

## Refractive changes in soft contact lens corrected pediatric patients with progressive myopia

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### Зміни рефракції у пацієнтів дитячого віку з прогресуючою міопією за умови оптичної корекції м'якими контактними лінзами

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#### Abstract

**Purpose:** To assess the annual gradient of myopia progression in soft contact lens (SCL) corrected myopic children of various age groups.

**Methods:** We retrospectively reviewed the medical records of 1380 SCL-corrected patients (1380 eyes; 378 boys and 1084 girls) aged 6 to 17 years who had been examined during routine optometric visits. Follow-up duration ranged from 12 to 36 months. Patients were divided into age groups of 6-8 years (14 individuals), 9-11 years (52 individuals), 12-14 years (230 individuals), and 15-17 years (1084 individuals). In the presence of anisometropia, the more myopic eye was chosen as the study eye. Low myopia ( $-0.50$  to  $-3.00$  D) was found in 278 eyes, moderate myopia ( $-3.25$  to  $-6.00$  D), in 278 eyes, and high myopia ( $\leq -6.00$  D), in 445 eyes. Astigmatism did not exceed 1.50 D. The progression of myopia was determined based on the spherical equivalent refraction (SER)

values. SER was measured by non-cycloplegic autorefraction during routine optometric visits.

**Results.** The annual gradient of myopia progression for the 6-8 year group was  $0.60 \pm 0.53$  D, for the 9-11 year group,  $0.49 \pm 0.15$  D, for the 12-14 year group,  $0.47 \pm 0.06$  D, and for the 15-17 year group,  $0.26 \pm 0.03$  D ( $p < 0.05$  for each).

**Conclusion.** The study findings on the annual gradient of myopia progression for various age groups of SCL-corrected children may be used for assessing the efficacy of interventions for slowing myopia progression.

**Keywords:** refractive errors, myopia, diagnosis, spherical equivalent refraction progression gradient, optometry, ophthalmology.

#### Резюме

**Мета.** Оцінити градієнт прогресування міопії у пацієнтів дитячого віку різних вікових груп за умови оптичної корекції м'якими контактними лінзами.

**Матеріал та методи.** Ретроспективно обстежено 1380 пацієнтів у віці від 6 до 17 років під час поточних оптометричних візитів в умовах оптичної корекції м'якими контактними лінзами. Строк спостереження становив 1–3 роки, але не менше 12 місяців. Всі пацієнти були розділені на вікові групи: 6–8 років (14 осіб), 9–11 років (52 особи), 12–14 років (230 осіб), 15–17 років (1084 особи). В дослідженні взяли участь 378 чоловіків (378 очей) та 1002 жінки (1002 ока). У кожного пацієнта досліджувалось одне око з більшим ступенем міопії за наявності анізотропії. Міопія I ступеня за сфереквівалентом виявлена у 278 пацієнтів, міопія II ступеня – у 657 пацієнтів та міопія III ступеня – у 445 пацієнтів. Ступінь астигматизму не перевищував 1,50 дптр. Всім пацієнтам проведена оцінка градієнта прогресування мі-

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опії за сфероеквівалентом рефракції, визначеним методом автоматичної рефрактометрії в природних умовах, без циклоплегії.

**Результати.** Проведений порівняльний аналіз прогресування міопії у дітей різних вікових груп з урахуванням ступеня міопії в умовах оптичної корекції м'якими контактними лінзами. Встановлено: для пацієнтів віком 6–8 років річний градієнт прогресування міопії становив  $0,60 \pm 0,53$  дптр/рік, для пацієнтів 9–11 років –  $0,49 \pm 0,15$  дптр/рік, для пацієнтів 12–14 років –  $0,47 \pm 0,06$  дптр/рік, для пацієнтів 15–17 років –  $0,26 \pm 0,03$  дптр/рік (рівень

значущості відмінностей показників для кожної вікової групи становив  $p < 0,05$ ).

**Висновок.** Отримані дані про річний градієнт прогресування міопії у дітей різних вікових груп в умовах оптичної корекції м'якими контактними лінзами в залежності від ступеня міопії дозволяють використовувати їх при дослідженні ефективності методів контролю прогресування міопії.

**Ключові слова:** аномалії рефракції, міопія, діагностика, сфероеквівалент рефракції, градієнт прогресування, оптометрія, офтальмологія.

## Introduction

The rising global prevalence of myopia poses a serious threat to public health, with 30% to 50% of adults in the United States and Europe being affected by the disease [1]. The age-standardized prevalence has been reported to be as high as 80% in children aged 12-18 years [2]. A study by Holden and colleagues [1] estimated that, by 2050, myopia and high myopia (a spherical equivalent of -5.00 D or less) will affect nearly 5 billion people (half of the world's population) and 1 billion people globally, respectively.

