

# Centre for Contact Lens Research

School of Optometry & Vision Science,  
University of Waterloo,  
Waterloo, Ontario, Canada.  
N2L 3G1  
Tel: 519-888-4742  
Fax: 519-888-4303  
<http://cclr.uwaterloo.ca>

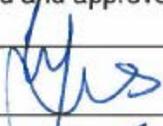


# Report

## MYOPIA PREVALENCE IN CANADIAN SCHOOL CHILDREN – A PILOT STUDY (FALCON)

**Sponsor:** Marc Tersigni ESSILOR CANADA (Montreal, QB), Howard Purcell, ESSILOR USA (Dallas, TX)

**CCLR study number:** P/441/13/E

	Reviewed and approved	Date DD/MM/YY
Principal investigator	Lyndon Jones: 	18 Jul 2016
Lead investigator	Mike Yang: 	18 Jul 2016
Report author	Mike Yang: 	18 Jul 2016
Quality assurance	Jill Woods: 	18 Jul 2016
Sponsor	MARC TERSIGNI 	20 July 2016



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## **Statement of Compliance**

This clinical study was designed to be in conformance with the ethical principles in the Declaration of Helsinki, with the ICH guidelines for Good Clinical Practice (GCP), with the University of Waterloo's Guidelines for Research with Human Participants and with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition.

- Declaration of Helsinki
- ICH E6 - International Conference on Harmonisation; Good Clinical Practice
- [https://uwaterloo.ca/research/sites/ca.research/files/uploads/files/uw\\_statement\\_on\\_human\\_research\\_access\\_checked.pdf](https://uwaterloo.ca/research/sites/ca.research/files/uploads/files/uw_statement_on_human_research_access_checked.pdf)
- <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default>

## **Disclaimer**

This study was conducted for research purposes only and was not intended to be used to support safety and efficacy in a regulatory submission.

## EXECUTIVE SUMMARY

The purpose of this pilot study was to determine the prevalence of myopia in Canadian school children living in the Waterloo Region.

The study objectives were:

- Determine the proportion of children with spherical equivalent refraction of at least -0.50D in at least one eye
- Estimate the prevalence of myopia in each age group
- Examine the risk factors for myopia

The study was a cross-sectional design with two study visits, Visit 1 was completed at local schools, and children who were myopic were invited to the research centre for a cycloplegic examination at Visit 2.

173 participants were enrolled across three age groups: 85 between ages 6 to 8 (Grades 1-2), 83 between ages 11 to 13 (Grades 6-7) and 4 between ages 17 to 18 (Grades 11-12). Data collected from 166 eligible participants were used in the analysis of this report.

Date first participant seen	Dec 06, 2013
Date of last study visit	Apr 28, 2015

Results:

- 17.5% of children had a spherical equivalent refraction of at least -0.50D in at least one eye.
- The prevalence of myopia increased from 6.0% at age 6-8 to 28.9% at age 11-13.
- 34.5% of the myopic children in the study were uncorrected, which represented 6.0% of the overall group of children tested.
- Mean spherical equivalent refraction in myopic children increased from -1.10D at age 6-8 to -2.44D at age 11-13.
- Axial length increased from 22.62 mm at age 6-8 to 23.65 mm at age 11-13. In general, 1mm change in axial length is equivalent to 2.50D change in refractive error.<sup>1</sup>
- Outdoor activity was the only modifiable risk factor in this study to have a statistically significant association with myopia. For one additional hour per week of outdoor activities, the odds of the child having myopia was lowered by 14.3%.

## 1 INTRODUCTION

The population of Canada is growing by ~3 million people every 10 years, primarily due to immigration.<sup>2</sup> More than 2/3 of the immigrants originate from countries with a high prevalence of myopia (near-sightedness), including East Asian countries and Europe.<sup>3</sup> The annual cost of vision loss in Canada has been estimated at \$15.8 billion in 2007,<sup>4</sup> with refractive error accounting for >60% of the health system expenditures.

The prevalence of myopia in 5-17 year-olds in the United States (US) is approximately 9%, ranging from 4-19% depending on the ethnic background,<sup>5</sup> and is almost 50% for 20-39 year olds.<sup>6</sup> Over the past few decades the prevalence of myopia has shown a strong increase worldwide<sup>7, 8</sup> and reports exist of >90% prevalence in some East Asian countries.<sup>9, 10</sup> The onset of myopia has shifted to a younger age<sup>11</sup> and the number of high myopes with prescriptions of >-5.00 dioptres has markedly increased, resulting in a growth in the number of related pathological complications such as myopic retinopathy, retinal detachment and glaucoma.<sup>8</sup>

## 2 OBJECTIVES

The objective of this pilot study was to determine the prevalence of myopia in school children living in Waterloo Region.

The primary outcome variable for this study was the number of children with a spherical equivalent refraction of at least -0.50D in at least one eye.

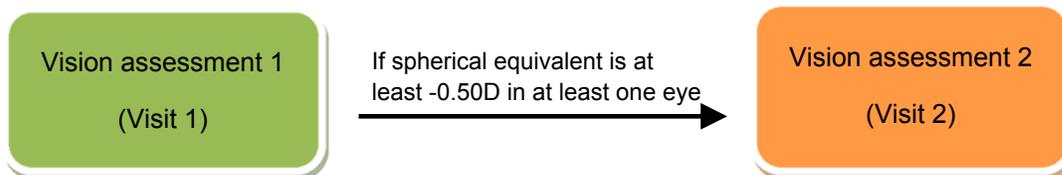
The secondary outcome variables include:

- The prevalence of myopia in each of 3 age groups
- Risk factors for myopia

## 3 MATERIALS AND METHODS

### 3.1 STUDY DESIGN

This study included up to two study visits. Participants were recruited from local schools in Waterloo Region and underwent an initial vision assessment (Visit 1). If a spherical equivalent refraction (SER) of at least -0.50D was found in at least one eye during Visit 1, participants were invited to attend Visit 2.



Written informed consent and assent were obtained from all participants prior to enrolment in the study. Ethics clearance was obtained through the Office of Research Ethics at the University of Waterloo, prior to commencement of the study.

## 3.2 STUDY VISITS

### 3.2.1 VISIT 1

Visit 1 procedures were mainly conducted at local schools. The investigator determined participant eligibility using the inclusion and exclusion criteria. Participants were assigned a study ID number. Ineligible participants were discontinued from the study. For detailed procedures see “Study Procedure” section 3.3 below.

### 3.2.2 VISIT 2

Visit 2 was conducted at the Centre for Contact Lens Research (CCLR) at the University of Waterloo. During Visit 2, refractive error and biometry were determined following cycloplegia, to provide more accurate results, which is particularly relevant for children.<sup>12</sup> A standard procedure typically used in optometry practice was followed: The eyes were anesthetised using one drop of 0.5% proparacaine hydrochloride (Alcaine, Alcon) instilled in both eyes. One minute after instillation one drop of 1% Tropicamide Ophthalmic Solution USP (Mydracyl, Alcon) was instilled. After five minutes another drop of 1% Tropicamide was instilled. The cycloplegic refraction was conducted 25 minutes after the last drop instillation.

## 3.3 STUDY PROCEDURES

The procedures conducted at each study visit are outlined in Table 1.

**Table 1: Study procedures/variables**

Study procedures/ variables		Visit 1 20 min	Visit 2 45 min
<b>Informed consent</b>	Child and parent/ legal guardian	X	
<b>Questionnaire</b>	Survey on family history of refractive corrections, child activities: outdoor/ indoor/ studying/ computer /video games (completed by the parents/guardian or child*)	X	
<b>Non-cycloplegic refraction</b>	Using an autorefractometer	X	
	Subjective refraction	X	
<b>Cycloplegic refraction</b>	Using an autorefractometer		X
	Subjective refraction		X
	Biomicroscopy assessment		X
<b>Visual acuity with subjective refraction</b>	Distance visual acuity (logMAR) high contrast, high illumination	X	X
<b>Ocular biometry (ultrasound)</b>	Measurement of central corneal curvature, anterior chamber depth, lens thickness, vitreous chamber depth and axial length	X Without cycloplegia	X With cycloplegia

### 3.4 PARTICIPANT RECRUITMENT

Approval was obtained from the research committee of the school boards in the region prior to the start of the study. Parental consent forms and prepaid return envelopes were delivered to classrooms for distribution, and signed consents were received at the CCLR before the initial Visit 1 were scheduled. Out of the 165 schools contacted about this study, 10 schools chose to facilitate data collection at their schools. 17 high schools were approached for distribution of consent forms and data collection at the schools. Due to low response rate from the school administration, we were unable to obtain permission to distribute consent forms at these schools. Only one high school program gave permission to recruit students from grade 11 to 12, of which only four students participated.

### 3.5 DATA ANALYSIS

Data analysis was conducted using Statistica 13 (Stat Soft, Inc) and SPSS (IBM, Inc). Descriptive statistics (mean, median, standard deviation, minimum, maximum) were conducted for the following variables in both eyes: age, gender, demographics and refractive error.

Prevalence of myopia was calculated for each age group, with myopia defined as a spherical equivalent of at least -0.50D in at least one eye. Mean and standard deviation were plotted for refractions and axial length. A paired t-test was used to compare measurements before and after cycloplegia.

Factors that may affect myopia development such as reported time spent on school work, reading, watching TV, computer, outdoor and indoor sports were analysed using simple binary logistic regression. These factors were analysed for their predictive value and correlation with whether the child had myopia. The exponent of the Beta coefficient—Exp(B) and its significance figure from SPSS binary logistic regression are reported. The percentage change in odds of having myopia was calculated by subtracting Exp(B) from the value 1.00, and the difference represented the percentage change in odds of myopia with 1 unit increase in one of the risk factors. Correlation between axial length and spherical equivalent refraction was determined using Pearson product-moment correlation in Statistica.

## 4 RESULTS

### 4.1 PARTICIPANTS

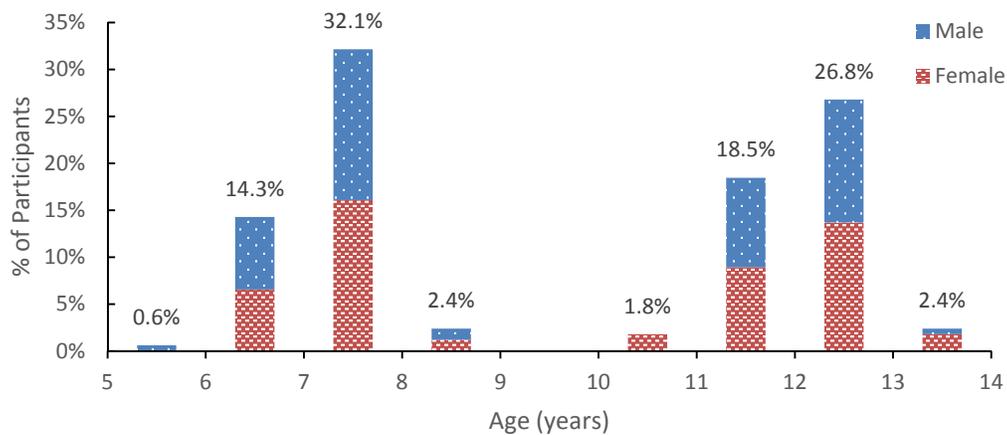
173 participants were enrolled in the study (89 female, 84 male). The mean age of the participants was 9.8 years (median 10.9 years, ranging from 5.9 to 18.2 years). Table 2 summarizes the participant characteristics according to their grade group.

