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INDUCED BY GLASSES "PERIFOCAL - M" PERIPHERAL DEFOCUS AND PROGRESSION MYOPIA IN CHILDREN

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Peripheral defocus plays a significant role in the formation of refraction. Spectacle lenses "Perifocal - M" allow differentiated correction of the central and peripheral refraction of the eye along the horizontal meridian. The effect of glasses with a Perifocal-M lens on wavefront aberrations, peripheral refraction and myopia in children was studied. A clinical prospective parallel cohort open-label study was carried out in which 75 children aged 9-14 years with progressive myopia from -1.0 to -6.0 diopters participated. The follow-up period was 6-18 months. Patients were randomly assigned to either Perifocal-M glasses or monofocal glasses. It was noted that "Perifocal-M" glasses form a relative peripheral myopic defocus in the eye or significantly reduce peripheral hyperopic defocus, and also induce positive spherical aberration. After 6 months of wearing glasses "Perifocal - M" compared

with control, a decrease in eye growth by 0.05 mm and a shift in refraction towards intensification were noted: manifest by 0.19 diopters, cycloplegic by 0.11 diopters. After 12-18 months of wearing glasses "Perifocal - M" on Compared with the control, there was a decrease in eye growth by 0.07 mm and a shift in refraction towards amplification: manifest - by 0.3 diopters, cycloplegic by 0.27 diopters. There were no cases of heterophoria decompensation when using glasses "Perifocal - M". Glasses "Perifocal - M" help to inhibit the progression of myopia in children.

Keywords: *refraction in children; peripheral refraction; relative peripheral defocus; progression of myopia; correction of myopia*

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PERIPHERAL DEFOCUS INDUCED BY "PERIFOCAL-M" SPECTACLES AND MYOPIA PROGRESSION IN CHILDREN

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Peripheral defocus plays a significant role in refraction development. Spectacle lenses "Perifocal-M" allows to perform a correction of the central and peripheral refraction in the horizontal meridian differentially. The purpose was to determine the effect of "Perifocal-M" spectacles on the wave front aberrations, peripheral refraction and myopia development in children. 75 myopic children aged 9-14 with spherical equivalent cycloplegic refraction between -1,0 D and -6,0 D took part in the clinical prospective parallel cohort open study. Patients were randomly assigned to wear "Perifocal-M" or monofocal spectacles. It is noted that "Perifocal-M" spectacles form relative peripheral myopic defocus in the eye or decrease peripheral hyperopic defocus significantly, as well as induce positive spherical aberration. Decrease of the eye growth on 0.05mm, decrease of the myopic shift manifest refraction on 0.19 D, cycloplegic refraction on 0.11 D as compared to the control group were revealed after 6 wearing months of "Perifocal-M" spectacles. Decrease of the eye growth on 0,07mm, decrease of the myopic shift manifest refraction on 0.3 D, cycloplegic refraction on 0.27 D as compared to the control group were revealed after 12-18 months wearing of "Perifocal-M" spectacles. No one case of heterophoriadecompensation occurred while wearing "Perifocal-M" spectacles. "Perifocal-M" spectacles arrest the myopia progression in children.

Key words: *children refraction; peripheral refraction; relative peripheral defocus; myopia progression; myopia correction*

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In recent years, peripheral defocus has been playing a significant role in the formation of refraction. The latter is understood as the relative attenuation or enhancement of the refraction of the rays at

transition from the center of the fovea to the peripheral parts of the retina. In the first case, they talk about relative peripheral hyperopia, or hyperopic defocus, in the second, about myopic peripheral

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richesky defocus. A number of experimental studies have shown that hyperopic defocus at the retinal periphery stimulates the growth of the eye and the formation of axial myopia, while myopic, on the contrary, inhibits refractogenesis [1, 2]. The results of clinical studies also testify to the stimulating role of hyperopic defocus, stimulating eye lengthening [3], and the relationship between myopia and peripheral hyperopia [4].

A lot of works are devoted to the study of peripheral refraction in various types of correction. It has been reported that conventional single vision glasses increase peripheral hyperopic defocus compared to uncorrected myopic eyes [5], that conventional spherical contact lenses create myopic defocus at the periphery, in contrast to glasses [6]; that these lenses, on the contrary, form a hyperopic defocus, and multifocal contact lenses create relative myopia at the periphery [7].

