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(72) Inventor; and
(71) Applicant: **IBATULIN, Rashid Adygamovich** [RU/RU]; Zhasminovaya st., 7, ap. 8, Naro-Fominsky district, g. Aprelevka, 143362 (RU).

(72) Inventor: **KOVYCHEV, Andrey Sergeevich**; Zhasminovaya st., 7, ap. 8, Naro-Fominsky district, g. Aprelevka, 143362 (RU).

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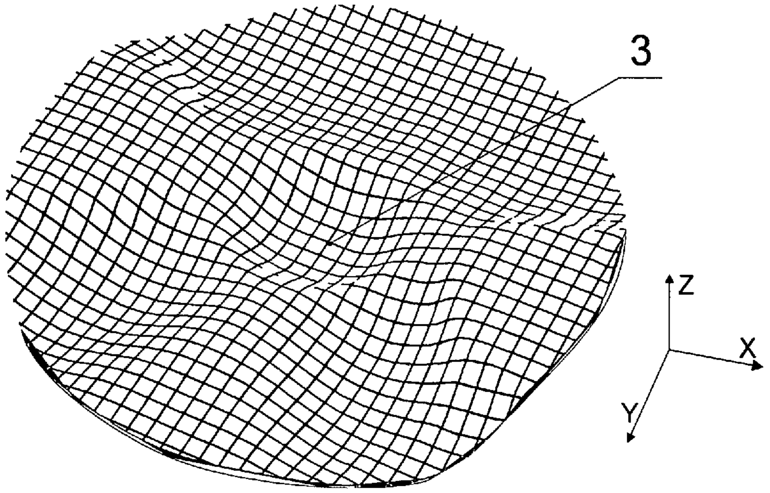

Fig. 19

(57) Abstract: Optical element, which embodiments are united by inventors conception, has central zone with stable distance refraction, which is nonaxis-symmetrical surrounded by ring-like zone of refraction progression (degression), to its outer edge at nasal and temporal sides connected different by area and refraction peripheral zones with stable refraction that is stronger (weaker) than central refaction, and to bottom edge connected zone with addition for near-work, from outer border of ring-like zone between outer borders of connected zones in all directions refraction is monotonically decreasing (increasing). Using of optical elements as spectacles during viewing regulates relation between axial and non-axial refraction value, changes relation between nasal and temporal halves refraction values, changes choroid thickness, increases accommodation, changes spherical aberration sign in the eye, saves and increases binocular vision. Multifactorial permanent synergic influence when using device predicts risk of myopia onset, and, in case of myopia manifestation, stops increasing of axial refraction or decreases refraction or slows myopia progression, in hyperopic subjects, conversely, axial refraction values increases.

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DEVICE FOR PROPHYLAXIS AND/OR TREATMENT OF VISUAL REFRACTIVE DISORDERS.

The invention relates to medicine, specifically to ophthalmology, and relates to devices for the prevention and/or treatment of refraction visual impairments.

Invention background.

Refraction visual impairments is most common nosology in eye diseases structure and causes lot of significant complications in the eye or whole visual system disorders.

So, in children of early age high degree farsightedness (hyperopia) is the cause of severe visual complications, such amblyopia and strabismus. In turn, the most prevalent visual disorder in older children and adults is myopia (nearsightedness). Myopia, commonly, developing through progression, which provoke several morphological changes and functional disorders of visual system at all. Complications of myopia are usually leads to visual disabilities, that's why myopia is significant medico-social problem, and it's prophylaxis and progression control is still the most current goal in ophthalmology. Drawbacks of present devices and methods to affect myopia in different cases are: absence of prophylaxis effect, disability to affect different etiopathogenetic factors of myopia progression in same time, side effects when using, contraindications to use, disability to affect myopogenic factors permanently, medical cabinet limitations to use, necessity of anesthesia, low efficiency, high expenses and so on. Creation of devices to control myopia progression with possibility to use it in different age groups, without complications, with high efficiency, permanently affecting on most myopogenic factors, without any limitations and economically affordable is the most important medico-social task.

Recent clinical trials shows that myopia has multi-factorial etiology, and leading factors in visual analyzer are: accommodation weakness(3), hydrodynamics malfunction(4), neuroregulation of biochemical processes from retina to choroid and to sclera disorders caused by relative peripheral hyperopic defocus in myopic eyes(9), mostly revealed in horizontal meridian(1), presence of negative spherical aberrations of the eye(8). Also myopia onset risk is increasing if peripheral refraction profile is not strengthened at nearwork(6), if there is some binocular vision impairments, such as heterophoria of esophoria type, which is predisposing to myopia factor(2). In turn, some trials shows, that refraction become more myopic in nasal half during myopia progression(7). Dynamic trials shows, that relations between nasal and temporal sides refraction values at 30 degrees from fovea is changing during myopia progression(11). Also, electrophysiological trials shows, that near periphery neurons more reactive on defocus sign(10).

It is known from literature, that non-axis-symmetric surface optical design spectacles(12), using to correct myopia shows high efficiency to control myopia progression, permanently affecting several myopogenic factors(13).

In daily practice, commonly using optical treatment methods for prophylaxis and prevention of myopia progression, including devices with spectacle lenses for everyday wearing. But, last time trials shows, that known strategies which using traditional spectacle lenses don't affecting several factors of etiopathogenetic mechanisms, in particular in progressive myopia, and has low effect or even negative therapeutic effect in some cases(5).

Undoubtedly, appearance of brand new production technology called FreeForm to make spectacle lenses, gives us wide possibilities to realize new inventions using free non-axis-symmetrical shapes of optical surfaces, which are available to consider much more unusual features of myopic refraction, creating by this optical conditions for safe therapeutic influence on different pathogenetic factors of myopia progression. Also, safety and permanent optical influence on eye regulating mechanisms using spectacles with non-axis-symmetrical design of lenses, allows to use it in early age (active refractogenesis period) and effectively fighting against congenital hyperopia, stimulating eye growth.

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It is known device (20150036102 от 05.02.2015, Ghosh et al.), an ophthalmic lens comprising one or more vertical or oblique prismatic components, wherein the lens slows myopia progression and/or treats or prevents myopia or a disease or condition associated with myopia.

Drawback of said device is that it not provide peripheral defocus, device is not designed to train accommodation, not decreasing accommodation strain at nearwork, not designed to create positive spherical aberrations in the eye.

There is also known device (20140132933 от 15.05.2014, Martinez et al.), An anti-myopia spectacle lens for a myopic eye of a patient, comprising: a base lens having an optic axis, a central optical zone of at least normal pupil diameter around said optic axis and having a negative central refractive power within said central zone for correcting central refractive error of the eye and providing good central vision to the eye, and a therapeutic lens attached to said base lens, said therapeutic lens having a plano central zone of at least normal pupil diameter that is substantially coaxial with said optic axis and having an annular peripheral zone surrounding said plano zone, said peripheral zone including an incident angle of 30 degrees relative to said axis and said peripheral zone having a peripheral refractive power that is more positive than said central refractive power so that the anti-myopia spectacle lens has peripheral defocus.

Drawback of said device is that it provides peripheral defocus after 30 degrees according to optic axis, which is not affecting close periphery under 30 degrees from optic axis, where located the most responsible on defocus sign neurons, construction is not provide asymmetric influence on peripheral retina to exchange relations between nasal and temporal peripheral refraction to stop progression of myopia by decreasing of axial length, device not provide accommodation training, not decreasing tension of ciliary muscle during nearwork, not provide conditions to develop binocular vision and not provide to create positive spherical aberrations in the eye.

It is known device (20090257026 от 15.10.2009, Varnas et al.), an ophthalmic lens element for correcting myopia in a wearer's eye, the lens element including: (a) a central zone providing a first optical correction for substantially correcting myopia associated with the foveal region of the wearer's eye; and (b) a peripheral zone surrounding the central zone, the peripheral zone providing a second optical correction for substantially correcting myopia or hyperopia associated with a peripheral region of the retina of the wearer's eye; wherein the mean value of the second refracting power is a mean refracting power at a radius of 20 mm from the optical centre of the ophthalmic lens element, as measured on the front surface of the lens element, and inscribes the peripheral zone over an azimuthal extent of at least 270 degrees, wherein the second refracting power is in the range of +0.50 D to +2.0 D.

Drawback of said device is that it includes stable central refraction to support clear foveal vision throughout an angular range of eye rotations which is not allows for accommodation training, for binocular vision developing, device not provides myopic defocus on close periphery around macula, where located the most responsible on defocus sign neurons, device not provides changing of relations between axial and non-axial refraction values, device not provides conditions to regulate relations between nasal and temporal peripheral refraction, device not provides near zone with stable refraction to decrease tension of ciliary muscle during nearwork, device not provides creation of positive spherical aberrations in the eye.

Closest known device is:

(WO/2013/134825 from 19.09.2013, Sankaridurg et al.) An ophthalmic lens for use in front of an eye of a recipient, the ophthalmic lens comprising in an optic zone: a first region including a distance point located to be substantially aligned with a location of an optical axis of the eye during ahead distance vision; a second region located laterally to one side of the distance point; a third region located laterally to the other side of the distance point; a fourth region located below the distance point; a fifth region located laterally to one side of the fourth region; and a sixth region located laterally to the other side of the fourth region; wherein the ophthalmic lens has a first refractive power at the distance point; the second and the third regions have second and third refractive powers with region two and region three ADD powers relative to the first refractive power respectively; the fourth region has a fourth refractive power with a region four ADD power relative to the first refractive power; and the fifth and sixth regions have fifth and sixth refractive powers, each one being one of: equal to the fourth refractive power; a region five or region six ADD power relative to the fourth refractive power respectively, wherein the region five or region six ADD power is less than or equal to the region two or region three ADD power relative to the first refractive power; and wherein the ophthalmic lens is in a configuration that provides relative movement with the eye, when the eye moves between looking ahead and downwards.

Drawback of said device is absence of ring-like zone with stronger refraction around distance zone which is necessary to create myopic defocus on close periphery of retina under 30 degrees from fovea, device is not providing asymmetric addition beginning along horizontal, passing through the "distance point" which is necessary to save and develop binocular vision using device when visual axes gazing along horizontal and creation of soft binocular dissociation which is stimuli for activation and training of bifoveal alignment and developing of fusion reserves, device is not providing asymmetric defocus in horizontal at nasal and temporal sides to change relations between on-axis and off-axis refraction and to create conditions for changing peripheral refraction values specific for stable myopia, device is not providing accommodation training, device is not providing creation of positive spherical aberrations in the eye, device is not providing centers of nasal and temporal fields located laterally on both sides from distance point in single line passing through distance point, which is not allowed uniform influence on peripheral refraction higher and lower than recipient's horizontal.

Main goal of invention is to create a device for prophylaxis and/or treatment of visual refractive disorders.

The goal is achieved by development and creation of device, with embodiments united by conception of invention, including optical element with non-axis-symmetric refraction distribution through surface such way, that using of said device embodiments provides conditions for diverse effects to an eye and visual system in total to achieve cumulative technical result, consisting of: regulation of relation between axial and non-axial refraction of close periphery, regulation of peripheral refraction values relation between nasal and temporal sides in horizontal, changing of spherical aberrations sign in the eye, changing of choroid thickness, increasing and/or saving binocular visual acuity, prediction, elimination or decreasing of oculomotor muscles imbalance, regulation of accommodation tension at nearwork, accommodation training with increasing of reserves and stocks of absolute and relative accommodation and ocular hydrodynamics improvement, that together provides synergistic effect, manifested in prediction of myopia onset risks, and in case of myopia manifestation stops axial refraction increasing or decreasing axial refraction power or slows myopia progression, and in hyperopes, conversely, manifested by axial refraction increasing.

Said before technical result in myopes reached using device of claim 1 oriented in spectacle frame, which situated at 90 degrees to horizontal sight line, with respect to nasal and temporal sides of right and left eyes respectively, lower zone at the bottom, optical elements locates in front of both eyes at vertex distance of 12-14mm from cornea, when looking through optical elements, gazing as usually into distance, visual axis of each eye is passing through optical center of the optical element with distance refraction, provides focusing of examined image on the retina in macula area, around the macula on close periphery image is focusing in front of retina when passing through ring-like zone with stronger refraction, and creates ring of slightly myopic defocus at area of most sensitive to defocus neurons localization, increases reactivity of amacrine cells which starts biochemical cascade from retina to choroid and to sclera, which increasing thickness and decreasing area of choroid, that decreasing pressure of choroid on sclera, and increasing rigidity of sclera by that, that together decreasing axial length and decreasing axial refraction power, slightly myopic defocus on close periphery of the retina eliminates off-foveal stimuli to accommodation tension, light rays passing through ring-like zone with stronger than central refraction of optical element at the edge of pupil, refracts stronger and focuses earlier than rays passing through center of the pupil, creates positive spherical aberration in the eye, provides by that wavefront specific for stable myopia and emmetropic eye, inhibiting eye grow by that, light passing through nasal and temporal zones of optical elements with stable asymmetric highest refraction power, focusing image on the area of middle and far periphery of retina in horizontal in each eye in front of retina farther on nasal side than the temporal, providing more myopic defocus on nasal side of the eye, counteracting more to elongation of nasal half of the eyeball, changing relation between nasal and temporal refraction and managing relation between axial and off-axis refraction in horizontal, that stimulating lateral eye growth and decreasing axial length, when looking at distance and examine images passing sight line through any point of ring-like zone with stronger refraction, undercorrection happens and that creates micro blur on fovea, causing stimuli to relax accommodation (decrease tonicity and tension) of cilliary muscle to increase image sharpness on fovea, when visual axis return to the central zone with stable distance refraction tension (tonicity) of accommodation is increasing, providing accommodation training with increasing of reserves and stocks of absolute and relative accommodation, eliminating habitually-excessive accommodation tension, supporting and increasing physiological accommodation parameters, optimizing uveoscleral outflow of intraocular liquid with decreasing of ophthalmic tonicity, decreasing it's influence on axial growth, when examining image and gazing visual axis of both eyes parallel out of optical center, which is located closer to temporal inner border of ring-like zone by 1-2mm along horizontal, visual axis of eye which moving outwards will reach ring-like zone earlier than visual axis of the eye which moving inwards, that creates monocular micro blurring on fovea with dissociation of binocular image, causing stimuli for fusion, increasing bifoveal merger by that with following saving and increasing of binocular vision, that decreases or eliminates heterophoria degree, when looking near and visual axis is passing through near zone with stable refraction, that is higher than refraction of optical center by 1,0-2,0 D, image is focusing on retina on macula with less stimuli or absence of stimuli to accommodation, providing decreasing of ciliary muscle tension, that prevents excess tension and spasm of accommodation.

