

INTRAOCULAR LENS WITH ACCOMMODATION

TECHNICAL FIELD

[0001] The present invention relates to implantable intraocular lenses ("IOL") suitable for the correction of myopia, hyperopia, presbyopia and astigmatism. More particularly, the invention relates to IOLs which are adapted to provide accommodation.

BACKGROUND ART

[0002] Implantation of artificial lenses into the human eye has been a standard technique for many years, both to replace the natural crystalline lens (aphakic eye) and to supplement and correct refractive errors of the natural lens (phakic eye). However, accommodation provided by such replacement lenses is minimal or non-existent.

[0003] The human eye includes an anterior chamber between the cornea and iris, a posterior chamber, defined by the iris, a capsular bag containing a crystalline lens, ciliary musculature, and a vitreous chamber behind the lens containing the vitreous humor with a retina at the rear of this chamber. The human eye has a natural accommodation ability. The contraction and relaxation of the ciliary muscle provides the eye with near and distant vision, respectively. This ciliary muscle action shapes the natural crystalline lens to the appropriate optical configuration for focusing light rays entering the eye on the retina. Other forces and pressures may additionally influence the eye's ability to accommodate for changes in vision. For example, changes in vitriol pressure or the exertion of forces by the extrinsic muscles of the eye.

[0004] After the natural crystalline lens is removed, for example because of cataract or other condition, a conventional monofocal IOL can be placed in the posterior

chamber. Such a conventional IOL provides very limited, if any, accommodation.

However, the wearer of such an IOL continues to require the ability to view both near, intermediate and distant objects. Corrective spectacles may be employed as a useful solution. Recently, multifocal IOLs, diffractive or refractive, divide light entering the eye and have been used to provide near and distant vision correction. Though they ~~do~~ may provide ~~some~~ a limited amount of accommodation, they decrease contrast sensitivity and cause photopic problems such as glare and halos.

[0005] Examples of implantable intraocular lenses include various design configurations without providing significant accommodation. Generally, the lenses are attached in some manner to the eye, usually by the use of sutures or some other supporting means, such as arms or haptics, extending from the optical lens portion of the intraocular lens.

[0006] U.S. Patent No. 6,241,777 describes a phakic intraocular lens assembly that has a lens with a circumferential edge, and a first haptic and a second haptic, which extend from the edge of the lens. Each of the haptics has a first leg extending from the lens edge to a distal end, and a second leg extending from the lens edge to a distal end, and a transverse member extending between the distal ends of each first and second leg. The transverse member can be substantially straight or bowed inward toward the lens. Each leg has a footplate at its distal end.

[0007] U.S. Patent No. 6,261,321 (Continuation-in-part of U.S. Patent No. 6,241,777) describes a phakic or aphakic intraocular lens assembly that has a lens with a circumferential edge, and a first haptic and a second haptic, which extend from the edge of the lens. Each of the haptics has a first leg extending from the lens edge to a distal end, and a second leg extending from the lens edge to a distal end, and a transverse member extending between the distal ends of each first and second leg. The

transverse member can be substantially straight or bowed inward toward the lens.

Each leg has a footplate at its distal end. Each leg of each haptic may be inwardly bowing, straight, and outwardly bowing. Additionally, each leg may have the same or different shape from the other legs.

[0008] U.S. Patent No. 6,015,435 describes a self-centering phakic intraocular lens inserted in to the posterior chamber for the correction of myopia, hyperopia, astigmatism, and presbyopia. Haptic bodies are attached to the optical body and extend outward from tangent points at the edge of lens in at least two generally opposite directions. Protruding surfaces protrude into pupil such that the iris interferes slightly with lens movement and provides the centering force to keep lens in place.

[0009] U.S. Patent No. 5,133,747 describes an intraocular lens device that is partially or completely within the capsular surface of the human crystalline lens. In one embodiment, the optic body has asymmetrical haptics extending outwardly from opposite sides of the circumferential edge of the optic body. In one embodiment, "J" shaped haptics extend from the circumferential edge of the optic body in a manner that encircles optic body. In another configuration, the haptics extend tangentially away from body, then reverse direction, giving the device an overall "S" shape with the lens at center portion of the S. The device is secured in place with an adhesive.

[0010] Attempts have been made to provide IOLs with accommodation, using movement along the optical axis of the eye as an alternative to shape changing.

Examples of such attempts are set forth in Levy U.S. Patent No. 4,409,691 and several patents to Cumming, including U.S. Patent Nos. 5,674,282 and 5,496,366.

These lenses are biased to be located in the posterior-most position in the eye under rest or resting conditions. When near focus is desired, the ciliary muscle contracts and the lens moves forwardly (positive accommodation). In the absence of ciliary muscle

contraction, the lens moves rearward to its posterior-most resting position. Because of this posterior bias and the configuration of the lens, the posterior wall of the capsular bag is subjected to a substantial degree of stretching when the lens is in the posterior-most position. One problem that exists with such IOLs is that they often cannot move sufficiently to obtain the desired accommodation.

[0011] The foregoing discussion does not constitute an admission that such devices and/or patents are either relevant or material to the present invention. Rather, such devices and patents relate only to the general field of the invention and do not constitute part of the prior art of the invention.

[0012] In light of the above, it would be advantageous to provide IOLs which can achieve an acceptable amount of accommodation with reduced risk of damaging the capsular bag.

SUMMARY OF THE INVENTION

[0013] An intraocular lens (IOL) assembly and method for correcting myopia, hyperopia, presbyopia and astigmatism using the intraocular lens assembly are provided. In particular, the intraocular lens assembly relates to intraocular lenses which provide accommodation when used as a replacement for the eye's natural lens. The intraocular lens assembly comprises a lens extending along an optical axis between an anterior optical surface and a posterior optical surface. The lens has a circumferential edge disposed about the optical axis at a junction of anterior and posterior optical surfaces. The lens further has N haptics, where N is an integer greater than 1. Furthermore, each haptic extends from an associated portion of the circumferential edge and along an associated haptic axis. In addition, each haptic is "loop-like" or "paddle-like" and extends between end portions at opposite ends thereof joined to the lens at the circumferential edge. It should be noted that each of the

haptics may include M footplates extending symmetrically about its associated haptic axis, where M is an integer greater than 0. Alternatively, each of the haptics may not include any footplates. IN a preferred embodiment, the lens has N haptics, where N is an integer greater than any one of: 2, 3, 4, 5, 6, 7, 8, 9 or 10.

[0014] In one embodiment of the present invention, an intraocular lens assembly may include a first pair of haptics extending from opposite portions of circumferential edge along an associated first pair of haptic axes, and having a second pair of haptics extending from opposite portions of circumferential edge along an associated second pair of haptic axes, wherein first pair of haptic axes and optic axis are coplanar in a first haptic plane wherein second pair of haptic axes and optic axis are coplanar in a second haptic plane. In addition, the first haptic plane may be perpendicular to second haptic plane, although angle arrangements other than perpendicular may be used in other forms of the invention. The haptics are angularly displaced with respect to optical axis in a direction away from the anterior optical surface by an angle A from a plane P transverse to optical axis. In an embodiment, an intraocular lens assembly can have an angle A with an approximate range of 4-7 degrees. It should also be noted that each haptic may include at least one footplate extending therefrom symmetrically about its associated haptic axis. Alternatively, each of the haptics may not include any footplates.

[0015] The invention also provides a method for implanting in an eye an intraocular lens assembly which provides accommodation. This includes the insertion of an intraocular lens (IOL) assembly into the eye, where the IOL assembly extends along an optical axis between an anterior optical surface and a posterior optical surface. The lens of the IOL has a circumferential edge disposed about an optical axis at a junction of the anterior and posterior optical surfaces. The circumferential edge can

have a particular shape or angle, for example, a square edge adjacent to one optical surface and a semi-rounded edge adjacent to a second optical surface. The lens further includes N haptics, where N is an integer greater than 1. Each haptic extends from an associated portion of the circumferential edge and along an associated haptic axis. Each of the haptics is "loop-like" or "paddle-like" and extends between end portions at opposite ends thereof. The end portions are joined to the lens at the circumferential edge. Also, the haptic axis is angulated away from anterior surface by angle A with respect to a plane P transverse to the optical axis. In one embodiment, angle A may be in an approximate range of 4-7 degrees.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The invention, and the various features thereof, may be more fully understood from the following description, when read together with the accompanying drawings, in which:

FIGS. 1 and 1A show a top view and a perspective view of the lens assembly of an embodiment of the present invention.

