Clinical Optometry

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ORIGINAL RESEARCH

Impact of Orthokeratology on Corneal Morphology, Ocular Health and Myopia Control in Children: A 12-Month Clinical Assessment in Myopic Children Living in Kuala Lumpur, Malaysia

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Purpose: This study evaluated the effects of orthokeratology (Ortho-K) lenses on corneal endothelial morphology, anterior segment health, myopia progression, and potential complications in children over 12 months, compared with single vision spectacles (SVS).

Methods: Seventy healthy myopic children aged 6–12 years, with 45 subjects in the Ortho-K group and 25 in the SVS group. Ortho-K lenses (Menicon Z) were worn overnight, while the SVS group wore single vision spectacles. Unaided VA, Spherical Equivalent (SE), axial length (AL), corneal curvature (FK), intraocular pressure (IOP), corneal endothelial morphology (endothelial cell density ECD, hexagonal cell percentage HEX, coefficient of variation COV), and central corneal thickness (CCT), Tear Break Up Time (TBUT) and corneal staining were assessed at baseline, 6 months, and 12 months.

Results: The Ortho-K group demonstrated significant improvements in unaided VA and reductions in SE at 12 months ($p < 0.05$). At 12 months, corneal curvature and axial length decreased significantly in the Ortho-K group but increased in the SVS group ($p < 0.05$). Corneal endothelial morphology remained stable in both groups over 12 months. Mild corneal staining and occasional infections were more frequent in the Ortho-K group, though not statistically different from the SVS group.

Conclusion: Ortho-K lenses are effective in controlling myopia progression in children, leading to significant improvements in VA, reductions in corneal curvature, and slowing of AL without significant adverse effects on corneal endothelial health. Minor complications were comparable to SVS wear, and all corneal changes remained within safe, reversible limits, underscoring the safety of Ortho-K treatment.

Keywords: myopia control, cornea, cornea endothelial cells, Ortho-K, complication, myopic children

Introduction

Myopia is prevalent among children, affecting one-third of children and adolescents worldwide. Scholars have reported that the estimated prevalence of myopia will reach 39.8% by 2050.[1] The condition is particularly widespread in East Asian countries, such as China, Japan, and Singapore, where up to 80–90% of high school students are affected.[2,3] This trend is thought to be driven by environmental factors, including more activities requiring up-close vision, excessive screen time, and reduced outdoor activity, all of which contribute to the early onset of myopia.[4] The increasing prevalence of myopia in younger children is of particular concern considering that such patients are at increased risk for high and potentially pathological myopia. This could result in irreversible visual impairment as myopia progresses.[5,6]

IMI studies have highlighted that the onset of high myopia can be delayed or even prevented through a variety of strategies aimed at slowing the progression of myopia, including optical interventions, contact lenses, pharmacological treatments, environmental modifications, and surgical approaches. Studies have shown that 0.05% atropine reduces the incidence of myopia by nearly 50%, but it is associated with significant rebound effects.[7] In another recent study, multifocal

Received: 3 June 2025
Accepted: 15 November 2025
Published: 25 November 2025

soft contact lens treatment group showed a 52.3% reduction in myopia progression compared to the control group.[8] Among these interventions, orthokeratology (Ortho-K) has emerged as one of the most effective methods for slowing axial elongation in myopic children, with reductions of up to 60%.[9,10] In addition to optical efficacy, Ortho-K offers practical benefits for children, such as overnight lens wear that minimizes daytime handling and improves compliance.

Ortho-K involves the overnight use of specially designed rigid gas permeable contact lenses, with a central base curve customized to temporarily flatten the central corneal curvature while steepening the peripheral cornea to correct refractive error. This reshaping of the cornea leads to thinning of the central corneal epithelium and thickening of the mid-peripheral cornea,[11] which alters how light is refracted. This induces myopic defocus on the peripheral retina, reducing the stimulus for axial length (AL) elongation and thereby slowing myopia progression[12,13] Researchers have found that orthokeratology lenses induce significant astigmatic peripheral myopic defocus in both the temporal and nasal retina, highlighting their potential for myopia control through peripheral refractive modulation.[14] As a result, Ortho-K has become a highly effective treatment for controlling myopia, particularly in school-aged children.

While the effects of reverse geometry lenses are generally reversible, there is ongoing debate about whether long-term wear can alter the corneal epithelial structure and affect the morphological characteristics of the cornea, particularly in children. Concerns have been raised regarding the safety of this approach, as it modifies the structure of the corneal epithelium, potentially impacting corneal endothelial cell morphology, corneal thickness, and overall ocular surface health —key indicators of ocular well-being. Research on corneal endothelial cells in myopic children is limited, and these parameters are crucial for understanding the impact of orthokeratology (Ortho-K) on corneal integrity during the reshaping process. Although studies have revealed the adverse corneal events associated with orthokeratology,[15] no studies have specifically investigated the long-term effects of Ortho-K wear on corneal endothelial cells in children. To address this gap, we conducted a study to examine the impact of Ortho-K lenses on corneal endothelial morphology and overall anterior segment health in myopic children over a 12-month period. This is the first such study in Malaysia, Kuala Lumpur.

Methods

All the subjects were healthy, had no history of myopia control interventions, and were free of ocular diseases. The parents of the participants were informed about the study and subsequently signed consent forms before the study began. The tenets of the Declaration of Helsinki were followed, and ethical clearance was obtained from the research ethics committee of Universiti Kebangsaan Malaysia (UKM PPI-800-1/1/5 JEP-2017-422). Written consent was obtained from the parents or guardians of all participants prior to data collection.