Interest in the study of peripheral refraction in recent years has been supported by the results of clinical observations of children using orthokeratological contact lenses. It is here that the inhibition of the progression of myopia and the growth of the anteroposterior axis (APA), noted by all, can most of all be associated with a significant constantly acting induced myopic peripheral defocus [8, 9]. This effect is provided by a change in the topography of the cornea under the action of OK lenses. The central part of the cornea is flattened, while the paracentral and peripheral ones acquire greater "steepness" and refractive power. This leads to the formation of positive spherical aberration and, due to stronger peripheral refraction, a relative myopic defocus at the periphery.

By analogy with multifocal contact and orthokeratological lenses, special design spectacle lenses are being developed [10] or lenses designed to create relative myopia in the periphery [11].

Such lenses were created several years ago and appeared on the Russian market. Spectacle lenses "Perifocal - M" have a special design, with a progression of refraction (addition) horizontally in both directions relative to the optical center, stable refraction in the geometric center, refraction along the vertical meridian has comparable values with refraction in the geometric center ... The lens "Perifocal - M" allows differentiated correction of the central and peripheral refraction of the eye along the horizontal meridian.

Physicomathematical calculations in modeling the design of the optical surface of the lens "Perifocal-M" were carried out by a leading specialist in the design of surfaces of optical devices and vision correction tools, Professor of the University of Madrid Jose Alonso (University Complutense of Madrid, Madrid, Spain). The unique properties of the lens "Perifocal-M" make it possible for the first time in practice to reveal the effectiveness of different in strength correction of nasal and temporal relative peripheral hyperopia for controlling the progression of myopia in children.

Purpose of the study - study the effect of points with lens "Perifocal - M" on wavefront aberrations, peripheral refraction and the course of myopia in children.

Material and methods... Clinical prospective parallel cohort open-label study, which involved 75 children aged 9-14 years with progressive myopia from -1.0 to -6.0 diopters and astigmatism no more than 1.0 diopters, which does not require optical correction, with the best-rigorous visual acuity of 0.8 and more, binocular vision. The observation period was 6-18 months. The patients of the main group (60 children) were assigned glasses "Perifocal - M" for constantly-wearing it. Patients in the control group wore monofocal glasses. The correction was prescribed 0.5 diopters weaker than the objectively detected cycloplegic refraction.

All children were examined before glasses were prescribed, after 6 months, and 12-18 months after the start of wearing glasses. The examination included: visometry without correction and with the best subjective correction, determination of the nature of vision, auto-refractometry before and after cycloplegia (cyclomed 1% 2 times), biomicroscopy, ophthalmoscopy, study of accommodation (determination of reserves of relative accommodation, objective accommodative response, measured by an open field autorefractometer Grand Seiko WR-5100K, absolute accommodation), study of muscle balance (phoria), study of the ratio of accommodative convergence and accommodation (AC / A) by the gradient method according to Von Noorden, objective research peripheral refraction at points 15° and 30° in the nasal (N15° and N30°) and temporal (T15° and T30°) meridian without correction and in new glasses using an open field autorefractometer Grand Seiko WR-5100K (Japan), ultrasonic echobiometry - A / B Scan System Model 837 from Allergan Humphrey (USA), aberrometry - ORDScan (Nidek, Japan).

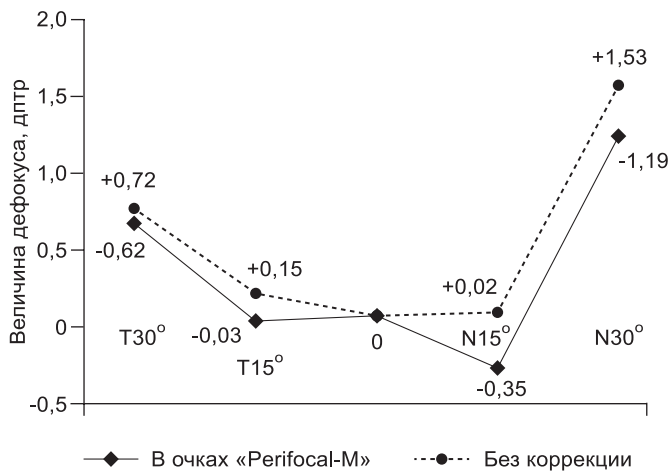
Results and discussion.