FIG. 2 shows a cross sectional view of the lens assembly of FIG. 1 along axis A.

FIG. 3 shows a top view of an alternative embodiment of the lens assembly with orientation tabs.

FIG. 4A shows a cross-sectional view of an eye with an phakic intraocular lens assembly of an embodiment of the present invention.

FIG. 4B shows a cross-sectional view of an eye with an aphakic intraocular lens assembly of an embodiment of the present invention.

FIG. 5A-5I show top views of alternative embodiments of lens assemblies of the present invention, with examples of haptic placement along a circumferential edge of a lens.

FIG. 6 shows a top view of an intraocular lens of the present invention, showing multiple lens zones.

FIG. 7 shows a cross-sectional view of an intraocular lens of the present invention, showing multiple optical devices embedded within the IOL of the present invention.

FIG. 8 shows a cross-sectional view of an IOL of the invention wherein compression forces act on the haptics to deform the lens assembly of the IOL of the invention, resulting in accommodation of the deformable lens assembly.

DETAILED DESCRIPTION OF THE INVENTION

[0017] In the eye, the natural lens of the eye separates the aqueous humor from the vitreous body. The iris separates the region between the cornea or anterior of the eye and the lens into an anterior chamber and a posterior chamber. The natural crystalline lens is contained in a membrane known as the capsule or capsular sac. When the natural lens is removed from the eye, the capsule may also be removed (intracapsular excision), or the anterior portion of the capsule may be removed with the natural crystalline lens, leaving the posterior portion of the capsule intact (extracapsular extraction), often leaving small folds or flaps from the anterior portion of the capsule. In an intraocular implant, an artificial lens may be inserted in the anterior chamber, the posterior chamber, or the capsular sac.

[0018] The design of intraocular lens assembly of the present invention and particularly the “loop-like” or “paddle-like”, flexible haptics, preferably with angulation, overcomes the lack of accommodation provided by prior intraocular devices. The intraocular lens assembly of the invention is primarily designed for placement in the anterior chamber of the eye and use as a refractive lens for the phakic eye. However, the unique design of the intraocular lens assembly also permits its use in the aphakic eye, and placement in the posterior chamber sulcus and the

posterior chamber bag. The intraocular lens assembly described herein is suitable for correction of myopia, hyperopia, presbyopia and astigmatism without compromising the anatomy or physiology of the eye. In a preferred embodiment, one or more haptics may be substantially rigid, such that a portion of any compressive force is transferred to the lens assembly. In an alternative preferred embodiment, one or more haptics are substantially compressive, such that the haptics absorb a portion of any compressive force via deformation.

[0019] The intraocular lens assembly of the invention is made from a biocompatible, flexible material. In one embodiment, the material is also a foldable material, which allows insertion of the device through small incisions, preferably less than 8mm, more preferably less than 5 mm and most preferably 3 mm or less,. In a further embodiment, the device is preferably inserted into the anterior chamber of the eye, where there is no contact with the natural crystalline lens, so that cataract formation is minimized. In a further embodiment, the device is inserted into the capsular sac following removal of the eye's natural lens, generally in replacement of a cataract lens. The design provides minimal contact with other tissues in the eye. Furthermore, the device can be easily removed and reinserted as needed. The combination of flexible materials and the haptic design allows the device to withstand some deforming forces, such as the patient rubbing his eyes, without the device breaking, warping, or becoming disengaged from the eye.

[0020] In an embodiment of the invention, the lens assembly of the present invention may be formed of a single focal lens. Said lens may have one or more portions of convex, concave, substantially flat or undulating curvature. In a more preferred embodiment, the single lens is biconvex in shape. As will be understood by a person skilled in the art, the refractive power of the single vision lens can be designed to

correct a specific vision abnormality, including, but not limited to, myopia, hyperopia, presbyopia and/or astigmatism. By altering the shape of the lens, the refractive power is altered such that either near, intermediate and/or distant objects are in focus.

[0021] It is contemplated that a single vision lens assembly can be combined with, for example, contact lenses and corrective spectacles, such that a patient has a wider range of in-focus vision available in everyday life.

[0022] The intraocular lens assembly of the invention may optionally comprise a progressive optical device. Said progressive optical device may have one or more portions of convex, concave, substantially planar, sinusoidal or undulating curvature. Preferably, said progressive optical device comprises a lens having a gradient of increasing or decreasing refractive power from a first portion of the lens to a second portion of the lens. For example, the lens may be arranged such that a first portion of the lens produces an image wherein distant objects are in focus, while a second portion of the lens produces an image wherein near objects are in focus and where the portions of the lens between the first and second portion render all distances between the distant and near objects in focus.

[0023] In a preferred embodiment, the gradient of change of refractive power is smoothed such that the increase or decrease in refractive power is perceived without the patient being aware of clear delineations of refractive power. In a further preferred embodiment, the gradient of the change of refractive power is substantially linear, exponential and/or parabolic. In an alternative embodiment, the progressive optical device is comprised of multiple lens zones, wherein each lens zone has a unique gradient of change. The gradient of change can be positive, negative or 0, provided the lens includes at least one lens zone with a gradient of increasing or decreasing refractive power.

[0024] In a preferred embodiment of the invention, the gradient of increasing or decreasing refractive power is perpendicular to the optical axis. In a most preferred embodiment, the gradient of change of refractive power is perpendicular to the optical axis and parallel to horizon when implanted into the eye of a patient. In such a most preferred embodiment, the bottom of the lens has a low refractive power suitable for focussing distance objects, while the top of the lens has a high refractive power, suitable for focussing near objects. A patient implanted with such a lens would visualise distant objects above the horizon as in focus, and near objects below the horizon also in focus. It is contemplated that such a lens would be suitable for reading items such as books and for distance vision such as driving.

[0025] The intraocular lens assembly of the invention may optionally include a multifocal optical device. Said optical device may have one or more portions of convex, concave, substantially flat or undulating curvature. Preferably, said multifocal optical device reduces or eliminates the unwanted effects of glaring and/or holoing produced by incident light, especially when such light is from a spot source.

[0026] The multifocal optical device may comprise at least two or more lens zones. Such zones may be of equal or unequal size and may be arranged in any shape within the multifocal optical device. In a preferred embodiment, each lens zone has a unique plane of focus e.g. a first lens zone may focus light from near objects onto the retina, while a second lens zone may focus light from intermediate objects onto the retina. In such a way, the multifocal optical device can be designed to treat a specific disease or to provide each patient with optimal vision correction.

[0027] In a preferred embodiment of the invention, the multifocal optical device comprises 5 lens zones: a first lens zone, being oblong in shape, is arranged perpendicular to the optical axis and parallel to the plane formed by bisecting both

eyes of the patient i.e. said first lens zone is parallel to the horizon; a second lens zone comprises the portion of the multifocal optical device above the first lens zone i.e. at the top of the multifocal optical device when implanted in a patients eye; a third lens zone is oblong in shape and is arranged parallel to and below the first lens zone; the fourth and fifth lens zones are approximately triangular in shape, with curved edges, and are located at the two distal edges of the third lens zone, thereby also intersecting the circumferential edge of the multifocal optical device and the first lens zone. By varying the refractive power of each lens zone, a multifocal optical device can be constructed that is suitable for a wide range of visual conditions. In a most preferred embodiment, the first lens zone is suitable for focussing near to intermediate objects; the second lens zone is suitable for focussing near objects; the third lens zone is suitable for focussing distant objects and the fourth and fifth lens zones are suitable for focussing intermediate objects. When implanted into a patient's eye, it is contemplated that a patient will view near to intermediate objects, such as those found inside a house, in focus through the first lens zone. The patient will view near objects, such as books, keyboards or cooking utensils in focus through the second lens zone. The patient will view distant objects above the horizon, such as landscapes and approaching cars or pedestrians while driving, as in focus through the third lens zone. Lastly, the patient will view intermediate objects above the horizon, such as traffic lights, buildings and street signs, as in focus through the fourth and fifth lens zones.