**Table 2: Participant characteristics at Visit 1 (n=172, Mean ± SD)**

		Grade 1-2	Grade 6-7	Overall*	Grade 11-12
<b>Gender</b>	Male	43	39	82	1
	Female	42	44	86	3
<b>Age</b>	Mean ± SD	7.2 ± 0.6	12.1 ± 0.6	9.6 ± 2.5	17.9 ± 0.3
	Median	7.3	12.2	8.3	17.9
	Range	5.9 to 8.3	10.9 to 13.3	5.9 to 13.3	17.6 to 18.2
<b>Subjective refractive error OD (D)</b>	Sphere	0.19 ± 0.89	-0.34 ± 1.50	-0.07 ± 1.25	-3.00 ± 3.89
	Cylinder	-0.19 ± 0.47	-0.23 ± 0.48	-0.21 ± 0.47	-0.31 ± 0.31
<b>Subjective refractive error OS (D)</b>	Sphere	0.18 ± 0.90	-0.39 ± 1.54	-0.10 ± 1.29	-3.19 ± 3.59
	Cylinder	-0.18 ± 0.52	-0.27 ± 0.49	-0.22 ± 0.51	-0.44 ± 0.24
<b>Best Corrected LogMar VA</b>	OD	0.05 ± 0.09	-0.01 ± 0.06	0.02 ± 0.08	-0.07 ± 0.11
	OS	0.04 ± 0.08	-0.01 ± 0.06	0.01 ± 0.07	-0.08 ± 0.09
<b>Corneal cylinder (D)</b>	OD	-0.81 ± 0.97	-0.75 ± 0.55	-0.78 ± 0.79	-0.81 ± 0.65
	OS	-0.71 ± 0.57	-0.89 ± 1.24	-0.80 ± 0.96	-0.94 ± 0.9
<b>Axial Length (mm)</b>	OD	22.63 ± 0.76	23.62 ± 0.87	23.12 ± 0.96	24.17 ± 1.43
	OS	22.61 ± 0.78	23.64 ± 0.90	23.12 ± 0.98	24.22 ± 1.33

\*Gr1-2 and Gr6-7 were included in the overall group. Gr11-12 were reported separately, as it was a small group and was excluded from the rest of the analysis in this report. Participant ID 9 was excluded due to screen failure.

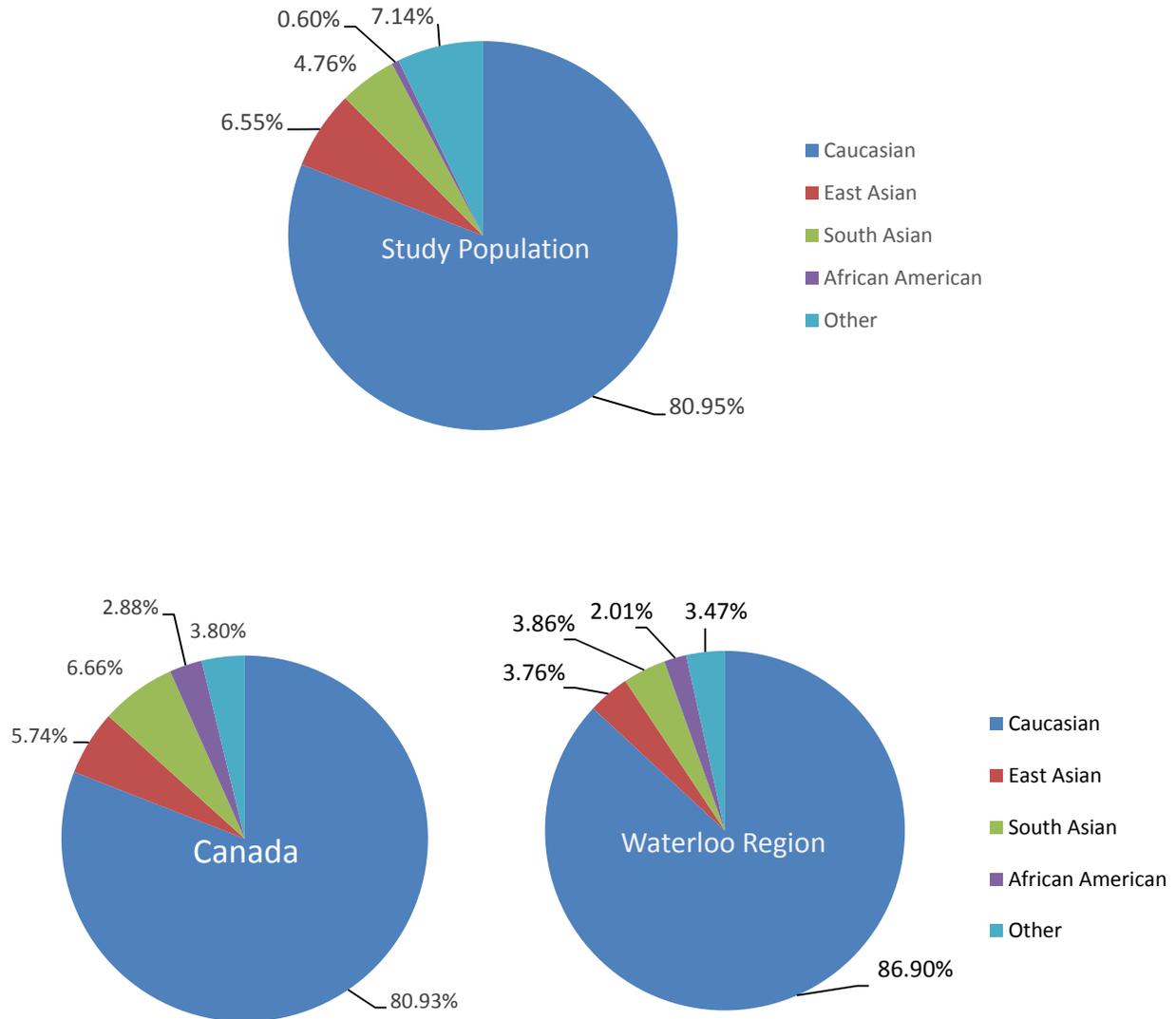
Refractions and Axial length results from above tables are analysed in more detail in section 4.6.2 and 4.8 of this report. Age distribution of the grade groups 1-2 and 6-7 can be visualized below in Figure 1.



**Figure 1: Frequency distribution of participant's age.**

## 4.2 DEMOGRAPHIC OF THE STUDY POPULATION

A comparison of the demographics of the study population with the demographics data of the region and of the country (Figure 2) from recent censuses showed that the study sample was a close representation of the general population.<sup>13, 14</sup> When children had more than one racial background, they chose “other” as their self-reported race.



**Figure 2: Comparison of Demographics of the study population with Demographic Data from Statistic Canada 2006 Census of Waterloo Region and 2011 Canadian Census.**

### 4.3 DISCONTINUATIONS

A total of eight participants were discontinued from the study before completing Visit 2 (Table 3). One participant did not meet the inclusion criteria at Visit 1 because of a history of amblyopia. One participant chose to withdraw from the study at Visit 2 because he chose not to undergo cycloplegia, the other six attended Visit 1 but did not return to attend Visit 2.

**Table 3: Participant discontinuations from the study**

ID	Reason for discontinuation	Time of discontinuation
9	Not eligible due to ocular history*	At Visit 1
39	Participant chose to discontinue due to inconvenience	At Visit 2
73	Participant lost to follow-up	After Visit 1
84	Participant lost to follow-up*	After Visit 1
117	Participant lost to follow-up	After Visit 1
155	Participant lost to follow-up*	After Visit 1
162	Participant lost to follow-up	After Visit 1
167	Participant lost to follow-up	After Visit 1

\*ID 9 excluded from analysis due to screen failure. Participant ID 84 and 155 were excluded from analysis as they had low myopia at V1 and were lost to follow-up before V2.

### 4.4 ADVERSE EVENTS

There were no adverse events during this study.

### 4.5 PROTOCOL DEVIATIONS

There were no protocol deviations during this study.

## 4.6 MYOPIA PREVALENCE AND REFRACTIVE DATA

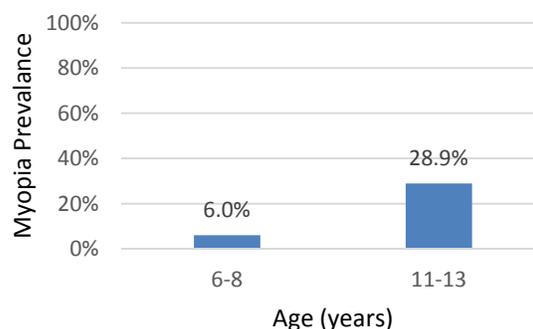
Prevalence was analysed using data from 166 eligible participants. Because of the low numbers in Grade 11-12 group, their data were not included in the subsequent analysis. Two participants from Gr 1-2 group were excluded, they were myopic at visit 1 but were lost to follow up at visit 2.

### 4.6.1 PREVALENCE DATA

Myopia was defined in the study protocol as having spherical equivalent refraction of at least -0.50D in at least one eye. By this definition, 17.5% of the total study population were myopic. Prevalence of myopia was further analyzed by age and gender (Table 4). Participants aged 11-13 had a higher prevalence of myopia (28.9%) compared to the 6-8 year olds (6.0%). The descriptive prevalence data below show females had a higher prevalence of myopia in both age groups. East and South Asians had higher prevalence compared to participants of other races (Table 5).

