



# Effect of cycloplegia on the refractive status of children



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Background: The American Optometric Association (AOA), in its 2017 Recommendation for Clinical Practice, proposed cycloplegic testing when initially screening preschool children to detect potential vision-impairing diseases such as strabismus, amblyopia and anisometropia.

Aim: This study aims to detect the effect of cycloplegia on the measurement of refractive errors in children.

**Setting:** Ophthalmology department, Al-Azhar University, Egypt.

Methods: This retrospective interventional study included 388 children with refractive error attending our outpatient clinic in the ophthalmology department, at Al-Azhar University between January 2020 and April 2022. Cycloplegia was induced in each child with topical eye drops of 1% cyclopentolate instilled two times at 5-min intervals. The same optometrist repeated an auto-refraction 30 min after the last eye drop was applied.

Results: We compared the pre- and post-cycloplegic refractions and found that the sphere, spherical equivalence and cylinder had significant hypermetropic shift after cycloplegia (P = 0.001).

Conclusion: Cycloplegic refractions are more accurate and eliminate the risk of inaccurate refractive error findings, which is essential when managing children.

**Contribution:** This article provides valuable insight, which may inform public health policy.

Keywords: ophthalmology; refractive errors; sphere; cycloplegia; myopia; hypermetropia; cyclopentolate.

### Introduction

Visual impairment, particularly treatable ocular diseases such as refractive errors, is a significant public health issue among children. The most frequent types of refractive errors are myopia, hypermetropia and stigmatism. Young children have a high prevalence of uncorrected refractive defects, which are frequently correctable with glasses or contact lenses.<sup>2,3</sup> Hashemi et al. reported the estimated prevalence of myopia, hypermetropia and astigmatism in children was 11.7%, 4.6% and 14.9%, respectively.4 As a result, accurate refractive status evaluation and adequate corrective procedures are critical for vision screening, particularly in epidemiological research. 5,6,7

Refractive error can be assessed using an autorefractor or optometer.8 Myopia is diagnosed when the spherical equivalent is -0.50 dioptres (D) or more negative, while hypermetropia is diagnosed when the spherical equivalent is more than +2.00 D.9

Refractions without cycloplegia may result in significant inaccuracies because of changes in the accommodation of the patient during the measurements to overcome this active accommodation response, cycloplegic refraction is recommended especially in children. An overestimation of myopia or underestimation of hyperopia is the most frequent misclassification of the refractive status.<sup>11,12</sup> A cycloplegic paediatric evaluation requires the practitioner to make numerous judgements such as which cycloplegic medicines to employ, optimal dose, preferable route of administration and possible side effects. Cycloplegics temporarily paralyse the accommodation system by acting on the ciliary body and inhibiting the acetylcholine receptor site. 13

There are five drug options available for cycloplegia (atropine, homatropine, scopolamine, tropicamide and cyclopentolate). Several studies have evaluated the efficacy of each of them. As atropine is the strongest cycloplegic drug, it has been referred to as the 'gold standard' for a thorough cycloplegic examination.14 Atropine can cause cycloplegia and mydriasis that can last up to 14 days, while scopolamine only has a three-day duration of effect. 15 Homatropine begins to

work within an hour and continues to do so for 1 to 3 days.<sup>15</sup> Tropicamide's mydriatic effect, which lasts for 1 h to 2 h, is stronger than its cycloplegic effect.<sup>15</sup> The most widely used cycloplegic drug, cyclopentolate, reaches its maximal effect within 30 min after instillation and continues to work for up to 24 h.<sup>13,16</sup>

The American Optometric Association (AOA), in its 2017 Recommendation for Clinical Practice, proposed cycloplegic testing when initially screening preschool children to detect potential vision-impairing conditions such as strabismus, amblyopia and anisometropia. Because these conditions can lead to long-term vision impairment, cycloplegic refractions are recommended to diagnose and treat these conditions early.

This study aims to determine the effect of cycloplegia on the measurement of refractive errors in children.

## Research methods and design

This retrospective interventional study included 388 children with refractive error attending the outpatient clinic in the ophthalmology department between January 2020 and April 2022. This study was guided by Helsinki Declaration principles. The inclusion criteria were: (1) age < 12 years old, (2) myopia or hyperopia or compound, myopic astigmatism and (3) normal intra-ocular pressure (IOP  $\leq$  21 mmHg). The exclusion criteria were: (1) previous ocular surgery, (2) any diagnosed ocular disease, (3) history of ocular trauma and (4) irregular astigmatism on corneal topography.