[0028] In an alternative embodiment of the invention, the multifocal optical device is formed from at least a centre lens zone and one or more concentrically located lens zones arranged thereabout. In a preferred embodiment, the centre lens zone is cylindrical and has a central axis aligned with the optical axis. However, in alternative embodiments, the central lens zone may be any shape, including conical or

elliptical, and may have a central axis displaced from the optical axis. In a further preferred embodiment, one or more of the concentrically located lens zones are torus, or ring-like, in shape. In an alternative embodiment, the torus may be elongated in one or more axis or plane. In an optional embodiment, said concentric lens zone may not extend completely about the centre lens zone, forming, for example, a half-torus shape. The multifocal optical device can thus be tailored to a patient's unique vision correction requirements or can be optimised for a particular vision situation, such as night vision, vision required when driving, near vision such as for reading or sewing, or long distance viewing such as for outdoor activities.

[0029] The lens zones of the present invention may be arranged on the anterior or posterior surface of the multifocal optical device. In a preferred embodiment, the lens zones extend substantially from the anterior surface to the posterior surface of the multifocal optical device. However, in an alternative embodiment of the invention, either or both of the anterior or posterior surfaces may be formed from a single lens zone, with at least one second lens zone embedded within the multifocal optical device. In a further alternative embodiment, two or more lens zones, including those embedded within the multifocal optical device, may overlap an axis parallel to the optical axis i.e. lens zones may be stacked within the lens assembly.

[0030] In order to facilitate the formation of lens zones, the multifocal optical device may be constructed from one or more lens zones formed individually. The individual lens zones may then be fused together, such as with heat or adhesive or held in place by the material of the IOL, whether encased partially, fully or joined by membranes or bridges. In a further embodiment, the lens zones may be formed of differing materials so as to impart unique refractive characteristics.

[0031] In an embodiment of the invention, the multifocal optical device is formed from two or more individual optical lenses, each having at least one but optionally two or more lens zones. In a preferred embodiment, said optical lenses are arranged substantially perpendicular to the optical axis and substantially parallel to the plane of the IOL (i.e. the plane of the lens assembly when flattened). In such an embodiment, the individual optical lenses mimic the arrangement of multiple lens elements found in modern camera lenses. Optionally, said individual lenses may be coated with a suitable transparent or semi-transparent material to inhibit or promote divergence or convergence of light passing through the optical lenses. In a preferred embodiment, at least one of the optical lenses is biconvex, biconcave, convex / concave, convex / planar, concave / planar or sinusoidal in shape.

[0032] In an alternative embodiment, one or more of the optical lenses is offset from the plane of the IOL by any one of: 1°, 2°, 3°, 4°, 5°, 6°, 7°, 8°, 9°, 10°, 11°, 12°, 13°, 14°, or 15°. In a more preferred alternative embodiment, said offset corrects for optical aberrations, include astigmatism or the effects of disease, in a patient's eye.

[0033] A multifocal optical device formed from multiple optical devices (a "compound multifocal optical device") may preferably be designed to correct one or more optical aberrations that arise due to the material, structure, refractive index, haptic positioning, accommodation or any other aspect of the IOL.

[0034] The compound multifocal optical device may be formed from two or more elements having varying degrees of asphericity. Optionally, the optical lenses may be biconvex, concave / convex, biconcave, or have one or more surfaces substantially planar. As will be known by a person skilled in the art, the angle of view and the amount of light transmitted through the lens will affect the number of elements required and the shape of each individual optical lens. Where the compound

multifocal optical device seeks to provide primarily improved distance vision, as little as two individual optical lenses may be required. Where improved near distance vision is the objective, a more complex construction having 3 or more elements may be required.

[0035] In a further embodiment, said lens zones may be interposed by an absorbing means for absorbing a portion of the light. The absorbing means may include a pigment, a paint, a dye, an ink, a metallic and/or a polymeric composition. In a further embodiment, the absorbing means is positioned to absorb portions of the incident light that would result in a greater amount of light being focused at a point(s) anterior or posterior to the retina. In a most preferred embodiment, said absorbing means is positioned to reduce the blurring of vision, glare from a light source and / or haloing as seen by a patient and produced by the multifocal optical device.

[0036] The light absorbing means may be opaque, translucent or transparent, provided such absorbing means has the capacity to absorb a portion of the light being transmitted through the multifocal optical device. In a preferred embodiment, the absorbing means absorbs greater than any one of: 2%, 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, 95%, 98% or 99% of the incident light at one or more wavelengths of visible light. In a preferred embodiment, said absorbing means absorbs light in the visible spectrum wavelength range of 350 nm to 750 nm. In a further preferred embodiment, said absorbing means absorbs wavelengths of light in a band of any one of: 10 nm, 25 nm, 50 nm, 75 nm, 100 nm, 150 nm, 200 nm, 250 nm or 300 nm within the aforementioned visible spectrum. For example, from 350nm to 360nm or from 400nm to 500nm. All such ranges are included within the scope of this specification and can be readily listed by a person skilled in the art, but have not been listed for the sake of brevity.

[0037] The geometry according to which the absorbing means is disposed creates a pattern of the transmission of light. The absorbing means can be provided in or on the lens in many ways to create various transmission profiles. The absorbing means may be arranged in any way. In an embodiment of the invention, the absorbing means is arranged in one or more radial planes, optionally extending from the optical axis. In a further embodiment, the absorbing means are arranged in concentric planes having a spherical, conical or cylindrical like shape, optionally centred about the optical axis. In a most preferred embodiment, the absorbing means are arranged in a conical shape or in a shape such that the absorbing means is not parallel to a plane of the optical axis, but rather forms a cone having a circular or semi circular radius on one surface of the multifocal optical device greater than the radius on the opposite surface of the multifocal optical device. In this way, a patient having an implanted lens will see only a thin line of obstructed vision. Alternatively, said absorbing means may be arranged in a plane parallel to the optical axis. Optionally, said parallel absorbing means is transparent or semi-transparent to more than about any one of: 25%, 40%, 50%, 60%, 75%, 90% and 95% of the visible light spectrum so as to minimise the region of vision obstructed from the patient.

[0038] The absorbing means may optionally be arranged in a geometric pattern within the multifocal optical device. In a most preferred embodiment, the absorbing means is arranged to separate the lens zones. The absorbing means may be arranged to absorb incident light non-uniformly, including absorbing a greater portion of the light which passes through the lens and is associated with vision above the plane of the Earth's surface. By absorbing an increased incidence of light from, for example, the horizon, sky or the sun, artefacts such as glare and/or halos are reduced. As a patient's neurological system inverts the image formed from light onto the retina, in

an optional embodiment, the absorbing means may be arranged to absorb a greater portion of the light at the bottom of the lens when orientated inside a patient's eye.

[0039] The refractive properties of materials can be adjusted through changes in temperature. It will be understood by a person skilled in the art that in producing the IOL of the present invention, whether the IOL includes a single or multi-focal optical device, the lens will be designed for optimal operation at body temperature.

[0040] The refraction of light having a high angle of incidence is greater than light having a small angle of incidence. As such, optical aberrations, such as glare, haloing, blurring and/or colour fringes are more likely to occur with light having a high angle of incidence.

[0041] To counteract these optical aberrations, one or more surfaces of the optical lenses, lens zones and/or the anterior or posterior surfaces of the single or multi-focal optical device can be coated using known thin-film coatings.

[0042] In a preferred embodiment, the index of refraction of any such thin layer should be approximately equal to the square root of the index of refraction of the optical lens, lens zones or optical device. However, material of any refractive index may be used. The index of refraction can be varied so as to result in destructive interference of any portion of the visible and/or non-visible spectrum. In a preferred embodiment, the thin layer coating has a thickness of between 130 nm to 145 nm. In a more preferred embodiment, the thin layer coating has a thickness of about 137.5 nm. In an alternative embodiment, the thin layer coating has a thickness of between 87.5 nm and 187.5 nm. It will be understood that where the IOL of the present invention is to be used to reduce optical aberrations at the blue end of the visible spectrum, a thin layer coating of between 87.5 nm and 125 nm should be used. Alternatively, where optical aberrations at the red end of the visible spectrum are to

be reduced, a thin layer coating of between 150nm and 187.5 nm should be used. In a most preferred embodiment of the invention, a compound multifocal optical device has one or more thin film coatings and, optionally, two or more coatings having different film thicknesses.

