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Stabilizing effect of orthokeratology lenses (ten-year follow-up results)

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The global prevalence of myopia in adults varies between 20-50% in Europe and the US and 60-90% in Asian countries. According to WHO, myopia is one of five leading causes of blindness and low vision in the world. Prevention or deceleration of myopia progression is an important public health problem. In recent years, orthokeratology (ortho-k) contact lenses worn at night have been found effective in slowing down the progression of myopia, however, the follow-up period in related studies is no longer than five years. **Aim** — to investigate the effects of long-term (10 years) overnight wear of ortho-k lenses on the dynamics of the axial eye growth in children and adolescents. **Material and methods.** This is a prospective cohort study of the effects of ortho-k lenses on the dynamics of anterior-posterior elongation of the eyeball in 84 patients (168 eyes) aged 7 to 16 years and diagnosed with progressive myopia of 1.0 to 7.0 diopters. Patients were examined every three months, including the slit lamp examination to detect possible side effects of lens wear. **Results.** The study proves the decelerating effect of the method on disease progression: the average 10-year increase in the axial eye length was 0.7±0.02 mm that corresponds to myopia progression of 2.4 diopters. A comparative analysis of the annual axial eye growth depending on patient age and the degree of myopia at baseline was performed. The increase was found to be generally greater in young children with higher initial myopia. **Conclusion**. Long-term wear of orthokeratology lenses is able to slow down the axial eye growth, i.e. the progression of myopia.

Keywords*: myopia, orthokeratology, long-term wearing of orthokeratology lenses, slowing down myopia progression, long-term follow-up, axial length, children and adolescents.*

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Presently, myopia is so common around the world that it would not be overstating to consider its scope close to being epidemic. Myopia prevalence varies from 20 to 50 per cent of the adult population of Europe and the USA, while in Asian countries the rate reaches 60—90 per cent [1]. Specific countries show surge in myopia prevalence in recent years. According to some researchers, at this rate myopia will be diagnosed in half of the Earth's population by the end of 2050 [2].

Particularly interesting is the fact that patients with myopia diagnosed in early years are more often subject to complications, including disabling ones, in the future. Myopia is a predisposing factor for retinal separation, macular degeneration and glaucoma that lead to eyesight decline and in some cases to its total loss. The risk of such complications rises with faster myopia progression and elongation of the axial eye length. According to WHO, myopia is on the five leading causes of eyesight decline and loss in the world [3].

When it comes to quality of life standards in patients with high myopia, dependency on constant usage of corrective optics and progressive decline of visual functions play substantial role. It was proved in a number of studies that the quality of life is lower in high myopic patients than in cases with low and moderate myopia, therefore prevention or deceleration of myopia progression is an important healthcare task.

Social and economic well-being of patients is also significantly affected by myopia. J. Javitt and Y. Chiang [4] showed that in the USA annual costs for ophthalmologic check-ups, as well as for spectacle and contact lenses (CL) correction, amount to approximately $4.6 billion. Severe myopia complications primarily occur in socially and economically active population of able-bodied age. Slowing down the progression of the disease positively affects social and economic well-being of myopia patients.

Overnight orthokeratology (ortho-k) contact lenses produced in recent years provide the possibility to decelerate the progression of myopia.

A study by P. Cho et al. conducted in 2005 [5] showed that axial eye length in children that used orthokeratology correction increased in 2 years by 0.29±0.27 mm, while in control group patients that used spectacles it increased by 0.54±0.27 mm. In 2009 J. Walline et al. also published [6] results of a two-year follow-up study where mean axial eye length increase was 0.25 mm in orthokeratology group and 0.57 mm in control group. In 2011 T. Kakita et al. [7] reported axial eye length increase of 0.39±0.27 mm in orthokeratology group and 0.61±0.24 mm increase in control group.

The positive effect of orthokeratology in terms of controlling the myopia progression was evidenced in various studies but their follow-up period did not exceed 5 years [1, 5—16].