**Table 4: Myopia prevalence by age and gender**

		Count	Prevalence
<b>Ages 6-8</b>	Male	43	4.7%
	Female	40	7.5%
	<b>Overall</b>	<b>83</b>	<b>6.0%</b>
<b>Ages 11-13</b>	Male	39	28.2%
	Female	44	29.5%
	<b>Overall</b>	<b>83</b>	<b>28.9%</b>



**Figure 3: Myopia prevalence by age group**

**Table 5: Myopia prevalence by subject reported race**

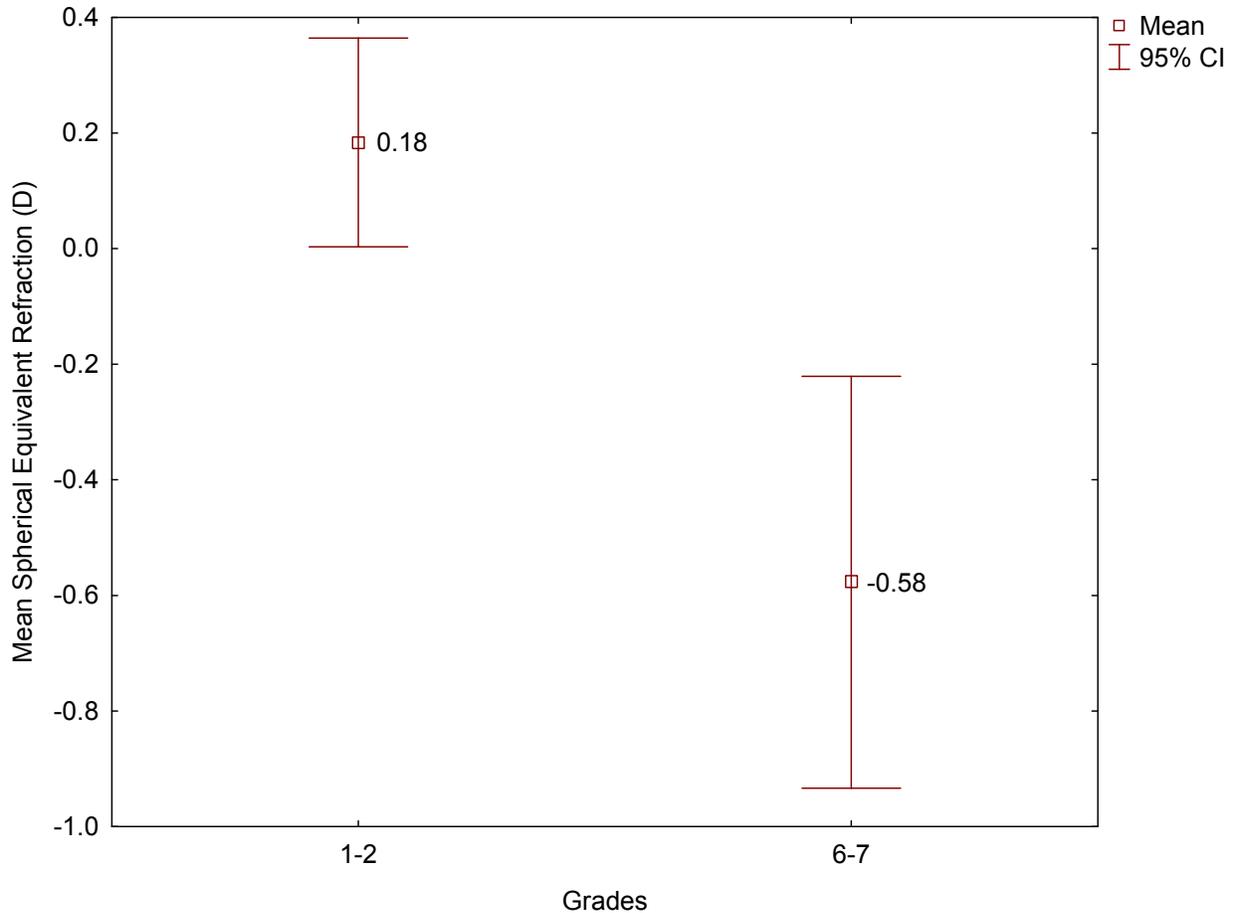
	Count	Prevalence
Caucasian	135	11.1%
East Asian	11	54.5%
South Asian	7	71.4%
Other	12	25.0%
African American	1	0.0%
Native	0	n/a
<b>Overall</b>	<b>166</b>	<b>17.5%</b>

Out of the 29 participants who were myopic in the study, 10 were uncorrected prior to the study, which amounted to 34.5% of the myopic children and 6.0% of the overall group. The parents of these 10 children were made aware of the refractive error and encouraged to seek professional eye care. 5 other participants were encouraged to seek eye care due to uncorrected or undiagnosed ocular conditions that was detected during the study such as hyperopia, irregular pupils, color deficiency, and amblyopia.

#### 4.6.2 SUBJECTIVE REFRACTIVE DATA

In addition to higher prevalence of myopia in older children, the degree of myopia was greater as well. When data from the more myopic eye (or least hyperopic eye) of each child was examined, 11 to 13 year olds had a statistically more minus mean SER than the 6 to 8 year olds (difference of -0.76D,  $p < 0.001$ ). (Figure 4) The data is further divided according to gender in Figure 5.

For children who met the definition of myopia, the mean subjective SER was -1.10D in children aged 6-8, and -2.44D in children aged 11-13 (Figure 6). The difference was -1.34D ( $p = 0.104$ ).



**Figure 4: Mean subjective spherical equivalent refraction of the more myopic eye of all children in Grades 1-2 (n=83) and 6-7 (n=83).**

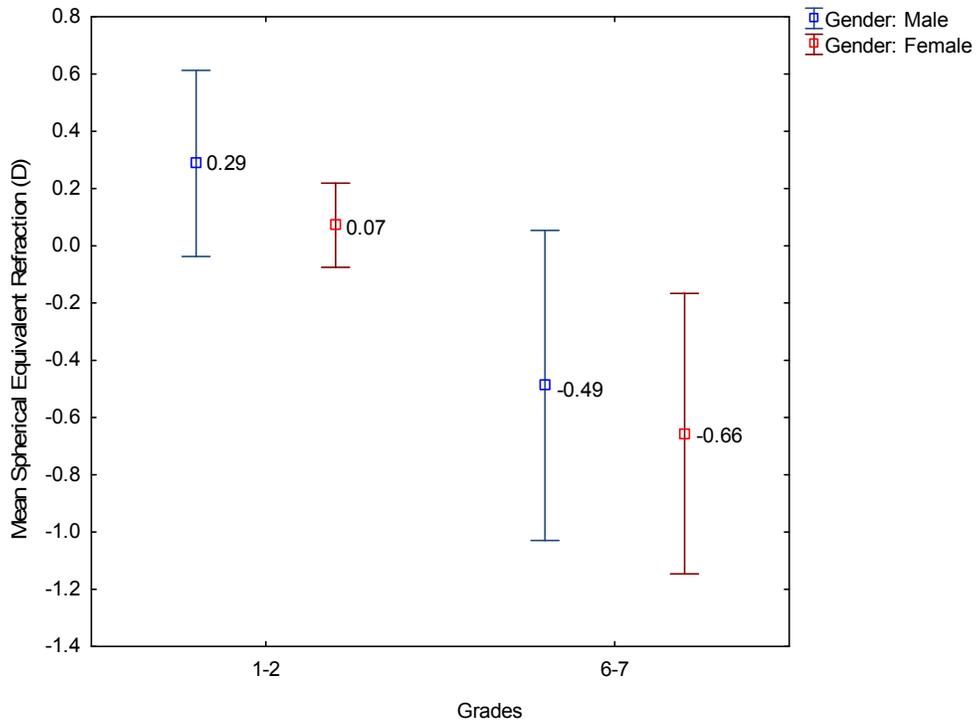


Figure 5: Mean subjective spherical equivalent refraction of the more myopic eye of all children in Grades 1-2 and 6-7, sub-grouped by gender. Vertical bars represent 95% confidence interval.

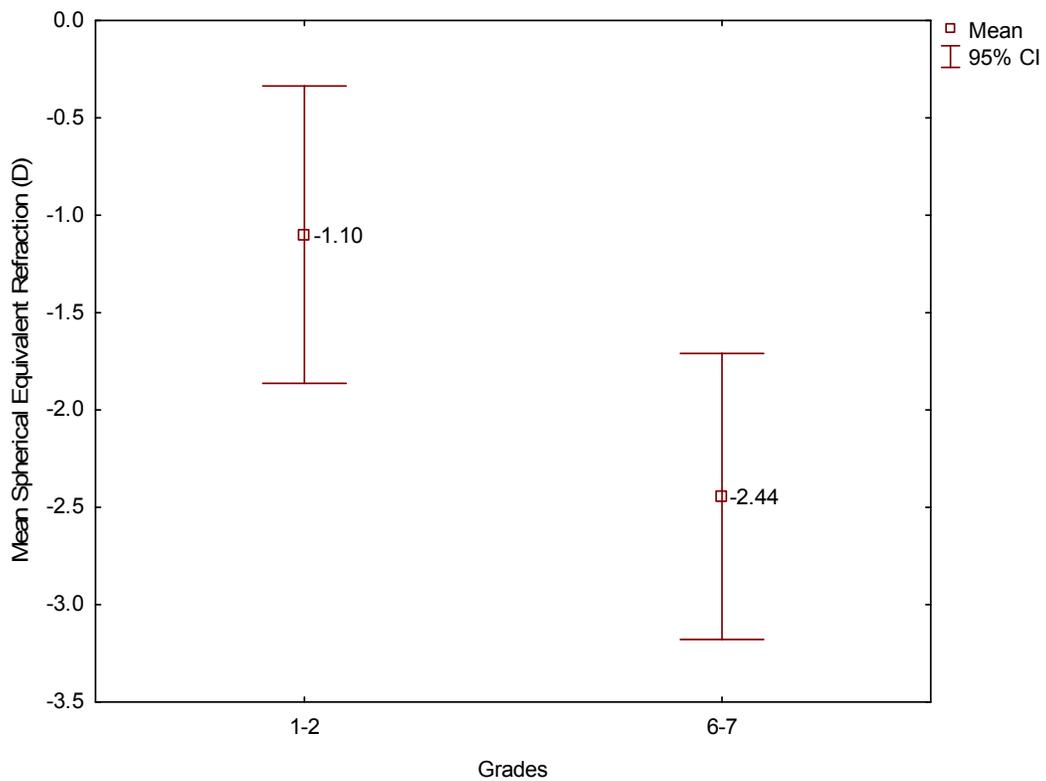


Figure 6: Mean subjective spherical equivalent refraction of the more myopic eye of only the myopic children in Grades 1-2 (n=5) and 6-7 (n=24).

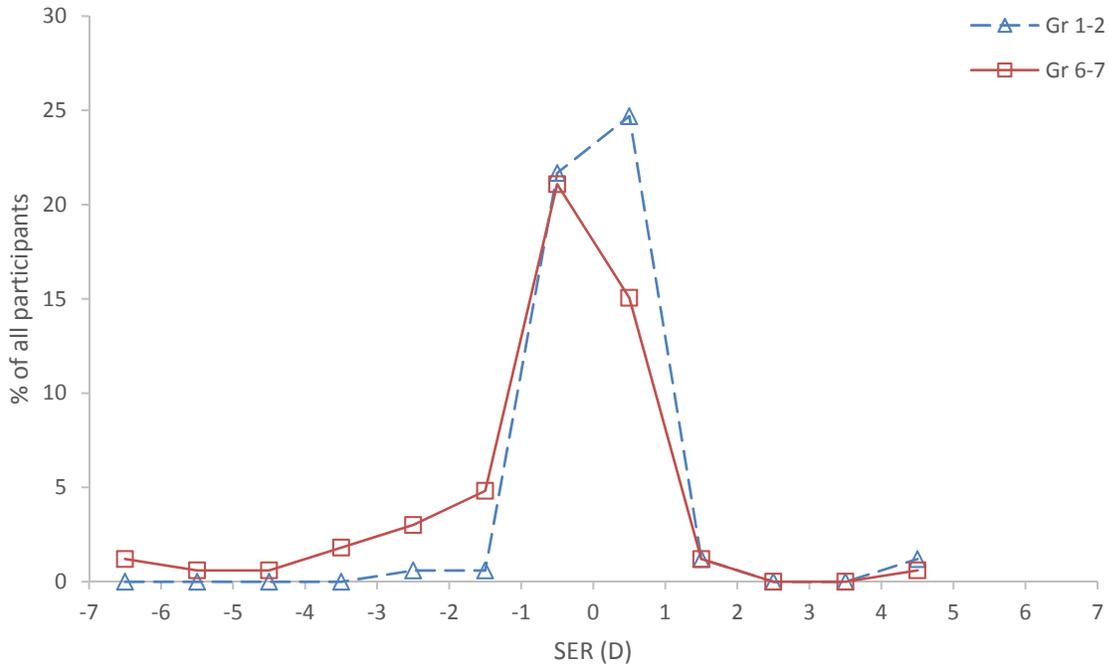


Figure 7: Frequency distribution of subjective spherical equivalent refraction (SER)