In 2025, a network meta-analysis (NMA) was conducted within the framework of Cochrane Eyes and Vision US Project to assess the comparative efficacy and safety of interventions for slowing myopia progression in children [3]. The authors included randomized controlled trials of optical, pharmacological, light therapy and behavioral interventions for slowing myopia progression in children, up to 18 years old. Most of the control groups received a placebo (sham) treatment or single vision eyeglasses or contact lenses. In terms of a minimally important difference of the key efficacy outcomes in myopia control trials, an expert panel concluded that a mean difference between intervention groups of 0.25 D per year would be regarded as clinically significant. This would correspond to a change in axial length (AL) of approximately 0.1 mm per year [3]. The median change in spherical equivalent refraction (SER) for controls was -0.65 D (55 studies, 4888 participants; one-year follow-up) [3].

The data on the change in SER for controls specified in the meta-analysis is overgeneralized and does not take into account the differences between child age groups.

The purpose of this study was to assess the annual gradient of myopia progression in soft contact lens (SCL) corrected myopic children of various age groups depending on the severity of the disease.

## Material and Methods

We retrospectively reviewed the medical records of 1380 SCL-corrected patients (1380 eyes; 378 boys and 1084 girls) aged 6 to 17 years who had been examined during routine optometric visits. Follow-up duration ranged from 12 to 36 months. Patients were divided into age groups of 6-8 years (14 individuals, 14 eyes), 9-11 years (52 individuals, 52 eyes), 12-14 years (230 individuals,

230 eyes), and 15-17 years (1084 individuals, 1084 eyes). In the presence of anisometropia, the more myopic eye was chosen as the study eye. Astigmatism did not exceed 1.50 D. The progression of myopia was determined based on the spherical equivalent refraction (SER) values. SER was measured by non-cycloplegic autorefraction during routine optometric visits.

The inclusion criteria were patient age 6 to 17 years and measurement of SER at baseline and at the final visit.

The analysis assumed that refraction growth over a short period of time (12-26 months) was linear, and annual myopia progression gradient was computed as the difference in SER between the final and baseline visits divided by the difference in month dates between these visits and multiplied by 12:

$$GR = (SER_{\text{final}} - SER_{\text{baseline}}) / (\text{month}_{\text{final}} - \text{month}_{\text{baseline}}) \times 12$$

The EZR software (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R statistics (R Foundation for Statistical Computing, Vienna, Austria), and Excel 2023 (Microsoft Corp., Redmond, WA) were used for statistical analysis [4]. Statistical significance was set at  $P < 0.05$  for all analyses.

## Results

Table 1 shows percentage patient distribution by age and sex.

The 15-17 years age group (1084 individuals; 78.55%) was the largest, and girls outnumbered boys in all age groups (1002, 72.6%).

Table 2 shows myopia severity distribution among age groups.

Low myopia (-0.50 to -3.00 D) was found in 278 eyes, moderate myopia (-3.25 to -6.00 D), in 278 eyes, and high myopia ( $\leq -6.00$  D), in 445 eyes (Table 2).

Table 3 shows annual gradients of myopia progression in low, moderate and high myopes of various age groups.

It is natural that the myopia progression gradient was found to increase with disease severity and gradually decrease with age.

Table 4 shows the generalized annual myopia progression gradients for age groups.

**Table 1.** Distribution of patients by age and sex

| Age         | Number of patients |        |       |        |       |        |
|-------------|--------------------|--------|-------|--------|-------|--------|
|             | Boys               | %      | Girls | %      | Total | %      |
| 6-8 years   | 6                  | 1.59   | 8     | 0.80   | 14    | 1.01   |
| 9-11 years  | 18                 | 4.76   | 34    | 3.39   | 52    | 3.77   |
| 12-14 years | 64                 | 16.93  | 166   | 16.57  | 230   | 16.67  |
| 15-17 years | 290                | 76.72  | 794   | 79.24  | 1084  | 78.55  |
| Total       | 378                | 100.00 | 1002  | 100.00 | 1380  | 100.00 |
| %           | 27.4               |        | 72.6  |        | 100.0 |        |

Of note, because there was an uneven patient distribution as well as myopia severity distribution (which was a limitation of this study), generalized data are presented in the table purely for illustrative purposes.

Changes in corneal curvature radius in myopic eyes wearing SCLs were assessed by automated keratometry; these changes may potentially cause an increase in corneal refraction and affect changes in myopic refraction.

**Discussion**

An NMA [3] included 104 studies that randomized 17,509 children, aged 4 years to 18 years. Of these studies, 84 (80.8%) compared myopia control interventions against inactive controls. Most of the control groups received a placebo (sham) treatment or single vision eyeglasses or contact lenses. Study durations ranged from 12 months to 48 months. The studies took place in China or other Asian countries (69 studies, 66.3%), North America (15 studies, 14.4%), and Europe (nine studies, 8.7%).