Claimed device, when using, providing safe, permanent, multi-factoral synergic functional and therapeutic influence on eye's structures and functions and visual system in total when doing usual visual distance and near tasks, that does not follow from the prior art, which is prevents and/or restrain myopia development and/or decreasing eye refraction power.

In particular, in myopic subjects technical result is achieving using device for prophylaxis and/or treatment of progressive myopia, including optical elements, each of said elements includes front and back surface, optical center, nasal and temporal sides, vertical and horizontal, passing through optical center, *characterized that* in all radial directions not less than 3 mm and not more than 6mm from optical center with distance refraction, refraction starts to monotonically increasing outwards in range of from 0,25 D to 3,0 D for 1,5mm-16mm, creating ring-like zone with stronger refraction than in optical center, inner edge of said ring-like zone passing through all points of refraction increasing beginning, which limits central zone with stable refraction corresponding with refraction of optical center which is situated closer to the inner edge of ring-like zone at temporal side by 1-2mm, outer edge of ring-like zone is passing through all points of refraction increasing completion, from nasal and temporal edges of outer edge of ring-like zone, which is situated asymmetrically from optical center, starts and spreads outwards asymmetrical by area and refraction power, zones with stable refraction, wherein refraction is more than refraction of optical center by 2,0-3,0 D, area of each of said nasal and temporal zones is less than 1/8 of optical element area, centers of said zones is passing through horizontal of optical element which is passing through optical center, from bottom edge of outer edge of ring-like zone starts near zone with stable refraction which is more than refraction of optical center by 1,0-2,0 D, area of near zone is less than 1/8 of optical element area, center of near zone is located in nasal half of optical element about for 0,5-4,0mm from vertical of optical element, from outer edge of ring-like zone between edges of nasal, temporal and near zones in all directions outwards refraction is monotonically decreasing or decreasing up to optical center refraction value.

Also, in myopic subjects technical result is achieving using device for prophylaxis and/or treatment of progressive myopia, including optical elements, each of said elements includes front and back surface, optical center, nasal and temporal sides, vertical and horizontal, passing through optical center, *characterized that* in all radial directions not less than 3 mm and not more than 6mm from optical center with distance refraction, refraction starts to monotonically increasing outwards in range of from 0,25 D to 3,0 D for 1,5mm-16mm, creating ring-like zone with stronger refraction than in optical center, inner edge of said ring-like zone passing through all points of refraction increasing beginning, which limits central zone with stable refraction corresponding with refraction of optical center which is situated closer to the inner edge of ring-like zone at temporal side by 1-2mm, outer edge of ring-like zone is passing through all points of refraction increasing completion, from nasal and temporal edges of outer edge of ring-like zone, which is situated asymmetrically from optical center, starts and spreads outwards asymmetrical by area and refraction power, zones with stable refraction, wherein refraction is more than refraction of optical center by 2,0-3,0 D, area of each of said nasal and temporal zones is less than 1/8 of optical element area, centers of said zones is passing through horizontal of optical element which is passing through optical center, from outer edge of ring-like zone between edges of nasal and temporal zones in all directions outwards refraction is decreasing up to optical center refraction value.

Said technical result in hyperopic subjects is achieving using device claimed in clause 4 of claims oriented in frame which is situated at 90 degrees to horizontal sightline, with respect to nasal and temporal sides for each eye, near zone at the bottom, optical elements is situated in front of each eye with 12-14 mm of vertex distance from the cornea, when looking distance through optical elements forward, visual axis is passing optical center of optical element with distance refraction providing focus of image on macula, around macula at close periphery of retina image is focusing behind the retina, passing through ring-like zone with weaker refraction of optical element, creating ring of weak hyperopic defocus in area of localization of most responsible to defocus retinal neurons, increasing by that reactivity of amacrine cells, which provokes biochemical cascade from retina to choroid and to sclera by decreasing thickness and increasing area of choroid, creating pressure on sclera, decreasing of scleral rigidity, providing increasing of axial length and strengthening of on-axis refraction, lightrays passing through ring-like zone with weaker refraction than in optical center, getting into the eye near the edge of pupil with less refraction than in the center of pupil, creating by that negative spherical aberrations providing spherical front specific for axial growth, at the area of middle and far retinal periphery in horizontal image is focusing behind the retina farther in nasal part of the eye than in temporal, providing stronger hyperopic defocus in nasal part of the eye, making more expressed action to stretch nasal part of eyeball, contributing to exchange relations between nasal and temporal peripheral refraction and regulating relations between axial and peripheral refraction in horizontal, providing conditions for increasing of axial length, when looking distance and examining image so, that visual axis is passing through any point of ring-like zone with weaker refraction, providing vision through undercorrection, causing micro-blurring effect on fovea, providing stimuli for accommodation to tense ciliary muscle to increase sharpness of image on fovea, when visual axis return into central zone with stable distance refraction accommodation tension is decreasing, providing accommodation training with following increasing of relative accommodation reserves and reserves of absolute accommodation, regulation of ophtalmic tone, when examining image and gazing parallel from optical center, which is situated closer to temporal inner edge of ring-like zone by 1,0-2,0mm, along horizontal of optical elements, visual axis of an eye moving outwards will reach ring-like zone with weaker refraction earlier, creating monocular micro-blurring on fovea and providing dissociation of binocular image, stimulating intensification of bifoveal fusion, keeping and increasing binocular visual acuity and eye movement balance, when looking near and visual axis is passing through near zone with stable refraction with more refraction power than in optical center by 1,0-2,0D, image is focusing on macula with less or absence of stimuli for accommodation, providing decreasing of ciliary muscle tension and stimuli for convegence.

Claimed in clause 4 device, when using, providing permanent multi-factoral synergic functional and therapeutic influence on eye's structures and functions, and whole visual system during visual tasks at distance and nearwork, which is not known yet, creating conditions for increasing axial length and refraction power in the eye.

In particular in hyperopic subjects, said before technical result is achieving using device for prophylaxis and/or treatment of hyperopia, including optical elements, each of said elements includes front and back surface, optical center, nasal and temporal sides, vertical and horizontal, passing through optical center, *characterized that* in all radial directions not less than 3 mm and not more than 6mm from optical center with distance refraction, refraction starts to monotonically decreasing outwards in range of from 0,25 D to 3,0 D for 1,5mm-16mm, creating ring-like zone with weaker refraction than in optical center, inner edge of said ring-like zone passing through all points of refraction decreasing beginning, which limits central zone with stable refraction corresponding with refraction of optical center which is situated closer to the inner edge of ring-like zone at temporal side by 1-2mm, outer edge of ring-like zone is passing through all points of refraction decreasing completion, from nasal and temporal edges of outer edge of ring-like zone, which is situated asymmetrically from optical center, starts and spreads outwards asymmetrical by area and refraction power, zones with stable refraction, wherein refraction is less than refraction of optical center by 2,0-3,0 D, area of each of said nasal and temporal zones is less than 1/8 of optical element area, centers of said zones is passing through horizontal of optical element which is passing through optical center, from bottom edge of outer edge of ring-like zone starts near zone with stable refraction which is less than refraction of optical center by 1,0-2,0 D, area of near zone is less than 1/8 of optical element area, center of near zone is located in nasal half of optical element about for 0,5-4,0mm from vertical of optical element, from outer edge of ring-like zone between edges of nasal, temporal and near zones in all directions outwards refraction is changing up to optical center refraction value.

Also, in hyperopic subjects, said before technical result is achieving using device for prophylaxis and/or treatment of hyperopia, including optical elements, each of said elements includes front and back surface, optical center, nasal and temporal sides, vertical and horizontal, passing through optical center, *characterized that* in all radial directions not less than 3 mm and not more than 6mm from optical center with distance refraction, refraction starts to monotonically decreasing outwards in range of from 0,25 D to 3,0 D for 1,5mm-16mm, creating ring-like zone with weaker refraction than in optical center, inner edge of said ring-like zone passing through all points of refraction decreasing beginning, which limits central zone with stable refraction corresponding with refraction of optical center which is situated closer to the inner edge of ring-like zone at temporal side by 1-2mm, outer edge of ring-like zone is passing through all points of refraction decreasing completion, from nasal and temporal edges of outer edge of ring-like zone, which is situated asymmetrically from optical center, starts and spreads outwards asymmetrical by area and refraction power, zones with stable refraction, wherein refraction is less than refraction of optical center by 2,0-3,0 D, area of each of said nasal and temporal zones is less than 1/8 of optical element area, centers of said zones is passing through horizontal of optical element which is passing through optical center, from bottom edge of outer edge of ring-like zone starts near zone with stable refraction which is less than refraction of optical center by 1,0-2,0 D, area of near zone is less than 1/8 of optical element area, center of near zone is located in nasal half of optical element about for 0,5-4,0mm from vertical of optical element, from outer edge of ring-like zone between edges of nasal, temporal and near zones in all directions outwards refraction is monotonically increasing or increasing up to optical center refraction value.

Device is illustrated by following graphic material, where figures 1-28 shows embodiments of said device for prophylaxis and/or treatment of visual refractive disorders.

Fig.1 shows front view of device, constructed as a spectacles with frame 1 and optical elements 2, each having optical center 3 and horizontal axis 4, inserted in the frame 1.

Fig.2 shows front view of device using spectacle frame 5 with holders 6 for optical elements 3, nose pad 7, where holders 6 able to move in horizontal plane (shown by arrows), nose pad 7 constructed with ability to move in vertical direction (shown by arrows).

Fig.3 shows the same with Fig.2, but from top view, where shown fixators 8, scales 9 which situated on top end 10 of frame 5, scales consigned to measure distance between holders 6 and center of nose pad 7 (mm), wherein fixators 8 constructed with ability to move in radial direction (shown by arrows).

Fig.4 shows optical element 2 with horizontal 11 and vertical 12 both passing through optical center 3.

Figs 5, 7, 9, 11 shows refraction power from optical center 3 outwards in horizontal 11, wherein Y-axis shows refraction (D.) and X-axis shows distance from optical center 3.

Figs 6, 8, 10, 12, shows refraction power from optical center 3 outwards in vertical 12, wherein Y-axis shows refraction (D.) and X-axis shows distance from optical center 3.

Fig.13 shows one of embodiments of refraction distribution of optical element claimed in clause 1, where refraction power is increasing from light to dark.

Fig.14, shows one of embodiments of refraction distribution of optical element claimed in clause 4, where refraction power is increasing from light to dark.

Fig.15 shows principle of accommodation training mechanism when looking through optical element 2, so, fig.15a shows focusing of image on retina when visual axis 13 is passing through central part of optical element 2, where refraction is corresponds to axial refraction of the eye, and ciliary muscle 14 is in tension, strengthening crystalline lens 15 refraction power by that, when gazing in horizontal visual axis 13 is passing through progression zone Fig.15b and image focus 16 on visual axis 13 is moving in front of retina at first, it provokes stimuli for accommodation, accommodation reflex is activating, revealing by relaxation of ciliary muscle 14, that providing focusing image 16 on retina shown at Fig.15c, then focusing image 16 on retina providing by tension of ciliary muscle 14 when visual axis 13 returns into initial position shown at Fig.15d.

Fig.16a and 16b shows influence on bifoveal fusion principle mechanism with it's developing and keeping binocular visual acuity, so, Fig.16a shows focusing image on retina when visual axes 13 is passing through central part of optical elements 2 with refraction corresponding to axial refraction of eyes, wherein images 17 is focused on retina 16, so images are equally sharp for both eyes. Fig.16b shows that when gazing visual axes 13 of both eyes in horizontal from optical center which is closer by 2mm to temporal edge of inner border of ring-like zone of optical element, visual axis of an eye moving outwards will reach ring-like zone with stronger refraction earlier and focus 16 of image 17L will be in front of retina, creating monocular micro blur of an image 17L on fovea, that provokes dissociation of binocular image and creates stimuli for fusion and activation of fusion reserves for bifoveal fusion of monocular images 17L and 17R, that provides developing of bifoveal fusion, saves and increases binocular visual acuity, contributes for elimination of heterophorias.

