Long-term results of perifocal defocus spectacle lens correction in children with progressive myopia

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ABSTRACT

Peripheral defocus plays a significant role in the formation of refraction. Perifocal spectacles allow differentiating correction of central and peripheral refraction of the eye along the horizontal meridian and can correct or reduce peripheral hyperopia.

Purpose — to study the long-term results of wearing perifocal spectacles on the refraction in children with progressive myopia.

Material and methods. Perifocal spectacles were assigned to children of 7—14 years old with progressive myopia from –1.0 to –6.0 D in terms of refractive spherical equivalent. The children were examined before the prescription of perifocal spectacles and after 6 months, 12—18 months, 2 years, 3 years and 4—5 years. We measured visual acuity, the character of vision, refractive error before and after cycloplegia, performed biomicroscopy, ophthalmoscopy and biometry. Peripheral refraction was studied at 15° and 30° points in the nasal (N15 and N30) and temporal (T15 and T30) meridians without correction and while wearing perifocal spectacles.

Results. In perifocal spectacles, in the 15° zone, 100% of the eyes formed myopic defocus, which averaged –0.05±0.1 D in T15°, –0.25±0.16 D in N15° and –0.44±0.03 D in T30°. In the N30° zone, the hypermetropic defocus decreased by 4 times and amounted to 0.38±0.03 D. The rate of progression of myopia decreased from 0.8 D of baseline values to 0.17 D at 4—5 years of follow-up. After 6 months of wearing perifocal spectacles, the refraction gain was –0.2±0.02 D (in the control group it was –0.38±0.04 D), after 12—18 months — (–)0.38±0.04 D (–0.63±0.09 D in the control group), after 2 years — (–)0,78±0,06 D (–1.18±0,15 D in the control group), after 3 years — (–)0.99±0.12 D (–1.65±0.20D in the control group). During the 4—5 years of the follow-up, the refractive error in treatment group was –1.16±0.2 D, which is 60% less than in the control group (–1.95±0.2 D).

Conclusion. Constant wearing of perifocal spectacles reduces the rate of myopia progression in children by 4.5 times compared with the initial rate, and by 1.6 times (by 60%) in comparison with the control group. Perifocal spectacles are recommended as optical means to slow the progression of myopia.

Keywords: refraction, myopia, progressive myopia, myopia control, peripheral refraction, myopic defocus, myopia correction.

Influence of different ways of correction and it's completeness to affects the development and progression of myopia continue to occupy the minds of researchers [1-3]. In the light of the hypothesis about the effect of induced peripheral defocus on the refractogenesis [4] we can see more often attempts are made to manage growth eyes with devices inducing myopic peripheral defocus in the eye. In the experiment, it is shown that the induced peripheral hyperopic defocus stimulates eye growth and formation of axial myopia, and myopic, on the contrary, has a retarding effect on the refraktogenesis [5,6]. The results of clinical studies also indicate the role of peripheral hypermetropic defocus in stimulating eye elongation [7, 8]. The formation of peripheral myopic defocus is explained by stabilizing effect of orthokeratological lenses on refraktogenesis [9-13]. Undertake attempts to create spectacles and contact lenses that can form relative peripheral myopia in the eye. In 2002 was provided a