#### Data collection

Full detailed history and general examination were performed on each patient. Comprehensive ophthalmic examinations were performed before and after cycloplegia, including uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA) and autorefraction by Topcon RM 800 (Topcon health care, Japan).

Cycloplegia was induced in each child with topical eye drops of 1% cyclopentolate two times at 5-min intervals. The same optometrist repeated an auto-refraction 30 min after the last eye drop was applied. We considered the cycloplegia was complete when the diameter of the pupil was greater than 6 mm.

Refraction data included the following parameters: sphere (S), spherical equivalence (SE), cylinder (C) and axis ( $\theta$ ). Spherical equivalence of more than -0.5 D was diagnosed as myopia. Spherical equivalence of more than +1.0 D was diagnosed as hyperopia.

### Statistical analysis

Statistical analysis was performed using the SPSS version 26 (IBM Corp., Armonk., New York, United States). The normality of the data was tested by the Kolmogorov–

Smirnov test. As all data were not parametric, we presented the quantitative data as medians and interquartile range (IQR). Categorical variables were described as numbers (*n*) and percentages (%). Categorical data were compared using the McNemar test. Continuous paired data were compared using the Wilcoxon test and continuous non-paired data were compared using the Mann–Whitney *U*-test. *P*-values less than 0.05 were considered statistically significant.

#### **Ethical considerations**

Ethical approval was obtained from the Institutional Review Board of the Faculty of Medicine, Damietta (reference number 00012367-21-09-006). Written informed consent was obtained from a parent of each child. Also, our study was registered on the Clinicial Trial website (registration number NCT05585736), available at https://clinicaltrials.gov.

### Results

Our study included 388 children with either a myopic or a hypermetropic refractive error. Table 1 shows the demographic characteristics of the patients; the median age of the patients was 6 and IQR 5–8 years, with 51% of the included patients under the age of 6 years and other patients were in the age category of > 6 years. Fifty-one per cent of the patients were females. Myopia represents 51% of the included children and hypermetropia represents the remainder.

We compared the pre- and post-cycloplegic refractions, and we found that the sphere, spherical equivalence and cylinder had significant hypermetropic shift after cycloplegia (P = 0.001) (Table 2). The median sphere changed significantly from 0.25 D before cycloplegia to 1.25 D post-cycloplegia

TABLE 1: Demographic characteristics of the patients.

Variable	n	%
Age (years)		
≤ 6	198	51
> 6	190	49
Gender		
Male	190	49
Female	198	51
Type of refraction before cyclop	olegia	
Myopia	197	51
Hypermetropia	191	49

Note: Age (years): Median, 6; interquartile range, 5–8; range, 2–10.

 TABLE 2: Comparison between the pre- and post-cycloplegic refraction.

Outcome	Pre-cycloplegia		Post-	P	
	Median	IQR	Median	IQR	
Sphere (D)	0.25	- 0.50 – 1.25	1.25	0.25 - 2.75	0.001*
Spherical equivalence (D)	-0.12	-1.50 – 1.50	1.25	-0.37 – 3.10	0.001*
Cylinder (D)	-0.50	-1.75 – 0.75	0.50	-1.50 - 1.10	0.001*
Axis (°)	92.00	49.00 - 163.00	89.00	73.00 - 145.00	0.230

Note: P-values were calculated using the Wilcoxon test.

IQR, interquartile range.

<sup>\*,</sup> Significant difference.

with a median difference of 0.75 D (P = 0.001). The median SE changed from -0.12 D before cycloplegia to 1.25 D after cycloplegia with a median change of 1.05 D (P = 0.001). Also, the cylinder had changed from -0.5 D pre-cycloplegic to 0.5 D after cycloplegic with a median difference of 0 D and mean difference of 0.4 D (P = 0.001). However, we found no significant difference between the pre- and post-cycloplegic axis (P = 0.23).