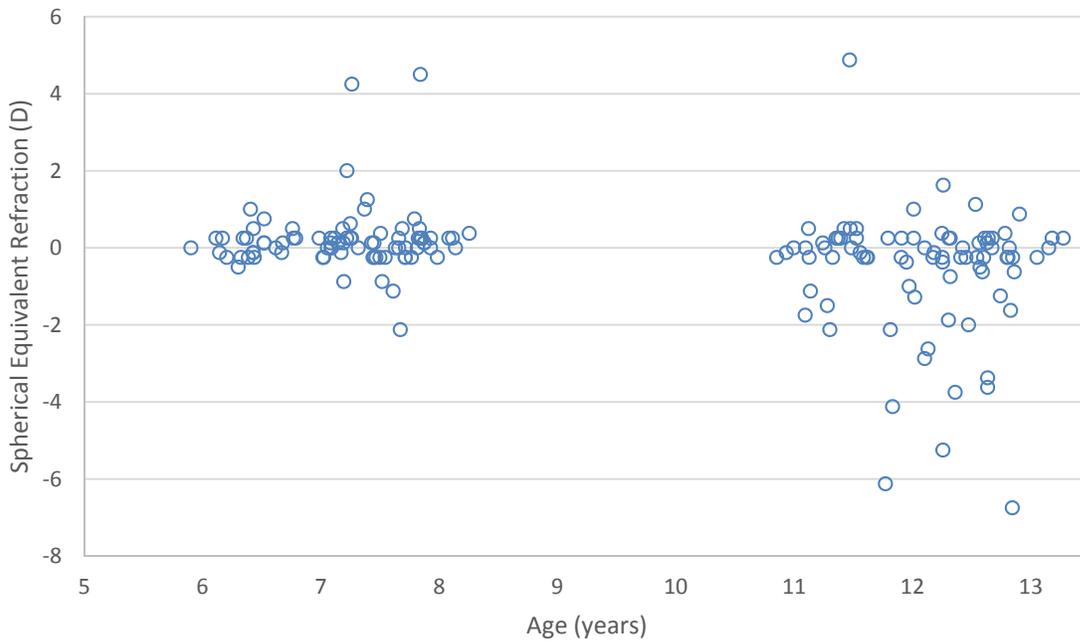


Figure 8: Refractive error of all participants plotted over age.

### 4.6.3 NON-CYCLOPLEGIC VS CYCLOPLEGIC REFRACTIVE RESULTS

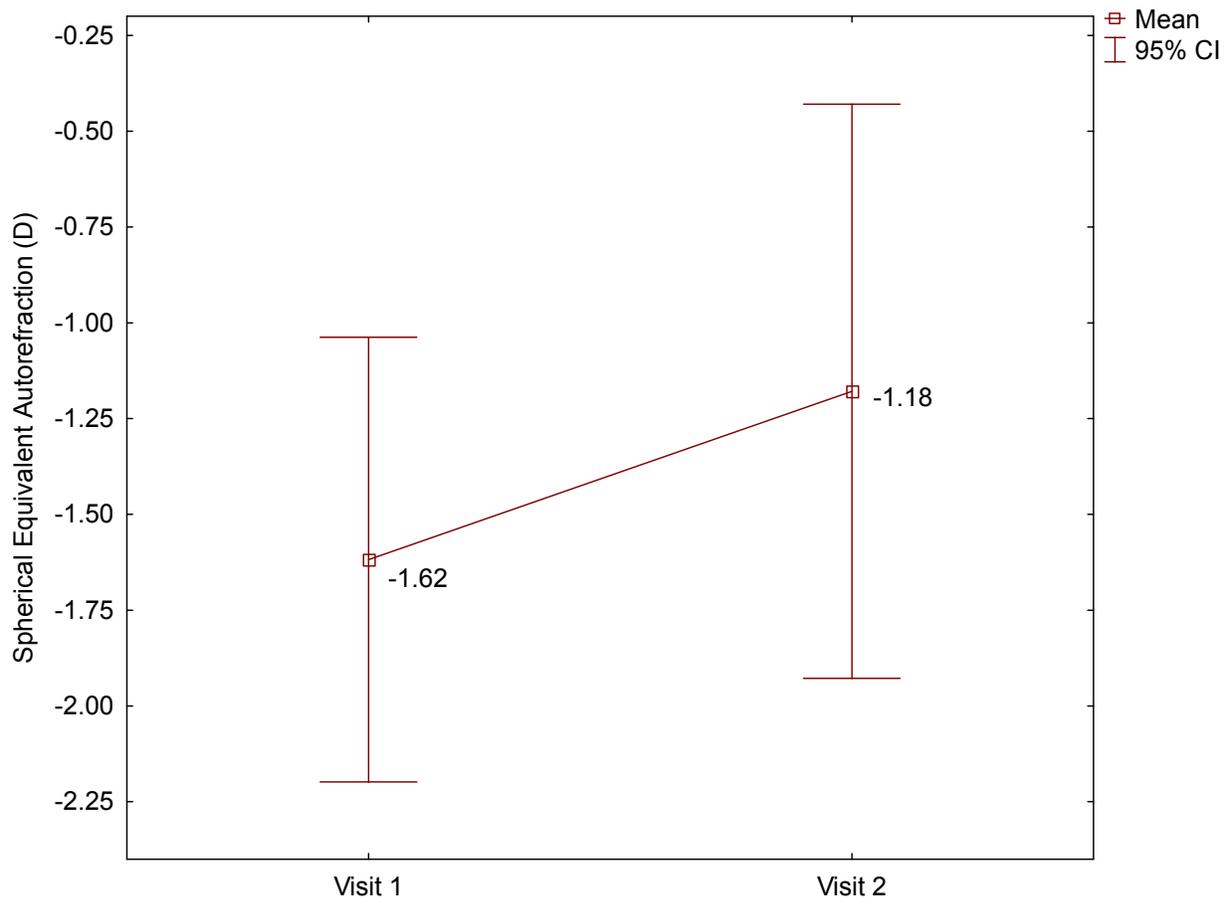
Only children who were found to be myopic at Visit 1 were invited to attend Visit 2. Refraction at Visit 2 was completed after cycloplegia, as described in study procedures in Section 3.2.2-Visit 2.

The spherical equivalent auto-refraction measured more plus at Visit 2 by +0.44D (p=0.029) in the more myopic eye (Figure 9). The spherical equivalent subjective refraction measured more positive at Visit 2 as well by +0.36D (p=0.050, Figure 10). The difference was statistically significant for auto-refraction but only marginally significant for subjective refraction.

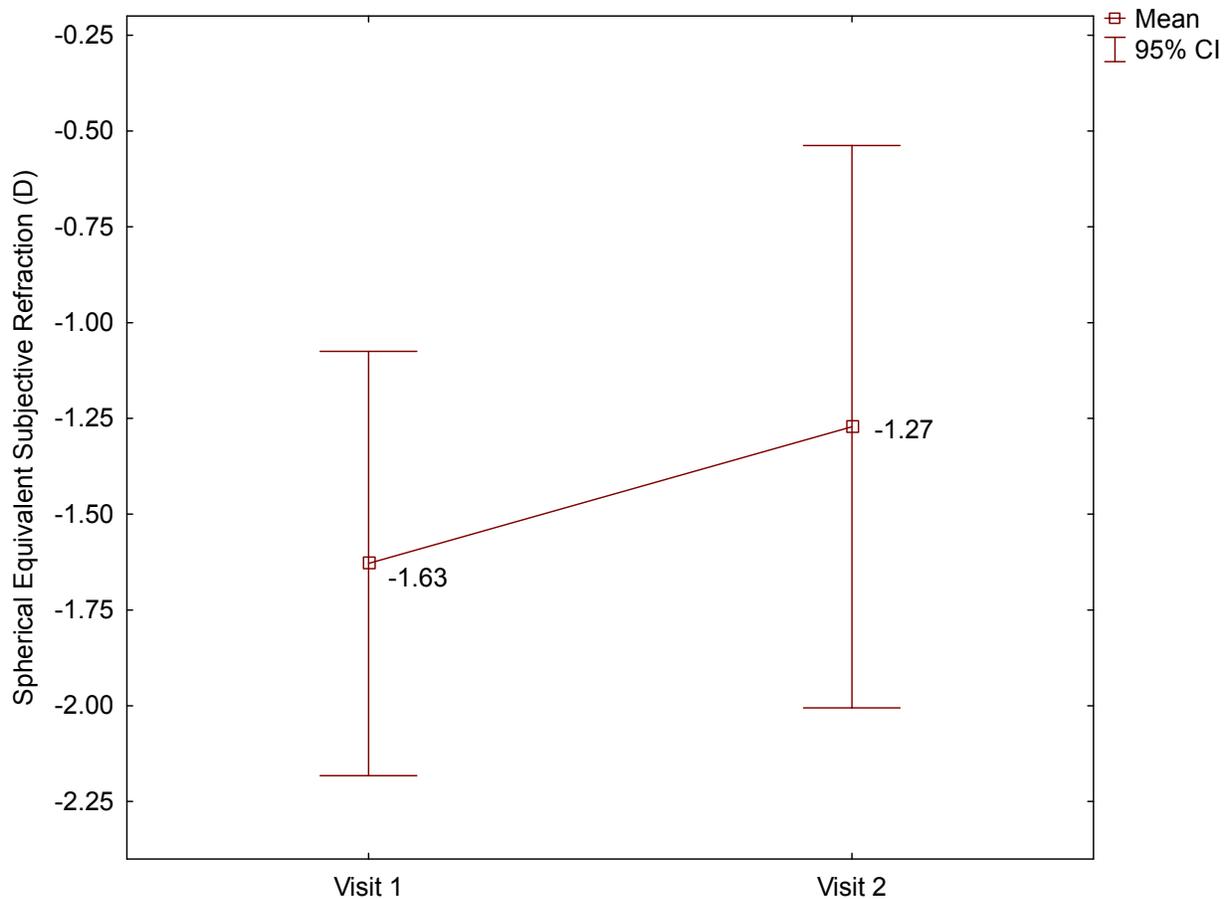
**Table 6 Comparison of mean spherical equivalent refraction in the more myopic eye at each visit**

	Visit 1	Visit 2	Difference	p-value*
Auto-refraction (D)	-1.62	-1.18	+0.44	<b>0.029</b>
Subjective Refraction (D)	-1.63	-1.27	+0.36	0.050

\*matched paired t test



**Figure 9: Comparison of mean spherical equivalent autorefracton for the more myopic eye measured at each visit. Visit 1 was non-cycloplegic and Visit 2 was cycloplegic. (n=36)**