description of potential designs of spectacle lenses for the correction of off-center refraction at emmetropia, myopia and hypermetropia, which, however, had significant aberrations [14]. Later, RRG lenses were designed to maintain high Central vision and increase the positive optical power in all radial directions. Enhancement of the refractive index in RRG lenses from the center to the periphery was about 1.0 D for every 10° compared to uncorrected peripheral refraction [15]. In Russia, the lens, capable of correcting peripheral refraction horizontal Meridian, first appeared in 2012. Declared that this lens enhances refraction from the center to the periphery on the nasal side by 2.0 D, temporal by 2.5 D. Results of a study conducted at the Helmholtz's Moscow state research Institute, it was shown that the Perifocal-M lens corrects peripheral hypermetropia in 15°, forms myopia in 15° to the nose and to the temple from fovea and in 30° of the temporal periphery, in 30° of the nasal periphery it reduces peripheral hypermetropia by 5 times [16, 17]. Different designs of soft contact lenses were proposed for forming peripheral myopic defocus - bi- and multifocal [18-20]. The first data on the effect of spectacles and contact lenses that induce peripheral myopic defocus on the progression of myopia and eye growth are ambiguous. Our Chinese colleagues did not receive convincing data on the stabilizing effect of spectacles designed to reduce peripheral hyperopia during their 6-12-month use. The stabilizing effect was observed only in children 6-12 years old with a burdened family history (which seems very significant to us!). Reduction of myopia progression in this group compared to control (monofocal spectacles) was 0.29 D during the specified period observations (less than 1 year) [21]. In studies of the effect of progressive spectacles on the progression of myopia it is noted that such spectacles can reduce hypermetropic defocus at least in the upper half of the field of view that provides them stabilizing effect. The results of a randomized study to evaluate the effect of progressive spectacles showed the ability of such spectacles reduce peripheral hypermetropia and slow the progression of myopia. Shift of the refractive index for 1 year in children who wore spectacles that induce myopic defocus in the upper half of the field of view were (–)0.38 D, while those who wore spectacles that induce a similar hypermetropic defocus had (–) 0.65 D [22]. A more significant reduction in the progression of myopia was obtained in children using special bifocal contact lenses. During 1 year of follow-up, the difference compared to the control was 0.57 D [18]. Our previous studies of the stabilizing effect of Perifocal-M spectacles on the progression of myopia have shown that the proposed design of spectacles that induce myopic defocus gives convincing results for stabilizing myopia in comparison with the indicators of the control group in terms of up to 18 months [17]. Continued monitoring of children using perifocal spectacles to correct progressive myopia will allow us to assess their impact on refractogenesis in terms of up to 5 years. The aim of the study is to study the long-term effects of wearing perifocal spectacles on refractive dynamics in children with progressive myopia.

Material and methods

The study was conducted on the basis of the Federal state budgetary institution "scientific medical research center of eye diseases. Helmholtz" Ministry of health of Russia in the period from 2012 to 2018 under the supervision of 94 children of treatment group. Perifocal spectacles were assigned to children aged 7-14 years with progressive myopia from (–) 1.0 to (–) 6.0 D according to the refractive index, with the best corrected visual acuity of 0.8 and higher, binocular character of vision. The average age of starting wearing spectacles was 10.5±0.14 years. Spectacles with perifocal defocus were always designated for permanent wear.

The correction was performed close to complete, no more than 0.5 D weaker than cycloplegic refraction. Examination of children was performed before the appointment of spectacles, after 6 months, 12-18 months, 2 years, 3 years and 4-5 years from the beginning of wearing spectacles. The maximum period of observation is 5 years. In children who wore perifocal spectacles, the refraction dynamics was evaluated: after 6 months — in 94 children (188 eyes), after 12-18 months-in 72 children (142 eyes), after 2 years-in 58 children (116 eyes), after 3 years-in 42 children (84 eyes), in 4-5 years-in 28 children (56 eyes). The control group consisted of 52 children with progressive myopia aged 8-14

years. All children in the control group were assigned monofocals spectacles for constant wear, with correction, is close to full. The average age at the time of inclusion in the control group was 10.5±0.15 years.

The dynamics of refraction in children of treatment and control groups was evaluated in comparison with the indicators at the beginning of the observation. It was believed that refraction stable if its value increased by no more than 0.5 DPT over the entire period of observation (dynamics from 0 to 0.5 DPT over 5 years).

The survey of children was carried out before the appointment of spectacles and in each of the designated periods. The examination included visometry without correction and with optimal correction, determination of the nature of vision, refractometry before and after cycloplegia (1% cyclopentolate 2 times), biomicroscopy, ophthalmoscopy, determination of relative accommodation reserves, study of muscle balance (phoria), objective study of peripheral refraction at 15° and 30° points in the nasal (N15 and N30) and temporal (T15 and T30) Meridian without correction, and in perifocal spectacles using an automatic "open field" refkeratometer WR-5100K ("Grand Seiko Co. Ltd.", Japan), measured the length of the axial length (AL) of the eye using biometrics using partially coherent interferometry on the IolMaster device ("Carl Zeiss", Germany).