Table 3 shows the distributions of sphere, SE, cylinder and axis before and after cycloplegia, stratified by age. All these differences before and after cycloplegic refraction were statistically significant (P = 0.001), except for the axis in which there was no significant difference between the pre- and post-cycloplegic axis (P > 0.05). However, in Table 4, we compared between the two age categories that included in our study either  $\leq 6$  years or > 6 years with regard to all measured refractions, and we found that no significant difference between them (P > 0.05).

In our study, myopia significantly decreased from 50.7% before cycloplegia to 29.8% post-cycloplegia (P=0.001); however, we found a significant increase in the percentage of the hypermetropia, which increased from 49.2% before cycloplegia to 70.01% after cycloplegia (P=0.001) (Table 5 and Figure 1).

A Spearman's correlation analysis was performed to detect correlation between the age and the change of refractive measurements, and we found no statistically significant correlation between the age and the sphere, SE and the cylinder (P > 0.05). However, we found a weak positive correlation between the axis change and the age (r = 0.1, P = 0.02) (Table 6).

### **Discussion**

One of the most common reasons for impaired vision in Egyptian children is uncorrected refractive errors, representing 90% of the causes of visual impairment and 1.1% of the reasons for legal blindness. Refractive errors may affect any age category; however, the children are the

critical category; as if it is not corrected or corrected improperly, it may result in amblyopia, which will affect the educational and learning process of the children.<sup>19</sup>

Accurate correction of the refractive errors in children is challenging, because of the high accommodation power in children, which may affect the accuracy of measurement.<sup>20</sup> According to the literature, non-cycloplegic auto-refraction overestimates myopia and underestimates hyperopia in children with functional accommodative responses.<sup>21</sup>

Our study included 388 children with refractive errors. In our study, the most prevalent refractive error is myopia, which represent 51% of the included patients. This agrees with the result of Loday Bhutia et al.<sup>22</sup> and Mostafa et al.<sup>18</sup> Also, we found that refractive error in females is more prevalent than

**TABLE 4:** Comparison between the age categories based on the mean difference of measured outcomes.

Outcomes	Age ≤ 6 years		Age >	P	
_	Mean	IQR	Mean	IQR	
Sphere difference	0.75	0.25 - 1.75	1.00	0.25 - 1.75	0.5
Spherical equivalence difference	1.00	0.30 – 2.15	1.00	0.30 - 1.80	0.6
Cylinder mean difference	0.00	-0.25 – 0.40	0.00	0.00 - 0.50	0.4
Axis difference	-0.50	-8.00 - 5.00	-0.00	-4.2 – 5.00	0.3

Note: P-values were calculated using the Mann–Whitney test

s.d., standard deviation; IQR, interquartile range.

**TABLE 5:** Comparison between the pre- and post-cycloplegia as regarding to percentages of the patients with myopia or hypermetropia.

Variables	N	Pre-cycloplegia		Post-cycloplegia		P
	_	n	%	n	%	
≤ 6 years	198					0.001*
Myopia		107	54.03	61	26.90	
Hypermetropia		91	45.90	137	69.10	
> 6 years	190					0.001*
Myopia		90	47.30	55	28.90	
Hypermetropia		100	52.60	135	71.05	
Overall years	388					0.001*
Myopia		197	50.70	116	29.80	
Hypermetropia		191	49.20	272	70.01	

Note: P-values were calculated using the McNemar test.

TABLE 3: Comparison between the pre- and post-cycloplegic refraction based on the age category of the studied patients.

Outcome	Pre-cycloplegia Pre-cycloplegia		Post-cycloplegia		P
_	Mean	IQR	Mean	IQR	
Sphere (D)					0.001*
≤ 6 years	0.25	-0.50 - 1.06	1.00	0.25 – 2.75	
> 6 years	0.25	-0.75 – 1.25	1.25	0.25 - 2.56	
Spherical equivalence (D)					0.001*
≤ 6 years	-0.25	-1.25 – 1.30	1.10	-0.25 – 3.04	
> 6 years	0.06	-1.60 - 1.60	1.30	-0.47 – 3.00	
Cylinder (D)					0.001*
≤ 6 years	-0.75	-1.75 – 1.00	0.30	-1.50 – 1.25	
> 6 years	-0.50	-2.25 – 0.50	0.50	-2.00 – 1.00	
Axis (°)					
≤ 6 years	94.00	68.25 - 165.20	89.00	71.50 – 148.20	0.100
> 6 years	88.00	21.75 – 162.00	89.00	73.70 – 145.20	0.840

Note:  $\ensuremath{\textit{P}}\xspace$ -values were calculated using the Wilcoxon test.