The goal of this research is to track the long-term (10 years) impact of overnight OCL usage on the dynam-

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ics of anterior-posterior axis elongation in children and adolescents.

Material and methods

The research was done in the form of a prospective cohort unmasked study with the use of clinical, instrumental, analytical and statistical methods. The study was conducted from March, 2005 to June, 2015 and was based at Moscow Helmholtz Research Institute of Eye Diseases. The study included 84 patients (168 eyes) of aged 7 to 16 (at the moment of the initiation of orthokeratology correction the mean age was 10.15±3.87 years). Among the patients there were 37 males and 47 females. As of the time of orthokeratology correction initiation the level of myopia varied from (-)1.0 to (-)7.0 Dioptre and on the average amounted to (-)3.88±0.12 Dioptre.

Study entry criteria:

1. Baseline age between 7 and 16 years (inclusive).
2. No previous OCL usage.
3. Initial annual progression rate (APR) of 0.92 Dioptre/year.
4. Myopia level of (–)1.0 to (–)7.0 Dioptre (mean (-)3.88±0.12 Dioptre) according to the data of non-cycloplegic autorefractometry examination.
5. Astigmatism not exceeding (–)1.5 Dioptre according to the data of non-cycloplegic autorefractometry examination.
6. Anisometropia not exceeding (–)1.5 Dioptre according to the data of non-cycloplegic autorefractometry examination.
7. Corrected visual acuity 1.0 or higher.
8. No associated eye diseases (heterotrophy, inflammatory diseases, glaucoma etc.).
9. No data on eye, systemic or neurologic diseases or development abnormalities that could potentially affect the refraction development.
10. No medicaments that can affect the condition of refraction were administered.

The patients underwent a check-up every 3 months; they were also examined with the slit-lamp in the like periods to reveal any side effects of contact lens usage. Furthermore, the condition of the lenses was also assessed and they were exchanged if the visual acuity decreased to 0.7 or less.

The eye axial length was measured using ultrasound biometry by means of A/B Scan System Model 837 (Allergan Humphrey, USA) before the start of OK-correction and then every 6 months during the whole follow-up period of 10 years. All the measurements were taken by the same technician who didn't know the initial refraction figures of the patients and their study group affiliation. Every examination consisted of 5 consequent measurements; the mean number was entered in the study database. The measurements were performed between 12 and 15 hours to minimise diurnal oscillations.

The decreasing of corneal thickness is known to stabilize by the end of first week of orthokeratology correction and to continue for another 1—2 months. Accordingly, the axial length was measured 3 months after the start of OCL usage; the result was marked as baseline value. The initial refraction and visual acuity were measured prior to the OCL usage.

In order to get more detailed picture of the long-term OCL usage effect on the axial length depending on patient age and initial myopia level, all the patients were divided into 4 groups (**Table 1**).

At the beginning of the study the patients used reverse geometry lenses CONTEX OK-E System. Starting from November, 2012 they switched to reverse geometry 6-zone lenses DL-ESA manufactured by Dr. Lens Techno, Russia. The lenses were made of Boston XO (Polymer Technology Corp. Wilmington, MA) material with (DK) of 100 x 10–11(cm2/sec)(mL O2/mL.mm Hg). Central thickness of the lens is 0.22 mm, diameter – 10.8 mm. The lenses were selected according to the manufacturer's recommendations. After that the patients were told to wear them every night for at least 7 hours (on average 7–8 hours) of sleep.

Results and discussion

The axial length in the patient's study group prior to OK-correction varied within the range of 22.29–26.75 mm and on average amounted to 24.52±0.06 mm. By the end of the study follow-up period the axial length values were ranged from 23.2 to 27.36 mm (mean 25.28±0.05 mm) (**Fig. 1**).

The elongation of axial length over the 10 year period amounted to 0.76±0.02 mm, which corresponds to the myopia progression of 2.4 Dioptres. Therefore, the annual progression rate was 0.24 Dioptre/year which is considered slow progression.