Fig. 17 shows, that when gazing both eyes along horizontal and visual axes 13 passing through zones with different additions of optical elements 2 it creates different values of blur for images 17L and 17R, stimulates dissociation of binocular vision by that and provoking stimuli for sensory fusion and activation of fusion reserves which keeping and develops bifoveal fusion, contributing to save binocular visual acuity and decrease or eliminate heterophorias.

Figs. 18-21 shows topographic embodiments of optical element refraction changing, wherein X-axis and Y-axis shows distance from optical center 3, and Z-axis shows refraction value relatively to optical center 3 refraction.

Fig. 22 shows example of positive aberrations creation.

Fig. 23 shows example of negative aberrations creation.

Fig. 24 shows photo of optical element with projection of horizontal lines through optical element.

Fig. 25 shows photo of optical element with projection of horizontal lines through optical element with contours of central, ring-like, temporal and nasal zones which showed by dotted line.

Fig. 26 shows projection of an image through optical element 2 on the retina 18, area shaded by vertical lines is close periphery of the retina 18, which is under an influence of said ring-like zone of optical element 2, areas shaded by horizontal lines are peripheral parts of the retina 18, which are under influence of nasal and temporal zones of optical element 2, areas shaded by inclined lines of the retina 18, where influence of defocus is not provided by optical element.

Embodiments of invention.

Optical elements of claimed invention are produced by free-form generator controlled by original software. In clinical trials of claimed device were 32 participants aged from 6 to 20, patients has progressive myopia with gradient of progression more than 0,5 D. per year and 6 patients aged from 2 to 3,5 with high degree hyperopia.

Excerpts from some protocols of clinical trial results.

Excerpt 1. Patient born in 2003, diagnosis: progressive low degree myopia. Progression gradient of last year is 0,75D.

Status ophthalmicus on 2.10.2013:

On-axis cycloplegic refraction: OD sph -2,25 D., cyl -0,25 D., ax 10deg., OS sph -2,75 D., cyl -0,12 D., ax 168 deg.

Visual acuity with optimal correction: OD 0,1 with sph -2,25 D., cyl -0,25 D., ax 8 deg. = 1,0, OS 0,09 with sph -3,0 D. = 0,9 - 1,0.

Binocular vision with optimal correction = 1,0

Cycloplegic Off-axis refraction in horizontal at 30 degrees from fovea:

OD nasal side sph - 0,5 D., cyl -1,25 D., ax 100deg.,

c temporal side sph +0,50 D., cyl -1,50 D., ax 86 deg.,

OS c nasal side sph +0,25 D., cyl - 1,0 D., ax 90deg.,

c temporal side sph +0,75 D., cyl -1,75 D., ax 105deg..

Relative accommodation reserves: +1,0 D. Visual nature: binocular, heterophoria by esophoria type 6 prism. D. (Shober's test), synoptophore data OA(objective angle) =SA (subjective angle = + 5 deg., fusion reserves +25/-1 deg.

Accommodation answer with optimal correction for distance to 33cm stimuli: OD = 1,75 D., OS= 1,5 D.

A-scan: AL (axial length) - OD = 24,19 mm, OS = 23,93 mm.

Biomicroscopy OU: anterior eye segment: calm, optical structures clear.

Ocular fundus: macular reflex precise. OND (optic nerve disc) pale pink, borders are precise, vascular stroke and caliber not changed. Normal periphery.

Status ophthalmicus on 2.10.2014 after constant using of device as spectacles, including optical elements graphically showed at fig.1, fig.4, fig.5, fig.6, fig.13, fig.19.

Refraction of right optical element: optical center and central zone refraction: sph. - 2,25D., cyl. – 0,25D. ax 8 deg., refraction by spherical equivalent in different points of ring-like zone is in range from +0,62D. to -2,0D. by spherical equivalent, temporal zone refraction +0,62D., nasal zone refraction +0,25 D., near zone refraction: sph. - 1,0 D., cyl. – 0,25D. ax 8 deg.

Refraction of left optical element: optical center and central zone refraction: sph. - 3,00 D., refraction by spherical equivalent in different points of ring-like zone is in range from +0,62D. to -2,0D., temporal zone refraction +0,12D., nasal zone refraction -0,37D., near zone refraction sph. - 1,75 D.

Off-axis refraction examination at 15 degrees from fovea on nasal and temporal sides when patient wearing traditional monofocal lenses and claimed devise as spectacle lenses using autorefkeratometer Shin Nippon NVISION-5001. Statistical analysis was by spherical equivalent regarding to refractometer data. Formula: M = S+C/2. (M- sherical equvalent, S – sphere, C – cylinder.)

Correction	off-axis refraction at 15 deg.	Sph. D.	Cyl. D.	Ax. Deg.	Spherical equivalent D.
Monofocal correction	OD nasal	+ 0,75	- 0,5	68	+ 0,5
	OD temporal	+ 1,25	- 1,12	110	+ 0,69
Claimed device correction	OD nasal	- 0,5	- 0,75	72	- 0,87
	OD temporal	- 0,12	- 1,25	95	- 0,74
Monofocal correction	OS nasal	+1,0	-1,5	80	+ 0,25
	OS temporal	+ 1,5	-2,0	91	+ 0,5
Claimed device correction	OS nasal	- 0,25	- 1,75	81	- 1,12
	OS temporal	- 0,12	-1,62	92	- 0,93

Claimed device providing strengthening of peripheral refraction by creating focus in front of peripheral retina.

Patient wore spectacles permanently, without period of adaptation, without complaints.

On-axis cycloplegic refraction: OD sph -2,0 D., cyl -0,25 D., ax 6 deg., OS sph - 2,5 D., cyl -0,12 D., ax 175 deg.

Visual acuity with optimal correction OD 0,3 with sph -2,0 D., cyl -0,25 D., ax 10 deg. = 1,0, OS 0,2 with sph -2,5 D. = 1,0,.

Binocuar visual acuity with optimal correction= 1,2

Cycloplegic refraction Off-axis in horizontal at 30 deg. from fovea:

OD nasal side sph + 0,5 D., cyl -1,75 D., ax 95 deg.,

temporal side sph - 0,12 D., cyl -2,25 D., ax 82 deg.,

OS nasal side sph +0,75 D., cyl - 1,25 D., ax 94deg.,

temporal side sph +0,5 D., cyl -3,0 D., ax 105deg..

Relative accommodation reserves: +2,5 D. Vision nature: binocular, orthophoria(Shober's test), synoptophore OA=SA= + 1 deg., fusion reserves +25/-5 deg.

Accommodation answer with optimal correction for distance to 33cm stimuli: OD = 2,5 D., OS= 2,25 D.

A-scan (AL): OD = 23,9 mm, OS = 23,87 mm.

Biomicroscopy OU: anterior eye segment calm, optical structures clear.

Ocular fundus: macular reflex precise. ODN pale pink, borders precise, vascular stroke and caliber not changed. Normal periphery.

Aberrometry data collected from OPD Scan ARK 10000 (Nidek, Japan).

High order spherical aberrations	Aberrometer data (micrometer)		
	Without correction before trial	Monofocal spectacles	Spectacles with claimed lenses
OD	0,006±0,02	-0,08±0,04	0,042±0,03
OS	- 0,002±0,01	-0,11±0,01	0,034±0,02

Thereby, using claimed device it was achieved technical result - end of myopia progression with decreasing of axial length and cycloplegic refraction value, increasing of relative accommodation reserves, strengthening of accommodation answer, changing of relations between axial and off-axis refraction and relations between peripheral refraction (nasal refraction become weaker, temporal refraction become stronger), positive spherical aberrations is induced in the eye, esophoria is eliminated, binocular visual acuity is increased, it is objectively shown that claimed device makes peripheral refraction stronger by focusing image in front of retina.

Excerpt 2. Patient born in 1999, diagnosis: progressive myopia mid degree of both eyes. Progression gradient of last year is 1,25 D.

Status ophthalmicus on 18.11.2013:

On-axis cycloplegic refraction: OD sph -4,5 D., cyl -0,75 D., ax 45 deg., OS sph -4,25 D., cyl -0,5D., ax 136 deg.

Visual acuity with optimal correction: OD 0,08 with sph -4,75 D., cyl -0,75 D., ax 45 deg. = 1,0, OS 0,09 with sph -4,5 D. , cyl -025 D., ax 136 deg. = 1,0.

Binocuar visual acuity with optimal correction= 1,0

Cycloplegic refraction Off-axis in horizontal at 30 deg. from fovea:

OD nasal side sph - 2,75 D., cyl -0,5 D., ax 14deg.,

temporal side sph - 1,75 D., cyl -2,25 D., ax 90 deg.,

OS nasal side sph – 1,75 D., cyl - 1,0 D., ax 23deg.,

temporal side sph -1,5 D., cyl -1,62 D., ax 105deg..

Relative accommodation reserves: +0,5D. Vision nature: binocular not stable, heterophoria by exophoria type 5 prismatic D. (Shober's test), synoptophore OA=SA= - 2 deg., fusion reserves +12/-6 deg.

Accommodation answer with optimal correction for distance to 33cm stimuli: OD = 1,25 D., OS= 1,25 D.

Biometry (AL): OD = 25,07 mm, OS = 24,89 mm.

Biomicroscopy OU: anterior eye segment calm, optical structures clear.

Ocular fundus: macular reflex precise. ODN pale pink, borders precise, myopic cone, vascular stroke and caliber not changed. Periphery with non-significant hyperpigmentation.

Status ophthalmicus on 28.04.2015 after constant using claimed device as spectacles. Optical elements features shown at fig.1, fig.4, fig.5, fig.6, fig.13, fig.19.

Right optical element refraction: optical center and central zone refraction: sph. -4,5 D., cyl. –0,75 D. ax 45deg., refraction by spherical equivalent in different points of ring-like zone is in range from от - 4,25 D. до - 1,75 D., temporal zone refraction- 1,75 D., nasal zone refraction - 2,25 D., near zone refraction sph. - 3,0 D., cyl. – 0,75 D. ax 45 deg.

Left optical element refraction: optical center and central zone refraction: sph. – 4,5 D., cyl -025 D., ax 135 deg., refraction by spherical equivalent in different points of ring-like zone is in range from от – 4,12 D. до -1,12 D., temporal zone refraction- 1, 12 D., nasal zone refraction - 1, 87 D., near zone refraction sph. . – 3,0 D., cyl -025 D., ax 135 deg.

Off-axis refraction examination at 15 degrees from fovea on nasal and temporal sides when patient wearing traditional monofocal lenses and claimed devise as spectacle lenses using autorefkeratometer Shin Nippon NVISION-5001. Statistical analysis was by spherical equivalent regarding to refractometer data. Formula: M = S+C/2. (M- sherical equvalent, S – sphere, C – cylinder.)

Correction	On-axis /off-axis (15 deg.) refraction	Sph. D.	Cyl. D.	Ax. Deg.	Spherical equivalent D.
Claimed device lens	OD nasal	- 0,5	- 1,0	20	- 1,00
	OD temporal	+ 0,75	- 2,00	96	- 0,25
	Axial	0,00	- 0,12	48	- 0,06
Claimed device lens	OS nasal	+ 0,25	- 1,25	30	- 0,37
	OS temporal	+ 0,75	-2,12	102	- 0,31
	Axial	0,00	0.00		0,00

Claimed device providing strengthening of peripheral refraction by focusing image in front of retina, with correction of axial refraction on retina.

Patient wore spectacles permanently with complaints.

On-axis cycloplegic refraction: OD sph -4,5 D., cyl -0,5 D., ax 55 deg., OS sph -4,25 D., cyl -0,5D., ax 137 deg.

Visual acuity with optimal correction: OD with sph -4,75 D., cyl -0,5 D., ax 55 deg. = 1,0, OS 0,1 with sph -4,5 D. , cyl -025 D., ax 136 deg. = 1,0.

Binocuar visual acuity with optimal correction= 1,0

Cycloplegic refraction Off-axis in horizontal at 30 deg. from fovea:

OD nasal side sph - 2,5 D., cyl -0,25 D., ax 28deg.,

temporal side sph - 2,12 D., cyl -2,75 D., ax 92 deg.,

OS nasal side sph – 1,75 D., cyl - 0,5 D., ax 24deg.,

temporal side sph -2,0 D., cyl -1,72 D., ax 108deg..

Relative accommodation reserves: +3,0 D. Vision nature: binocular, orthophoria (Shober's test), synoptophore OA=SA= + 0 deg., fusion reserves +18/-5 deg.

Accommodation answer with optimal correction for distance to 33cm stimuli: OD = 2,25 D., OS= 2,0 D.

Biometry (AL): OD = 25,05 mm, OS = 24,92 mm.

Biomicroscopy OU: anterior eye segment calm, optical structures clear.

Ocular fundus: macular reflex precise. ODN pale pink, borders precise, myopic cone, vascular stroke and caliber not changed. Normal periphery.

Aberrometry data collected by OPD Scan ARK 10000 (Nidek, Japan).

