mostly with-the-rule and Mayer et al. (13) found mostly against-the-rule. The different instruments used for collecting

data could be responsible for these differences, as discussed in our previous study ^[7],
that using non-cycloplegic refraction like the PlusoptiX finds a mean cylinder of -0.66
 ± 0.77 , whereas cycloplegic refraction finds -0.61 ± 0.74 . Another cause of the
discrepancy could be the differences in lighting conditions (14).

Few reports exist on normative data concerning pupil size, anisocoria and laterality in
children. Using an infrared pupillometer, Silbert and colleagues (15) studied 1,306
children, finding an average pupil size of 5.92 mm for 4- to 7-year-old children, with
no significant difference between left and right pupillary sizes. 219 children (16.77%)
had anisocoria of 0.5-0.9 mm, and 30 children (2.3%) had anisocoria of > 1.0 mm. This
is similar to our findings of $5.83\text{mm} \pm 0.87$ for the right pupil and $5.82\text{mm} \pm 0.88$ for
the left. 13.26% (13,448 children) were found to have anisocoria $\geq 0.4\text{mm}$; of these,
6.23% (6,314 subjects) had anisocoria of 0.5-0.9mm, and 0.66% (669 subjects) had
anisocoria of $> 1.0\text{mm}$. Boev and colleagues (16) studied 90 children, finding average
pupillary resting diameter in ambient lighting conditions to be 4.11 mm for 2- to 6-
year-olds. The difference could be due to the fact that Silbert and colleagues ^[16] used a
PlusoptiX device as we did, whereas Boev and colleagues (16) used a Neuroptic
device. Discrepancies could also be due to the fact that we studied over 100,000
children between only 4 and 5 years old, whereas Silbert and colleagues studied
children up to the age of 17 years, and Boev and colleagues up to 18 years.

MacLachlan C and Howland HC (17) studied interpupillary distance (IPD) of 155
males with average age 5.48 years and 144 females with average age 5.48 years,
reporting a mean of $52.02\text{ mm} \pm 2.55$ for males and $51.03\text{ mm} \pm 2.65$ for females. Our
results were lower, with a mean of $49.58\text{ mm} \pm 3.50$ for both sexes, possibly due to the

measuring technique. Discrepancies could also be due to differences in the populations; 186
little is known regarding the influence of ethnicity. 187
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We found no statistical correlation between pupil size and SE, which had a Pearson 189
correlation for the right eye of 0.053, and left eye of 0.033. There was also no significant 190
correlation between pupil size and IPD, which had a Pearson correlation for the right 191
eye of 0.192, and left eye of 0.189. 192
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We based our amblyopia risk factor thresholds for referral on the AAPOS revised 194
screening criteria (18); for children over two years, the threshold for hyperopia is > 3.5 195
D, myopia is > -1.5 D, astigmatism is > 1.5 D, and anisometropia is > 1.5 D. We had a 196
total of 15,362 referrals (15.15%) out of 101,417 children. 807 children (0.80%) had 197
hyperopia and 171 children (0.17%) had myopia. 6,307 children (6.22%) had 198
astigmatism and 11,008 children (10.85%) had anisometropia. According to Dan 199
Huang et al. (19) who studied Chinese children aged 3 to 4 years also using a PlusoptiX 200
device, only 14 children (3.90%) out of 359 had refractive amblyopia risk factors; 2 201
(0.56%) had hyperopia, 10 (2.79%) had astigmatism, 3 (0.84%) had anisometropia. 202
Their significantly lower referrals are possibly due to population differences; different 203
ethnicities were studied, although of a similar age group. Li Deng and Jane E. Gwiazda 204
(20) investigated anisometropia in 1,827 US Children by non-cycloplegic retinoscopy. 205
They found a prevalence of 1.96% at 6 months, 1.27% at 5 years, and 5.77% from 12 206
to 15 years. Surprising, they found a lower prevalence of anisometropia despite using a 207
lower threshold for referral of 1.0 D. 208
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The effects of the potentially low sensitivity of the PlusoptiX S12, resulting in false negatives, may have resulted in a falsely lower number of referrals. Noelle S. *et al.* (21) studied amblyopia risk factors with the PlusoptiX S04 and found a sensitivity of 98% and a false negative rate of 1.4% based on the old AAPOS screening criteria. For further studying, the sensitivity of the PlusoptiX S12 could be investigated against the current AAPOS screening guidelines.

After searching the literature on amblyopia, paediatric normal ocular indices, refractive error in paediatric population, this is the largest study population for this topic to our knowledge, which is one of the major strengths of this study. However, this study only represents Israeli children, not the general paediatric population. We tested children of a specific age, 4 to 5 years old, denying us the opportunity to study the dynamics of changes throughout development. Data was not collected on comorbidities and drug history, potential confounding variables affecting pupil size. Although examination rooms were standardised, we were not able to provide conditions for dark adaptation. However, although pupil size is affected by varying ambient lighting, Ettinger and colleagues (14) showed that a tenfold change in luminance caused no more than a 1mm change in pupil size, so variability should not significantly affect our study.

For further studying, we propose that more data from other geographic areas and among other age groups should be done to further establish normative data, producing data that could be used worldwide.

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