**Figure 10: Comparison of mean subjective spherical equivalent refraction for the more myopic eye at each visit. Visit 1 was non-cycloplegic and Visit 2 was cycloplegic. (n=36)**

#### 4.7 RISK FACTORS FOR MYOPIA

Surveys were completed by parents about family history of refractive corrections and the child's activities, including the number of hours the child spent on each activity. From the survey data, multiple risk factors were analyzed for their predictive value for myopia by calculating odds ratios. An odds ratio >1 indicates a positive association with myopia and <1 indicates a negative association with myopia. Two out of the seven risk factors analyzed had a significant relationship to myopia (Table 7). Their relationship can be interpreted as:

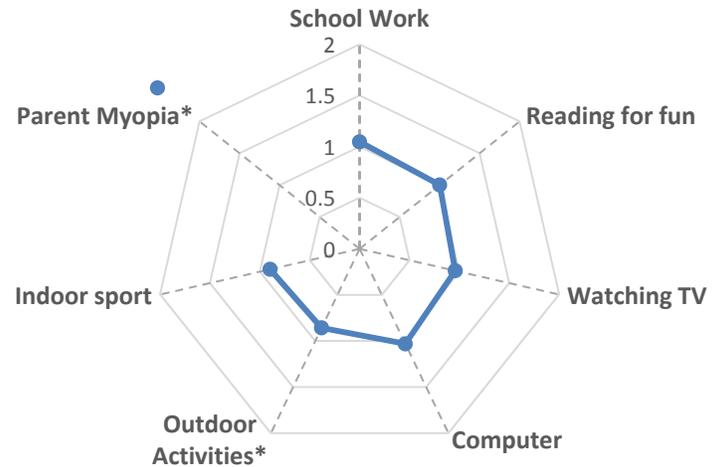
- for one additional hour of outdoor time per week, the odds of the child having myopia was lowered by 14.3%<sup>†</sup>, and
- if at least one parent is myopic, the odds of the child having myopia was increased by 152%<sup>††</sup>. In other words with at least one myopic parent, the child is 2.52 times more likely to develop myopia compared to a child with two non-myopic parents.

**Table 7: Binary logistic regression of risk factors for myopia.**

Activities (hrs/wk)	Odds Ratio Exp(B)	p-value
School Work	1.047	0.381
Reading for fun	1.002	0.962
Watching TV	0.959	0.282
Computer	1.031	0.278
Outdoor Activities*	<b>0.857</b>	<b>0.007</b>
Indoor Sport	0.897	0.091
Parental Myopia*	<b>2.524</b>	<b>0.033</b>

† Change in odds for an extra hour/wk of outdoor activity was  $\text{Exp}(B)-1$  i.e.  $(0.857-1) \times 100 = 14.3\%$  less likely myopic.

†† When at least one parent was myopic, change in odds of myopia was  $(2.524-1) \times 100 = 152.4\%$ .



**Figure 11: Binary logistic regression of risk factors for myopia. Odds ratio for each activity is plotted. Odds ratio of 1 means the activity had no impact on myopia. Odds ratio > 1 has positive association with myopia and < 1 has negative association with myopia. Risk factors marked with an asterisk have odds ratio (Exp B) significantly different from 1 ( $p < 0.05$ ).**

The numbers of hours spent on each activity were analyzed for their correlation to myopia, and only outdoor activities were found to be statistically significantly correlated to subjective refraction, with a Pearson correlation coefficient of 0.264,  $p=0.001$  (Table 8).

**Table 8: Correlation between child’s activities and subjective spherical equivalent refraction**

	Pearson Correlation	p-value (2-tailed)
School Work	-0.096	0.217
Reading for fun	-0.070	0.367
Watch TV	-0.001	0.986
Computer	-0.120	0.123
Outdoor Activities*	0.264	<b>0.001*</b>
Indoor Sports	0.147	0.059

\* Correlation was significant

## 4.8 BIOMETRIC DATA

The mean axial length of the more myopic eye, (or least hyperopic eye) was 1.03mm longer in children aged 11-13 than that measured in children aged 6-8 (Figure 12) and this difference between the age groups was statistically significant ( $p < 0.01$ ).

**Table 9: Mean axial lengths of two age groups, most myopic eye per child**

	Age 6-8	Age 11-13	Difference	p-value*
Myopic Children	22.95	24.29	1.34	<b>&lt;0.01</b>
Non-Myopic Children	22.56	23.30	0.74	<b>&lt;0.01</b>
<b>Overall</b>	<b>22.62</b>	<b>23.65</b>	<b>1.03</b>	<b>&lt;0.01</b>

\*independent samples t-tests

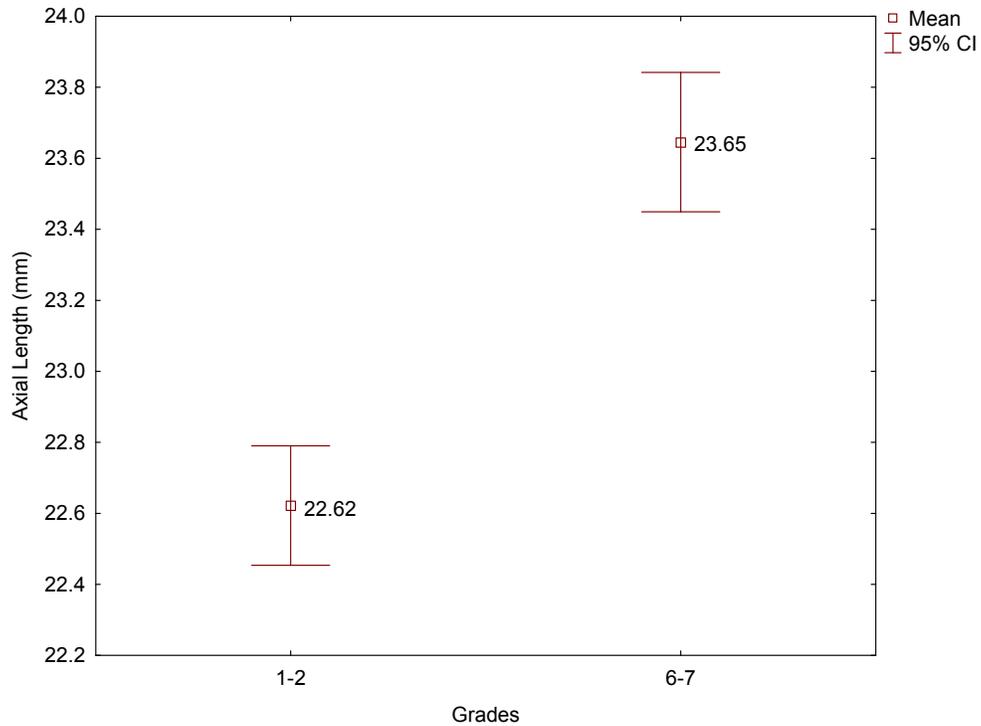


Figure 12: Mean axial length (95% CI) in the more myopic eye of all participants grouped by grades.

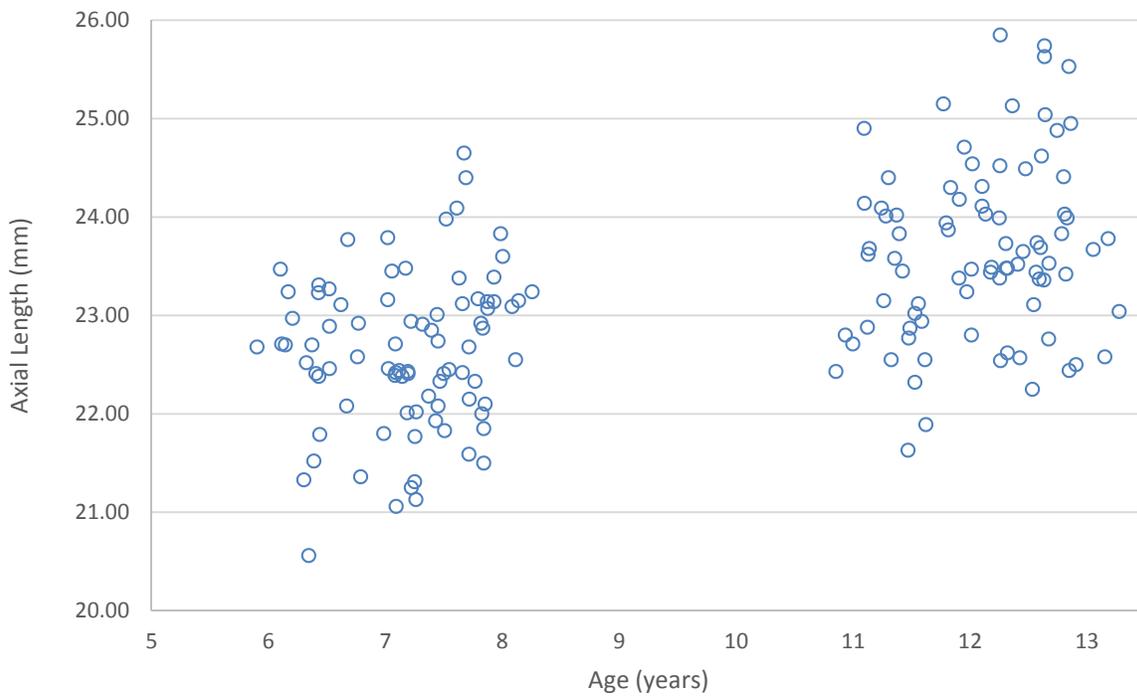
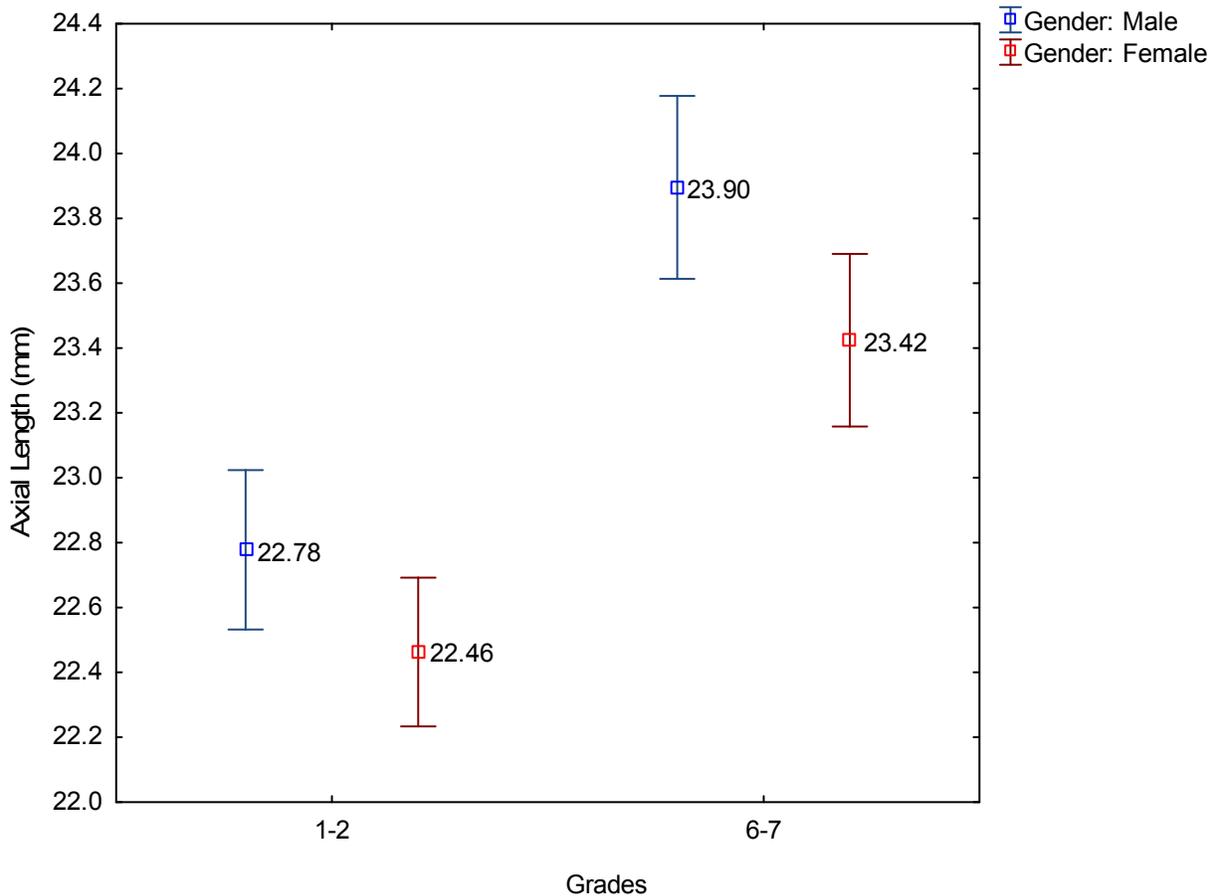