High order spherical aberrations	Aberrometry data (micrometer)	
	Without correction before trial	Using claimed device
OD	- 0,056±0,06	0,36±0,31
OS	- 0,022±0,04	0,27±0,16

Thereby, after long using of claimed device technical result was achieved – progression of myopia stops, relative accommodation reserves increased, accommodation answer become stronger, changing of relations between axial and off-axis refraction and relations between peripheral refraction (nasal refraction become weaker, temporal refraction become stronger), it is objectively shown that device is inducing in the eye's optical system relative peripheral myopia and positive spherical aberrations, exophoria was eliminated, was increased binocular visual acuity and fusion reserves.

Excerpt 3. Patient born in 2007, diagnosis: myopia risk group, both eyes accommodation spasm. Both parents has mid degree myopia.

Status ophthalmicus on 2.02.2014:

On-axis refraction non-cycloplegic: OD sph -0,5 D., cyl -0,25 D., ax 0 deg., OS sph -0,75 D., cyl -0,25D., ax 178 deg.

On-axis cycloplegic refraction: OD sph + 0,75 D., cyl -0,25 D., ax 10 deg., OS sph +0,5 D.

Visual acuity with optimal correction before cycloplegia: OD 0,4 with sph -0,5 D., cyl -0,25 D., ax 0 deg. = 0,8, OS 0,09 with sph -0,75 D., cyl -0,25 D., ax 178 deg. = 0,7.

Visual acuity with optimal correction after cycloplegia using aperture 3 mm: OD = 1,0 OS = 0,9.

Cycloplegic refraction Off-axis in horizontal at 30 deg. from fovea:

OD nasal side sph +0,75 D., cyl -0,5 D., ax 98 deg.,

temporal side sph +2,12 D., cyl -1,0 D., ax 78 deg.,

OS nasal side sph + 1,0 D., cyl - 0,5 D., ax 104 deg.,

temporal side sph +1,75 D., cyl -0,75 D., ax 88 deg..

Relative accommodation reserves: 0 D. Vision nature: binocular, heterophoria by exophoria type 8 prismatic D. (Shober's test), synoptophore OA=SA= +6 deg., fusion reserves +14/0 deg.

Accommodation answer without correction (5th text of reading control table) to 33cm stimuli: OD = 0,75 D., OS= 1,25 D.

A-scan (AL): OD = 22,44 mm, OS = 22,67 mm.

Biomicroscopy: anterior eye segment calm, optical structures clear.

Ocular fundus: macular reflex precise. ODN pale pink, borders precise, vascular stroke and caliber not changed. Periphery with non-significant hyperpigmentation.

Status ophthalmicus on 9.09.2014 after using by subject claimed device as spectacles. Device was used periodically: about 6 hours per day. Spectacles were used during usual visual tasks at distance and at nearwork. Optical elements features are shown on fig.1, fig.4, fig.5, fig.6, fig.13, fig.19.

Right optical element refraction: optical center and central zone refraction: sph. Planum, refraction by spherical equivalent in different points of ring-like zone is in range from от +0,25 D. до +3,0 D., temporal zone refraction+3,0 D., nasal zone refraction +2,5D., near zone refraction sph. +1,75 D.

Left optical element refraction: optical center and central zone refraction: sph. Planum, refraction by spherical equivalent in different points of ring-like zone is in range from от +0,5 D. до +3,0 D., temporal zone refraction+3,0 D., nasal zone refraction +2,5D., near zone refraction sph. +1,75 D.

Off-axis refraction examination at 15 degrees from fovea on nasal and temporal sides when patient wearing traditional monofocal lenses and claimed devise as spectacle lenses using autorefkeratometer Shin Nippon NVISION-5001.Statistical analysis was by spherical equivalent regarding to refractometer data. Formula: M = S+C/2. (M- sherical equvalent, S – sphere, C – cylinder.)

Correction	On-axis /off-axis (15 deg.) refraction	Sph. D.	Cyl. D.	Ax. Deg.	Spherical equivalent D.
Claimed device lens	OD nasal	- 1,25	- 0,5	99	- 1,5
	OD temporal	- 0,5	- 1,0	82	- 1,0
	Axial	+ 0,25	-	-	+0,25
Claimed device lens	OS nasal	- 1,0	- 0,75	89	- 1,37
	OS temporal	+ 0,12	-1,37	109	- 0,56
	Axial	+0,12	-	-	+0,12

Claimed device providing strengthening of peripheral refraction by focusing image in front of retina, with correction of axial refraction on retina.

Patient wore spectacles constantly without complaints .

On-axis refraction non-cycloplegic: OD sph + 0,25 D., cyl -0,25 D., ax 12 deg., OS sph + 0,12 D., cyl + 0,25 D., ax 89 deg.

On-axis cycloplegic refraction: OD sph + 0,5 D., OS sph +0,5 D., cyl + 0,25 D., ax 78 deg..

Visual acuity with optimal correction before cycloplegia: OD = 0,9 -1,0 OS = 0,9 -1,0.

Cycloplegic refraction Off-axis in horizontal at 30 deg. from fovea:

OD nasal side sph +1,12 D., cyl -0,5 D., ax 96 deg.,

temporal side sph +1,87 D., cyl -1,25 D., ax 79 deg.,

OS nasal side sph + 1,0 D., cyl - 0,5 D., ax 107 deg.,

temporal side sph +1,75 D., cyl -1,0 D., ax 85 deg..

Relative accommodation reserves: +2,0D. Vision nature: binocular, orthophoria (Shober's test), synoptophore OA=SA= +2 deg., fusion reserves +25/-4 deg.

Accommodation answer with optimal correction for distance to 33cm stimuli: OD = 2,75 D., OS= 2,75 D.

A-scan (AL): OD = 22,49 mm, OS = 22,64 mm.

Biomicroscopy OU: anterior eye segment calm, optical structures clear.

Ocular fundus: macular reflex precise. ODN pale pink, borders precise, vascular stroke and caliber not changed. Normal periphery.

Thereby, after using of embodiment of claimed device technical result is achieved, factors of myopia onset are eliminated – accommodation spasm is treated, relative accommodation reserves increased, accommodation answer become stronger, relations between on-axis and off-axis refraction are changed, it is objectively shown that device is inducing in the eye's optical system relative peripheral myopia, creates conditions for accommodation training at distance and supports accommodation during nearwork without vergence tension, increases binocular functions with elimination of esophoria and development of fusion reserves.

Excerpt 4. Patient born in 2010, diagnosis: High degree hyperopia of both eyes.

Status ophthalmicus on 17.10.2013:

On-axis refraction after cycloplegia (cyclomed 0,5% - 2 times) OD sph + 7,5 D., cyl +0,5 D., ax 85 deg., OS sph +8,25 D. , cyl +0,5 D., ax 102 deg.

Eye's position correct, in full motion.

Visual acuity: OD 0,3 with sph +7,5 D., = 0,7, OS 0,2 with sph +8,0 D. = 0,6.

Binocuar visual acuity with optimal correction= 0,7

Cycloplegic refraction Off-axis in horizontal at 30 deg. from fovea:

OD nasal side sph +5,75 D., cyl -0,75 D., ax 90deg.,

temporal side sph +6,25 D., cyl - 0,5 D., ax 93 deg.,

OS nasal side sph +7,25 D., cyl - 1,25 D., ax 82deg.,

temporal side sph +6,75 D., cyl -1,0 D., ax 102deg..

Vision nature: binocular, synoptophore OA=SA= +6 deg., fusion reserves +15/-2 deg.

A-scan (AL): OD = 21,2 mm, OS = 20,94 mm.

Biomicroscopy OU: anterior eye segment calm, optical structures clear.

Ocular fundus: macular reflex tracked. ODN pale pink, borders precise, vascular stroke and caliber not changed. Normal periphery.

Status ophthalmicus on 9.08.2015 after using claimed device as spectacles. Optical elements features are shown on fig.1, fig.4, fig.9, fig.10, fig.21.

Right optical element refraction: optical center and central zone refraction: sph. +7,5 D., refraction by spherical equivalent in different points of ring-like zone is in range from от +6,92 D. до +4,50 D., temporal zone refraction+4,50 D., nasal zone refraction +5,0 D., near zone refraction sph +9,5.

Left optical element refraction: optical center and central zone refraction: sph. +8,0 D., refraction by spherical equivalent in different points of ring-like zone is in range from от +7,5 D. до +5,0 D., temporal zone refraction+5,0 D., nasal zone refraction +5,5 D., near zone refraction sph +10,0 D.

Off-axis refraction examination at 15 degrees from fovea on nasal and temporal sides when patient wearing claimed devise as spectacle lenses using autorefkeratometer Shin Nippon NVISION-5001.Statistical analysis was by spherical equivalent regarding to refractometer data. Formula: M = S+C/2. (M- sherical equvalent, S – sphere, C – cylinder.)

Correction	Refraction	Sph. D.	Cyl. D.	Ax. Deg.	M D.
Claimed device lens	OD nasal 15 deg.	+1,5	-0,5	94	+1,25
	OD temporal 15 deg.	+1,25	-0,5	92	+1,0
	Axial	+0,12	+0,5	85	+0,5
Claimed device lens	OS nasal 15 deg.	+2,25	-1,25	86	+1,62
	OS temporal 15 deg.	+1,25	-0,75	100	+0,87
	Axial	+0,25	+0,37	100	+0,43

Claimed device providing weakening of peripheral refraction by focusing image behind the retina, with correction of axial refraction on the retina.

Patient wore spectacles constantly without complaints.

On-axis refraction after cycloplegia (cyclomed 0,5% - 2 times) OD sph +5,75 D., cyl +0,75 D., ax 92 deg., OS sph +6,75 D. , cyl +0,25 D., ax 97 deg.

Visual acuity: OD 0,4 with sph + 5,5 D., cyl +0,5 D., ax 90 deg., = 0,8, OS 0,4 with sph +6,5 D. = 0,8. Binocular with correction 0,9.

Cycloplegic refraction Off-axis in horizontal at 30 deg. from fovea:

OD nasal side sph +4,0 D., cyl -1,25 D., ax 105deg.,

temporal side sph +3,75 D., cyl - 0,75 D., ax 97 deg., OS nasal side sph +5,5 D., cyl - 1,5 D., ax 92deg.,

temporal side sph +6,25 D., cyl -0,75 D., ax 105deg..

Vision nature: binocular, orthophoria (Shober's test), synoptophore OA=SA= +2 deg., fusion reserves +20/-4 deg.

A-scan (AL): OD = 21,94 mm, OS = 21,48 mm.

Biomicroscopy OU: anterior eye segment calm, optical structures clear.

Ocular fundus: macular reflex precise. ODN pale pink, borders precise, vascular stroke and caliber not changed. Normal periphery.

Thereby, after using claimed device technical result is achieved: hyperopia value is reduced with following axial length increasing of both eyes, relation between nasal and temporal refraction is changed, relation between on-axis and off-axis refraction is changed, it is objectively shown that device induces relative peripheral hyperopia in eye's optical system, creates conditions for accommodation support during nearwork without vergence tension, increases binocular vision, eliminates esophoria and develops fusion reserves.

Excerpt 5. Patient born in 2004, diagnosis: low degree myopia with relatively high intraocular pressure of both eyes.

Status ophthalmicus on 14.11.2015:

On-axis cycloplegic refraction: OD sph – 2,62 D., cyl -0,25 D., ax 75 deg., OS sph -2,62 D., cyl -0,37 D., ax 131 deg.

Visual acuity with optimal correction: OD 0,09 with sph - 3,0 D. = 0,9 OS 0,1 with sph - 3,0 D. = 1,0.

Cycloplegic refraction Off-axis in horizontal at 30 deg. from fovea:

OD nasal side sph + 0,35 D., cyl -1,25 D., ax 109deg.,

temporal side sph -0,62 D., cyl -1,5 D., ax 106deg.,

OS nasal side sph + 1,37 D., cyl - 1,87D., ax 16deg.,

temporal side sph – 0,62 D., cyl - 1,37D., ax 99deg., Relative accommodation reserves: + 1,5 D. Vision nature: binocular, exophoria 2 prismatic D. (Shober's test), synoptophore OA=SA= - 1 deg., fusion reserves +16/-7 deg.

IOP (intraocular pressure) (non-contact tonometry using Reichert AT- 555): OD=22, OS=24

Biomicroscopy OU: anterior eye segment calm, optical structures clear. Cornea diameter OU = 11,5 mm, limb width – less than 1 mm.

Gonioscopy: anterior chamber angle is opened, all identification zones are viewed, comb isolated ligament pre trabecular. ГДГ- 1 ст.

Ocular fundus: macular reflex precise. ODN pale pink, borders precise, vascular stroke and caliber not changed. Periphery with non-significant hyperpigmentation.

HRT. Retinal tomography using "Heidelberg Engineering HRT II"

OD: cup area – 0,986 mm^2; mean cup depth – 0,356 mm; max.cup depth – 0,995 mm; rim area – 1,629 mm^2;

OS: cup area – 1,494 mm^2; mean cup depth – 0,334 mm; max.cup depth – 0,790 mm; rim area – 1,255 mm^2.

IOP in dynamics (non-contact tonometry using Reichert AT- 555):

21.11.2015

OD = 23, OS = 27

26.12.2015

OD = 20, OS = 22

28.12.2015

OD = 21, OS = 24

Then there was prescription for spectacles including optical elements shown on fig.1, fig.4, fig.7, fig.8, fig.14, fig.18.