Adaptation

Spectacles with Perifocal - M lenses were prescribed for constant wear. All patients adapted to the lenses easily. The timing and ease of adaptation to the "Perifocal - M" glasses did not differ from the adaptation to any new glasses. The maximum adaptation period was 7 days. There were no cases of refusal to wear Perifocal-M glasses associated with difficult adaptation.

Influence of "Perifocal - M" glasses on peripheral refraction of the eye

Perifocal - M glasses form myopic or reduce hyperopic relative peripheral defocus in myopic eyes. The results of the study of peripheral refraction for all types of lenses "Perifocal - M", obtained on the Grand Seiko WR - 5100K apparatus without correction and in glasses "Perifocal - M", showed that without correction, hyperopic defocus occurs: in 61.5% of eyes in T15° and T30°; in 46% of eyes in N15°; in 100% of eyes in N30°... Without correction, hyperopic defocus was on average: + 0.1 ± 0.11 diopters in T15° and already



The magnitude of the relative peripheral defocus without correction and glasses "Perifocal - M".

The abscissa is the measurement area of the relative peripheral defocus: T15° and T30° lie at 15° and 30° horizontally from the center on the temporal side, N15° and N30° lie at 15° and 30° horizontally from the center on the bow side; along the ordinate - ve-face of relative peripheral defocus, diopters.

+ 0.72 ± 0.28 diopters at T30°; + 0.02 ± 0.1 diopters in N15° and already + 1.53 ± 0.2 diopters in N30°...

Wearing Perifocal - M glasses in zone 15° myopic defocus was formed, which averaged - 0.03 ± 0.1 diopters at T15° and -0.35 ± 0.16 diopters in N15°... In zone 30° hyperopic defocus decreased by an average of 0.1 ± 0.35 diopters at T30° and 0.34 ± 0.07 diopters in N30° (see figure).

Thus, glasses with lenses of a special design with horizontal progression "Perifocal - M" form a relative peripheral myopic defocus in the eye or significantly reduce peripheral hyperopic defocus.

Effect of "Perifocal - M" glasses on eye aberrations

In our study, according to aberrometry data, without correction in 50% of the examined eyes with myopia, the higher-order spherical aberration had a negative sign. Negative spherical aberration is attributed to an unfavorable role in the progression of myopia, since it creates a hyperopic peripheral defocus. The average value of the higher-order spherical aberration in the survey

Table 1

Aberrometry data in children with myopia without correction, in monofocal glasses and in glasses "Perifocal - M"

Indicators aberrometry	Aberrometry values, μm		
	without corrections	in mono focal glasses	with glasses "Perifocal - M"
General aberration order	4.19 ± 0.5	2.9 ± 0.2	1.66 ± 0.3
Spherical aberration lower order	0.35 ± 0.05	0.65 ± 0.09	0.42 ± 0.1
Coma	0.15 ± 0.02	0.24 ± 0.03	0.23 ± 0.09
Trefoil	0.17 ± 0.02	0.17 ± 0.02	0.27 ± 0.09
Spherical aberration high order	0.003 ± 0.01	- 0.06 ± 0.01	0.022 ± 0.04
Aberration of the highest order	0.282 ± 0.03	0.36 ± 0.04	0.58 ± 0.3

the given group was positive and amounted to 0.003 ± 0.01 μm.

Aberrometry in monofocal glasses showed an increase in negative spherical aberration. It was found already in 75% of the eyes and its average value was -0.06 ± 0.01 μm (R < 0.01). Along with the natural, due to a decrease in defocus, a decrease in the total level of aberrations (Total RMS) from 4.19 ± 0.5 μm without correction to 2.9 ± 0.2 μm in monofocal glasses (R < 0.05), there was a tendency to an increase in higher-order aberrations (RMS - HO) from 0.282 ± 0.03 μm to 0.36 ± 0.04 μm when correcting myopia with monofocal glasses (R > 0.05).

In "Perifocal - M" glasses, due to a more complete correction of central refraction, the decrease in the overall level of aberrations was even more pronounced than in monofocal glasses. Its value in glasses "Perifocal - M" was 1.66 ± 0.3 microns compared with 4.19 ± 0.5 before correction (R < 0.01). The spherical aberration of the lowest order tended to increase from 0.35 ± 0.05 μm to 0.42 ± 0.1 μm (p > 0.05). Coma and trefoil increased insignificantly: from 0.15 ± 0.02 μm to 0.23 ± 0.09 μm and from 0.17 ± 0.02 μm to 0.27 ± 0.09 μm, respectively (p > 0.05).