The study in perifocal spectacles was performed by turning the head in the direct direction of the eye, in order to preserve the situation of the peripheral defocus induced by spectacles in natural conditions when looking into the distance.

Results and discussion

Influence of spectacles with perifocal defocus on the peripheral refraction of the eye.

The results of the peripheral refraction study for spectacles with perifocal defocus, obtained using the automatic open field refkeratometer WR-5100K without correction and in Perifocal-M spectacles, showed that without correction, hypermetropic defocus occurs in 61.5% of eyes in T15° and T30°; in 46% of eyes in N15°; in 100% of eyes in N30°. The magnitude of hyperopic defocus without correction, it averaged +0.11±0.11 D in T15°; +0.72±0.28 D in T30°; +0.02±0.1 D in N15°; +1.53±0.2 D in N30°. In Perifocal-M spectacles, a myopic defocus was formed in the 15° zone in 100% of the eyes, which averaged (–) 0.05±0.1 D in T15°, (–) 0.25±0.16 D in N15°, and (–) 0.44±0.03 D in T30°. In the N30° zone, the hypermetropic defocus decreased by 4 times and amounted to 0.38±0.03 D (Fig. 1). Thus, spectacles with special design lenses with horizontal progression - Perifocal-M form a relative peripheral myopic defocus in the eye or significantly reduce the peripheral hypermetropic defocus.

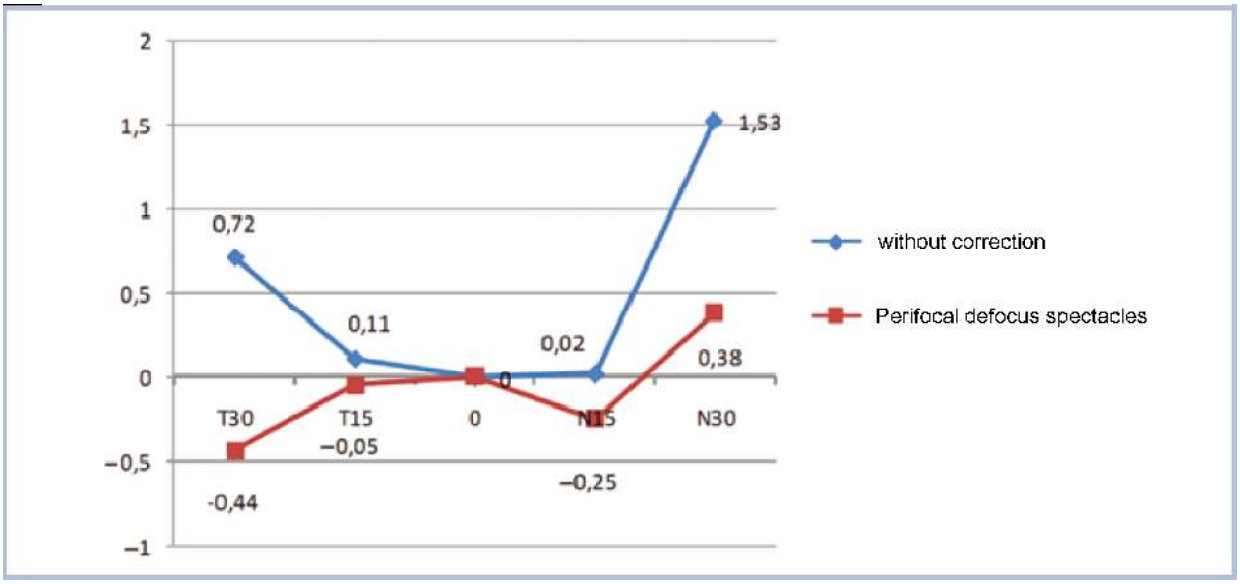

Fig. 1. Amount of peripheral defocus without correction and in perifocal spectacles. Horizontal axis — area of measurement of relative peripheral defocus: T30 and T15 lie in 30° and 15° across from center in the temporal side, N15 and N30 — in 15° and 30° across the nasal side; vertical axis — amount of relative peripheral defocus, Dioptres.