The required sample size for this study was calculated using G*Power version 3.1.9.7, which was based on the mean and standard deviation (SD) of overall vision scores for Ortho-K lens wearers and spectacle wearers from previous clinical trials (16). Assuming a standard deviation of 0.25 mm for the change in axial length (AL) over two years and aiming for 95% power with a significance level of $\alpha = 0.05$, the calculation indicated that 14 participants were needed for each group to detect a difference in AL variation of 0.25 mm (equivalent to approximately 0.75 D). The ratio between groups was set at 1.0, with an effect size of 1.077. Given an estimated dropout rate of 17% among Ortho-K lens-treated participants, the final sample size was adjusted to at least 25 subjects per group to ensure adequate statistical power.

The inclusion criteria were a spherical equivalent refractive error (SER) of −0.75 to −4.00 D, astigmatism ≤ 1.50 D in both eyes, best corrected visual acuity (BCVA) of 0.0 logMAR in each eye, birth weight ≥ 2000 g, and no history of ocular or systemic disease, contact lens use, or myopia treatment. All the participants wore single-vision spectacles prior to the study. The participants were assigned to either the Ortho-K or single vision spectacle (SVS) group on the basis of their parents' or guardians' choice of treatment, with the advantages and disadvantages of each modality explained at the start of the study, without suggesting that one might outperform the other in controlling myopia progression.

The patients in the SVS group were prescribed distance single vision spectacles made of plastic with a refractive index of 1.56 (Integrated Lens Technology, Singapore) for full-time wear. The participants in the Ortho-K group were fitted with Menicon Z night lenses (Menicon, Japan) for overnight wear. Initial lens parameters were determined using Easyfit software (Menicon Co., Japan), which calculates the specifications for the trial lenses on the basis of corneal topography and cycloplegic refraction data. Ortho-K lenses were dispensed to the participants approximately three weeks after the baseline examination. In this study, we emphasized the importance of adhering to lens wear throughout the 12-

month period by providing clear instructions and reinforcing compliance at each visit. The participants returned for follow-up examinations at 1 week and at 1, 3, 6, 9, and 12 months. These scheduled visits allowed us to monitor lens-wearing habits, identify any deviations from the prescribed regimen, and assess participant adherence more accurately, ensuring that the treatment outcomes reflected consistent and proper lens use.

Central corneal endothelial cell morphologies (ECD, HEX, COV, and CCT) were assessed using a non-contact specular microscope (SP-3000P; Topcon, Tokyo, Japan), the accuracy and reliability of which have been validated in previous studies.[16–18] Measurements were taken in automatic mode under room illumination (480–600 lux) between 9 and 11 am to minimize diurnal variation. Three microphotographs were taken for each eye, and the average value was used for analysis.

To ensure accurate measurements, 50 adjacent CECs were selected from a 0.5×0.25 mm section of the central endothelial surface on the specular photomicrograph. The device then automatically analysed the selected area, calculating the average cell density (cells/mm^2) and CCT (μm). A histogram was generated to determine the endothelial cell density (ECD), population size, and minimum, maximum, and average cell sizes. The pleomorphism of endothelial cells, including the coefficient of variation (COV%) and the percentage of hexagonal cells (HEX%), was assessed. The procedure was repeated three times, and average values were recorded.

Standard slit lamp examinations were conducted using a binocular slit lamp (Righton MW50D LED, Tokyo, Japan) to evaluate the anterior segment, including the cornea, bulbar and tarsal conjunctiva (upper and lower), tear film quality, and Ortho-K lens fit. Tear film and corneal epithelial staining were assessed with a fluorescein strip (FLUO strips, fluorescein sodium 1 mg) following the Efron grading scale. The presence, type, location, and severity of any ocular conditions were recorded, with grades ranging from 0 (normal) to 4 (severe). Participants with a redness grade of 2 or higher were excluded. Photographs of the eye and lens fitting were taken and stored using ImageLink software throughout the study.

A computerized noncontact tonometer (Topcon CT-80; Topcon Corporation, Tokyo, Japan) was used to measure the participant's intraocular pressure. The participant was seated in a comfortable position with his or her chin and forehead rested on the machine. When the cornea is aligned, the machine automatically blasts an air puff, and the IOP is displayed in a digital format. The procedure was performed three times on the right eye followed by three times on the left eye; all three readings were recorded in mmHg, and the average was taken for data collection.

An ultrasound direct contact A-Scan (PacScan Plus, Sonomed Escalon, NY) was used to measure AL. One drop of local topical anaesthetic (proxymetacaine hydrochloride 0.5%, Alcaine, Alcon, 15 mL) was dispensed into the participant's eye before the measurement procedure started. The participant was then seated on a chair looking straight ahead with their gaze fixed on an object without accommodation. When the measurements were taken, the hand-held transducer probe was placed perpendicular to the centre to ensure contact with the cornea with minimal possible compression. The measurement was calculated after a single long beep, and the mean of three measurements with a standard deviation of <0.10 mm was automatically recorded.

Statistical Package for the Social Sciences (SPSS) version 21.0 was used to evaluate the data. Given that both eyes of an individual are anatomically and functionally correlated, treating them as independent data points may violate the assumption of independence required for many statistical tests. This inter-eye correlation can lead to an underestimation of variability and an inflation of statistical significance. By analyzing only one eye per participant—typically the right eye, as is standard practice—this study aimed to reduce the risk of such confounding effects and ensure the robustness and validity of the results. To minimize statistical bias, only data from the right eye were included in the analysis.

The Shapiro–Wilk test was used to test normality and whether the baseline demographic, refractive and biometric data were significantly different between the groups. The participants' demographics were analysed using frequencies and descriptive tests. A parametric test (paired test) was used for comparisons of parameters before and after ortho-K or SVS intervention. Independent t tests were used to compare the parameters measured between the Ortho-K group and the SVS group. Pearson chi-square tests were used to compare corneal fluorescein staining, tear film stability, and complications between the Ortho-K group and the SVS group. A p value<0.05 indicated statistical significance.