Higher-order spherical aberration in the eyes, where it had a negative value without correction, decreased or even turned into a positive one. The average value of spherical aberration (HO-sph) was 0.022 ± 0.04 μm, that is, there was a tendency to an increase in positive spherical aberration by 7 times compared with uncorrected eyes (p > 0.05), the difference is not significant. As already noted, positive spherical aberration forms myopic peripheral defocus, which is assigned a decisive role in inhibiting the progression of myopia. The main purpose of the "Perifocal - M" glasses is precisely the formation of such a defocus due to the special design of this lens. Studies have confirmed that "Perifocal" glasses induce positive spherical aberration, while monofocal spectacle lenses form negative (Table 1).

Influence of "Perifocal - M" glasses on the dynamics of refraction of the eye and the magnitude of the PZO

The dynamics of central refraction and PZO values were monitored in patients who used Perifocal-M glasses at different times: in 60 for 6 months, in 51 patients for 12-18 months (see Table 1; Table 2). The dynamics of refraction in all patients in the control group was monitored for 12-18 months with intermediate control at 6 months.

Manifest subjective refraction across 6 months of using "Perifocal - M" glasses increased on average by 0.09 ± 0.04 diopters (changed from 0

Table 2

Dynamics of objective cycloplegic refraction in children who wore glasses "Perifocal - M"

The dynamics of the objective cycloplegic refraction	Observation period, months	
	6	12-18
Weakening	40%	9.8%
Stabilization	16.7%	39.2%
Gain	43.3%	51%

Dynamics of refraction and PZO length in the main and control groups

Group	Change objective refraction to cycloplegia, diopters		Change objective cycloplegic refraction, diopters		Increase in length of PZO, mm	
	observation period, months					
	6	12-18	6	12-18	6	12-18
Wearers of glasses	-0.15 ± 0.04	-0.28 ± 0.04	+0.02 ± 0.01	-0.28 ± 0.04	0.03 ± 0.02	0.08 ± 0.02
"Perifocal - M"	-0.25 ± 0.04	-0.55 ± 0.03	-0.13 ± 0.1	-0.55 ± 0.15	0.08 ± 0.02	0.15 ± 0.03

up to -1.0 diopters), after 12-18 months - by 0.28 ± 0.04 diopters (varied from 0 to -1.5 diopters). The shift of the manifest subjective refraction towards its enhancement was significantly less than in the control group. In the control group, the manifest subjective refraction after 6 months increased by an average of 0.23 ± 0.04 diopters, after 12-18 months - by 0.55 ± 0.03 diopters ($R < 0.01$).

Manifest objective refraction, measure autorefractometer, after 6 months increased by an average of 0.15 ± 0.04 diopters, after 12-18 months by 0.28 ± 0.04 diopters. In the control group, the manifest objective refraction after 6 months increased on average by 0.25 ± 0.04 diopters, after 12-18 months by 0.55 ± 0.03 diopters. The difference between the main and control groups was significant for each of the observation periods ($p < 0.01$).

Cycloplegic objective refraction across 6 months of using "Perifocal - M" glasses changed - from $+0.25$ diopters to -1.25 diopters. The average shift of cycloplegic objective refraction was $+0.02 \pm 0.01$ diopters. Stabilization of cycloplegic refraction was observed in 16.7% of cases (20 eyes), weakening of cycloplegic refraction was observed in 40% of cases (48 eyes), in 41.6% of cases (50 eyes), the main refraction increased by 0.25 - 0.75 diopters (on average -0.29 ± 0.04 diopters), 1 child (1.7%) showed a bilateral increase in cycloplegic refraction by -1.25 diopters.

After 12-18 months of using Perifocal-M glasses, the cycloplegic objective refraction increased on average by -0.28 ± 0.04 diopters. Stabilization of cycloplegic refraction was observed in 39.2% of cases (40 eyes), weakening - in 9.8% of cases (10 eyes), in 51% of cases (52 eyes) cycloplegic refraction increased on average by -0.4 ± 0.03 diopters.

The shift of objective cycloplegic refraction towards its enhancement was significantly less in children wearing Perifocal-M glasses than in the control group. In the control group, the cycloplegic objective refraction after 6 months increased by an average of -0.13 ± 0.04 diopters ($p < 0.01$) after 12-18 months by -0.55 ± 0.03 diopters ($p < 0.01$).