Both optical elements refraction: optical center and central zone refraction: sph. – 2,75 D., refraction by spherical equivalent in different points of ring-like zone is in range from – 2,5 D. to +0,25 D., temporal zone refraction+0,25 D., nasal zone refraction - 0, 25 D.

Status ophthalmicus on 26.03.2016.:

On-axis cycloplegic refraction: OD sph – 2,5 D., cyl -0,25 D., ax 165 deg., OS sph -2,25 D., cyl -0,5 D., ax 155 deg.

Visual acuity with optimal correction: OD 0,1 with sph – 2,75 D. = 1,0, OS 0,2 with sph – 2,5 D. = 1,0.

Visual acuity with spectacles OU 1,2

Cycloplegic refraction Off-axis in horizontal at 30 deg. from fovea:

OD nasal side sph + 0,5 D., cyl -1,0 D., ax 162deg.,

temporal side sph -1,25 D., cyl -1,25 D., ax 100deg.,

OS nasal side sph + 0,25 D., cyl - 1,5D., ax 17deg.,

temporal side sph – 1,12 D., cyl - 1,5D., ax 101deg.,

Relative accommodation reserves: +2,5 D. Vision nature: binocular, orthophoria (Shober's test), synoptophore OA=SA= 0 deg., fusion reserves +20/-7 deg.

Biomicroscopy OU: anterior eye segment calm, optical structures clear.

Ocular fundus: macular reflex precise. ODN pale pink, borders precise, vascular stroke and caliber not changed. Periphery with non-significant hyperpigmentation.

IOP (non-contact tonometry using Reichert AT- 555) : OD = 19, OS = 18.

HRT. Retinal tomography using "Heidelberg Engineering HRT II"

OD: cup area – 0,843 mm^2; mean cup depth – 0,312 mm; max.cup depth – 0,894 mm; rim area – 1,772 mm^2;

OS: cup area – 1,472 mm^2; mean cup depth – 0,324 mm; max.cup depth – 0,720 mm; rim area – 1,278 mm^2.

Excavation parameters:

	Parameter	14.11.2015	26.03.2016
OD	Mean cup depth (мм)	0,356	0,312(-0,044)
	Maximum cup depth (мм)	0,995	0,894(-0,101)
OS	Mean cup depth (мм)	0,334	0,312(-0,010)
	Maximum cup depth (мм)	0,790	0,720(-0,070)

Thereby, after using one of embodiment of claimed device technical result is achieved: axial myopia is reduced, relation between nasal and temporal refraction is changed, relation between on-axis and off-axis refraction is changed, intraocular pressure is decreased, area and depth of excavation is decreased with increasing of neuronal density, exophoria is eliminated, relative accommodation reserves increased.

Claimed embodiments of device were used in long-term clinical trials in children and teenagers with refraction infringements. In all cases of using claimed device, regarding to clinical, functional, refractometric, biometric and other trials, positive data is achieved, which is corresponding to claimed technical result and shows it's approachability.

Claims

1. Device for prophylaxis and/or treatment of progressive myopia, including optical elements, each of said elements includes front and back surface, optical center, nasal and temporal sides, vertical and horizontal, passing through optical center, *characterized that* in all radial directions not less than 3 mm and not more than 6mm from optical center with distance refraction, refraction starts to monotonically increasing outwards in range of from 0,25 D to 3,0 D for 1,5mm-16mm, creating ring-like zone with stronger refraction than in optical center, inner edge of said ring-like zone passing through all points of refraction increasing beginning, which limits central zone with stable refraction corresponding with refraction of optical center which is situated closer to the inner edge of ring-like zone at temporal side by 1-2mm, outer edge of ring-like zone is passing through all points of refraction increasing completion, from nasal and temporal edges of outer edge of ring-like zone, which is situated asymmetrically from optical center, starts and spreads outwards asymmetrical by area and refraction power, zones with stable refraction, wherein refraction is more than refraction of optical center by 2,0-3,0 D, area of each of said nasal and temporal zones is less than 1/8 of optical element area, centers of said zones is passing through horizontal of optical element which is passing through optical center, from bottom edge of outer edge of ring-like zone starts near zone with stable refraction which is more than refraction of optical center by 1,0-2,0 D, area of near zone is less than 1/8 of optical element area, center of near zone is located in nasal half of optical element about for 0,5-4,0mm from vertical of optical element, from outer edge of ring-like zone between edges of nasal, temporal and near zones in all directions outwards refraction is monotonically decreasing or decreasing up to optical center refraction value.

2. Device of claim 1, wherein stable refraction value of zone in nasal half is more than stable refraction value of zone in temporal half.
3. Device of claim 1, wherein stable refraction value of zone in nasal half is less than stable refraction value of zone in temporal half.
4. Device for prophylaxis and/or treatment of hyperopia, including optical elements, each of said elements includes front and back surface, optical center, nasal and temporal sides, vertical and horizontal, passing through optical center, *characterized that* in all radial directions not less than 3 mm and not more than 6mm from optical center with distance refraction, refraction starts to monotonically decreasing outwards in range of from 0,25 D to 3,0 D for 1,5mm-16mm, creating ring-like zone with weaker refraction than in optical center, inner edge of said ring-like zone passing through all points of refraction decreasing beginning, which limits central zone with stable refraction corresponding with refraction of optical center which is situated closer to the inner edge of ring-like zone at temporal side by 1-2mm, outer edge of ring-like zone is passing through all points of refraction decreasing completion, from nasal and temporal edges of outer edge of ring-like zone, which is situated asymmetrically from optical center, starts and spreads outwards asymmetrical by area and refraction power, zones with stable refraction, wherein refraction is less than refraction of optical center by 2,0-3,0 D, area of each of said nasal and temporal zones is less than 1/8 of optical element area, centers of said zones is passing through horizontal of optical element which is passing through optical center, from bottom edge of outer edge of ring-like zone starts near zone with stable refraction which is less than refraction of optical center by 1,0-2,0 D, area of near zone is less than 1/8 of optical element area, center of near zone is located in nasal half of optical element about for 0,5-4,0mm from vertical of optical element, from outer edge of ring-like zone between edges of nasal, temporal and near zones in all directions outwards refraction is changing up to optical center refraction value.

5. Device of claim 4, wherein stable refraction value of zone in nasal half is more than stable refraction value of zone in temporal half.
6. Device of claim 4, wherein stable refraction value of zone in nasal half is less than stable refraction value of zone in temporal half.
7. Device for prophylaxis and/or treatment of progressive myopia, including optical elements, each of said elements includes front and back surface, optical center, nasal and temporal sides, vertical and horizontal, passing through optical center, *characterized that* in all radial directions not less than 3 mm and not more than 6mm from optical center with distance refraction, refraction starts to monotonically increasing outwards in range of from 0,25 D to 3,0 D for 1,5mm-16mm, creating ring-like zone with stronger refraction than in optical center, inner edge of said ring-like zone passing through all points of refraction increasing beginning, which limits central zone with stable refraction corresponding with refraction of optical center which is situated closer to the inner edge of ring-like zone at temporal side by 1-2mm, outer edge of ring-like zone is passing through all points of refraction increasing completion, from nasal and temporal edges of outer edge of ring-like zone, which is situated asymmetrically from optical center, starts and spreads outwards asymmetrical by area and refraction power, zones with stable refraction, wherein refraction is more than refraction of optical center by 2,0-3,0 D, area of each of said nasal and temporal zones is less than 1/8 of optical element area, centers of said zones is passing through horizontal of optical element which is passing through optical center, from outer edge of ring-like zone between edges of nasal and temporal zones in all directions outwards refraction is decreasing up to optical center refraction value.
8. Device of claim 7, wherein stable refraction value of zone in nasal half is more than stable refraction value of zone in temporal half.
9. Device of claim 7, wherein stable refraction value of zone in nasal half is less than stable refraction value of zone in temporal half.

10.Device for prophylaxis and/or treatment of hyperopia, including optical elements, each of said elements includes front and back surface, optical center, nasal and temporal sides, vertical and horizontal, passing through optical center, *characterized that* in all radial directions not less than 3 mm and not more than 6mm from optical center with distance refraction, refraction starts to monotonically decreasing outwards in range of from 0,25 D to 3,0 D for 1,5mm-16mm, creating ring-like zone with weaker refraction than in optical center, inner edge of said ring-like zone passing through all points of refraction decreasing beginning, which limits central zone with stable refraction corresponding with refraction of optical center which is situated closer to the inner edge of ring-like zone at temporal side by 1-2mm, outer edge of ring-like zone is passing through all points of refraction decreasing completion, from nasal and temporal edges of outer edge of ring-like zone, which is situated asymmetrically from optical center, starts and spreads outwards asymmetrical by area and refraction power, zones with stable refraction, wherein refraction is less than refraction of optical center by 2,0-3,0 D, area of each of said nasal and temporal zones is less than 1/8 of optical element area, centers of said zones is passing through horizontal of optical element which is passing through optical center, from bottom edge of outer edge of ring-like zone starts near zone with stable refraction which is less than refraction of optical center by 1,0-2,0 D, area of near zone is less than 1/8 of optical element area, center of near zone is located in nasal half of optical element about for 0,5-4,0mm from vertical of optical element, from outer edge of ring-like zone between edges of nasal, temporal and near zones in all directions outwards refraction is monotonically increasing or increasing up to optical center refraction value.

11.Device of claim 10, wherein stable refraction value of zone in nasal half is more than stable refraction value of zone in temporal half.

12.Device of claim 10, wherein stable refraction value of zone in nasal half is less than stable refraction value of zone in temporal half.

13. Method of production of optical elements of claim 1 by molding from polymeric or mineral materials or cutting of front and/or back surfaces.
14. Method of production of optical elements of claim 4 by molding from polymeric or mineral materials or cutting of front and/or back surfaces.
15. Method of production of optical elements of claim 7 by molding from polymeric or mineral materials or cutting of front and/or back surfaces.
16. Method of production of optical elements of claim 10 by molding from polymeric or mineral materials or cutting of front and/or back surfaces.