Results

Demographic Data

A total of 70 patients were included in this study. Among these, 45 patients were fitted with Ortho-K lenses, and 25 subjects were fitted with single vision lenses (SVSs). No significant differences were found in the baseline demographics, refractive data, or biometric measurements between the Ortho-K and SVS groups ($p > 0.05$). The baseline characteristics of the myopic patients were also comparable between the two groups, as shown in Table 1.

Table 1 shows that the mean baseline unaided visual acuity (VA) was 1.21 ± 0.65 in the Ortho-K group and 1.12 ± 0.62 in the SVS group. No significant differences were observed at baseline ($p = 0.577$). In the Ortho-K group, unaided VA improved significantly from 1.21 ± 0.65 at baseline to −0.03 ± 0.08 at 6 months and −0.03 ± 0.09 at 12 months after treatment ($p < 0.05$). In contrast, in the SVS group, the unaided VA deteriorated significantly from 1.12 ± 0.62 at baseline to 1.43 ± 0.78 at 6 months and 1.73 ± 0.95 at 12 months ($p < 0.05$). Additionally, unaided VA in the Ortho-K group improved significantly compared with that in the SVS control group at both the 6-month and 12-month follow-ups ($p < 0.001$), as shown in Table 2.

In the Ortho-K group, the spherical equivalent (SE) decreased significantly from −2.92 ± 1.07 D at baseline to −0.15 ± 0.13 D at 6 months and −0.06 ± 0.12 D at 12 months after treatment ($p < 0.05$). In contrast, in the SVS group, the SE increased significantly from −2.51 ± 1.12 D at baseline to −3.15 ± 1.08 D at 6 months and −3.77 ± 1.23 D at 12 months ($p < 0.05$). The SE in the Ortho-K group was significantly lower than that in the SVS control group at both the 6-month and 12-month follow-ups ($p < 0.001$), as shown in Table 3. At the 6- and 12-month follow-ups, the mean SEs in the SVS group increased to −0.65 ± 0.54 D and −1.26 ± 1.01 D, respectively (Table 3).

The mean baseline corneal curvature (FK) was 43.6 ± 1.27 D in the Ortho-K group and 43.12 ± 1.03 D in the SVS group. No significant differences were observed at baseline ($p > 0.05$). At the 6- and 12-month follow-ups, the FK in the Ortho-K group decreased significantly from 43.6 ± 1.27 D at baseline to 42.17 ± 1.52 D at 6 months and to 40.69 ± 2.54 D at 12 months after Ortho-K treatment ($p < 0.05$). In contrast, in the SVS group, the FK increased significantly from 43.12 ± 1.03 D at baseline to 43.3 ± 1.00 D at 6 months and to 43.47 ± 1.10 D at 12 months ($p < 0.05$). Compared with that in the SVS group, the FK in the Ortho-K group was significantly lower at both the 6-month and 12-month follow-ups ($p < 0.001$) (Table 4).

Table 1 Demographic and Baseline Data

Parameters (Baseline)	Total (n=70)	Ortho-K (n=45)	SVS (n=25)	p value
Age (y)	8.31 ± 0.47	8.38 ± 0.49	8.2 ± 0.41	0.110
Male/Female*	35/35	20/25	15/10	0.289
Unaided VA	1.18 ± 0.63	1.21 ± 0.65	1.12 ± 0.62	0.577
Spherical Equivalent (D)	−2.77 ± 1.1	−2.92 ± 1.07	−2.51 ± 1.12	0.529
ECD	3222.45± 229.13	3251.24 ± 238.16	3170.64 ± 206.41	0.160
HEX	61.26± 10.21	60.54 ± 10.57	62.56 ± 9.35	0.429
COV	38.61±8.91	38.12 ± 8.47	39.52 ± 9.77	0.532
Cornea FK (D)	43.43 ± 1.21	43.6 ± 1.27	43.12 ± 1.03	0.116
Corneal thickness (CCT)	531.71±24.57	528.53±22.26	537.44±27.83	0.147
Axial length (mm)	23.72 ± 0.82	23.85 ± 0.71	23.49 ± 0.95	0.082

Notes: *Independent t test; Pearson chi-square test.

Table 2 Comparison of the Mean (±SD) Unaided VA Between the Ortho-k Group and the SVS Group

Unaided VA	OK (n=45)	SVS (n=25)	p value
Baseline	1.21 ± 0.65	1.12 ± 0.62	0.577
6 months	−0.03 ± 0.08	1.43 ± 0.78	<0.001
12 months	−0.03 ± 0.09	1.73 ± 0.95	<0.001

Notes: Statistically significant difference in unaided VA between the two groups at 6 months. Statistically significant difference in unaided VA between the two groups at 12 months.

Table 3 Comparison of the Mean (±SD) SE Between the Ortho-k Group and the SVS Group

SE (D)	OK (n=45)	SVS (n=25)	p value
Baseline	−2.92 ± 1.07	−2.51 ± 1.12	0.127
6 months	−0.15 ± 0.13	−3.15 ± 1.08	<0.001
12 months	−0.06 ± 0.12	−3.77 ± 1.23	<0.001

Notes: Statistically significant difference in SE or spherical equivalent (D) between the two groups at 6 months. Statistically significant difference in SE or spherical equivalent (D) between the two groups at 12 months.

Table 4 Comparison of the Mean (±SD) FK Between the Ortho-k Group and the SVS Group

FK	OK (n=45)	SVS (n=25)	p value
Baseline	43.6 ± 1.27	43.12 ± 1.03	0.116
6 months	42.17 ± 1.52	43.3 ± 1	0.001
12 months	40.69 ± 2.54	43.47 ± 1.1	<0.001

Notes: Statistically significant difference in the FK and cornea curvature (D) between the two groups at 6 months. Statistically significant difference in the FK and cornea curvature (D) between the two groups at 12 months.