The authors of that work assessed the risk of bias (RoB) for SER and AL using the Cochrane RoB 2 tool [3]. They rated the certainty of evidence using the GRADE approach for change in SER and AL at one and two years. Additionally, they used the surface under the cumulative ranking curve (SUCRA) to rank the interventions for all available outcomes. The higher the SUCRA value, the higher the probability for the interventions to be the best option [5, 6]. At two-year follow-up, change in SER was reported in 34 studies (3556 participants). The median change in SER for controls was -1.01 D. The ranking of interventions to reduce SER progression was close to that observed at one year; there were insufficient data to draw conclusions on cumulative effects. The highest-ranking interventions were: high-dose atropine (HDA) (SUCRA = 97%); medium-dose atropine (MDA) (NMA estimate SUCRA = 69.8%); and peripheral plus spectacle lenses (SUCRA = 69.1%). At two-year follow-up, change in AL was reported in 33 studies (3334 participants). The median change in AL for controls was 0.56 mm. The ranking of interventions to reduce axial elongation was similar to

**Table 2.** Myopia severity distribution among age groups

| Age         | Myopia grade |                |            |
|-------------|--------------|----------------|------------|
|             | Low (n/%)    | Moderate (n/%) | High (n/%) |
| 6-8 years   | 6            | 3              | 5          |
| 9-11 years  | 24           | 16             | 12         |
| 12-14 years | 57           | 113            | 60         |
| 15-17 years | 191          | 525            | 368        |
| Total       | 278/20.1     | 657/47.6       | 445/32.2   |

**Table 3.** Annual gradient of myopia progression in low, moderate and high myopes of various age groups

| Age         | Gradient of myopia progression (diopter/year): M ± m; p < 0.05 |             |             |
|-------------|--|-------------|-------------|
|             | Low  | Moderate    | High        |
| 6-8 years   | 0.10 ± 0.77  | 1.72 ± 0.18 | 0.52 ± 0.78 |
| 9-11 years  | 0.43 ± 0.22  | 0.52 ± 0.26 | 0.55 ± 0.31 |
| 12-14 years | 0.35 ± 0.11  | 0.43 ± 0.08 | 0.67 ± 0.14 |
| 15-17 years | 0.25 ± 0.06  | 0.25 ± 0.04 | 0.29 ± 0.06 |

Notes: M, mean value; m, standard error of mean; P, P-value

**Table 4.** Generalized annual myopia progression gradient for age groups

| Age         | Gradient of myopia progression (diopter/year): M ± m; p < 0.05 |
|-------------|--|
| 6-8 years   | 0.60 ± 0.53  |
| 9-11 years  | 0.49 ± 0.15  |
| 12-14 years | 0.47 ± 0.06  |
| 15-17 years | 0.26 ± 0.03  |

that observed at one year; there were insufficient data to draw conclusions on cumulative effects. The highest-ranking interventions were: ortho-K plus low-dose atropine (SUCRA = 94.2%); HDA (SUCRA = 96.8%); and MDA (NMA estimate SUCRA = 88.4%). There was limited evidence on whether cessation of myopia control therapy increases progression beyond the expected rate of progression with age. Adverse events and treatment adherence were not consistently reported.

The authors of that work were unable to draw firm conclusions regarding the relative costs or efficiency of different myopia control strategies in children. Longer term and better quality studies comparing myopia control interventions alone or in combination are needed, with improved methods for monitoring and reporting adverse effects [3].

The median change in SER for controls (including the control groups that received single vision contact lenses) was  $-0.65$  D (55 studies, 4888 participants; one-year follow-up) [3]. The authors of that work [3] did not specify the gradient of myopia progression for various child age groups.

Our findings, however, will allow more accurate determination of the efficacy of myopia control techniques by comparing gradients of myopia progression while taking into consideration the age of contact lens corrected patients.

### Conclusion

Developing and introducing into clinical practice new optical, pharmacological, light therapy and behavioral interventions for slowing myopia progression require assessing their efficacy on the basis of more significant and stable reference points while taking into consideration the age and ethnicity of the patient. The results of this study may be used as descriptive reference data for comparing longitudinal changes in refraction among SCL-corrected children of various age groups.

### Author Contributions

SII: Investigation, Data Analysis and Interpretation, Writing – original draft; SIV: Conceptualization, Methodology, Writing – review & editing; KOV: Database Development, Writing – original draft. All authors reviewed the results and approved the final version of the manuscript.

### Disclaimer

The opinions presented in this article are those of the authors and do not necessarily represent those of their institutions.

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### Conflict of interest

The authors state that they have no conflict of interest that could influence their view on the subject matter or materials described and discussed in this manuscript.

### Ethical Statement

This study involved human subjects, was approved by the local bioethics committee, and followed ethical standards as outlined in the Declaration of Helsinki of the World Medical Association and the European Convention on Human Rights and Biomedicine, and relevant laws of Ukraine. Informed consent was obtained from all subjects or their representatives.

### Data Availability Declaration

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

### Abbreviations

AL, axial length; D, diopter; GR, refraction gradient; NMA, network meta-analysis; SER, spherical equivalent refraction; SUCRA, surface under the cumulative ranking curve

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