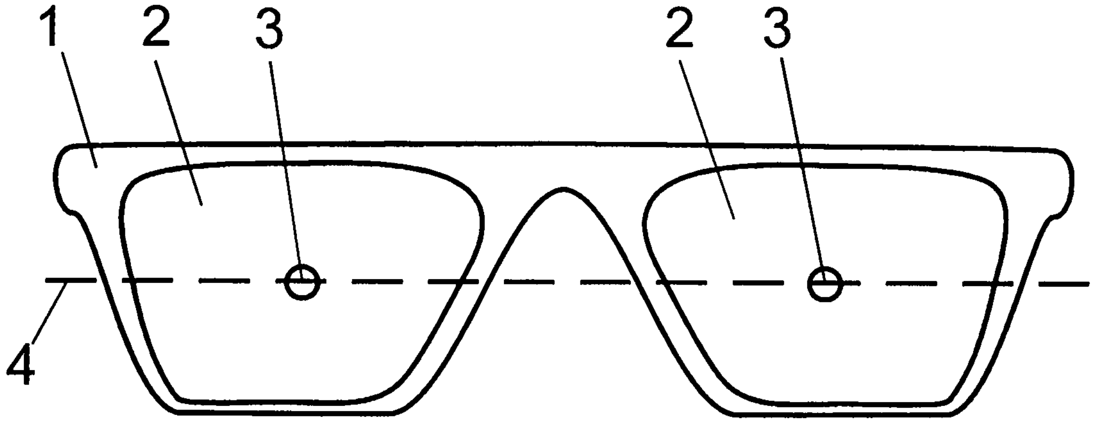


Fig. 1

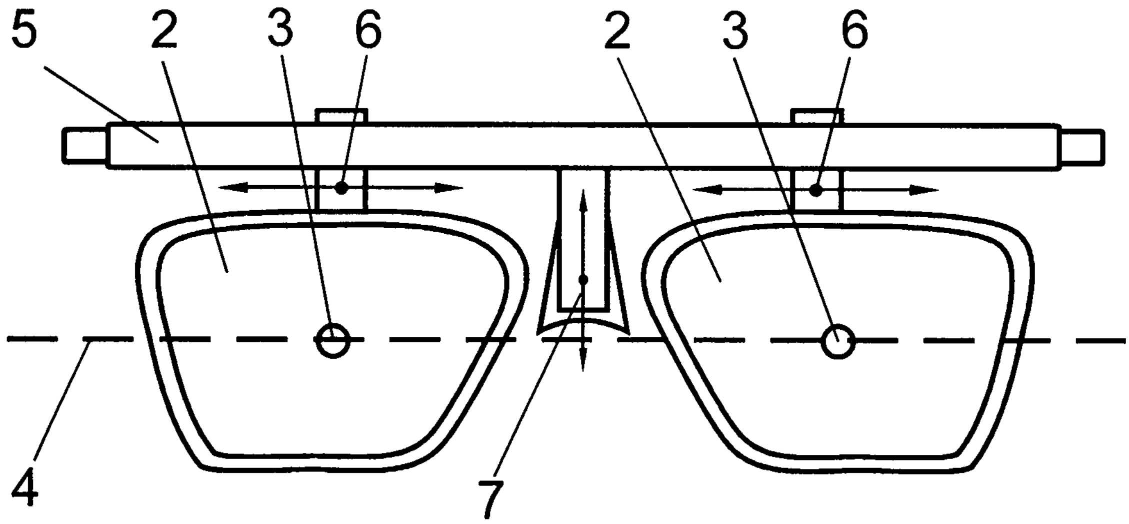


Fig. 2

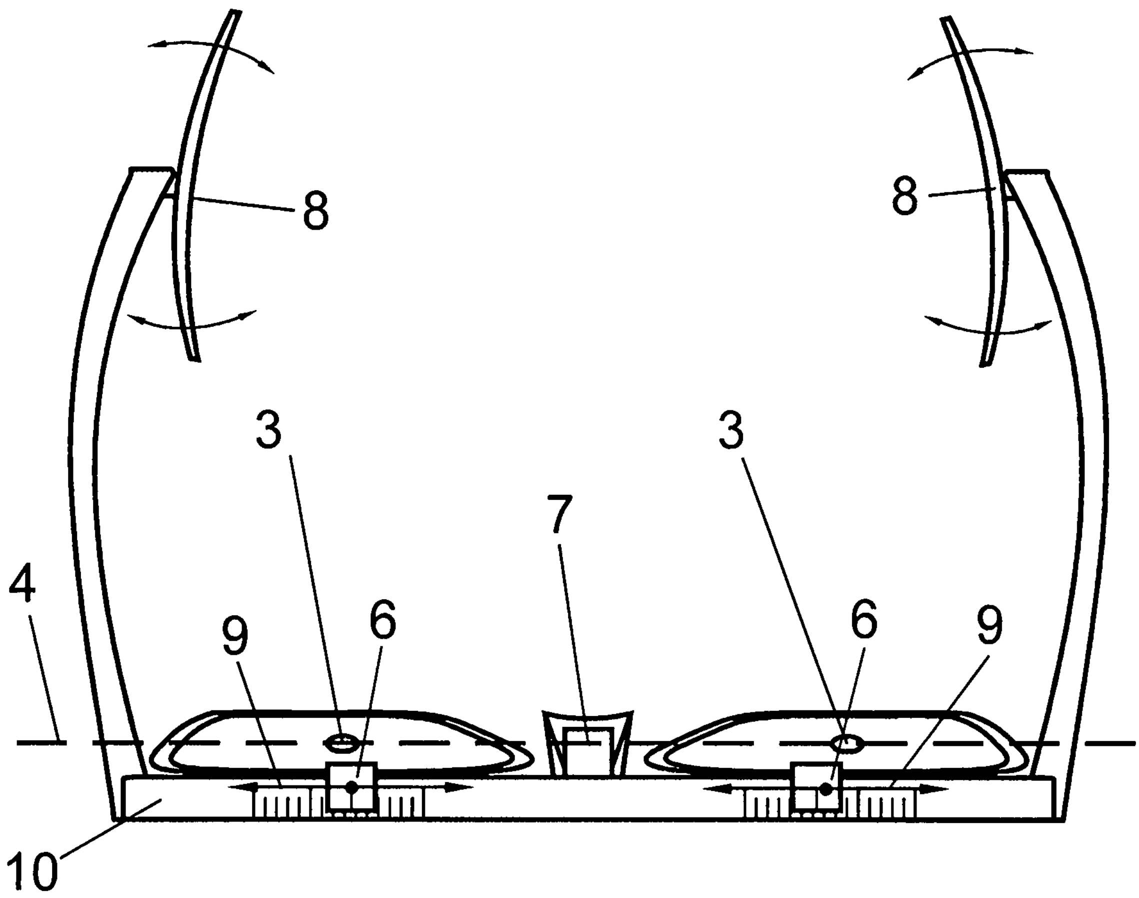


Fig. 3

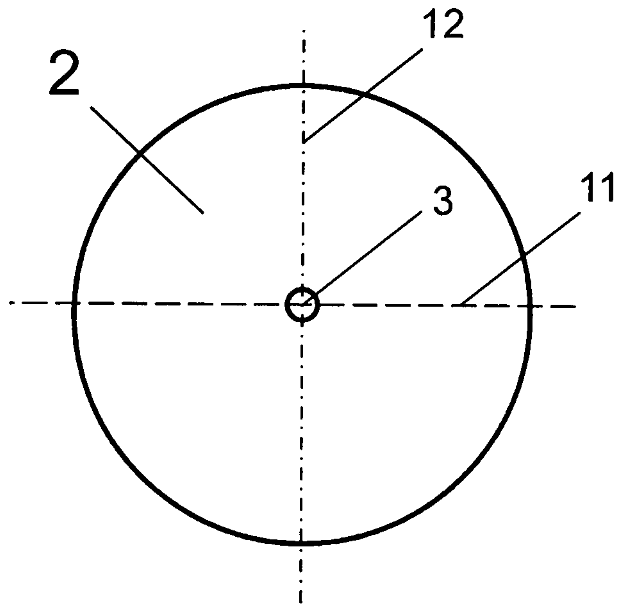
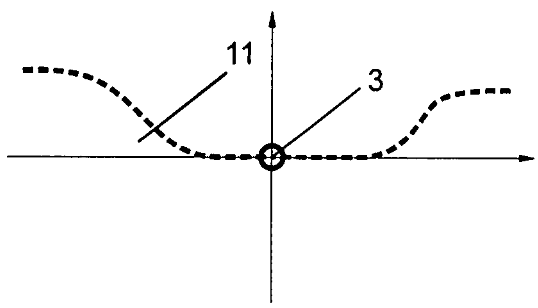


Fig. 4



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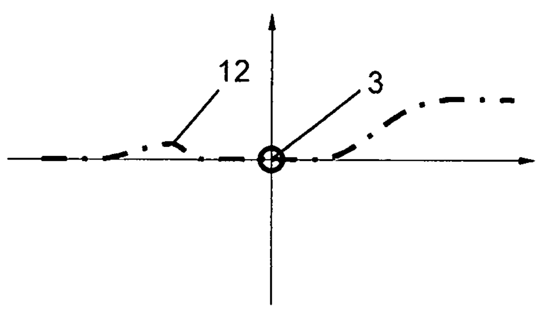