There were no significant differences in axial length (AL) at baseline between the two groups ($p = 0.081$). During the first 6 months of treatment, no significant differences in AL were observed between the Ortho-K and SVS groups ($p > 0.05$). However, after 12 months of treatment, significant differences were observed between the groups ($p < 0.05$). In the Ortho-K group, the AL decreased significantly from 23.85 ± 0.71 mm at baseline to 23.64 ± 0.59 mm at 12 months ($p < 0.05$). In contrast, in the SVS group, the AL increased significantly from 23.49 ± 0.95 mm at baseline to 23.97 ± 0.59 mm at the 12-month follow-up ($p < 0.05$), as shown in Table 5.

In the Ortho-K group, the endothelial cell density (ECD) decreased from 3251.24 ± 238.1 cells/mm^2 at baseline to 3234.03 ± 237.72 cells/mm^2 at 12 months; however, this change was not statistically significant ($p > 0.05$). Similarly, in the SVS group, the ECD remained nearly the same, with no significant difference observed, at 3169.84 ± 205.3 cells/mm^2 at 12 months ($p > 0.05$). When the two groups were compared, no significant differences in ECD were found between the Ortho-K and SVS groups at either the 6-month ($p > 0.05$) or the 12-month follow-up ($p > 0.05$), as shown in Table 6.

In the Ortho-K group, the hexagonal cell (HEX) percentage decreased from 60.54 ± 10.57% at baseline to 60.04 ± 10.34% at 12 months; however, this change was not statistically significant ($p > 0.05$). Similarly, in the SVS group, the HEX remained largely unchanged, with no significant difference observed at 12 months. When the two groups were compared, no significant differences in the HEX were found between the Ortho-K and SVS groups after 12 months of treatment ($p > 0.05$), as shown in Table 7.

In the Ortho-K group, the coefficient of variation (COV) remained the same at 38.1 ± 8.47% at 12 months, which was not significantly different from the baseline value ($p > 0.05$). Similarly, in the SVS group, the COV remained relatively

Table 5 Comparison of the Mean (±SD) AL (Mm) Between the Ortho-k Group and the SVS Group

AL	OK (n=45)	SVS (n=25)	p value
Baseline	23.85 ± 0.71	23.49 ± 0.95	0.081
6 months	23.75 ± 0.49	23.73 ± 0.54	0.868
12 months	23.64 ± 0.59	23.97 ± 0.59	0.035

https://doi.org/10.2147/OPTO.S544550

Table 6 Comparison of the Mean (±SD) ECD Between the Ortho-k Group and the SVS Group

ECD	OK (n=45)	SVS (n=25)	p value
Baseline	3251.24 ± 238.16	3170.64 ± 206.41	0.160
6 months	3249.77 ± 238.83	3171.19 ± 206.76	0.172
12 months	3234.03 ± 237.72	3169.84 ± 205.3	0.261

Table 7 Comparison of the Mean (±SD) HEX Scores Between the Ortho-k Group and the SVS Group

HEX	OK (n=45)	SVS (n=25)	p value
Baseline	60.54 ± 10.57	62.56 ± 9.35	0.429
6 months	60.42 ± 10.51	62.56 ± 8.96	0.394
12 months	60.04 ± 10.34	62.64 ± 8.24	0.284

unchanged at 39.86 ± 9.86% at 12 months, with no significant difference ($p > 0.05$). There were no significant differences in the COV between the Ortho-K and SVS groups after 12 months of treatment ($p > 0.05$) (Table 8).

When the groups were compared, no significant differences were observed in central corneal thickness (CCT) between the Ortho-K and SVS groups during the 12 months of treatment ($p = 0.051$). However, the mean CCT was significantly lower than the baseline value in the Ortho-K group at the 12-month follow-up. In the Ortho-K group, the CCT decreased from 528.53 ± 22.26 μm at baseline to 526.89 ± 21.81 μm at 12 months ($p = 0.032$). In contrast, in the SVS group, the CCT remained stable, with no significant change at 12 months ($p = 0.767$), as shown in Table 9.

Table 10 shows that the mean intraocular pressure (IOP) was 14.6 ± 1.57 mmHg in the Ortho-K group and 14 ± 1.22 mmHg in the SVS group. No significant differences in the baseline measurement were observed ($p > 0.05$). Furthermore, no significant differences were found between the Ortho-K and SVS control groups at the 6-month and 12-month follow-up points, with all p values > 0.05. The changes in IOP from baseline to 6 months and 12 months were minimal and not statistically significant in either the Ortho-K lens group or the SVS group (both $p > 0.05$).

The results of this study revealed that the incidence of complications was higher in the Ortho-K group. After 12 months of Ortho-K lens wear, 5 participants reported having a stye, 1 reported a foreign body (FB) sensation, 1 reported a contact lens peripheral ulcer (CLPU), and 2 reported conjunctivitis. In contrast, in the SVS group, only 1 participant reported a stye after 12 months of wearing SVS lenses. However, when the SVS and Ortho-K groups were compared,

Table 8 Comparison of the Mean (±SD) COV Between the Ortho-k Group and the SVS Group

COV	OK (n=45)	SVS (n=25)	p value
Baseline	38.12 ± 8.47	39.52 ± 9.77	0.532
6 months	38.16 ± 8.15	39.56 ± 9.68	0.522
12 months	38.1 ± 8.47	39.86 ± 9.86	0.433

Table 9 Comparison of the Mean (±SD) CCT Between the Ortho-k Group and the SVS Group

CCT	OK (n=45)	SVS (n=25)	p value
Baseline	528.53 ± 22.26	537.44 ± 27.83	0.147
6 months	526.89 ± 21.81	537.28 ± 26.97	0.084
12 months	524.87 ± 23.15	537.12 ± 27.44	0.051