Annual elongation of the anterior-posterior axis over the 10-year period varied in the range of 0.01 to 0.2 mm with mean value of 0.076. Maximum increase of the axial length was observed during the period from 2nd to 5th year

Table 1. **Patient allocation by age and myopia level (M±m)**

Group	Number of patients (eyes)	Age, years (range and mean value)	Myopia level (range)
1st	12 (24)	7–9 (8.0±0.08)	(–)1.0–(–)3.0
2nd	20 (40)	7–9 (8.4±0.06)	(–)3.25–(–)7.0
3rd	20(40)	10–16 (10.9±0.08)	(–)1.0–(–)3.0
4th	32 (64)	10–16 (11.5±0.11)	(–)3.25–(–)7.0

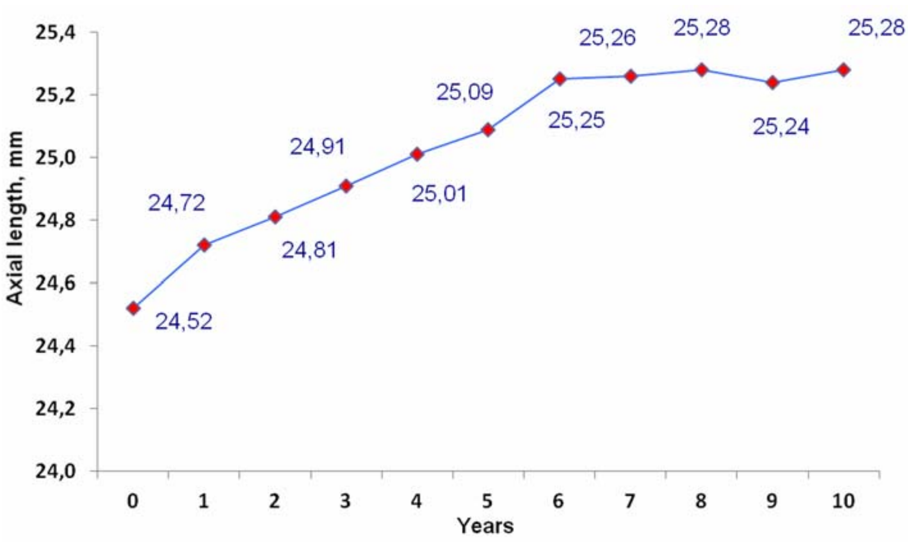

Fig. 1. **Graph of axial length changes in the study group over the 10-year follow-up period.**

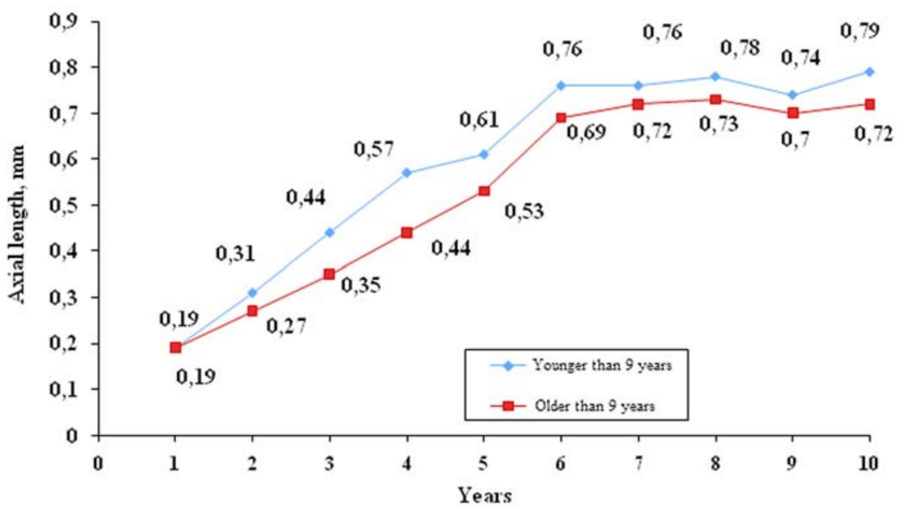

Fig. 2. **Graph of axial length changes in patients of different age.**

when annual axial elongation was statistically valid. After 7 years of lenses usage the axial length increase was almost absent.