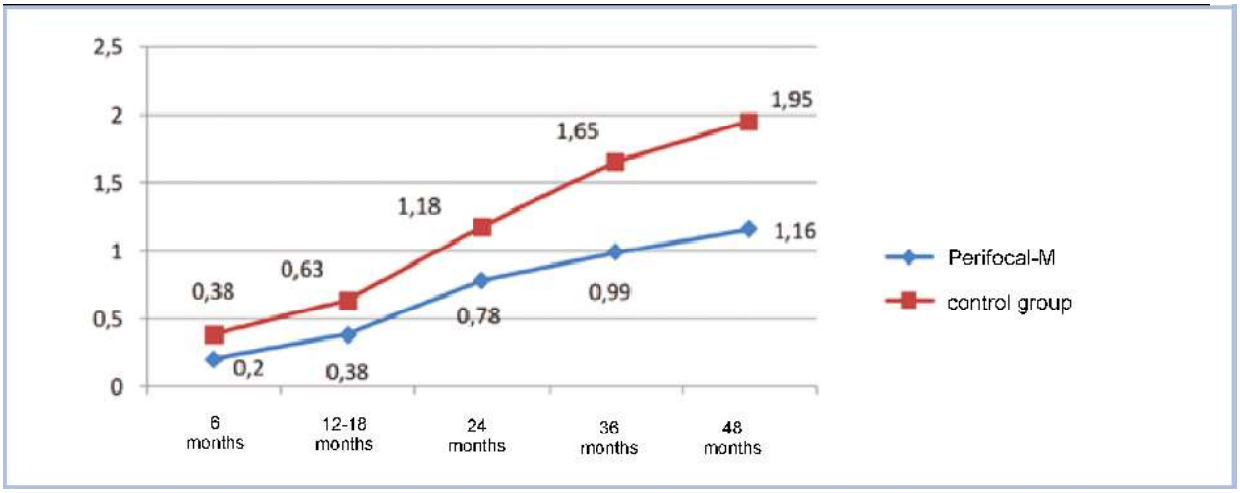

Fig. 2. Increase of refraction in children of treatment and control groups at different follow-up points.

Influence of spectacles with perifocal defocus on dynamics of eye refraction and AL value.

After 6 months of wearing bifocal spectacles, cycloplegic objective refraction in treatment group of patients changed by + 0.5 D (weakening!) — (–) 1.25D. The average change in objective cycloplegic refraction was (–)0.2±0.01 D (Fig. 2). In the first six months of follow-up, 39.4% (74%) of cases showed a weakening of cycloplegic refraction; stabilization of cycloplegic refraction was observed in 36.7% (69 eyes) cases. Refraction strengthening was observed only in 23.9% (45 eyes) of cases (table. 1). Refraction in children of this group increased by 0.63 D and more by the spherical equivalent. Only 1 (1.1%) child had a bilateral strengthening in cycloplegic refraction by (–) 1.25 D. During the first 6 months of observation, the annual progression gradient (AGP) in perifocal spectacles decreased by 2 times compared to the initial values (0.4 and 0.8 D, respectively, $p<0.05$) (table. 2). AL after 6 months of the perifocal spectacles using increased by an average of 0.05±0.02 mm.

Table 1. Stabilization of refraction at various follow-up points in children wearing perifocal spectacles

Objective cycloplegic refraction dynamics	Follow-up period				
	6 months (188 eyes)	12-18 months (144 eyes)	24 months (116 eyes)	36 months (84 eyes)	48-60 months (56 eyes)
Weakening,%	39,4	9,7	2,6	2,4	3,6
Stabilization,%	36,7	52,8	47,4	46,4	37,5
Strengthening,%	23,9	37,5	50,0	51,2	58,9

Table 2. Gradient of myopia progression at various follow-up points when wearing perifocal spectacles

Myopia progression gradient,D	Follow-up period					
	Baseline	6 months	12-18 months	24 months	36 months	48-60 months
Group						
treatment	0,8±0,06	0,4±0,06	0,33±0,05	0,30±0,05	0,21±0,03	0,17±0,02
control	0,8±0,05	0,8±0,05	0,53±0,08	0,62±0,08	0,47±0,08	0,3±0,06

In children of the control group, after 6 months, the average change in cycloplegic refraction was (–) 0.38±0.04 D (see Fig. 2). Refraction remained stable only in 40.4% (42 eyes) of cases. In other cases, refraction was increased from (–)0.63 to 1.12 diopters for spherical equivalent. AGP in children of the control group was 0.8±0.05 D. The increase in the length of AL in children of the control group was 2 times greater than in treatment one, and was 0.11±0.03 mm ($p<0.05$).