[0043] In a preferred embodiment, such coating is a thin layer of, for example, magnesium fluoride. Said magnesium fluoride may be applied by any suitable means, including by deposited under high vacuum or baking of an applied solution or deposit. Further examples include silicon dioxide (refractive index of 1.45) and cryolite (refractive index of 1.4). In an alternative embodiment, any of the aforementioned coatings can be combined with a thin metal layer formed from nickel, chromium, Inconel and Nichrome (a material comprising substantially nickel and chromium). While it is contemplated that silver and aluminium can be used in the present invention, it is necessary that the thin layers be deposited uniformly. Alternatively, a thin metal layer of thickness identical to that of the thin layers outlined above may be used alone or on one or more optical lens, lens zones or optic device.

[0044] In a further preferred embodiment of the invention, the lens assembly includes a material suitable for decreasing transmission of UV and short wavelength blue light. Such a lens may also optionally include a yellow dye, such as Eastman Yellow 035-MA1.

[0045] In a preferred embodiment of the invention, the lens assembly can correct for spherical aberrations and the chromatic aberrations as defined by a model eye. Spherical aberrations of an eye are usually between 0 and 1.5 diopters, while chromatic aberrations are usually between 0 and 2.5 diopters ("Optics of the Human Eye" written by David A. Atchison and George Smith). In a preferred embodiment of the invention, the lens assembly corrects for up to 3 diopters of spherical aberration

and/or up to 5 diopters of chromatic aberration. In a more preferred embodiment of the invention, the lens assembly corrects for up to 1.5 diopters of spherical aberration and/or up to 2.5 diopters of chromatic aberration.

[0046] In a preferred embodiment of the invention, forces acting on the haptics compress the lens assembly of the IOL, altering the shape of the lens assembly to produce, for example, asphericity (i.e. an increase in the radius of curvature of a portion of the lens assembly). Such bulging changes the curvature of the lens assembly. In a preferred embodiment, the change in curvature results in increased refractive power such that the lens assembly focuses objects at shorter distances onto the retina.

[0047] In a most preferred embodiment, the IOL of the present invention is able to increase refractive power when exposed to the normal compressive forces of the zonules, ciliary muscles, extrinsic muscles of the eye, any changes in vitriol pressure. Such compressive forces result in asphericity of the lens assembly, bringing objects closer to or further away from the patient into focus.

[0048] In an alternative embodiment, the haptics are arranged to act on a first portion of the lens assembly, for example a lens zone or optical lens, such that the first portion of the lens assembly undergoes asphericisation to a greater extent than a second portion of the lens assembly. Optionally, such an arrangement results in a baseline refractive power due to the second portion, with a variable refractive power due to the difference between the refractive power of the first portion when the muscles of the eye are relaxed, and the refractive power when the muscles of the eye are exerting a compressive force on the haptics and therefore the first portion.

[0049] In a preferred embodiment of the invention, the asphericisation of the lens assembly increases or decreases the refractive power of the lens by at least any one of:

1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 diopters. In a more preferred embodiment, the asphericisation of the lens assembly increases the refractive power of the lens by at least 2 diopters. In a more preferred embodiment, the asphericisation of the lens assembly increases the refractive power of the lens by at least 2 diopters to less than 5 diopters. In a further more preferred embodiment, the asphericisation of the lens assembly increases the refractive power of the lens by from 1 to 2 diopters. In a most preferred embodiment, the asphericisation of the lens assembly increases the refractive power of the lens by from 2 to 4 diopters.

[0050] In an optional embodiment of the invention, a portion of the lens assembly may be rigid or substantially non-deformable, such that asphericisation does not occur or does not occur to an extent such that any increase or decrease in refractive power is less than 0.5 diopters. In such an embodiment, the haptics of the IOL may be arranged to act on the deformable portion of the lens, for example by positioning the haptics to be in the same plane as the deformable portion but not the same plane as the rigid or substantially non-deformable portion. It is contemplated that such a rigid or substantially non-deformable portion of the lens may provide a minimum refractive power, while the deformable portion will provide accommodation in response to compressive forces acting on the IOL.

[0051] The rigid or substantially non-deformable portion of the lens may be configured for placement against the posterior capsule of an eye. Optionally, said rigid or substantially non-deformable portion of the lens may reduce the optical effects of an ocular aberration, including astigmatism.

[0052] The lens assembly may further comprise a stiffening layer that is stiffer than the deformable portion. In a preferred embodiment, the deformable portion is disposed between the stiffening layer and the rigid or substantially non-deformable

portion. In such embodiment, the deformable portion may be made of a first material and the stiffening layer may be made of a second material. It is contemplated that the refractive index of the deformable, stiffening and rigid / non-deformable portions need not be identical.

[0053] In an alternative embodiment, the deformable or rigid portions may further comprise a relief portion for providing a volume into which material from the deformable portion may expand or enlarge when the deformable portion is deformed. The relief portion may comprise at least a portion of a periphery about the deformable portion and/or one or more voids within the deformable portion.

[0054] In a further embodiment of the invention, the deformable portion does not extend to the circumferential edge of the IOL. In such an embodiment, the deformable portion may be any shape, as discussed above, including circular, oblong, torus, semi-torus, triangular, star or any other geometric shape. In a preferred embodiment, the deformable portion is a central circular portion, either having a centre point located at the optical axis or otherwise. In such a preferred embodiment, the diameter of the deformable portion is at least 2mm. In a more preferred embodiment, the diameter of the deformable portion is from between 2mm to 5mm. In a most preferred embodiment, the diameter of the deformable portion is greater than 5mm.

[0055] In a preferred embodiment of the invention, compressive forces act to aspherisize a convex lens. However, it is contemplated within this invention that compressive forces may act on a lens with a concave surface so as to collapse the centre portion of the surface, or act to aspherisize a convex lens located towards the posterior of the IOL and the eye, in both examples so as to decrease the refractive power of the lens, in accordance with the ranges discussed above.

[0056] In a preferred embodiment of the invention, compression of the haptics or an increase in vitriol pressure results in the translation of the lens assembly from the uncompressed state towards the front of a patient's eye. It is contemplated that such translation may increase the refractive power of the lens by up to about 2 diopters per 1 mm of translation. In a preferred embodiment of the invention, the lens assembly may translate by more than 1.5mm from an uncompressed state in reaction to compression of the haptics or an increase in vitriol pressure. In a more preferred embodiment, the lens assembly may translate by more than 2mm in reaction to compression of the haptics or an increase in vitriol pressure. In a most preferred embodiment, the lens assembly may translate from 2 mm to 3mm forward in reaction to compression of the haptics or an increase in vitriol pressure. Optionally, the haptics may translate the lens assembly by greater than 3mm in reaction to compression of the haptics or an increase in vitriol pressure, provided such a lens assembly is sufficiently small so as to avoid damaging pressure on the capsular bag. Optionally, in such a preferred embodiment, the diameter of the lens assembly is equal to or less than the diameter of the pupil of the patient, when maximally dilated.

[0057] In a preferred embodiment of the invention, an aphakic IOL lens assembly provides between 10 and 40 diopters of correction. In a more preferred embodiment, an aphakic IOL lens assembly provides between 15 and 30 diopters of correction. In a further more preferred embodiment, an aphakic IOL lens assembly provides between 18 and 22 diopters of correction. In a most preferred embodiment, an aphakic IOL lens assembly provides between 19 and 21 diopters of correction. It is contemplated that a person skilled in the art can determine, using wavefront technology, pupil diameter and the natural lens size and shape, the diopters of correction required in an aphakic IOL for each individual patient.

[0058] In a preferred embodiment of the invention, a phakic IOL lens assembly provides between 1 and 20 diopters of correction. In a more preferred embodiment, a phakic IOL lens assembly provides between 2 and 15 diopters of correction. In a further more preferred embodiment, a phakic IOL lens assembly provides between 5 and 10 diopters of correction. In a most preferred embodiment, a phakic IOL lens assembly provides between 6 and 8 diopters of correction. It is contemplated that a person skilled in the art can determine, using wavefront technology, pupil diameter and the natural lens size and shape, the diopters of correction required in a phakic IOL for each individual patient.

[0059] In an alternative embodiment, the above ranges provided for both phakic and aphakic IOL diopter power can be increased or decreased by any one of: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, or 40 diopters due to optical aberrations in a patient's eye or due to ophthalmic surgery or disease, including but not limited to: damage to the cornea, LASIK surgery, LASEK surgery, implantation of foreign bodies including lenses, the presence of one or more phakic or aphakic IOLs and/or the presence of an ophthalmic device.