The comparison of the axial length dynamics of younger and older children showed that in the group of younger than 9 years the elongation relative to the baseline value was faster (statistically significant; $p<0,05$) than in the group of older than 9 years; the difference is most noticeable for the 2nd to 5th year period of OCL usage (**Fig. 2**). During that period the patients of the younger group grew up to the age of 10—13 years which is the phase of body growth, hormonal changes and most active myopia progression, while the patients of the older group grew up to the age of 13—16 years when the period of “refraction jump” was already over.

The next study phase consisted of analysing the axial length dynamics of younger and older children groups depending on the myopia level. In the younger group (less than 9 years) there was no statistically significant difference in the elongation of anterior-posterior axis between the patients with initial myopia of lower than 3.0 Dioptre and higher than 3.0 Dioptre (**Fig. 3**).

As seen depicted in **Fig. 3**, during the first 5 years of OCL usage in groups with low and moderate myopia the increase of axial length relative to the initial value was equal. From 6th to 8th year of the observation the elonga-

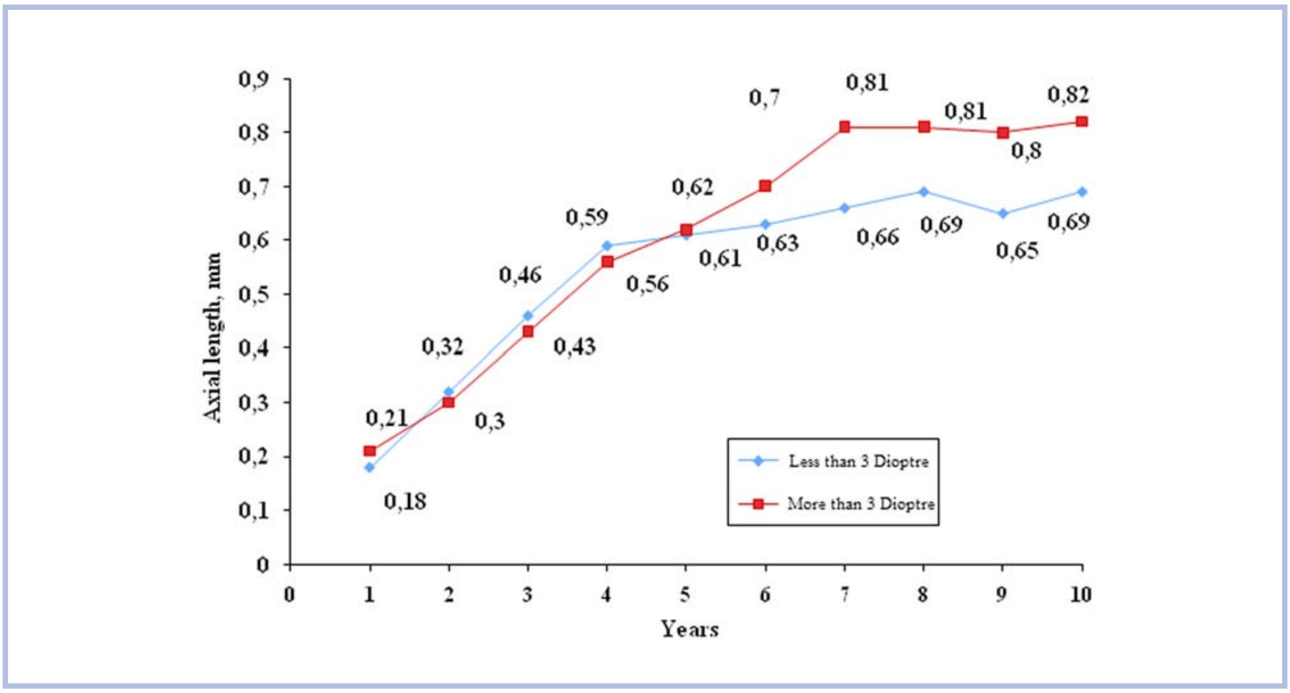

Fig. 3. **Graph of axial length changes in patients younger than 9 years with low and moderate myopia.**

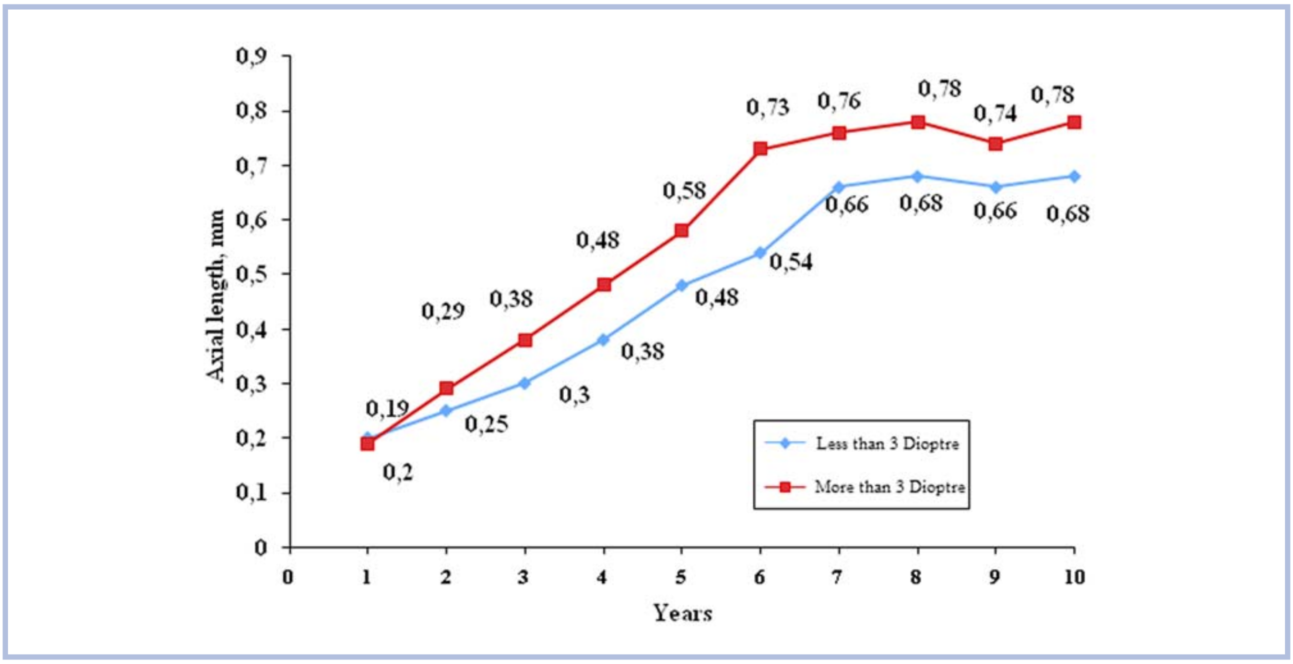

Fig. 4. **Graph of axial length changes in patients older than 9 years with low and moderate myopia.**

tion of the anterior-posterior axis in eyes with initial myopia of higher than 3.0 Dioptre was faster relative to comparable figures for the eyes of initially low myopia level. By that time the mean age of the patient group was 13 years and the mean axial length in the group with initial myopia of higher than 3.0 Dioptre was 25.19 mm which corresponds to severe myopia. It is evident that the decelerating effect of OCL, attributed to optical factors (peripheral myopic defocus), can't prevent the progression of severe myopia caused by abnormalities of structural and biomechanical properties of scleral capsule. Similar findings are seen in the work of R.R. Toloraya where in the setting of OCL usage the eyes with progressing myopia had significantly lower scleral echodensity (intravital measure of its biophysical stability) than the eyes with stable myopia level [17].