Figure 13: Axial length of all participants plotted over age.

Axial length (Figure 14) and anterior chamber depth (Figure 15) were longer in older children, and these findings are consistent with the higher degree of myopia found in older children (Figure 5). Axial length and SER had a significant negative correlation with a coefficient  $r = -0.618$  ( $p < 0.01$ ). Central corneal curvature was flatter in older children, thus steepening corneal curvature was not a factor in increased myopia (Figure 16). The increase in myopia between the age groups was accounted for by the increase in axial length rather than corneal curvature changes.

Females had shorter axial length ( $\Delta = -0.36\text{mm}$ ,  $p = 0.019$ , Figure 14) but more myopia ( $\Delta = -0.23\text{D}$ ,  $p = 0.275$ , Figure 5) in both age groups. This discrepancy can be explained by females having steeper corneal curvature in both groups ( $\Delta = 0.86\text{D}$ ,  $p < 0.001$ , Figure 16).



**Figure 14: Mean (95%CI) axial length of each gender in both age groups.**

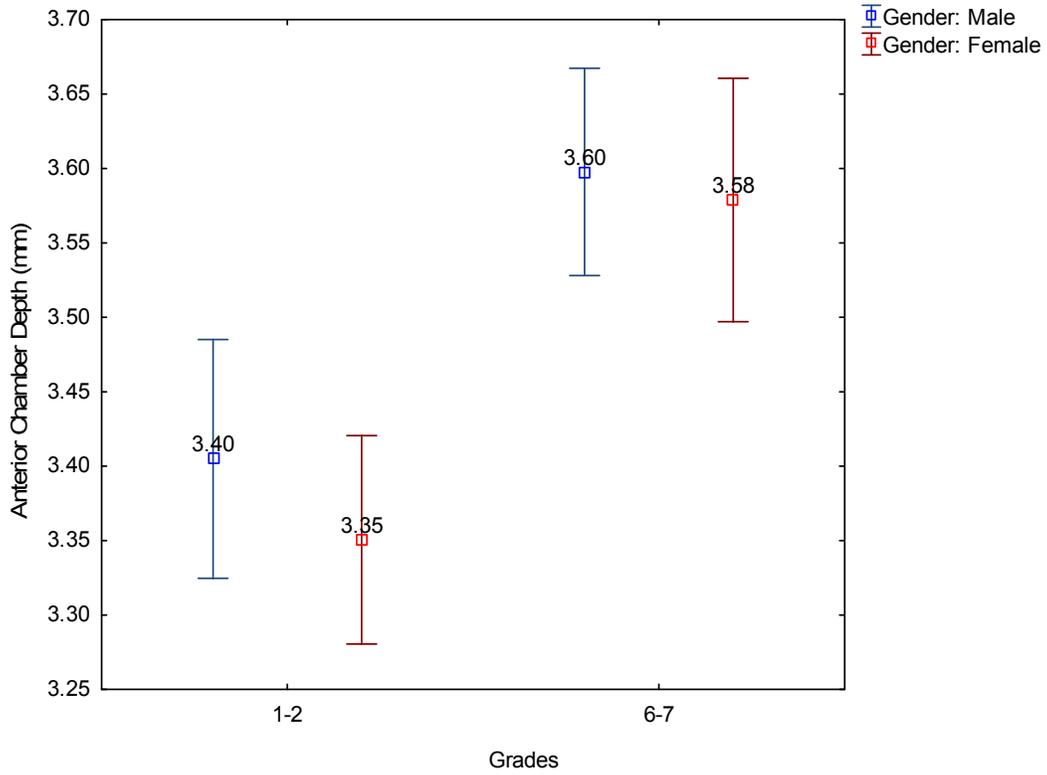


Figure 15: Mean (95% CI) anterior chamber depth in each gender grouped by grades

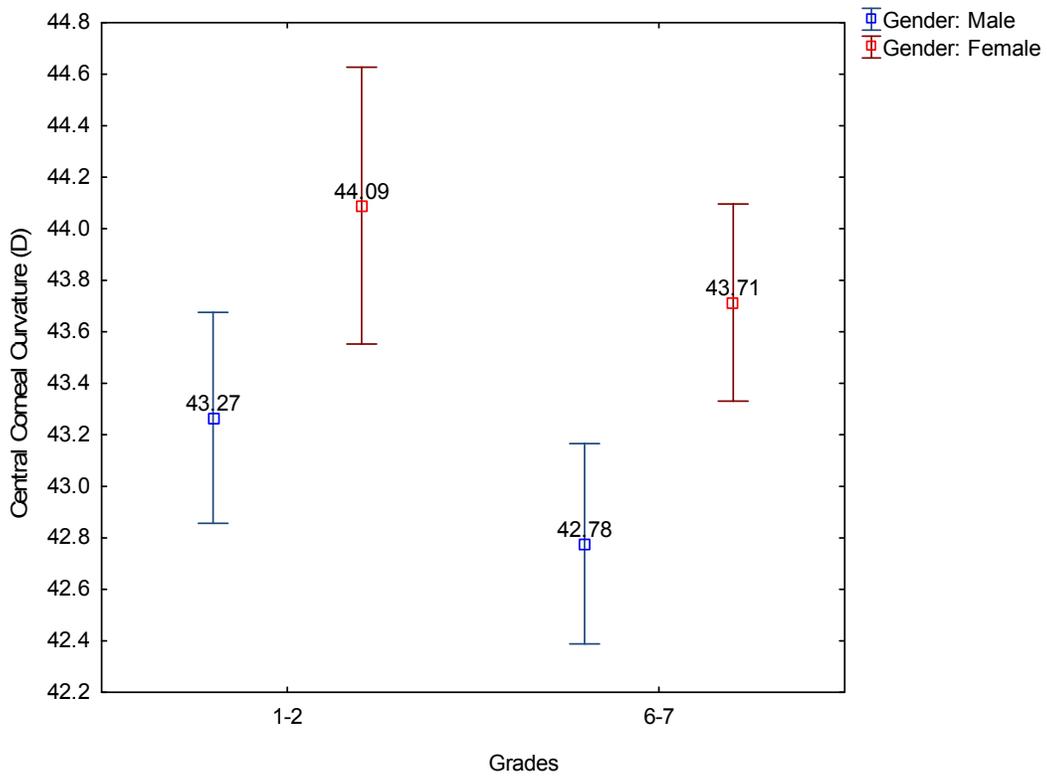
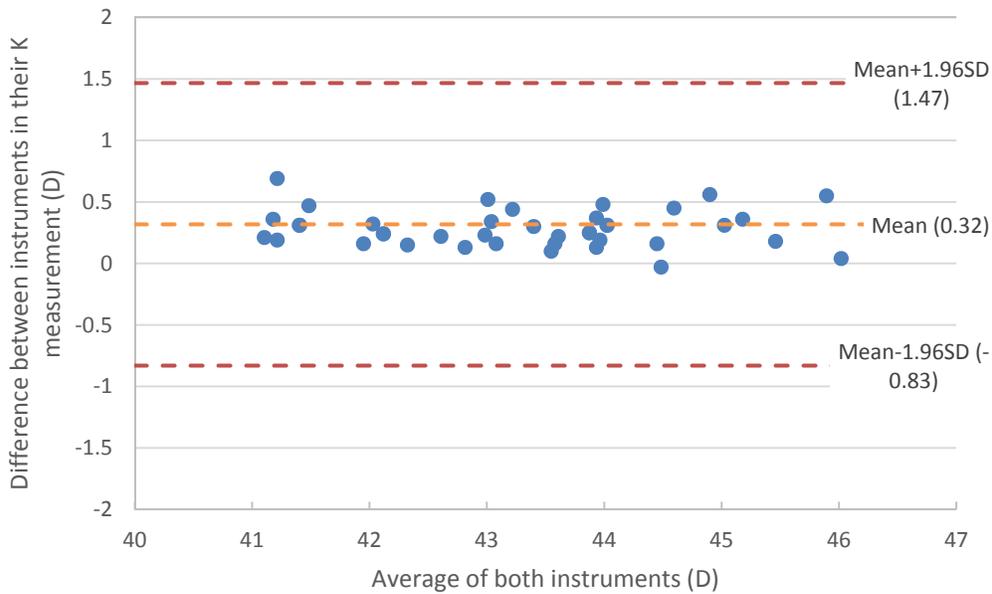


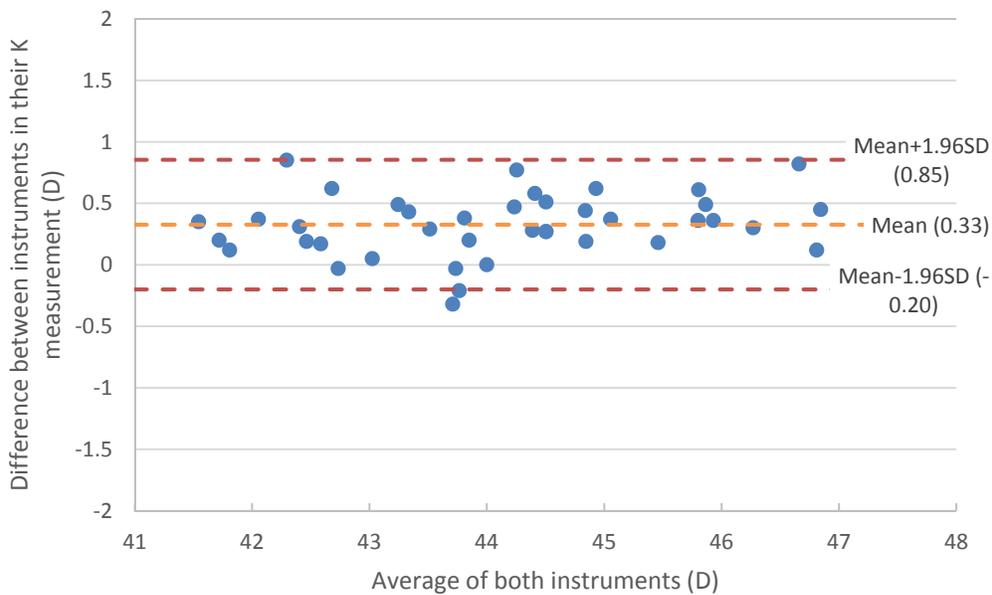
Figure 16: Mean corneal curvature in each gender grouped by grades