<sup>\*,</sup> Significant difference.

IQR, interquartile range

<sup>\*,</sup> Significant difference.

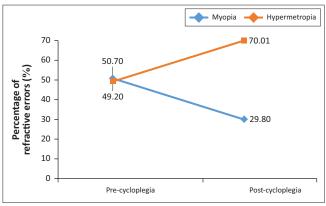


FIGURE 1: The percentages of refractive errors pre- and post-cycloplegia.

**TABLE 6:** Spearman's correlation analysis between the age of the patients and the mean difference of the measured outcomes.

Parameter (mean difference)	Age		
_	r	P	
Sphere	-0.010	0.70	
Spherical equivalence	-0.005	0.90	
Cylinder	0.030	0.50	
Axis	0.100	0.02	

males, which agrees with in-depth study performed on Egyptian children by Abdelrheem et al.,<sup>23</sup> and reported that 1723 children from a sample of 14787 children had a refractive error with female percentage of 51%, which is similar to our finding. We compared the refractive error in our study preand post-cycloplegia by measuring the sphere, cylinder, SE, and we found that myopia was prevalent before cycloplegia, which was shifted to hypermetropia after cycloplegia; this is in line with the finding of Zhu et al.,<sup>24</sup> who found that myopic prevalence reduces when cycloplegic examination findings are considered. The mean difference of SE between pre- and post-cycloplegia was 1.38 D.

In a study performed on 42 eyes by Moghaddam et al.,25 to evaluate the cycloplegic effect on the ocular biometrics, they found a mean difference of 0.22 D with a significant hyperopic shift in cycloplegic refraction. In another study of 5999 children, Hu et al.26 found the mean difference of 0.78 D between the cycloplegic and non-cycloplegic refraction. Zhu et al.24 found a mean difference of 0.57 D between cycloplegic and non-cycloplegic refraction. The difference between our study and other studies may be because of different characteristics of the study subjects, such as ethnicity, age and the methods of refraction measurement such as objective versus subjective; different methods of objective refraction; etc. and cycloplegia. The cycloplegic effect may be different depending on the type of cycloplegia; the cycloplegic effect of tropicamide was much less than that of cyclopentolate in children.<sup>21</sup> Although atropine is considered the most powerful medicinal cycloplegic agent, 27,28 it is not available in our areas such as cyclopentolate availability.

The SE difference between pre- and post-cycloplegia was correlated with the age of the patients (very weakly), which is in line with the finding of Li et al.<sup>21</sup> Suggesting

that age had a big role in accommodation and the mean difference of SE change post-cycloplegia. The effect of accommodation on refractive measurements increases in younger patients.

#### Limitations

Limitations of our study included a short follow-up period and so longitudinal long-term follow-up is needed to assess the stability of refractive changes post-cycloplegia. Also, our study included Caucasian population only and a larger study of different ethnicities are needed to ensure that the findings are applicable to a wide population.

### Conclusion

Cycloplegia refractions are more accurate and eliminate the risk of inaccurate refractive error findings, which is essential when managing children.

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### **Competing interests**

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

### **Authors' contributions**

E.T. was responsible for designing and writing the protocol, collecting data and writing the report and was also responsible for drawing tables. M.H. was responsible for designing the protocol, analysing data, interpreting results and writing the report and contributed to writing the methodology. E.R.E. was responsible for the research topic choice, designing the protocol and editing the protocol and report. H.B.S. was responsible for the research topic choice, designing the protocol and editing the protocol and report. B.E. was responsible for the research topic choice, designing the protocol and editing the protocol and report. A.F.E. was responsible for the research topic choice, designing the protocol and editing the protocol and report. W.S.A. was responsible for the research topic choice, designing the protocol and editing the protocol and report. A.M.E.A. was responsible for the research topic choice, designing the protocol and editing the protocol and report.

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### Data availability

Raw data were generated at Al-Azhar University. Derived data supporting the findings of this study are available from the corresponding author, E.T., upon reasonable request.

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