Table 10 Comparison of the Mean (±SD) IOP Between the Ortho-k Group and the SVS Group

IOP	OK (n=45)	SVS (n=25)	p value
Baseline	14.6 ± 1.57	14 ± 1.22	0.104
6 months	14.58 ± 1.54	14.12 ± 1.17	0.201
12 months	14.49 ± 1.44	14.08 ± 1.19	0.231

Table 11 Comparison of Complications Between the SVS Group and the Ortho-K Lens Group After 12 months of Wear

Group	Stye	FB sensation	CLPU	Conjunctivitis
SVS (n=25)	1 (4.0%)	0 (0.00)	0 (0.00)	0(0.00)
Ortho-K (n=45)	5 (11%)	1 (2.2%)	1(2.2%)	2 (4.7%)

Notes: Pearson chi-square test, p value: $X^2 = 1.037$, $p = 0.309$; $X^2 = 5.064$, $p = 0.453$; $X^2 = 0.564$, $p = 0.453$; $X^2 = 1.041$, $p = 0.187$.

Table 12 Fluorescein Staining Between the SVS Group and the Ortho-K Lens Group After 12 months of Wear

Group	Grade 0	Grade 1	Grade 2	Grade 3
SVS (n=25)	21	2	1	0
Ortho-K (n=45)	38	5	2	0

Notes: Pearson chi-square = 0.254, p = 0.969.

Table 13 Tear Break-up Time (TBUT) Between the SVS Group and the Ortho-K Lens Group After 12 months of Wear

Group	5s	6s	7s	8s
SVS (n=25)	1	3	8	13
Ortho-K (n=45)	4	5	7	29

Notes: Pearson Chi-Square = 3.274, p = 0.351.

a Pearson chi-square test revealed that the difference in complication rates were not statistically significant between the two groups ($p > 0.05$), as shown in Table 11.

After 12 months of Ortho-K lens wear, 5 participants were found to have Grade 1 corneal staining, and 2 had Grade 2 corneal staining. In contrast, in the SVS group, 2 patients had Grade 1 corneal staining, and 1 had Grade 2 staining. When the SVS and Ortho-K groups were compared, a Pearson chi-square test revealed no significant difference in corneal fluorescein staining between the two groups at 12 months ($p > 0.05$), as shown in Table 12. Similarly, the Pearson chi-square test revealed no significant difference in tear break-up time (TBUT) between the SVS and Ortho-K groups after 12 months ($p > 0.05$), as shown in Tables 12 and 13.

Discussion

The aim of this study was to evaluate the safety and effectiveness of Ortho-K lens-wearing in myopic children over a 12-month period. Specifically, it focused on assessing the impact of Ortho-K lens wearing on myopia control, corneal endothelial morphology, anterior segment health, and overall ocular well-being, with comparisons made to a control group of single-vision lens wearers.

https://doi.org/10.2147/OPTO.S544550

The results of this study indicate that Ortho-K lenses are effective in controlling myopia progression in children over a 12-month period. In the Ortho-K group, unaided visual acuity (VA) significantly improved, with a reduction in the spherical equivalent (SE) of −2.92 ± 1.07 D to −0.06 ± 0.12 D after 12 months. In contrast, the single vision spectacle (SVS) group presented a significant deterioration in unaided VA and an increase in SE over the same period (Figure 1, 2). Furthermore, the Ortho-K group presented a reduction in corneal curvature (FK), with a decrease from 43.6 ± 1.27 D to 40.69 ± 2.54 D after 12 months, whereas the SVS group presented an increase in FK, indicating the continued progression of myopia. These results are consistent with previous studies revealing that Ortho-K lenses are effective for correcting myopia, likely because of their reshaping effect on the cornea.[19] The significant reduction in SE in the Ortho-K group ($p < 0.05$) further highlights the effectiveness of Ortho-K lenses in managing myopia compared with conventional spectacle correction.

In terms of axial length (AL), a critical biomarker for myopia progression, the Ortho-K group experienced a reduction in AL, whereas the SVS group showed a significant increase in AL. After 12 months, the mean AL was 23.64 ± 0.59 mm in the Ortho-K group and 23.97 ± 0.59 mm in the SVS group, highlighting the superiority of Ortho-K lenses in slowing axial elongation (Figure 3). These results align with those of recent studies on schoolchildren suggesting that Ortho-K lenses not only provide refractive correction but also help slow myopia progression by influencing both corneal curvature and axial length.[20,21] The significant reduction in axial length (AL) observed in the Ortho-K group after 12 months ($p < 0.05$) further supports their potential for myopia control, in contrast to the increase in AL observed in the SVS group.

Despite the significant refractive and corneal curvature changes observed in the Ortho-K group, no significant differences were found in endothelial cell density (ECD), hexagonal cell percentage (HEX), or coefficient of variation (COV) between the two groups over 12 months of treatment. These findings suggest that Ortho-K lens wear did not have a significant adverse effect on the overall health of the corneal endothelium over the 12-month period, which aligns with the findings of a previous study that revealed no major adverse effects of Ortho-K lenses on the corneal endothelium in children over a 2-year period.[22]

Similarly, central corneal thickness (CCT) decreased slightly in the Ortho-K group, but this change was not clinically significant, indicating that the corneal thickness remained stable with Ortho-K wear for 12 months. The SVS group showed no significant changes in the CCT, further supporting the stability of the corneal structure with both