Table 2. **Dynamics of anterior-posterior axis elongation in patients that used OCL and spectacle correction**

Studied parameter	Patients of the study group, OCL	Patients who underwent spectacle correction (literature data)	
		H. Takahiro et al. (2012)	T. Kakita et al. (2011)
Anterior-posterior axis length prior to study initiation, mm	24.52±0.06	24.22±0.71	No data
Change:			
over 1st year	0.19±0.1	0.38±0.20	No data
over 2nd year	0.1±0.2	0.33±0.18	0.61±0.24 (total change over 2 years)
over 3rd year	0.09±0.2	0.29±0.16	No data
over 4th year	0.11±0.2	0.24±0.18	No data
over 5th year	0.07±0.1	0.17±0.14	No data

In the older group the elongation of axial length was faster in eyes with initially high myopia (**Fig. 4**) which also supports the assumption.

We compared the study participants' results to literature data on axial length increase with spectacle correction which, according to various authors, amounted to 0.61±0.24 mm in 2 years or 1.41±0.68 in 5 years (**Table 2**).

Anterior-posterior elongation values for spectacle correction are significantly higher than those achieved in our study. This points to the fact that Ortho-K correction has a decelerating effect on the axial length elongation in myopia. A critical aspect of this study is the long duration of the follow-up period compared to similar studies conducted earlier. The 10-year follow-up helped demonstrate that the decelerating effect of Ortho-K correction lasts 7 years after which the anterior-posterior axial length stabilizes.

Previously we have conducted a study [18] to explain the decelerating effect of OCL usage on the myopia progression. It was established that relative hyperopic defocus is formed on the periphery of myopic eye's retina. During the spectacle or OCL correction the defocus persists and even increases which serves as an impulse for anterior-posterior elongation [19]. Orthokeratology flattens the central part of the cornea while mid-periphery part becomes sharper. Such topography of the cornea creates conditions for the development of positive spherical aberration and relative peripheral myopia. We deduced that OCL usage leads to the development of myopic peripheral defocus which is associated with the slowing down of anterior-posterior elongation amid continuous increase of the transverse diameter of the eye [17].

Similar results were achieved by P. Kang and H. Swarbrick [8] who described periphery hypermetropia relative to center in children with myopia. After 3 months of OCL usage the peripheral shift of refraction was measured at 30° from the center in temporal field of the eye and at 20° from the center in its nasal field. Temporal field refraction was equal to central refraction while nasal field refraction was shifted towards myopia. The patients that used standard gas-permeable contact lenses had no changes in either central or temporal refraction. The study authors concluded that using Ortho-K lenses leads to myopia development in place of relative peripheral hypermetropia. In authors' opinion the peripheral myopic defocus is the basis for deceleration of the myopia progression.

Conclusion

Long-term Ortho-K lenses usage can slow down the elongation of anterior-posterior axis and thus the progression of myopia. It is a significant beneficial factor for OCL correction in addition to the absence of necessity to wear contact lenses during day-time. Disadvantages of the Ortho-K include high cost, risk of infection, potential discomfort and problems associated with putting the lenses on and off, as well as lower provided visual acuity relative to the spectacle correction and day-time CL. As of today, the prognosis of the rate of deceleration of myopia progression for individual patients is still problematic and requires further research.

Author contributions:
Study concept and design: E.T.
Data collection and analysis: T.V.
Statistic analysis: T.V.
Text writing: T.V.
Text revision: E.T., T.V.

The authors declare that there are no conflicts of interest.

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