Fig. 6

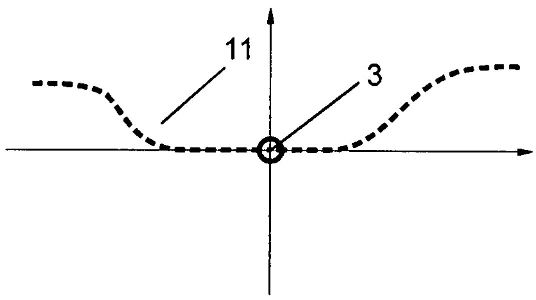

Fig. 7

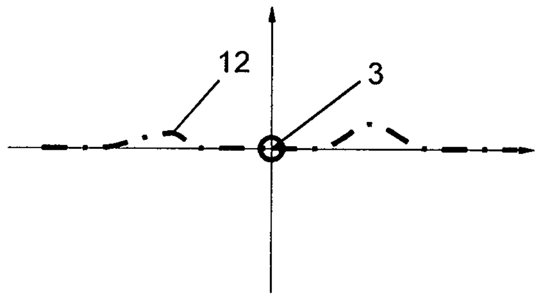

Fig. 8

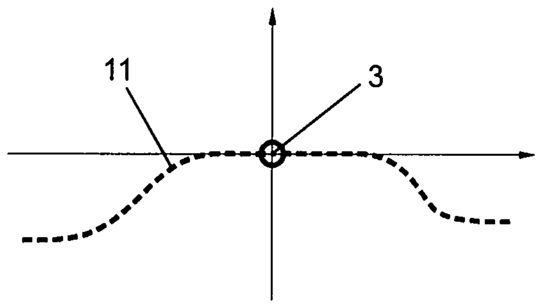

Fig. 9

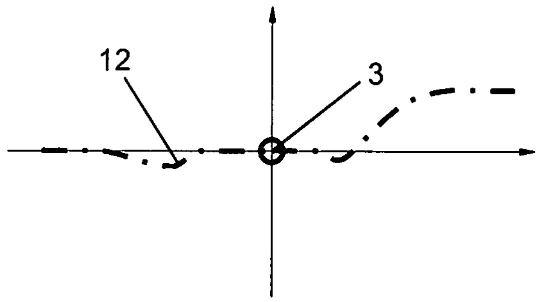

Fig. 10

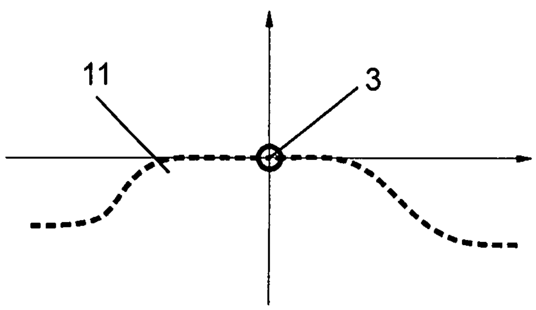

Fig. 11

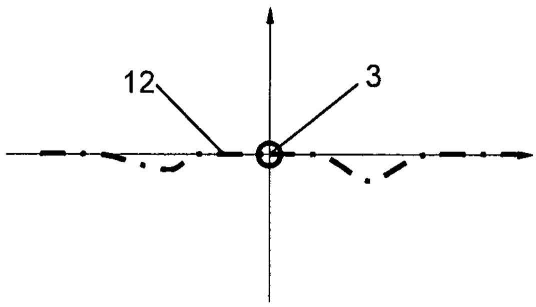

Fig. 12

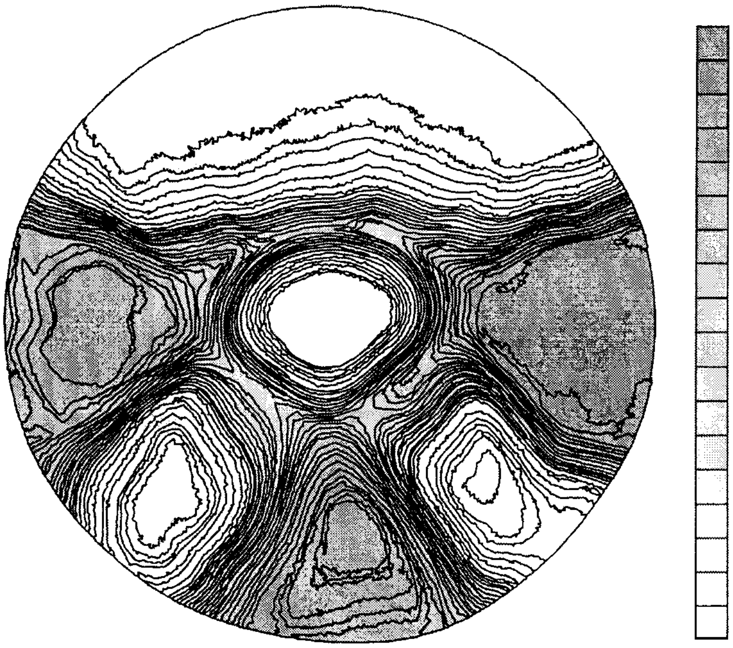

Fig. 13

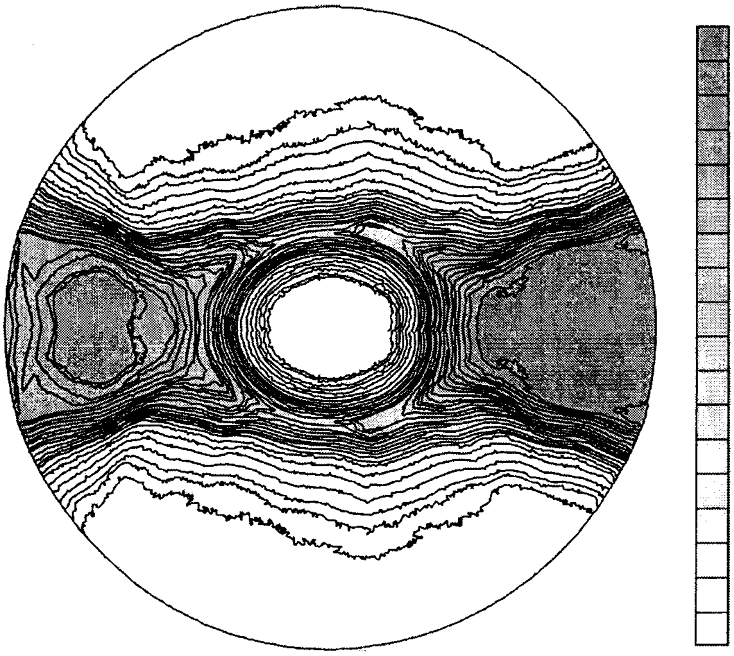

Fig. 14

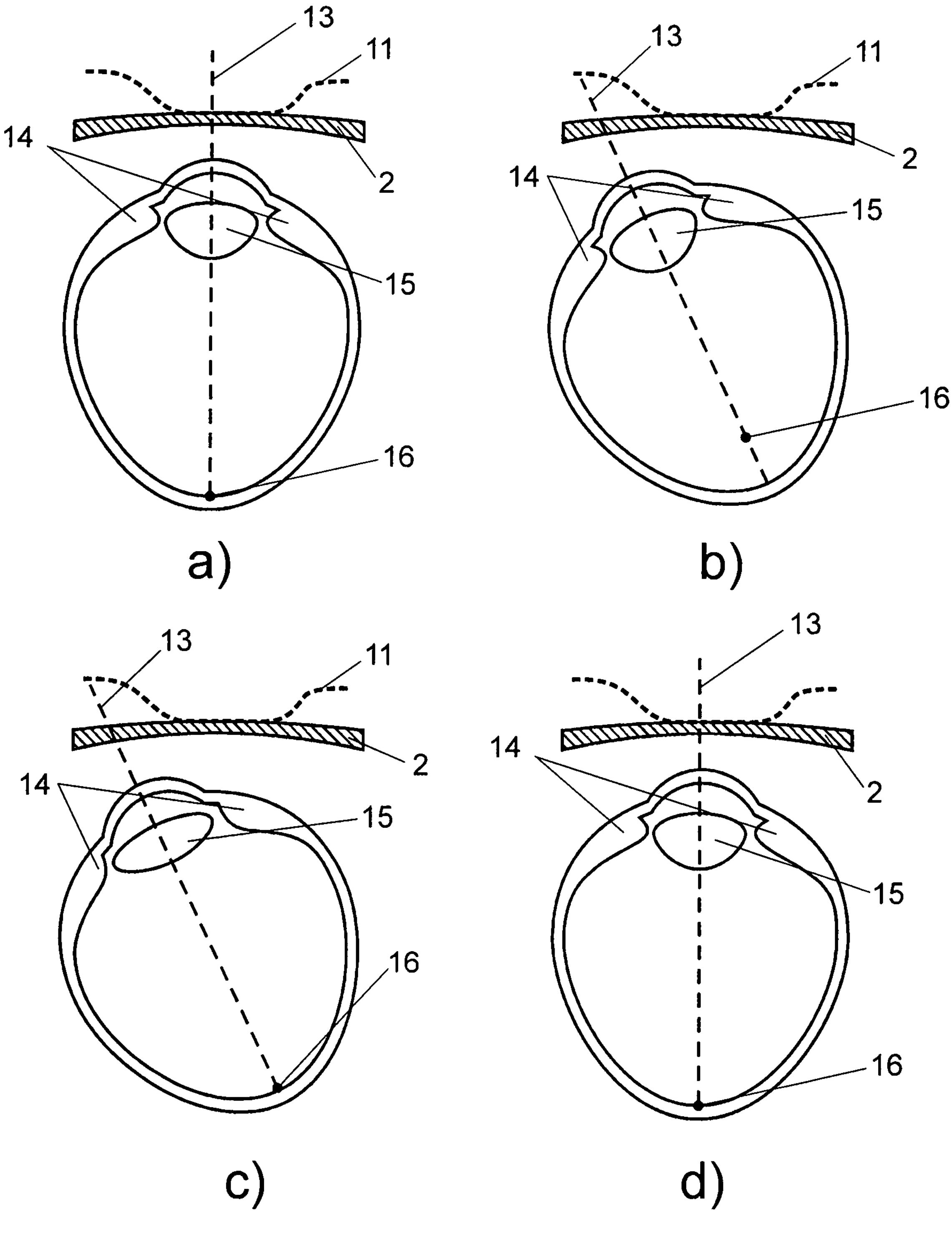

Fig. 15

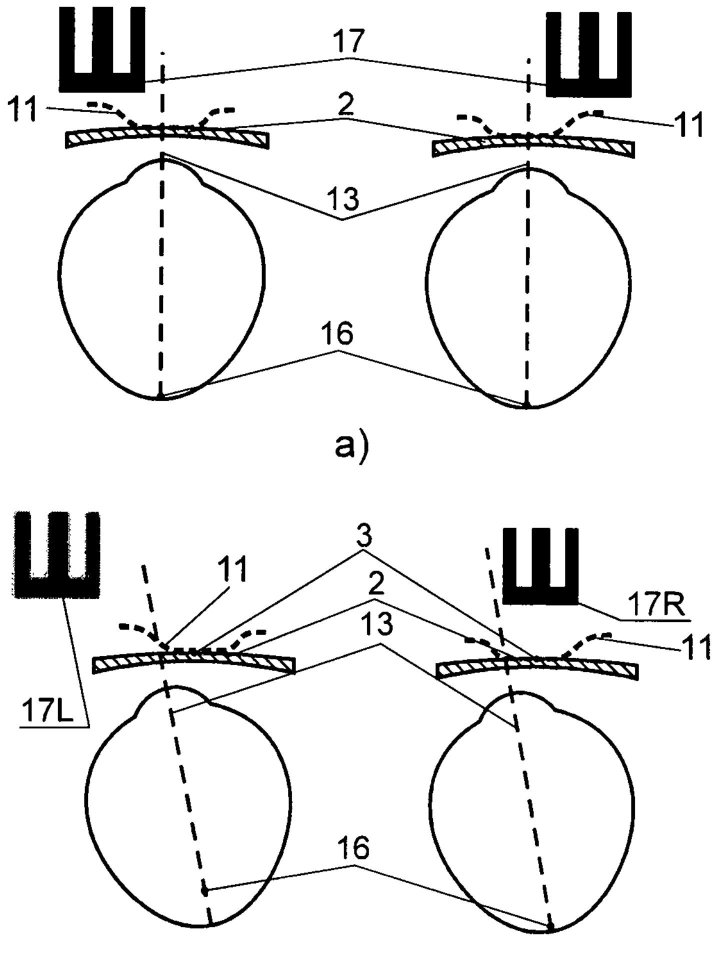

Fig. 16

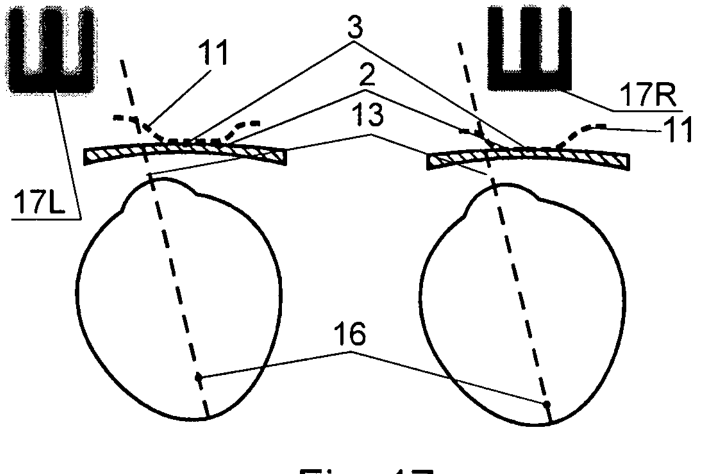

Fig. 17

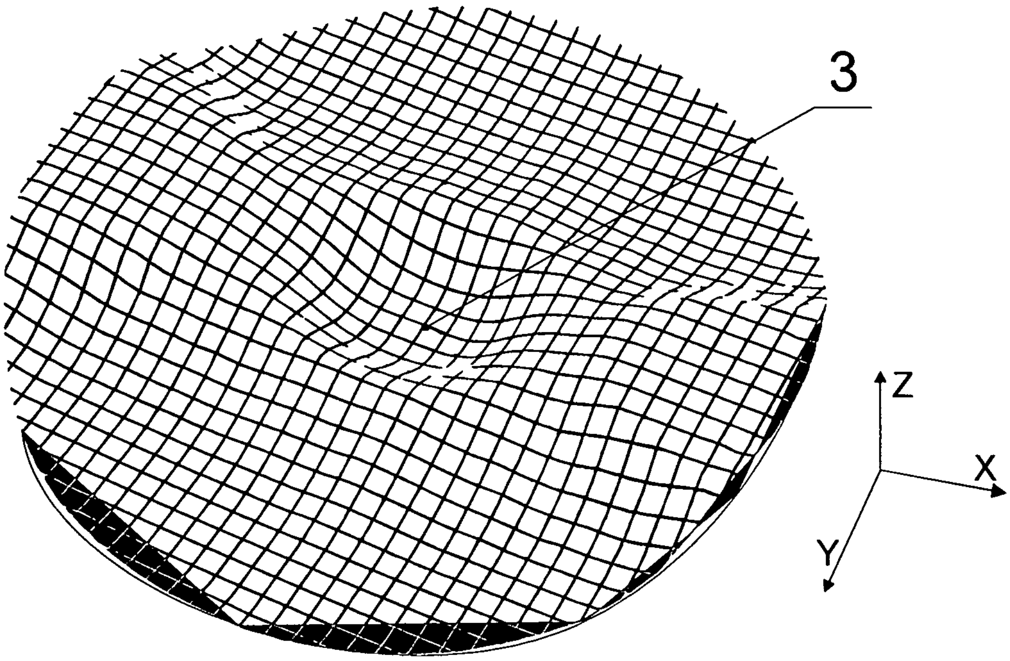

Fig. 18

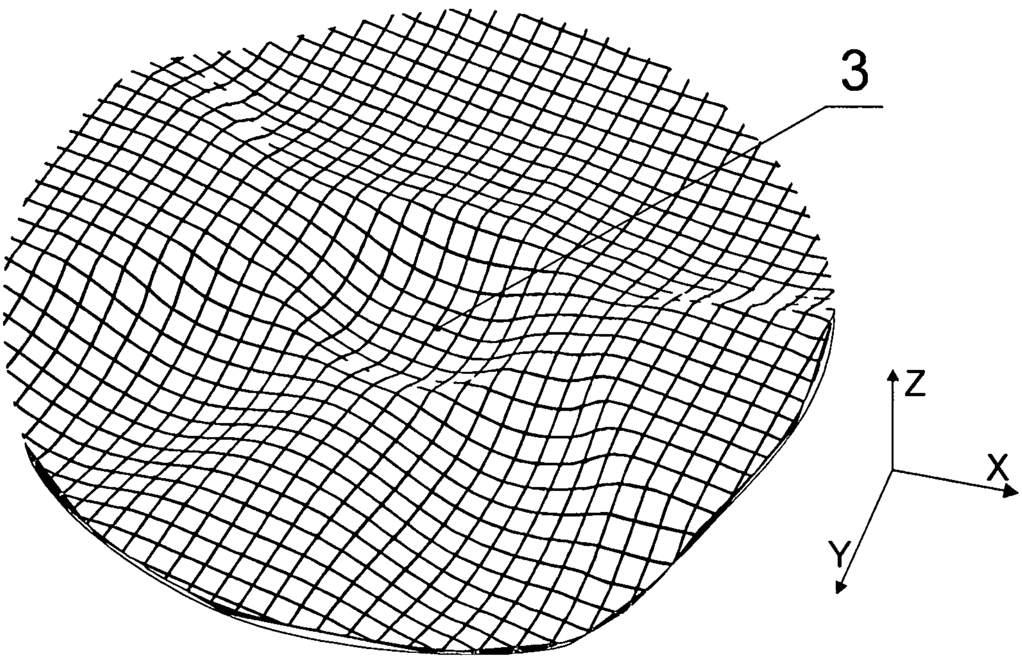

Fig. 19

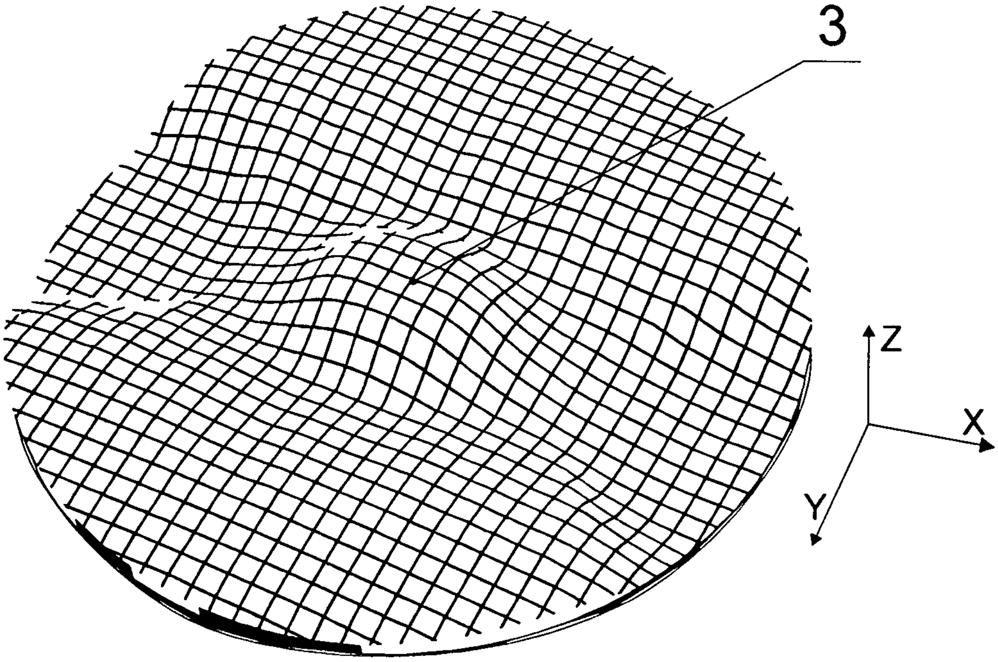

Fig. 20

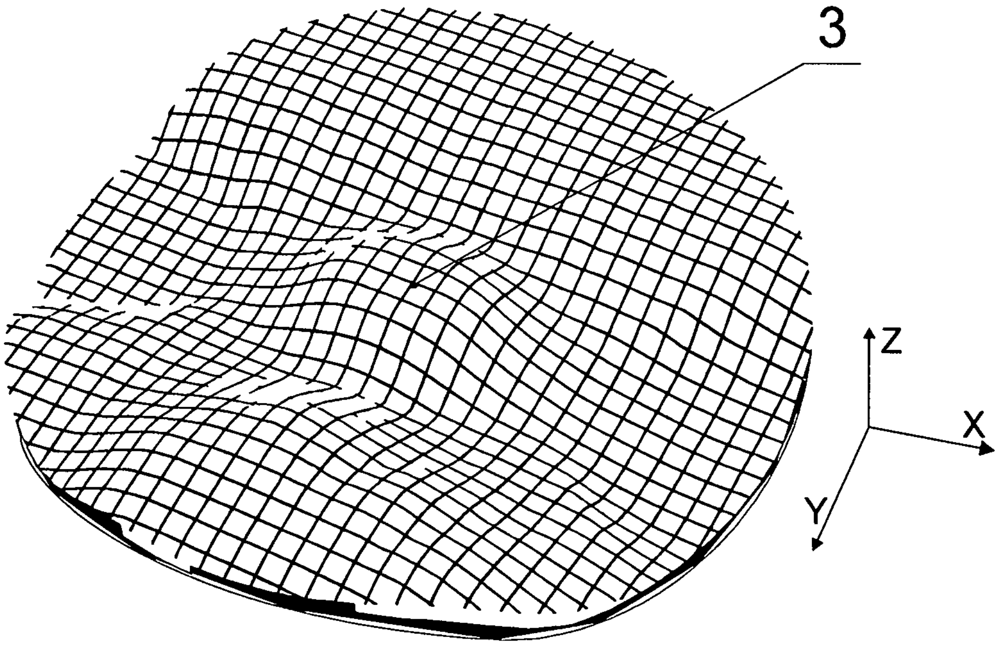

Fig. 21

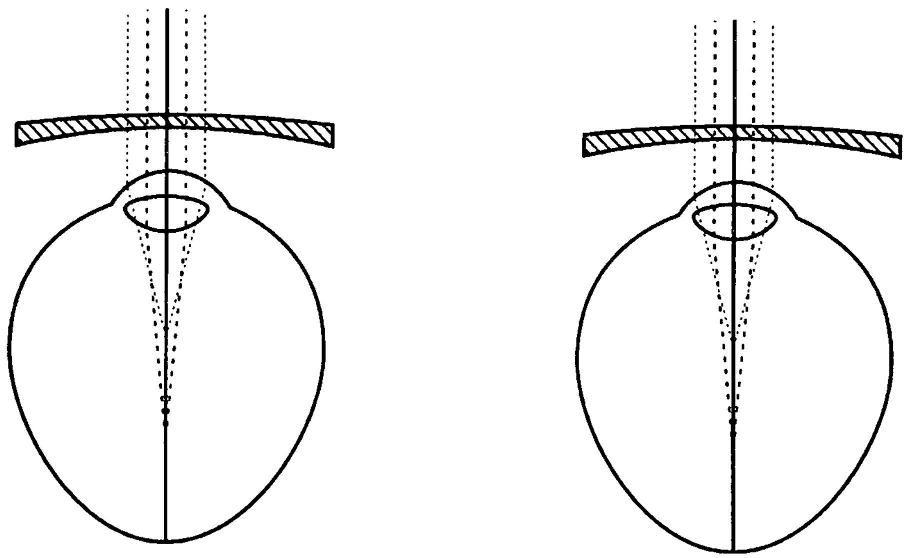

Fig. 22

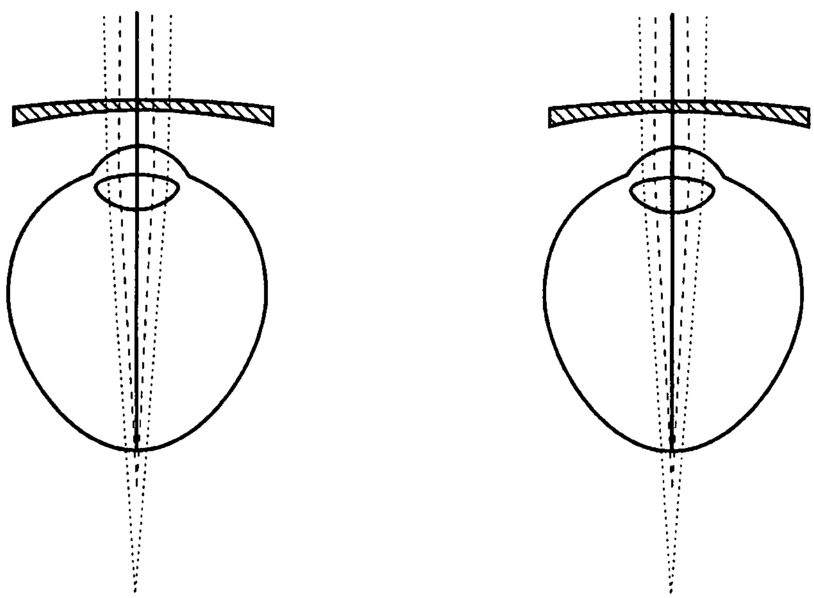

Fig. 23

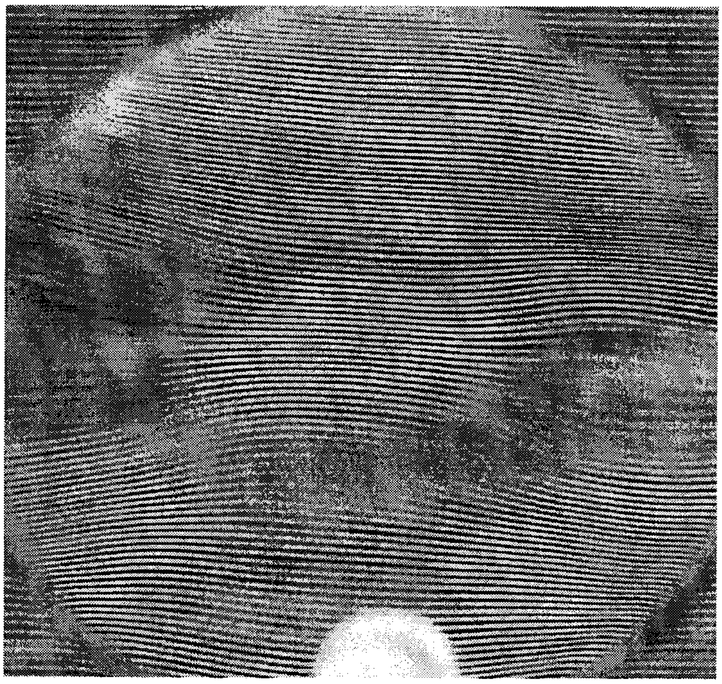

Fig. 24

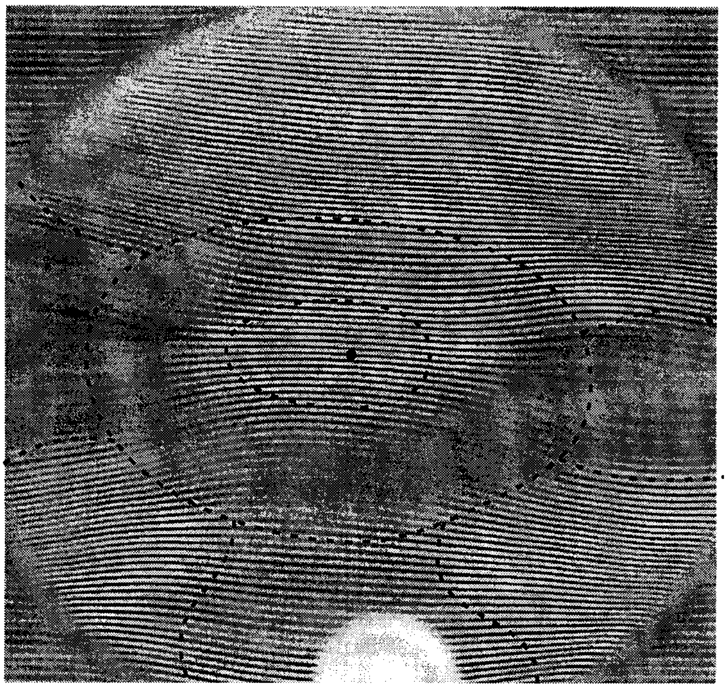

Fig. 25

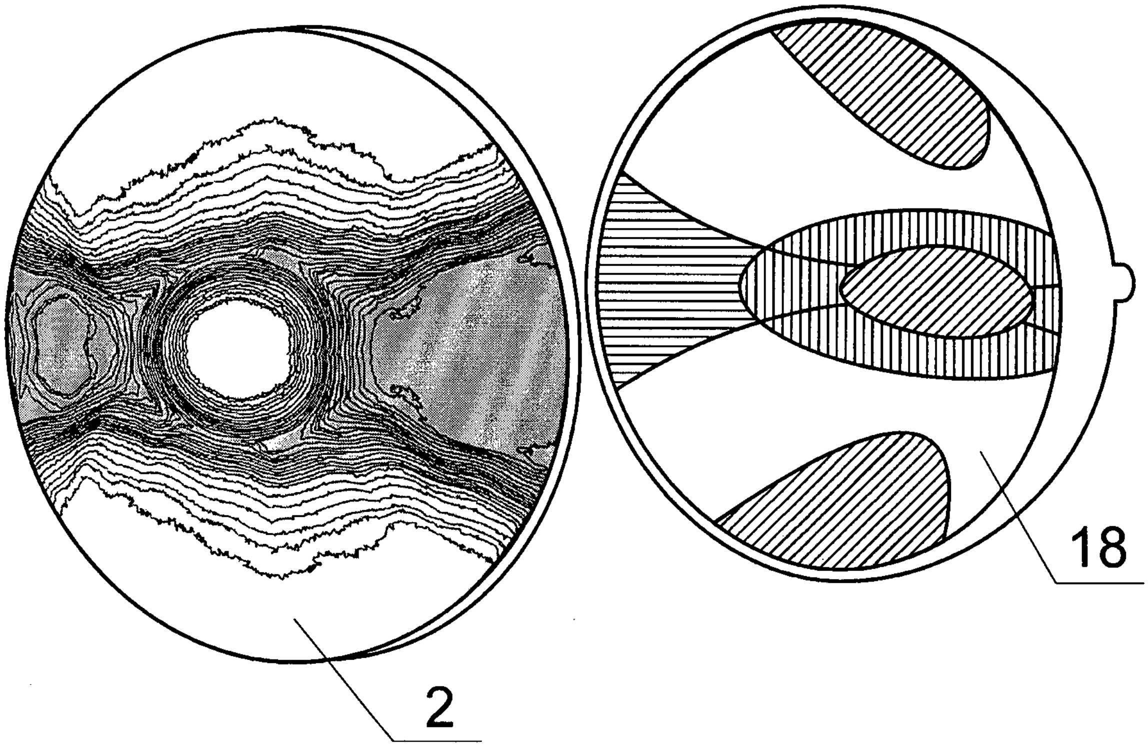

Fig. 26

INTERNATIONAL SEARCH REPORT

International application No.

PCT/RU 2017/000416

A. CLASSIFICATION OF SUBJECT MATTER

A61F 9/00 *(2006.01)*
G02C 7/02 *(2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F 9/00, G02C 7/02