PZO value across 6 months of using Perifocal-M glasses increased on average by 0.03 ± 0.02 mm, after 1 year - by 0.08 ± 0.02 mm. In the control group, the increase in PZO was 2 times greater: after 6 months PZO increased by 0.08 ± 0.02 mm, after 12-18 months - by 0.15 ± 0.03 mm (Table 3). The difference was significant for each of the observation periods ($p < 0.05$).

Influence of "Perifocal - M" glasses on visual acuity, accommodation, phoria, AK / A

When prescribing Perifocal - M glasses, the spherical component in glasses was prescribed 0.5 diopters weaker

objectively identified cycloplegic refraction. When prescribing such a correction, the binocular visual acuity in Perifocal-M glasses ranged from 0.9 to 1.0 and averaged 0.95 ± 0.04 .

Binocular acuity vision with glasses "Perifocal - M" after 6 months remained stably high and averaged 0.94 ± 0.04 , after 12-18 months it was 0.84 ± 0.04 .

In the control group, the binocular visual acuity with glasses at the beginning of the study was 0.88 ± 0.04 , after 6 months - 0.78 ± 0.04 , after 12-18 months - 0.67 ± 0.04 .

Stocks of relative accommodation (RHA) across 6 months of wearing Perifocal-M glasses increased by an average of 0.3 ± 0.04 diopters, after 12-18 months - by 0.4 ± 0.04 diopters from the initial values ($p > 0.05$). In the control group, ZOA did not change.

Absolute Accommodation Volume (AAA) across 6 months of wearing Perifocal-M glasses increased on average by 2.27 ± 0.16 diopters, after 12-18 months - by 3.0 ± 0.18 diopters compared with the initial value and by 27.5% (33 eyes) reached the values of the age norm.

In the control group, TAA increased in comparison with the initial values by 1.0 ± 0.12 diopters and by 1.4 ± 0.13 diopters, respectively, and at the end of the observation reached the age norm in 2 cases. The increase in TAA values in children wearing Perifocal-M glasses compared with children in the control group was significant for each of the observation periods ($p < 0.01$).

Objective accommodation response (OJSC) che- after 6 months of wearing Perifocal - M glasses, it increased slightly - by an average of 0.1 ± 0.04 diopters, after 1 year - by 0.3 ± 0.04 diopters ($p > 0.05$).

In children in the control group, OJSC did not change. The difference in the value of OAO in the main and control groups was insignificant.

Accommodation tone (TA) across 6 months of wearing Perifocal-M glasses changed insignificantly: it increased on average by 0.03 ± 0.02 diopters, and TA of the open field - by 0.08 ± 0.03 . TA after 12-18 months remained within the initial values, the open field accommodation tone changed - it decreased by 0.1 ± 0.03 diopters from the initial value. According to E.P. Tarutty and N.A. Tarasova, a decrease in TA is a favorable prognostic sign and is associated with a decrease in the rate of further progression of myopia [12].

In the control group, after 6 months, TA increased by 0.03 ± 0.02 diopters, open field - by 0.1 ± 0.02 diopters.

Forii. The main and control groups were included only those studied with physiological values of heterophoria for near. After 6 months and after

After 1 year from the start of wearing Perifocal - M glasses, in no case did the phoria values go beyond the physiological limits. This distinguishes "Perifocal - M" glasses from progressive glasses, when using which it is possible to form a decompensated exophoria for near and far, and in especially severe cases - exotropia [13].

In the control group, there were no cases of decompensated phoria during the observation period.

AK / A... The AK / A ratio slightly decreased on average by 0.2 dpt / d, presumably due to some increase in the accommodative ability of the eye, but this change was not significant.

conclusions

1. Glasses with lenses "Perifocal - M" can be used to be worn by children in the mode of constant wear, adaptation to the glasses is easy.

2. Glasses "Perifocal - M" form myopic or reduce hyperopic peripheral defocus in myopic eyes. Perifocal - M glasses induce positive spherical aberration in the eye, while monofocal spectacle lenses produce negative aberration.

3. Glasses "Perifocal - M" contribute to the relative noisy stabilization of refraction in children with myopia compared with children in the control group. The difference with the control group is manifested most of all in the first 6 months of observation.

Binocular visual acuity with one pair of Perifocal-M glasses remains high for 12-18 months.

Spectacles "Perifocal - M" have clear advantages over progressive glasses, because when using them, decompensated exophoria is not formed, which occurs in some cases when using progressive glasses.

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