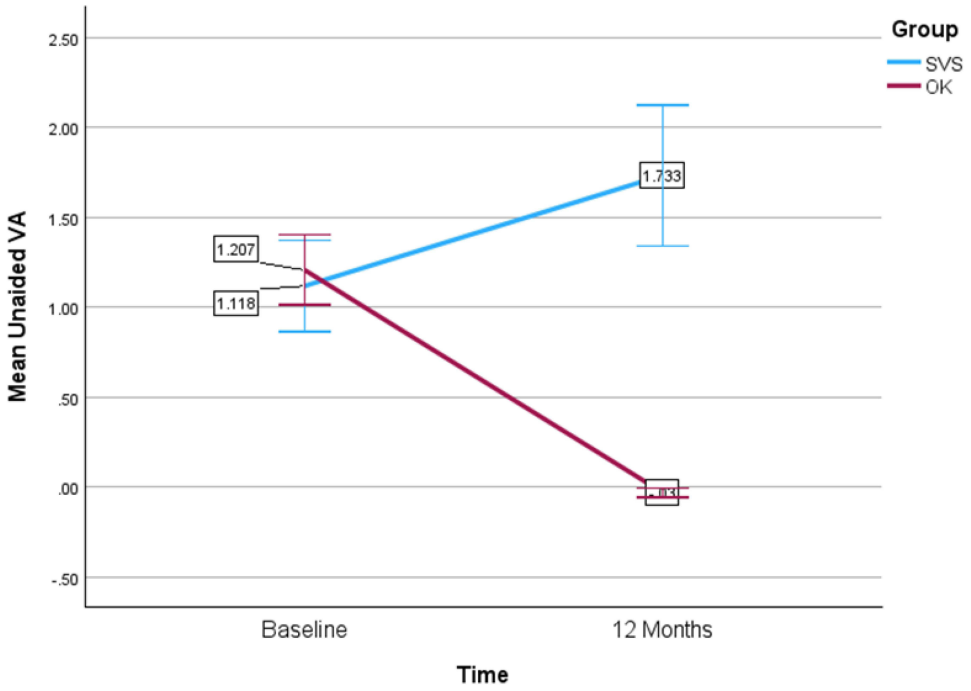

Figure 1 Changes in Mean Unaided Visual Acuity (VA) from Baseline to 12 months between Ortho-K group and SVS group. Mean ± SD values are shown. The Ortho-K group showed a significant improvement in unaided VA compared to the SVS group ($p < 0.001$).

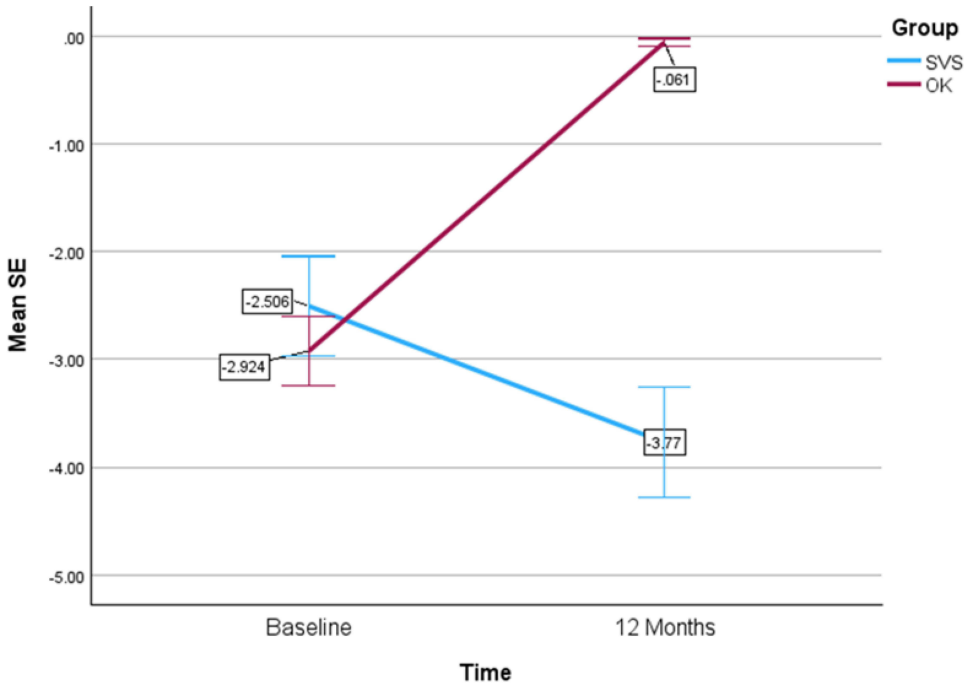

Figure 2 Changes in Mean Spherical Equivalent, SE from Baseline to 12 months between Ortho-K group and SVS group. Mean ± SD values are shown. The Ortho-K group demonstrated significantly less myopic progression compared to the SVS group ($p < 0.001$).