After 12-18 months of wearing perifocal spectacles, cycloplegic objective refraction increased on average by (–) 0.38±0.04 D (see Fig. 2). In 9.7% (14 eyes) of cases, there was a decrease in refraction compared to its initial values. Stabilization of cycloplegic refraction was observed in 52.8% (76 eyes) of cases. In 37.5% of cases, refraction increased by 0.63-1.63 D for the spherical equivalent. During 12-18 months of observation, the AGP in spectacles with perifocal defocus was 0.33±0.05 (see table. 2). AL after 12-18 months of wearing perifocal spectacles increased by an average of 0.11±0.02 mm compared to the initial values, i.e. only by this time AL indicators were closer to the values in children of the control group, estimated after 6 months of observation. In children of the control group, refraction strengthening was detected in 73.1% and during this period averaged (–) 0.63±0.09 D (see Fig. 2). The increase in AL was almost 2 times greater than this indicator in children of the treatment group, and after 12-18 months of observation, its values were 0.20±0.03 mm. the value of AGP in the control group during this period was 0.53±0.08 D. The difference between indicators in children of the treatment and control groups is statistically significant ($p<0.05$).

After 2 years of wearing perifocal spectacles, cycloplegic objective refraction increased by an average of (–) 0.78±0.06 D compared to the starting values. In 2.6% (3 eyes) of cases, there was a decrease in refraction compared to its initial values. Stabilization of cycloplegic refraction was observed in 47.4% (55 eyes) of cases, and in 50.0% (58 eyes) of cases, cycloplegic refraction increased compared to the values at the beginning of the observation. In children of this group, refraction increased by 0.63-2.25 D in the sphere equivalent: in 28.4% (33 eyes) of cases, the increase was insignificant, by 0.63-1.0 D, in 19.0% (22 eyes) - by 1.25-2.0 D, progression of more than 2.0 D was observed only in 2.6% (3 eyes) of cases (Fig. 3). On 2nd year of observation progression gradient in Perifocal-M was more than 2 times lower than the in control one and amounted to 0.3±0.05 D (see table. 2). AL value after 2 years of using Perifocal-M spectacles increased by an average of 0.22±0.03 mm compared to the starting values. In children of the control group, refraction strengthening was detected in 92.3% and during this period averaged (–) 1.18±0.15 D (see Fig. 2). The increase in AL was 0.50±0.06 mm. the difference between the indicators in children of the treatment and control groups is statistically significant ($p<0.05$). The value of the progression gradient for the 2nd year of follow-up in children of the control group was 0.62±0.08 D-2 times higher than in children of treatment group (see table. 2).