## 4.9 AGREEMENT BETWEEN STUDY INSTRUMENTS

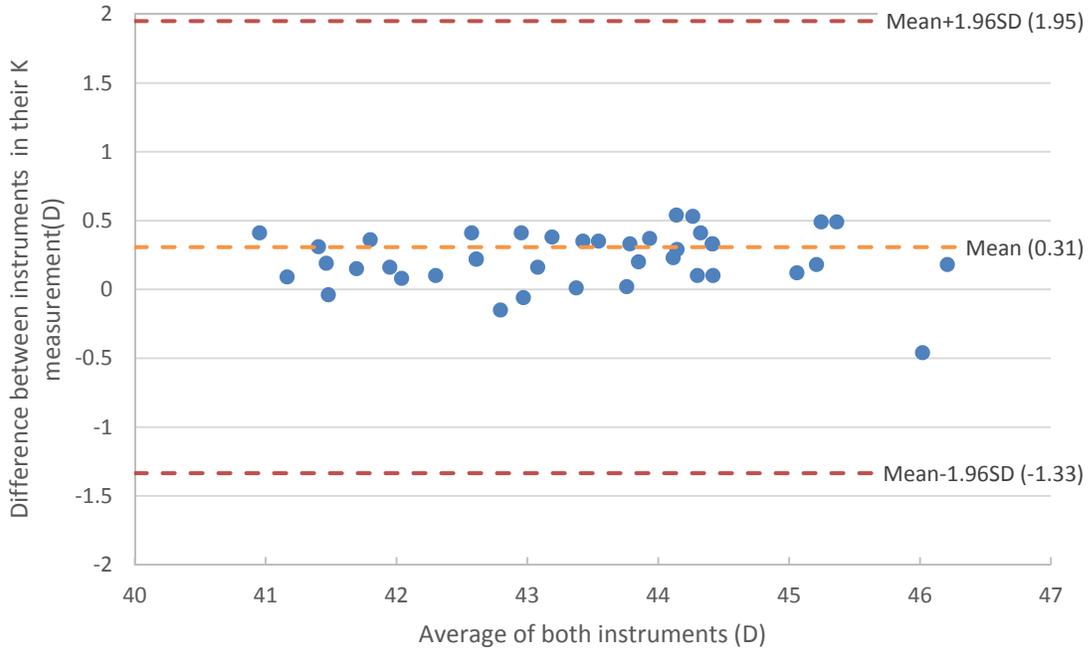
Keratometry (K) was measured with both an autorefractor and an IOLMaster at visit 1. Comparison of the two instruments were illustrated with Bland-Altman plots. For each plot, the dashed orange line close to zero represents the mean difference in K values between visits, with the upper and lower limit of agreement being shown as red dashed lines. There was an average small difference of 0.33D with IOLMaster measuring higher: OD Flat K (Figure 17), OD Steep K (Figure 18), OS Flat K (Figure 19), and OS Steep K (Figure 20).



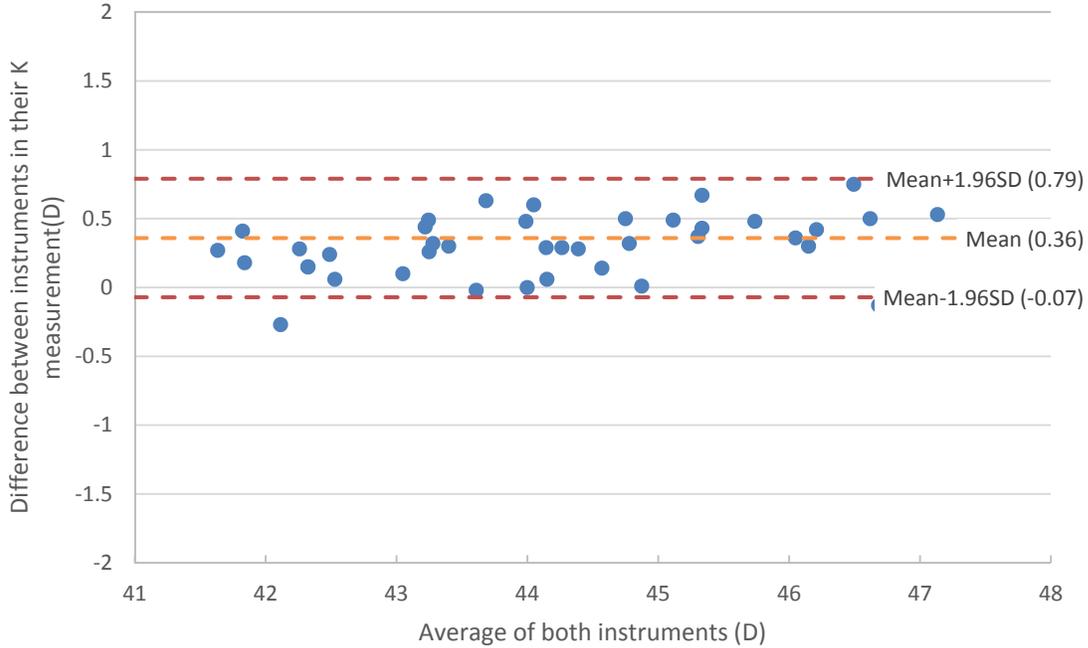
**Figure 17: Bland-Altman plot comparing OD flat-K values measured with autorefractor and IOLMaster**



**Figure 18: Bland-Altman plot comparing OD steep-K values measured with autorefractor and IOLMaster**



**Figure 19: Bland-Altman plot comparing keratometry values (OS flat-K) measured with autorefractor and IOLMaster**



**Figure 20: Bland-Altman plot comparing keratometry values (OS steep-K) measured with Autorefractor and IOLMaster**

## 5 DISCUSSION

Fewer than 14 percent of children in Canada under age six have had eye examinations by an eye doctor,<sup>15</sup> yet according to our study findings, more than one in six children between age six to thirteen have myopia. Comparing this pilot data to other studies with similar definition for myopia and subject age group, this study found a higher prevalence of myopia in the Waterloo Region (17.5%) than that reported in the US (9.2%),<sup>5</sup> but less than that reported in Korea (46.5%).<sup>16</sup> Generally, there is more myopia reported in Asians, with 38.1% reported in southern China,<sup>17</sup> 63.3% in Hong Kong<sup>18</sup> and 30% in Taiwan.<sup>19</sup> The high prevalence in Asia can be contrasted with 9.9% in Finland,<sup>20</sup> 12.8% in Australia,<sup>21</sup> and 14.6% in Ireland.<sup>22</sup>

Source	Location	Age	Myopia Prevalence, %
Laatikainen and Erkkila <sup>20</sup> (1979)	Finland	7-8, 11-12	1.9, 7.2
Lam et al. <sup>18</sup> (1999)	Hong Kong	6-17	63.3
Kleinstei et al. <sup>5</sup> (2003)	United States	5-17	9.2
He et al. <sup>17</sup> (2004)	China	6,7,11,12	5.9, 7.7, 41.7, 49.7
Rose et al. <sup>21</sup> (2008)	Australia	6,12	1.5, 12.8
Jang and Park <sup>16</sup> (2015)	Korea	11,12	54.6, 46.2
McCullough et al. <sup>22</sup> (2015)	Ireland	6-7,12-13	1.9, 14.6
This Study (Yang, 2016)	Canada	6-8, 11-13	6.0, 28.9

In this study, a child was categorized as having uncorrected myopia if he/she was found to have myopia ( $\leq -0.50D$  SER) during the study but did not have spectacles or any other refractive correction prior to enrollment into the study. Using this definition, 34.5% of the children deemed myopic in this cohort were found to be uncorrected, which represented 6.0% of the overall group of children tested. For comparison purposes, percentage of uncorrected myopia from studies in three other countries are shown in the table below. These percentages refer to the number of uncorrected myopes out of the overall study population, not just those that were myopic, therefore countries with lower prevalence of myopia would have lower overall percentage of uncorrected myopia as well.

Source	Location	Age	Uncorrected Myopia, %
Sewunet et al. <sup>23</sup> (2014)	Ethiopia	7-15	5.47
Paudel et al. <sup>24</sup> (2014)	Vietnam	12-15	20.4
Wang et al. <sup>25</sup> (2015)	China	10-12	77 (rural), 34.1 (urban)

In this current study, myopia prevalence increased significantly with age, from 6.0% in children between ages 6-8 to 28.9% in children between ages 11-13. Other studies found myopia further increased in prevalence from age 14 and onwards: in Ireland prevalence increased from 1.9% in age 6-7 to 14.6% in age 12-13 and later to 18.6% in age 18-20.<sup>22</sup> In a group of 15 year olds in China, 78.4% were myopic,<sup>17</sup> and in university students in China, 95.5% were myopic.<sup>10</sup> Given that 80% of children's learning is visual,<sup>26</sup> and a significant portion of children identified as needing special education has undiagnosed and untreated vision problems,<sup>27</sup> it would be cost effective to screen children's vision pre-kindergarten and continue the screening throughout all school grades.

When cycloplegic refraction was compared to non-cycloplegic results in this study, subjective spherical equivalent refraction was more plus in dioptric power with both auto-refraction ( $\Delta = +0.44D$ ,  $p = 0.029$ ) and subjective refraction ( $\Delta = +0.36D$ ,  $p = 0.050$ ). Similar increases in plus power with cycloplegia has been

reported in other studies,<sup>28, 29</sup> and it was suggested that this increase in plus power can be accounted for by a normal tone of accommodation that is eliminated after cycloplegia.<sup>30</sup>

An optimal prevalence study would take a random sample from the general population based on study criteria and examine this random sample. However, a potential weakness with this study, and all the referenced studies in this report, is selection bias of the study participants. A previous Canadian study reviewed pediatric patient charts at a teaching clinic, and found myopia prevalence to be 13.6% in 5-10 year olds and 42.2% in 10-15 year olds.<sup>31</sup> Another Canadian study reviewed patient charts (only Chinese-Canadian children) at a private office in Mississauga Ontario and found myopia prevalence increased from 22.4% at age 6 to 64.1% at age 12.<sup>32</sup> Unlike these two previous myopia studies in Canada, where only clinical populations presenting for examination were studied and thus the prevalence would be expected to be inflated, this study sampled from the general population of school-aged children. However, because parental consent was required on an individual basis, there was some degree of self-selection in the study sample. While there was no evidence to indicate whether this study sample would over or under estimate prevalence due to participant selection, this type of selection bias could be avoided by testing all children in a particular geographic area. New policies would be required to allow vision testing of every child in a particular grade in schools in Canada.