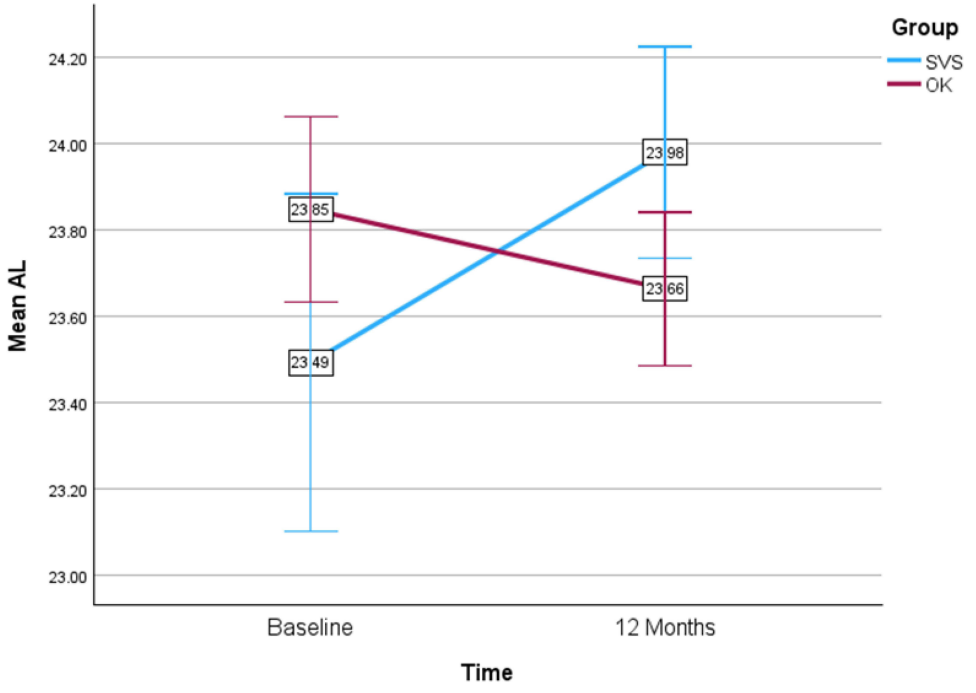

Figure 3 Changes in Mean Axial length, AL from Baseline to 12 months between Ortho-K group and SVS group. Mean ± SD values are shown. The Ortho-K group demonstrated significantly less axial elongation compared to the SVS group ($p < 0.001$).

interventions. Additionally, there were no significant differences in intraocular pressure (IOP) between the groups, suggesting that Ortho-K lenses do not significantly affect IOP during the study period. This finding is in line with previous studies showing that Ortho-K lenses do not significantly alter IOP or contribute to an increased risk of ocular hypertension.[23,24]

https://doi.org/10.2147/OPTO.S544550

This study revealed no significant long-term changes in corneal health parameters between the Ortho-K and SVS groups. While several adverse events, including styes, foreign body sensation, conjunctivitis, and instances of corneal staining, were reported in the Ortho-K group, these complications were not significantly more common in the Ortho-K group than in the SVS group ($p > 0.05$). Overall, the incidence of complications remained low and within clinically acceptable limits, with no significant differences observed between the groups regarding corneal health, tear break-up time (TBUT), or intraocular pressure (IOP) changes.

Hui et al[24] reported no significant differences in TBUT across all follow-up time points ($p > 0.05$). Consistent with these findings, this study also revealed no adverse effects of Ortho-K lenses on tear film stability at 12 months compared with the SVS group ($p > 0.05$). This lack of impact on tear film stability may be attributed to the three fenestration holes in the reverse curve zone of the Menicon Z lens, which facilitate tear exchange between the Ortho-K lens and the corneal epithelial surface. This design supports myopia control while minimizing disruption to tear film stability.[25]

The results of this study support the use of Ortho-K lenses as an effective and safe intervention for controlling myopia progression in children, particularly those at high risk for developing high myopia. The observed improvements in refractive error, axial length stabilization, and corneal curvature flattening after 12 months of Ortho-K lens wear are consistent with previous findings.[19–21,25] Similar refractive, biometric, and corneal topographic changes have been reported over a comparable 12-month treatment period, reinforcing the effectiveness of Ortho-K in myopia control.[26] Furthermore, the optical mechanism underlying Ortho-K efficacy may be influenced by peripheral astigmatic defocus. The interaction between astigmatism and peripheral image quality is thought to play a significant role in retinal defocus signaling, potentially contributing to inter-individual variability in treatment response.[14] Lastly, the effectiveness of Ortho-K in slowing axial elongation and myopia progression presents an important opportunity to mitigate the long-term visual impairment associated with high myopia, particularly in regions with high myopia prevalence, such as East Asia. As myopia rates continue to rise globally, Ortho-K lenses offer a promising solution for controlling myopia progression and preventing its associated complications, such as retinal detachment and glaucoma.

Limitations and Future Research

This study has several limitations, including the relatively small sample size and the lack of long-term follow-up beyond 12 months. Future studies with larger samples of patients and longer follow-up periods are needed to further evaluate the long-term safety and efficacy of Ortho-K lenses in myopia control. Another limitation of this study is that participants were not randomly assigned to the Ortho-K or single vision spectacle (SVS) groups; instead, group allocation was based on the parents' or guardians' treatment preference after being informed of the advantages and disadvantages of each modality. Although no suggestion was made that one treatment would be more effective than the other, this non-randomized design may introduce selection bias. Additionally, more comprehensive assessments of patient-reported outcomes, including comfort and quality of life, would provide valuable insights into the patient experience with Ortho-K lenses.

Conclusion

This study provides strong evidence supporting the efficacy of Ortho-K lenses as an effective option for controlling myopia progression in school-aged children. These findings suggest that Ortho-K treatment leads to significant improvements in visual acuity, as well as reductions in the spherical equivalent, axial length, and corneal curvature, without causing significant adverse effects on corneal health. Importantly, no statistically significant adverse effects on corneal endothelial morphology were observed. The few complications that did arise, such as mild corneal staining and minor infections were infrequent, self-limiting, and resolved with appropriate management. Nonetheless, practitioners should remain vigilant in monitoring ocular health and promptly addressing any complications to maintain a high standard of care.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This study was funded by Menicon Ltd., Japan (NN-2022-019).