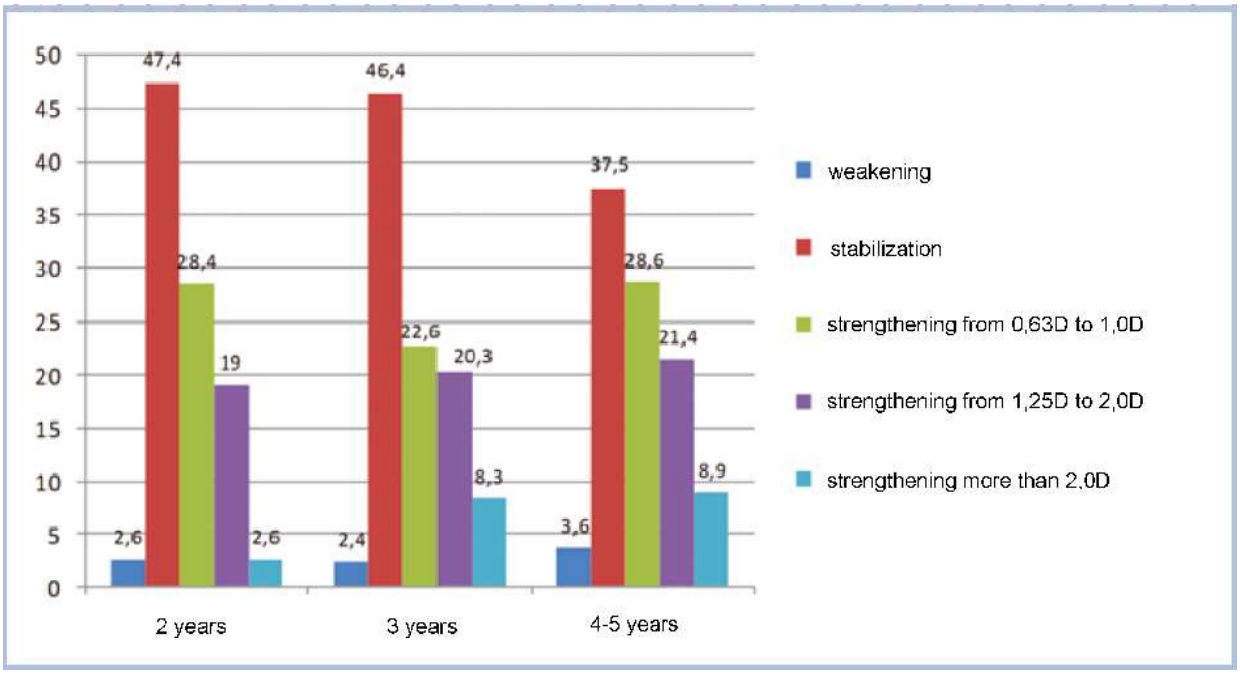

Fig. 3. Changes in cycloplegic refraction in children wearing perifocal spectacles in the long-term follow-up, compared to initial values.

After 3 years of wearing perifocal spectacles cycloplegic objective refraction increased by an average of (–) 0.99±0.12 D compared to the starting values (see Fig. 2). Stabilization of cycloplegic refraction was observed in 46.4% (39 eyes) of cases, in 2.4% (2 eyes) of cases there was a weakening of cycloplegic refraction, in 51.2% cases of cycloplegic refraction in 3 years increased by 0.63—2.88 D for the sphere equivalent (see table. 1): in 22.6% (19 eyes) of cases for 0.63-1.0 DPT, in 20.3% (17 eyes) of cases for 1.12-2.0 DPT, more than 2.0 DPT in 8.3% of cases (see Fig. 3). At the 3rd year of observation, the progression gradient in spectacles with perifocal defocus was 0.21±0.03 D (see table. 2). The value of AL after 3 years of using perifocal spectacles increased on average by 0.36±0.04 mm compared to the values at the beginning of the observation.

No cases of refraction stabilization were observed in children of the control group for 3 years. Objective refraction increased by an average of (–) 1.65±0.2 D after 3 years (see Fig. 2). The average gradient of progression in the 3rd year of follow-up was 0.47±0.08 D. AL increased by 0.58±0.08 mm; difference in refraction shift, AGP, and AL values in the treatment and control it is statistically significant ($p<0.05$).

After 4-5 years of continuous perifocal spectacles wearing, cycloplegic objective refraction increased on average by (–) 1.16±0.13 D compared to the initial values (see Fig. 2).

Refraction stabilization compared to the initial values was observed in 37.5% (21 eyes) of cases, weakening-in 3.6% (2 eyes). In other cases, refraction increased by 0.63—3.0 D by the spherical equivalent over 4-5 years (see table. 1): in 28.6% (16 eyes) of cases slightly-by 0.63-1.0 DPT, in 21.4% (12 eyes) of cases by 1.12—2.0 DPT, more than 2.0 D in 8.9% (5 eyes) of cases (see Fig. 3). There were no cases of refraction shift of more than (–)3.0 D compared to the initial values. In the last year of observation the progression gradient difference in Perifocal-M spectacles was 0.17±0.02 D (see table. 2), while during the entire follow-up period of 4-5 years, the AGP was 0.26 D/year. In the treatment group of patients, AL value increased by an average of 0.46±0.05 mm after 4-5 years of using perifocal spectacles compared to the initial values.