[0060] In a preferred embodiment of the invention, the diopters of correction provided by the lens assembly is altered according to the plane of focus desired. For example, where a multifocal lens assembly is used, a near focussing lens zone may require an increased diopter of correction of any one of +1, +2, +3, +4, +5, +6, +7, +8, +9, or +10, relative to the ranges outlined above. Similarly, a distant focussing lens zone may require a decreased diopter of correction of any one of -1, -2, -3, -4, -5, -6, -7, -8, -9, or -10, relative to the ranges outlined above. Lastly, an intermediate focussing lens zone may require a decreased or increased diopter of correction of any

one of -5, -4, -3, -2, -1, +1, +2, +3, +4, +5, relative to the ranges outlined above.

Similarly, in a progressive lens design, the difference between the highest diopter of correction and the lowest diopter of correction may be up to 30 diopters. In a preferred embodiment of the invention, the difference between the highest diopter of correction and the lowest diopter of correction is between from 5 diopters to 20 diopters. In a more preferred embodiment of the invention, the difference between the highest diopter of correction and the lowest diopter of correction is between from 10 diopters to 15 diopters. The average diopter of correction of a progressive lens may be any one of the values outlined above, including those with respect to aphakic or phakic IOLs.

[0061] In a preferred embodiment of the invention, the aspherisation of the lens assembly or a deformable portion thereof increases the diopters of correction by any one of +1, +2, +3, +4, +5, +6, +7, +8, +9 or +10 diopters. In a more preferred embodiment, the aspherisation of the lens assembly or a deformable portion thereof increases the diopters of correction by any one of 0.5 to 3; 0.5 to 4; 0.5 to 1; 0.5 to 2; 1 to 2; 1.5 to 2; 1.5 to 3; 2 to 3; 2 to 3.5; 2.5 to 3; 2.5 to 4; 3 to 4; 3 to 5; 3.5 to 4; 3.5 to 5; 4 to 5; 4.5 to 5; 5 to 6; 5.5 to 6; 6 to 7; 6 to 10; 7 to 10; 8 to 10; or, 9 to 10 diopters, relative to the ranges discussed above.

[0062] In an alternative embodiment of the invention, the aspherisation of the lens assembly or a deformable portion thereof or the collapse of a concave portion of the lens assembly, decreases the diopters of correction by any one of -1, -2, -3, -4, -5, -6, -7, -8, -9 or -10 diopters. In a more preferred embodiment, the aspherisation of the lens assembly or a deformable portion thereof or the collapse of a concave portion of the lens assembly, decreases the diopters of correction by any one of 0.5 to 3; 0.5 to 4; 0.5 to 1; 0.5 to 2; 1 to 2; 1.5 to 2; 1.5 to 3; 2 to 3; 2 to 3.5; 2.5 to 3; 2.5 to 4; 3 to 4; 3

to 5; 3.5 to 4; 3.5 to 5; 4 to 5; 4.5 to 5; 5 to 6; 5.5 to 6; 6 to 7; 6 to 10; 7 to 10; 8 to 10; or, 9 to 10 diopters, relative to the ranges discussed above.

[0063] In a preferred embodiment of the invention, the translation of the lens assembly or a deformable portion thereof increases the diopters of correction by any one of +1, +2, +3, +4, +5, +6, +7, +8, +9 or +10 diopters. In a more preferred embodiment, the translation of the lens assembly or a deformable portion thereof increases the diopters of correction by any one of 0.5 to 3; 0.5 to 4; 0.5 to 1; 0.5 to 2; 1 to 2; 1.5 to 2; 1.5 to 3; 2 to 3; 2 to 3.5; 2.5 to 3; 2.5 to 4; 3 to 4; 3 to 5; 3.5 to 4; 3.5 to 5; 4 to 5; 4.5 to 5; 5 to 6; 5.5 to 6; 6 to 7; 6 to 10; 7 to 10; 8 to 10; or, 9 to 10 diopters, relative to the ranges discussed above.

[0064] In a preferred embodiment of the invention, the IOL is implanted into the eye of a patient in either the anterior chamber of the eye (phakic), or the capsular bag of the eye to replace the natural lens (aphakic). When implanted into the anterior chamber, the IOL can be positioned in front of the iris, or between the iris and the capsular bag.

[0065] In a preferred embodiment, the required incision into ocular tissue is minimised by folding, including double folding and triple folding, and/or rolling the IOL. In a preferred embodiment, the IOL may be rolled into a cylinder like shape. After implantation, the IOL is allowed to or manipulated to unfold or unroll. In a most preferred embodiment, the IOL is positioned such that the lens assembly covers at least a portion of the optical axis.

[0066] To facilitate the transmission of fluids and/or nutrients about or through the IOL, including from the anterior to posterior chamber, or from behind the iris to in front of the iris, the lens assembly may comprises a plurality of holes and/or openings. In a preferred embodiment, such holes or openings are disposed at or near the

periphery of the lens assembly. In an optional embodiment, the transmission is effected by offsetting the lens assembly from a portion of the interior wall of the eye or capsular bag. In a preferred embodiment, the holes and/or openings communicate with both the posterior and anterior surface of the IOL. In an alternative embodiment, each hole and/or opening communicates with only one of the posterior or anterior surface of the IOL.

[0067] In one embodiment of the present invention, as illustrated in FIG.1, an intraocular lens assembly 10 includes a lens portion (the "optic") 12 extending along an optical axis OA between an anterior optical surface and a posterior optical surface. The lens 12 of the IOL has a circumferential edge 8 (disposed about the optical axis OA) at a junction of anterior and posterior optical surfaces. The lens 12 has two pairs of opposed, flexible haptics 14A, 14B, and 15A, 15B extending from circumferential edge 8 of optic 12. The haptics extend along an associated haptic axis HA: haptic 14A extends along haptic axis HA-14A, haptic 14B extends along haptic axis HA-14B, haptic 15A extends along haptic axis HA-15A and haptic 15B extends along haptic axis HA-15B. In the illustrated embodiment, each haptic axis HA is coplanar with optical axis OA in an associated haptic plane. In other embodiments, a different number of haptics may be employed. For example there may be N haptics, where N is an integer.

[0068] Each of the flexible, haptics 14A, 14B, 15A and 15B are flexible and "loop-like" or "paddle-like". As used here, the term "loop-like" refers to a smooth, curved portion of a loop, for example, having a "C-shaped" or U-shaped peripheral edge, with uniform or non-uniform width. As used herein, the term "paddle-like" refers to a solid element (without a central aperture) bounded by a C-shaped or U-shaped peripheral edge. The haptics extend between end portions thereof which are joined to

lens 12 at associated portions of circumferential edge 8. For example, haptic 14A extends between EP-14A and EP-14B, extending along haptic axis, HA-14A.

[0069] In the illustrated embodiments of FIG. 1, two pairs of opposed, flexible, loop-like haptics are spaced equidistant around circumferential edge 8 of optic 12. This symmetry provides the comfort to the patient and stability of the lens. Alternatively, two or more loop-like, flexible haptics may be attached at differently spaced, non-equidistant points or asymmetrically on a circumferential edge 8 extending along haptic axis HA, see FIGS 5D-5G. In addition, two or more flexible haptics may be attached, depending upon the individual eye anatomy or vision requirements, to maximize accommodation and stability of the lens assembly.

[0070] As shown in FIG 1A, the intraocular lens assembly 10 includes a first pair of haptics 14A, 14B extending from opposite portions of circumferential edge 8 (in a plane P) along an associated first pair of haptic axes HA-14A, HA-14B and a second pair of haptics 15A, 15B extending from opposite portions of circumferential edge 8 along an associated second pair of haptic axes HA-15A, HA-15B, wherein first pair of haptic axes and optic axis OA are coplanar in a first haptic plane HP1 and wherein second pair of haptic axes and optic axis OA are coplanar in a second haptic plane HP2. In addition, the first haptic plane HP1 is perpendicular to second haptic plane HP2. The haptics are angularly displaced with respect to optical axis in a direction away from anterior optical surface by an angle A from the plane P transverse to optical axis OA. Preferably, the intraocular lens assembly uses an angle A with an approximate range of 4-7 degrees. It should also be noted that each haptic includes at least one footplate FP extending therefrom symmetrically about its associated haptic axis HA. Alternatively, each of the haptics may not include any footplates extending symmetrically about its associated haptic axis.