Disclosure

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

1. Liang J, Sun S, Liang J, et al. Global prevalence, trend and projection of myopia in children and adolescents from 1990 to 2050: a comprehensive systematic review and meta-analysis. *Br J Ophthalmol*. 2024;108:607–612. doi:10.1136/bjo-2024-325427
2. Wu LJ, You QS, Duan JL, et al. Prevalence and associated factors of myopia in high-school students in Beijing. *PLoS One*. 2015;10:e0120764. doi:10.1371/journal.pone.0120764
3. Morgan IG, French AN, Ashby RS, et al. The epidemics of myopia: aetiology and prevention. *Prog Retin Eye Res*. 2018;62:134–149. doi:10.1016/j.preteyeres.2017.09.004
4. Grzybowski A, Kanclerz P, Tsubota K, Lanca C, Saw S-M. A review on the epidemiology of myopia in school children worldwide. *BMC Ophthalmol*. 2020;20:27. doi:10.1186/s12886-019-1220-0
5. Holden BA, Fricke TR, Wilson DA, et al. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. *Ophthalmology*. 2016;123:1036–1042. doi:10.1016/j.ophtha.2016.01.006
6. Wong Y-L, Saw S-M. Epidemiology of pathologic myopia in Asia and worldwide. *Asia Pac J Ophthalmol*. 2016;5:394–402. doi:10.1097/APO.0000000000000234
7. Zaabaar E, Zhang Y, Kam KW, et al. Low-concentration atropine for controlling myopia onset and progression in East Asia. *Asia-Pac J Ophthalmol*. 2024;13(6):100122. doi:10.1016/j.apjo.2024.100122
8. Liu YL, Lin KK, Cheng LS, et al. Efficacy of multifocal soft contact lenses in reducing myopia progression among Taiwanese Schoolchildren: a randomized paired-eye clinical trial. *Ophthalmol Ther*. 2024;13(2):541–552. PMID: 38127196; PMCID: PMC10787710. doi:10.1007/s40123-023-00859-x
9. Logan NS, Bullimore MA. Optical interventions for myopia control. *Eye*. 2024;38:455–463. doi:10.1038/s41433-023-02723-5
10. Charm J, Cho P. High myopia-partial reduction ortho-k: a 2-year randomized study. *Optom Vis Sci*. 2013;90(6):530–539. PMID: 23645372. doi:10.1097/OPX.0b013e318293657d
11. Kim WK, Kim BJ, Ryu I-H, Kim JK, Kim SW. Corneal epithelial and stromal thickness changes in myopic orthokeratology and their relationship with refractive change. *PLoS One*. 2018;13:e0203652. doi:10.1371/journal.pone.0203652
12. Hiraoka T, Kakita T, Okamoto F, Takahashi H, Oshika T. Long-term effect of overnight orthokeratology on axial length elongation in childhood myopia: a 5-year follow-up study. *Invest Opthalmol Vis Sci*. 2012;53:3913. doi:10.1167/iovs.11-8453
13. Low YC, Mohd-Ali B, Shahimin M, et al. Peripheral eye length evaluation in myopic children undergoing orthokeratology treatment for 12 months using MRI. *Clin Optom*. 2024;16:35–44. doi:10.2147/OPTO.S448815
14. Queirós A, Lopes-Ferreira D, González-Méijome JM. Astigmatic peripheral defocus with different contact lenses: review and meta-analysis. *J Refract Surg*. 2016;32(2):120–129.
15. Hu P, Zhao Y, Chen D, Ni H. The safety of orthokeratology in myopic children and analysis of related factors. *Contact Lens Anterior Eye*. 2021;44:89–93. doi:10.1016/j.clae.2020.08.011
16. Tai L-Y, Khaw K-W, Ng C-M, Subrayan V. Central corneal thickness measurements with different imaging devices and ultrasound pachymetry. *Cornea*. 2013;32:766–771. doi:10.1097/ICO.0b013e318269938d
17. Almubrad TM, Osuagwu UL, Alabbadi I, Ogbuehi KC. Comparison of the precision of the Topcon SP-3000P specular microscope and an ultrasound pachymeter. *Clin Ophthalmol*. 2011;5:871–876. doi:10.2147/OPTH.S21247
18. Ogbuehi KC, Osuagwu UL. Repeatability and interobserver reproducibility of Artemis-2 high-frequency ultrasound in determination of human corneal thickness. *Clin Ophthalmol*. 2012;6:761–769. doi:10.2147/OPTH.S31690
19. Hiraoka T. Myopia control with orthokeratology: a review. *Eye Contact Lens Sci Clin Pract*. 2021;48:100–104. doi:10.1097/ICL.0000000000000867
20. Wang A, Yang C, Shen L, et al. Axial length shortening after orthokeratology and its relationship with myopic control. *BMC Ophthalmol*. 2022;22:243. doi:10.1186/s12886-022-02461-4
21. Tang T, Li X, Chen S, et al. Long-term follow-up of changes in ocular biometric parameters in orthokeratology lens wearers with relatively large-scale axial length reduction. *Eye Vis*. 2023;10:6. doi:10.1186/s40662-022-00324-z
22. Cheung SW, Cho P. Does a two-year period of orthokeratology lead to changes in the endothelial morphology of children? *Contact Lens Anterior Eye*. 2018;41:214–218. doi:10.1016/j.clae.2017.10.006
23. Liu YM, Xie P. The safety of orthokeratology--a systematic review. *Eye Contact Lens*. 2016;42:35–42. doi:10.1097/ICL.0000000000000219
24. Hui W, Xiao-feng H, Song-guo L, et al. Application of orthokeratology on myopia control and its effect on ocular surface and meibomian gland function in Chinese myopic adolescents. *Front Med*. 2022;9:979334. doi:10.3389/fmed.2022.979334
25. Cho P, Cheung S-W. Retardation of myopia in orthokeratology (ROMIO) study: a 2-year randomized clinical trial. *Invest Opthalmol Vis Sci*. 2012;53:7077. doi:10.1167/iovs.12-10565
26. Queirós A, Lopes-Ferreira D, Yeoh B, et al. Refractive, biometric and corneal topographic parameter changes during 12 months of orthokeratology. *Clin Exp Optom*. 2020;103(4):454–462. PMID: 31694069. doi:10.1111/cxo.12976