In children of the control group, objective cycloplegic refraction increased by an average of (–) 1.95±0.26 D after 4-5 years, the gradient of progression in the last year of follow-up was 0.3±0.06 D, and for the entire period of follow-up-an average of 0.44 D/year. The AL increased by 0.71±0.09 mm. the Difference between the refraction shift, AGP, and AL in children of the treatment and control groups is statistically significant ($p<0.05$).

Analysis of results table. 1 and 2 shows that children in treatment group who wore spectacles with perifocal defocus had complete stabilization (and even a slight weakening of the refractive index was observed in 62.5% of cases during the first 12-18 months of observation and in 48.8% of cases within 3 years. In children of the control group, these indicators were 26.9 and 0%, respectively. Stabilization of myopia was observed in 41.1% of children in the treatment group after 4-5 years of follow-up. It should be noted that the observed children were at the age of the most active growth and progression of myopia — the average age of children at the beginning of observation was 10.5 years. At this age, spontaneous stabilization for 3 years is observed in no more than 3-7% of cases, and in our study, children in the control group did not have stabilization in any case. In the COMET study, the age of stabilization varied depending on gender and ethnic group. The average period of cessation of myopia progression was between 14.44 and 15.28 years for girls and from 15.01 to 16.66 years for boys. At 12 years of age, myopia was assessed as stable only in 37% (41 out of 112) of Africans, while in other ethnic groups, the index was significantly lower — 13% (8 out of 62) of Hispanics and 15% (5 out of 33) of Asians [23].

In our study, in addition to 41.1% of children with stable refraction for 4-5 years, 28.6% of children in treatment group had no more than 1.0 D progression over the entire follow-up period (i.e., the rate of progression was 0.15 D/year), and only 8.9% of children had increased refraction by more than 2.0 D over 4-5 years of follow-up.

The average AGP for 4.5 years of follow — up was 0.26 D/year in children of treatment group, and 0.44 D/year in the control group.

In table. 2 comparative data on the rate of progression of myopia in children of treatment and control groups are presented. Within 12-18 months the progression of myopia in comparison with indicators the control group decreased by 1.6 times, after 4-5 years — by 1.8 times. Compared with the baseline values, there was 4,7 times less progression. It should be noted that there were no cases of Exo - or esophoria induced by wearing perifocal spectacles during the entire period of observation.

The results obtained by us in children of the control group coincide with the data of other authors. K. Chung et al. (2002) in children who wore monofocal spectacles, the progression of myopia over 2 years was found to be 0.77 D if fully corrected, and 1.0 D if undercorrected [2]. On the contrary, in the observation of Y. Sun et al. (2017) in children 12.7 years of age with full monofocal correction of myopia of a weak degree, the progression was 1.04 D for 2 years, in the absence of correction-0.75 D [3].

In both cases, the AGP value varied from 0.5 to 0.38 D / year, which corresponds to the values of this indicator in children of our control group. It should be emphasized that the average age of children included in our study was 10.5 years. This means that the observation was carried out for children aged from 10.5 years to 15 years, i.e. during the period of growth of the body and the most active progression of myopia [10].

Conclusions

1. Perifocal spectacles form a myopic defocus of 15° in the nasal and temporal periphery of the retina and 30° in the temporal; in the 30° nasal periphery of the retina, the hypermetropic defocus is reduced by 4 times.

2. Against the background of constant wearing of perifocal spectacles, the rate of progression of myopia in children decreases by 4.7 times compared to the baseline level and by 1.6 times (by 60%) compared to the indicators in children of the control group.

3. Complete stabilization of myopia against the background of wearing perifocal spectacles in children in the prepubescent and pubertal periods was observed in 62.5% of cases during 12-18 months, in 50.0% of cases-within 2 years, in 41.1% of cases - within 4-5 years. In children of the control group, similar indicators were observed in 26.9% of cases within 12-18 months, in 7.7% of cases-within 2 years. In the long term, no cases of stabilization were observed.

4. Spectacles with perifocal defocus can be recommended as a reliable non-invasive optical tool that helps slow the rate of progression of myopia and even stabilize it.

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