[0071] Each haptic includes M footplates FP extending symmetrically about its associated haptic axis HA, where M is an integer greater than 0. In one embodiment, M equals 1. Alternatively, each of the haptics may not include any footplates. In FIGS. 1 and 1A, the footplates FP are integrally formed on the distal end of each haptic HA, preferably at the apex of the haptic. As illustrated in FIG. 1, each haptic 14A, 14B, 15A, and 15B includes an associated one of footplates FP-14A, FP-14B, FP-15A, and FP-15B disposed symmetrically about its associated haptic axis HA-14A, HA-14B, HA-15A, and HA-15B. In other embodiments, there may be multiple footplates symmetrically disposed about the associated haptic axis. By way of example, various footplate configurations are shown in FIGS. 5A-5I. Note, in one embodiment, the configurations may not have any footplates. It should also be noted that footplates FP are preferably lenticular-shaped in cross-section to allow for minimal contact with the eye structures yet provide the required stability for the desired visual results. FIGS. 5A-5E and 5I show loop-like haptics, where FIGS. 5A-5C show uniform width haptics and FIGS. 5D-5G show non-uniform width haptics. FIG. 5H shows paddle-like haptics.

[0072] FIG. 2 shows an intraocular lens assembly, similar to intraocular lens assembly 10 of FIG. 1, along plane HP1 defined by optical axis OA and haptic axis HA-14A and HA-14B. Optic 22 constitutes the optical portion of the lens assembly. The optic 22 comprises an anterior optical surface 24 and posterior optical surface 26. The combination of surface 24 and surface 26 may result in the optic being substantially planar, convex, plano-convex (illustrated in FIG. 2) and concave, bi-convex, concave-convex, or other known form. The diameter of optic 22 can vary as needed to accommodate the angle-to-angle measurement of the eye and curvature of the eye. The overall length of the intraocular lens (optic and haptics) to be inserted

into an individual patient's eye is determined by adding a 1 mm white-to-white measurement of the patient's eye. In one embodiment, Optic 22 has a 6 mm optical zone.

[0073] Optic 22 may be ground to the required diopter measurements necessary for vision correction. The lens may be a negative or positive meniscus lens and may include correction for astigmatism. Depending on the refractive index of the material used, and the required vision correction, optic 22 may have the same thickness at central portion 27 and circumferential edge 28, or central portion 27 may be thinner than circumferential edge 28. In one embodiment, the thickness of optic 22 is 1 mm.

[0074] In another embodiment, still referring to FIG. 2, flexible haptics 14A and 14B extend from circumferential edge 28 of optic 22 at a slight angle A from a plane P transverse to the optical axis OA. Vault distance V for assembly 20 is defined as the height of the lens assembly measured from a line Q, which is drawn horizontally (as shown) between footplates FP, to the apex 29 of inner optical surface 24 and along the optical axis OA. Angle A is in the approximate range 4 to 7 degrees, or more, as desired, to maximize accommodation of lens assembly 20. Preferably angle A is one that, when in combination with the size and shape of the optic and the flexible haptics and the assembly 20, and the anatomical angle of the eye, provides a 1 mm vault distance V, although other vault distances can be used. The vault distance insures adequate clearance for the intraocular lens assembly to be situated between the natural crystalline lens and the cornea in the anterior chamber.

[0075] As illustrated in FIG. 3, there is shown an intraocular lens assembly, similar to intraocular lens assembly 10 in FIG. 1, that includes a tab A and a tab B, extending from the circumferential edge 38 of optic 32. Those tabs assist the user (surgeon) in the identification of orientation of the lens assembly during implantation. The "left

diagonal" orientation of the tabs is shown in FIG. 3, as viewed by the surgeon, indicate that the lens assembly is correctly implanted, with the lens being vaulted-forward. A left-diagonal orientation of tabs A and B would indicate that lens assembly 30 has been implanted in a backwards or reversed manner.

[0076] The preferred embodiment intraocular lens assembly of the invention is designed to be foldable to facilitate insertion through small incisions, generally 3 mm in length or less. The device can be folded along axis A, transverse to axis A, at an angle offset from axis A, or in multiple directions. The device can be folded in the optic body, at any point in the flexible haptics, at the junction points between the optic body and the flexible haptics, or all of the above. The device can be folded with single or multiple folds along each direction.

[0077] Suitable materials for the lens assembly of the invention are solid, flexible, foldable optical, non-biodegradable materials such as hydrogel, collamer, collagel (hydrogel-collagen blends) acrylic polymers, polymethylmethacrylate (PMMA) and silicone polymers. The lens assembly may also be made of a composite of materials, i.e. where the flexible haptics are fabricated from one material and the optics from another material, for example, acrylic optics and hydrogel haptics. Where the lens assembly is used in the aphakic eye, flexible, but less foldable, materials may be preferred. For example, for the aphakic eye, the lens assembly may be made of all PMMA or a composite of PMMA optics and prolene haptics.

[0078] By way of example, the lens assembly may be made as a sterile UV-absorbing acrylic foldable form, for example using the same material as the AcrySof.TM. IOL manufactured by Alcon Laboratories, Inc. Moreover, in various forms the lens may be used in the anterior chamber, the posterior chamber sulcus and the posterior chamber bag.

[0079] In FIG. 4A, a phakic intraocular lens assembly 40 of the invention implanted is shown, in the anterior chamber of the eye 43 and fixated in the angle 44.

Alternatively, the phakic IOL of the invention may be implanted in the posterior chamber of the eye and fixated in the angle. Lens assembly 40 is positioned in anterior chamber C, between cornea 45 and iris 46. An optic 47 of assembly 40 is positioned over pupil 48. Flexible haptics 49 extend from optic 47, with footplates FP (distal from optic 47), extending into angle 44. With the configuration, movement of natural crystalline lens 50 is unobstructed in the posterior chamber 42. The relatively low vault height of lens assembly 40 insures that it does not contact cornea 44.

[0080] In FIG. 4B, an aphakic intraocular lens assembly 40 of the invention is shown, implanted in the capsular bag of the eye 43. Alternatively, the aphakic IOL of the invention may be implanted in the sulcus of the eye. Lens assembly 40 is positioned in capsular bag P, behind the iris 46 and cornea 45. An optic 47 of assembly 40 has flexible haptics 49, along with footplates FP (distal from optic 47), extending into angle 44. The relatively low vault height of lens assembly 40 insures that it does not contact cornea 44.

[0081] In FIG. 6, the top view of an intraocular lens assembly of the invention has a first lens zone 62 for intermediate vision; a second lens zone 63 for near vision; a third lens zone 64 for distant vision; and a fourth and fifth lens zones 66, 68 for intermediate vision.

[0082] In FIG. 7, the cross-sectional view of a compound multifocal optical device of the invention through a plane perpendicular to the optical axis and the haptics, shows a first biconvex optical lens 70, a second biconvex optical lens 72 and a third biconcave optical lens 74. As discussed, these optical lenses may be supported by the material of the optic 12, such as by embedding the optical lenses 70, 72, 74 within the

optic 12. Alternatively, the first, second and third optical devices 70, 72, 74 may be fused together (not shown).

[0083] In FIG. 8, a deformable lens assembly 80 of the invention having two haptics 82, 84 is exposed to compression forces (shown in black). As a result of these compression forces, the lens assembly 80 undergoes deformation such that the deformable lens assembly 80 alters shape to that of the deformed lens assembly 86. This is an example of the accommodation of the IOL of the present invention in reaction to compressive forces acting on the haptics 82, 84.

[0084] As mentioned above, the intraocular lens assembly of the invention can be usefully implanted into the eye as either a refractive phakic intraocular lens assembly or an aphakic intraocular lens assembly. Phakic intraocular lens implantation is becoming more popular because of their good refractive and visual results and because they are relatively easy to implant in most cases (Zaldivar & Rocha. 36 Int. Ophthalmol. Clin. 107-111 (1996); Neuhann et al., 14 J. Refract. Surg. 272-279 (1998); Rosen & Gore, 24 J. Cataract Refract. Surg. 596-606 (1998); Sanders et al., 24 J. Cataract Refract. Surg. 607-611 (1998). The implantation can be performed by an ordinarily skilled ophthalmologist. Little surgical injury occurs to the ocular tissues during such implantation. When the surgical quality is not compromised, the results are highly predictable, immediate, and lasting.

[0085] Phakic lens assembly implantation using the intraocular lens assembly of the invention has advantages over other forms of surgical vision enhancement. Unlike laser surgery, the implants are removable. The natural crystalline lens remains, and the patient doesn't lose the ability to accommodate. Refractive surgery by phakic intraocular lenses among patients with hyperopia is not yet as popular as patients with

myopia, but primarily because such surgery has not been available for as long (Fechner et al., 24(1) J. Cataract Refract. Surg. 48-36 (1998)).