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CIPO, DEPATISnet, DWPI, E-library, EAPATIS, Esp@cenet, Google, KIPRIS, Patentscope, PatSearch (RUPTO internal), PubMed, RUPTO, Rambler, SCOPUS, SIPO, USPTO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
D, A	WO 2013/134825 A1 (BRIEN HOLDEN VISION INSTITUTE) 19.09.2013, fig. 1, 3, p. 1, lines 6-8, p. 4, lines 17-18, p. 6, line 23 - p. 7, line 3, p. 7, lines 26-27, p. 9, lines 5-15	1-16
A	WO 2011/134948 A1 (CARL ZEISS MEDITEC AG) 03.11.2011, abstract, fig. 13, p. 44, line 27 - p. 46, line 11	1-16
A	US 8079704 B2 (HOYA CORPORATION) 20.12.2011, fig. 7-12, abstract	1-16
A	US 2015/0253587 A1 (SHAMIR OPTICAL INDUSTRY LTD) 10.09.2015, fig. 3a-4в, abstract	1-16
A	WO 2014/167425 A1 (DAVE, JAGRAT NATAVAR) 16.10.2014, p. 9, lines 9-19, p. 21, lines 3-13, p. 30, lines 7-19	1-16

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 October 2017 (02.10.2017)	12 October 2017 (12.10.2017)

Name and mailing address of the ISA/RU:
Federal Institute of Industrial Property,
Berezhkovskaya nab., 30-1, Moscow, G-59,
GSP-3, Russia, 125993
Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37

Authorized officer

O. Ryzhkova

Telephone No. (495)531-64-81