Time spent outdoors was the only surveyed child activity that correlated with refraction by regression analysis. It had a weak statistically significant correlation; Pearson Correlation Coefficient = 0.264,  $p=0.001$ . Other activities analyzed include time spent on computer, reading, and watching TV, and none had significant predictive value for myopia. There were no significant associations between indoor sports and myopia, so it was time spent outdoors rather than playing sports that had an impact on myopia. In this study, every additional hour spent outdoors per week was found to lower the odds of a child having myopia by 14.3%. Studies in Australia, China and Ireland reported similar results, where more outdoor activities were found to reduce the prevalence of myopia.<sup>21, 33, 34</sup>

When at least one parent was myopic, the child was 2.52 times more likely to develop myopia compared to a child with two non-myopic parents. This predictive value indicates that genetics continue to play an important role in the development of myopia, and it is a combination of both genetics and the child's environment that determines the final visual outcome.<sup>16, 33, 35</sup>

Axial length was negatively associated with spherical equivalent refraction ( $r=-0.618$ ,  $p<0.01$ ), and axial length increased from the younger group of children to the older group ( $\Delta=1.03\text{mm}$ ,  $p<0.01$ ). Halting this increase in axial length appears to be a natural target for therapy intervention to slow the development of myopia. The exact mechanism behind abnormal myopia-inducing axial length growth is still unknown and remains an active research area.<sup>36, 37</sup>

This pilot study provided the opportunity to collect initial study data, validate established procedures for recruitment and operational strategies and confirmed the appropriateness of study instruments used. These information are critical for the design and execution of a larger study, particularly for study timelines and budget calculations.

Ongoing prevalence studies in key Canadian locations are recommended, as Canada has a unique and dynamic demographic that is different even from the neighbouring United States, which has a higher percentage of African American, Hispanic and Latino populations.<sup>38</sup> Larger national studies should include children living in urban and rural areas and cover different provinces for a better representation of myopia prevalence in school children across Canada.

Understanding the current prevalence of myopia allows us to raise awareness and educate communities on local, provincial and/or federal levels. It may further be used to estimate the financial burden for vision correction and pathological complications associated with high myopia. While it is currently not possible to reduce existing myopia, numerous studies are currently trying to slow down the progression using pharmaceutical and optical treatment methods.<sup>36, 37</sup>

## 6 CONCLUSION

This pilot study estimated myopia prevalence to be 6.0% in ages 6 through 8 and increased to 28.9% in ages 11 through 13 in the Waterloo Region. In total, 6.0% of the children tested had uncorrected myopia. Time spent outdoors was the only child activity to have a significant impact on myopia and one additional hour of outdoor time per week lowered the odds of myopia by 14.3%. When at least one parent was myopic, the child was 2.52 times more likely to develop myopia compared to a child with two non-myopic parents. Axial length increased as myopia increased and is therefore a good target for intervention and control of myopia development. These study results have many potential implications for academic researchers, educators, and healthcare policy makers, and to our knowledge, this pilot study was the first of its kind studying the general population of school-aged children in Canada. Larger national studies would be able to extract more detailed information in various age and ethnic groups, aid in identifying prevention strategies, and provide evidence based recommendations to the general public and Canadian healthcare stakeholders.

## REFERENCES

1. Meng W, Butterworth J, Malecaze F, Calvas P. Axial length of myopia: a review of current research. *Ophthalmologica Journal internationale d'ophtalmologie International journal of ophthalmology Zeitschrift fur Augenheilkunde* 2011;225:127-134.
2. Canada S. Population growths in Canada: From 1851 to 2061 [http://www12.statcan.gc.ca/census-recensement/2011/as-sa/98-310-x/98-310-x2011003\\_1-eng.cfm](http://www12.statcan.gc.ca/census-recensement/2011/as-sa/98-310-x/98-310-x2011003_1-eng.cfm). accessed 05 July 2012.
3. Canada S. Immigrant population by place of birth and period of immigration (2006 Census) <http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/demo24a-eng.htm>. accessed 05 July 2012.
4. Cruess AF, Gordon KD, Bellan L, Mitchell S, Pezzullo ML. The cost of vision loss in Canada. 2. Results. *Canadian journal of ophthalmology Journal canadien d'ophtalmologie* 2011;46:315-318.
5. Kleinstein RN, Jones LA, Hullett S, et al. Refractive error and ethnicity in children. *Archives of ophthalmology* 2003;121:1141-1147.
6. Vitale S, Ellwein L, Cotch MF, Ferris FL, 3rd, Sperduto R. Prevalence of refractive error in the United States, 1999-2004. *Archives of ophthalmology* 2008;126:1111-1119.
7. Vitale S, Sperduto RD, Ferris FL, 3rd. Increased prevalence of myopia in the United States between 1971-1972 and 1999-2004. *Archives of ophthalmology* 2009;127:1632-1639.
8. Jones D, Luensmann D. The prevalence and impact of high myopia. *Eye & contact lens* 2012;38:188-196.
9. Jung SK, Lee JH, Kakizaki H, Jee D. Prevalence of myopia and its association with body stature and educational level in 19-year-old male conscripts in seoul, South Korea. *Investigative ophthalmology & visual science* 2012;53:5579-5583.
10. Sun J, Zhou J, Zhao P, et al. High prevalence of myopia and high myopia in 5060 chinese university students in shanghai. *Investigative ophthalmology & visual science* 2012;53:7504-7509.
11. Lin LL, Shih YF, Hsiao CK, Chen CJ. Prevalence of myopia in Taiwanese schoolchildren: 1983 to 2000. *Ann Acad Med Singapore* 2004;33:27-33.
12. Zadnik K, Mutti DO, Adams AJ. The repeatability of measurement of the ocular components. *Investigative ophthalmology & visual science* 1992;33:2325-2333.
13. Canada S. Waterloo, Ontario (Code3530) (table). 2006 Community Profiles. <http://www12.statcan.gc.ca/census-recensement/2006/dp-pd/prof/92-591/index.cfm?Lang=E>. *Statistics Canada Catalogue no 92-591-XWE*; accessed 13 aug 2015.
14. Canada S. Canada (Code 01) (table). National Household Survey (NHS) Profile. 2011 National Household Survey. <http://www12.statcan.gc.ca/nhs-enm/2011/dp-pd/prof/index.cfm?Lang=E>. *Statistics Canada Catalogue no 99-004-XWE*; accessed 10 may 2016.
15. Breslin DC. Vision Loss in Canada 2011. [http://www.cos-sco.ca/wp-content/uploads/2012/09/VisionLossinCanada\\_e.pdf](http://www.cos-sco.ca/wp-content/uploads/2012/09/VisionLossinCanada_e.pdf). National Coalition for Vision Health; 2011.
16. Jang JU. The status of refractive errors in elementary school children in south Jeolla Province, south Korea. 2015.
17. He M, Zeng J, Liu Y, Xu J, Pokharel GP, Ellwein LB. Refractive error and visual impairment in urban children in southern China. *Investigative ophthalmology & visual science* 2004;45:793-799.

18. Lam CSY, Edwards M, Millodot M, Goh WSH. A 2-year longitudinal study of myopia progression and optical component changes among Hong Kong schoolchildren. *Optometry & Vision Science* 1999;76:370-380.
19. Lin LLJ, Hung PT, Ko LS, Hou PK. Study of myopia among aboriginal school children in Taiwan. *Acta Ophthalmologica* 1988;66:34-36.
20. Laatikainen L, Erkkilä H. Refractive errors and other ocular findings in school children. *Acta ophthalmologica* 1980;58:129-136.
21. Rose KA, Morgan IG, Ip J, et al. Outdoor activity reduces the prevalence of myopia in children. *Ophthalmology* 2008;115:1279-1285.
22. McCullough SJ, O'Donoghue L, Saunders KJ. Six Year Refractive Change among White Children and Young Adults: Evidence for Significant Increase in Myopia among White UK Children. *PLoS ONE* 2016;11.
23. Sewunet SA, Aredo KK, Gedefew M. Uncorrected refractive error and associated factors among primary school children in Debre Markos District, Northwest Ethiopia. *BMC ophthalmology* 2014;14:1-6.
24. Paudel P, Ramson P, Naduvilath T, et al. Prevalence of vision impairment and refractive error in school children in Ba Ria - Vung Tau province, Vietnam. *Clinical & experimental ophthalmology* 2014;42:217-226.
25. Wang X, Yi H, Lu L, et al. Population Prevalence of Need for Spectacles and Spectacle Ownership Among Urban Migrant Children in Eastern China. *JAMA ophthalmology* 2015;133:1399-1406.
26. Imus H. Visual efficiency. *Hygeia, The Health Magazine* 1941;1.
27. Smeltzer D. New Jersey Commission on Business Efficiency of the Public Schools; <http://www.njleg.state.nj.us/committees/ANNUAL0304final.pdf>. 2005.
28. Suryakumar R, Bobier WR. The manifestation of noncycloplegic refractive state in pre-school children is dependent on autorefractor design. *Optometry and vision science : official publication of the American Academy of Optometry* 2003;80:578-586.
29. Hopkins S, Sampson GP, Hendicott P, Lacherez P, Wood JM. Refraction in children: a comparison of two methods of accommodation control. *Optometry and vision science : official publication of the American Academy of Optometry* 2012;89:1734-1739.
30. Borghi RA, Rouse MW. Comparison of refraction obtained by "near retinoscopy" and retinoscopy under cycloplegia. *American journal of optometry and physiological optics* 1985;62:169-172.
31. Hrynychak PK, Mittelstaedt A, Machan CM, Bunn C, Irving EL. Increase in myopia prevalence in clinic-based populations across a century. *Optometry and vision science : official publication of the American Academy of Optometry* 2013;90:1331-1341.
32. Cheng D, Schmid KL, Woo GC. Myopia prevalence in Chinese-Canadian children in an optometric practice. *Optometry and vision science : official publication of the American Academy of Optometry* 2007;84:21-32.
33. O'Donoghue L, Kapetanankis VV, McClelland JF, et al. Risk factors for childhood myopia: Findings from the NICER study. *Investigative Ophthalmology and Visual Science* 2015;56:1524-1530.
34. Jin JX, Hua WJ, Jiang X, et al. Effect of outdoor activity on myopia onset and progression in school-aged children in northeast China: the Sujiatun Eye Care Study. *BMC ophthalmology* 2015;15:73.

35. Wojciechowski R. Nature and nurture: the complex genetics of myopia and refractive error. *Clinical genetics* 2011;79:301-320.
36. Smith EL, 3rd. Optical treatment strategies to slow myopia progression: effects of the visual extent of the optical treatment zone. *Experimental eye research* 2013;114:77-88.
37. Walline JJ. Myopia Control: A Review. *Eye & contact lens* 2016;42:3-8.
38. Bureau USC. United States Quick Facts. <https://www.census.gov/quickfacts/table/PST045215/00>. accessed 18 May 2016.