[0086] For a phakic lens assembly implantation, the intraocular lens assembly of the invention is preferably located in the anterior chamber of the eye. Following the appropriate implantation, the intraocular lens of the assembly invention can be either an angle-supported phakic intraocular lens located in front of the iris or a sulcus-supported phakic intraocular lens located behind the iris in the posterior chamber. The haptic lens features of the intraocular lens assembly of the invention fixate the distal haptic portions of the lens, thus preventing dislocation and slipping or shifting of the intraocular lens from its proper position.

[0087] The implantation assembly of the intraocular lens assembly of the invention can generally be performed as provided by (Singh, emedicine Ophthalmology (2000) <http://www.emedicine.com/cgi-bin/foxweb.exe/showsection@d:/em/ga?book=oph&topicid=662>):

[0088] First, the administration of local antibiotic drops is begun. A useful antibiotic is Tobramycin 0.3%, 1 drop, 6 times a day. Then, the pupil of the eye is contracted with 1% pilocarpine drops, administered for example at 15-minute intervals, starting 45 minutes before surgery. Drops (such as NSAID drops) are administered 2 times before surgery to minimize inflammation.

[0089] General anesthesia can be performed on the patient, but local anesthesia is preferred. For local anesthesia, 2% lidocaine with 7.5 U/ml hyaluronidase can be given 10 minutes before surgery. Orbital compression is applied to make the eye soft and to reduce orbital pressure.

[0090] For preparation of the surgical field, the periorbital skin of the patient is painted with iodine, then 5% povidine is applied. 5% povidine is also applied two-

three times to the lid margin and the conjunctival fornices. Then, the eye is washed with saline.

[0091] An eye speculum is used for exposure of the surgical field. Upper and lower lid sutures, as well as superior rectus sutures can be applied in place of the speculum. (A sutureless procedure can also be used.) Adhesive plastic, applied to the surface of the eyelids, is used to pull the eyelashes.

[0092] For making small intraoperative incisions, a side port (for example, 0.6 mm) is made in the anterior chamber. This injection is started at the opposite limbus. As the aqueous fluid drains, it is replaced, for example, with a viscoelastic agent. The depth of the anterior chamber is not reduced at any time.

[0093] In one embodiment, for implantation of the intraocular lens assembly of the invention into the eye, two side ports are made to introduce the instruments that are used to fix the iris to the haptics. The width of the incision depends on the diameter of the intraocular lens assembly of the invention (being, for example, 4-5 mm). The incision may be made at the limbus or in the clear cornea. If a pocket section is made, wound closure (see, below) can be made without sutures. The intraocular lens assembly of the invention can then be introduced in the pre-crystalline space with angled-suture forceps the lens is positioned, for example, behind the iris on a horizontal axis with a cyclodialysis spatula. The intraocular lens assembly of the invention is then manipulated to center the optic on the pupil. During implantation of the phakic intraocular lens assembly of the invention into the anterior chamber, the lens is centered and fixed so that it does not slip out of position. The lens can be positioned between the cornea and the iris, but avoiding contact with either to prevent corneal damage, proliferation of corneal epithelium on the anterior surface of the lens causing opacification, or iris. If the lens is not positioned properly with respect to the

pupil, too much light may be admitted to the retina, causing serious vision difficulties. The haptics generally lodge in the angle of the anterior chamber. Also, the anterior chamber of the eye is filled with the aqueous humor, a fluid secreted by the ciliary process, passing from the posterior chamber to the anterior chamber through the pupil, and from the angle of the anterior chamber it passes into the spaces of Fontana to the pectinate villi through which it is filtered into the venous canal of Schlemm. The implanted lens is positioned so the flow of fluid is not blocked.

[0094] After the intraocular lens assembly of the invention is implanted, the viscoelastic material (if previously introduced into the eye chambers) is removed from the anterior and posterior chambers of the eye with an aspiration syringe (such as a 24-gauge cannula). The intraocular lens assembly of the invention is fixed to the anterior surface of the iris by the haptics of the lens. To achieve fixation, the haptic holds a fold of the iris on either side of the pupil. The anterior chamber is washed thoroughly with saline. The pupil is contracted with intraocular acetylcholine 1 %, carbachol 0.01%, or pilocarpine 0.5% solution. The incision is closed by hydrating the corneal incisions. A suture rarely is needed.

[0095] In another embodiment, for implantation of the intraocular lens assembly of the invention, the main incision is made at the ventral area of the eye (at the "top" of the eye, at "12 o'clock"). The width is preferably equal to the size of the optic, which may be 4-5 mm. Side incisions are made, approximately 1 mm wide. The lens assembly of the invention is inserted then vertically. The lens assembly of the invention is rotated inside the viscoelastic-filled anterior chamber; the haptics are placed horizontally.

[0096] Fixating the lens assembly of the invention is a bimanual procedure. Lens assemblies are implanted using special tools to compress the haptics, such as forceps

or cannulae, or rely on microhooks to manipulate the optic through a hole in the surface of the optic (see discussion in U.S. Patent No. 6,142,999). A vertically-holding lens forceps, which enters the anterior chamber through the main incision, centers the optic on the pupil and holds it steadily. A thin forceps is introduced from the side incision and grasps the iris, passing a portion or fold of the iris through the haptics. Both instruments are withdrawn, and the surgeon changes hands for holding each tool. The anterior chamber of the eye is again deepened with viscoelastic material, and the lens-fixation instruments are reintroduced. The second haptic-fixation manoeuvre is performed through the incision on the opposite side.

[0097] A peripheral iridectomy can then be performed. Then, the introduced viscoelastic material (if any) is aspirated through the three incisions. The anterior chamber is gently irrigated and inflated with air to remove all viscoelastic material.

[0098] For closure of the incision line, the apposition of the sides of the incision may be achieved by one or two superficial sutures. Alternatively, a large air bubble may be left inside the anterior chamber to effect an apposition. If the limbal incision was made without a pocket, then a closure of the incision line should be performed using sutures.

[0099] At the end of the surgery, 20 mg of gentamycin and 2 mm of dexamethasone are subconjunctivally injected. A sterile pad and a protective shield are applied.

[0100] Alternatively, the intraocular lens assembly of the invention can be located in the posterior chamber of the eye, using methods known to those of skill in the ophthalmic art (see, U.S. Patent No. 6,110,202; Pesando et al., 15(4) J. Refract Surg. 415-23 (1999); Sanders et al., 15(3) J. Refract Surg 309-15 (1999). In posterior chamber implants, the haptics normally lodge in the ciliary sulcus.

[0101] Aphakic intraocular lens assembly implantation is also usefully provided for by the intraocular lens assembly of the invention. The lens assembly can be surgically implanted in the evacuated capsular bag of the lens of an eye (for example, through the anterior capsule opening in the bag) in a position such that the lens optic of the intraocular lens assembly is aligned with the opening defined by the anterior capsular remnant, and the outer ends of the lens distal portions are disposed within the outer perimeter of the bag. The intraocular lens assembly of the invention has a radial dimension from the outer end of each distal or extended portion to the axis of the intraocular lens assembly. Thus, with the intraocular lens assembly implanted within the capsular bag, the outer ends of the extended portions engage the inner perimetrical wall of the capsular bag with no or minimal stretching of the bag. After implantation of the intraocular lens assembly in the capsular bag, active ectodermal cells on the posterior surface of the anterior capsule rim of the bag cause fusion of the rim to the elastic posterior capsule of the bag by fibrosis about the lens extended portions. Because of the haptic design, the intraocular lens assembly of the invention can, when placed in the capsular bag of the eye, provide accommodation for the patient.

[0102] Advantageously, post-operative atropinization of the optic ciliary muscle is not required for the intraocular lens assembly of the invention (when implanted either as a refractive phakic intraocular lens or an aphakic intraocular lens) to achieve accommodation. During surgery, especially for implantation of aphakic intraocular lenses, the ciliary muscle of the eye had previously and typically been paralyzed with a ciliary muscle relaxant to place the muscle in its relaxed state. Ciliary muscle relaxants include anticholinergics such as atropine, scopolamine, homatropine, cyclopentolate and tropicarnide. Atropine is preferred. Proprietary preparations of atropine include Isopto Atropine (eye drops); Minims Atropine Sulphate (single-dose

eye drops); Min-I-Jet Atropine (injection); Actonorm Powder (combined with antacids and peppermint oil); Atropine-1; Atropine-Care; Atropisol; Isopto Atropine; Ocu-tropine; Atropair; Atropine Sulfate S.O.P.; Atrosulf; 1-Tropine; Isopto Atropine; and Ocu-Tropine. Prior to this invention (i.e. while implanting intraocular lenses not having the advantages of the foldable intraocular lens assembly of the invention), the patient's eye would be atropinized following surgery, to allow for accommodation of the lens of the implanted aphakic intraocular lens assembly to the eye (see discussion, U.S. Patent No. 6,051,024). Following surgery, the ciliary muscle relaxant (such as atropine) would be periodically introduced throughout a post-operative fibrosis and healing period (such as two to three weeks) to maintain the ciliary muscle in its relaxed state until fibrosis was complete. This drug-induced relaxation of the ciliary muscle prevented contraction of the ciliary muscle and immobilized the capsular bag. Thus, the implanted intraocular lens optic fixed during fibrosis in its distant vision position within the eye relative to the retina (accommodation). The implanted lens pressed backward against and thereby forwardly stretched the elastic posterior capsule of the capsular bag. By contrast, because of the haptic design of the intraocular lens assembly of the invention, the lens can, when placed in the capsular bag of the eye, provide accommodation for the patient without the administration of post-operative atropine.

[0103] In another form of the present invention, there is also provided a method for implanting an intraocular lens assembly in an eye which provides accommodation. This includes the insertion of an intraocular lens (IOL) assembly into the eye, where the IOL assembly extends along an optical axis between an anterior optical surface and a posterior optical surface. The lens has a circumferential edge disposed about an optical axis at a junction of the anterior and posterior optical surfaces. The lens further

includes N haptics where N is an integer greater than 1. Each haptic extends from an associated portion of the circumferential edge and along associated haptic axis. Each of the haptics is loop-like or paddle-like and extends between end portions at opposite ends thereof. The end portions are joined to the lens at the circumferential edge. Also, the haptic axis is angulated away from anterior surface by angle A with respect to a plane transverse to optical axis. In one embodiment, angle A may be in an approximate range of 4-7 degrees.

[0104] It will be apparent to those skilled in the art that other changes and modifications can be made in the above-described invention and methods for making and using the same, without departing from the scope of the invention herein, and it is intended that all matter contained in the above description shall be interpreted in an illustrative and not in a limiting sense.

[0105] Throughout the specification and the claims, and unless the context requires otherwise, the term "comprise", or variations such as "comprises" or "comprising", will be understood to apply the inclusion of the stated integer or group of integers but not the exclusion of any other integer or group of integers.

[0106] Throughout the specification and the claims and unless the context requires otherwise, the term "substantially" or "about" will be understood to not be limited to the value for the range qualified by the terms.

What is claimed is:

1. An intraocular lens assembly comprising:
a lens extending along an optical axis between an anterior optical surface and a posterior optical surface and having a circumferential edge disposed about said optical axis at a junction of said anterior and posterior optical surfaces, and having N haptics, each of said haptics extending from an associated portion of said circumferential edge and along an associated haptic axis, where N is an integer greater than 1,
wherein each of said haptics has a smooth, curved peripheral edge and extends between end portions at opposite ends thereof, said end portions being joined to said lens at said circumferential edge.
2. An intraocular lens assembly according to claim 1, wherein said haptics are loop-like.
3. An intraocular lens assembly according to claim 1, wherein said haptics are paddle-like.
4. An intraocular lens assembly according to claim 1, having a first pair of haptics extending from opposite portions of said circumferential edge along an associated first pair of haptic axes, and having a second pair of haptics extending from opposite portions of said circumferential edge along an associated second pair of haptic axes,
wherein said first pair of haptic axes and said optic axis are coplanar in a first haptic plane,

wherein said second pair of haptic axes and said optic axis are coplanar in a second haptic plane.

5. An intraocular lens assembly according to claim 4 wherein said first haptic plane is perpendicular to said second haptic plane.

6. An intraocular lens assembly according to claim 5 wherein said haptics are angularly displaced with respect to said optical axis in a direction away from said anterior optical surface by an angle A from a plane transverse to said optical axis.

7. An intraocular lens assembly according to claim 6 wherein A is in the approximate range 4-7 degrees.

8. An intraocular lens assembly according to claim 4 wherein each of said haptics includes M footplates extending therefrom symmetrically about its associated haptic axis, where M is an integer greater than 0.

9. An intraocular lens assembly according to claim 8 where $M = 1$ for each of said haptics.

10. An intraocular lens assembly according to claim 4 wherein each of said haptics includes M footplates, where $M = 0$.

11. An intraocular lens assembly according to claim 5 wherein each of said haptics includes M footplates extending therefrom symmetrically about its associated haptic axis, where M is an integer greater than 0.

12. An intraocular lens assembly according to claim 1 where $M = 1$ for each of said haptics.

13. An intraocular lens assembly according to claim 5 wherein each of said haptics includes M footplates, where $M = 0$.

14. An intraocular lens assembly according to claim 6 wherein each of said haptics includes M footplates extending therefrom symmetrically about its associated haptic axis, where M is an integer greater than 0.

15. An intraocular lens assembly according to claim 14 where $M = I$ for each of said haptics.

16. An intraocular lens assembly according to claim 6 wherein each of said haptics includes M footplates, where $M = 0$.

17. An intraocular lens assembly according to claim 7 wherein each of said haptics includes M footplates extending therefrom symmetrically about its associated haptic axis, where M is an integer greater than 0.

18. An intraocular lens assembly according to claim 17 where $M = I$ for each of said haptics.
19. An intraocular lens assembly according to claim 7 wherein each of said haptics includes M footplates, where $M = 0$.
20. An intraocular lens assembly according to claim 1 wherein each of said haptic axis is coplanar with said optic axis in an associated haptic plane.
21. An intraocular lens assembly according to claim 1 where N is odd.
22. An intraocular lens assembly according to claim 21 where $N = 3$.
23. An intraocular lens assembly according to claim 21 where $N = 5$.
24. An intraocular lens assembly according to claim 1 where N is even.
25. An intraocular lens assembly according to claim 24 where $N = 2$.
26. An intraocular lens assembly according to claim 24 where $N = 4$.
27. An intraocular lens assembly according to claim 1 wherein each of said haptics includes M footplates extending therefrom symmetrically about its associated haptic axis, where M is an integer greater than 0.

28. An intraocular lens assembly according to claim 27 where $M = I$ for each of said haptics.
29. An intraocular lens assembly according to claim 1 wherein each of said haptics includes M footplates, where $M = 0$.
30. An intraocular lens assembly according to claim 20 wherein each of said haptics includes M footplates extending therefrom symmetrically about its associated haptic axis, where M is an integer greater than 0.
31. An intraocular lens assembly according to claim 30 where $M = 1$ for each of said haptics.
32. An intraocular lens assembly according to claim 20 wherein each of said haptics includes M footplates, where $M = 0$.
33. An intraocular lens assembly according to claim 1, wherein the intraocular lens assembly includes either a monofocal or multifocal lens.
34. A method for implanting a phakic intraocular lens assembly in an eye, comprising:
- inserting into the eye, a lens extending along an optical axis between an anterior optical surface and a posterior optical surface and having a circumferential edge disposed about said optical axis at a junction of said anterior and posterior optical surfaces, and N haptics, each of said haptics

extending from an associated portion of said circumferential edge and along associated haptic axis, where N is an integer greater than 1, wherein each of said haptics has a smooth, curved peripheral edge and extends between end portions at opposite ends thereof, said end portions being joined to said lens at said circumferential edge.

35. An intraocular lens assembly according to claim 34, wherein said haptics are loop-like.

36. An intraocular lens assembly according to claim 34, wherein said haptics are paddle-like.

37. The method of claim 34 wherein said haptic axis are angulated away from said anterior surface by angle A with respect to a plane transverse to said optical axis.

38. The method of claim 37 wherein A is in the approximate range 4-7 degrees.

39. The method of claim 34 wherein the intraocular lens assembly includes an aphakic intraocular lens assembly.

40. The method of claim 34 permitting the eye to heal in the absence of a ciliary muscle relaxant; wherein the implanted intraocular lens provides an accommodating lens to the eye.