

(19) United States

(12) Patent Application Publication **Cumming**

(10) Pub. No.: US 2011/0313525 A1

Dec. 22, 2011 (43) **Pub. Date:**

(54) TILT STABILIZING ACCOMMODATING INTRAOCULAR LENS

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(21) Appl. No.: 13/111,599

(22) Filed: May 19, 2011

Related U.S. Application Data

(60) Provisional application No. 61/398,107, filed on Jun. 21, 2010, provisional application No. 61/398,098, filed on Jun. 21, 2010, provisional application No.

61/398,115, filed on Jun. 21, 2010, provisional application No. 61/398,099, filed on Jun. 21, 2010.

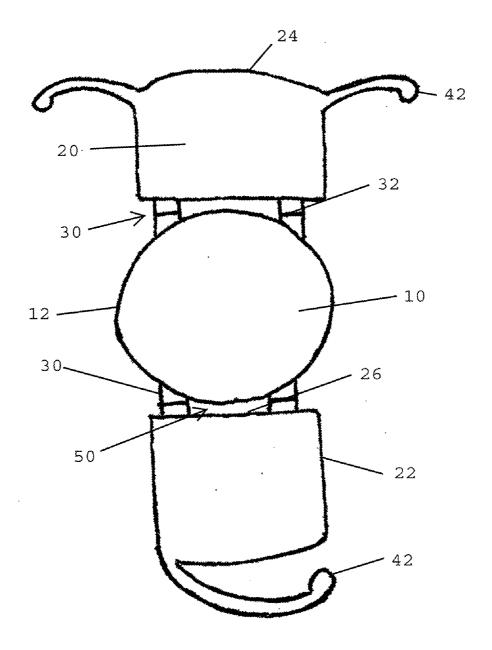
Publication Classification

(51) Int. Cl. A61F 2/16 (2006.01)

(52) U.S. Cl. 623/6.44

ABSTRACT (57)

An intraocular lens for insertion into a capsular bag of an eye. A plurality of flexible connecting members couples a lens optic to a pair of opposing of plate haptics. The coupling members stabilize the optic with respect to the haptics. The coupling members are spaced apart straps having grooves that increase lens response to changes in vitreous pressure.



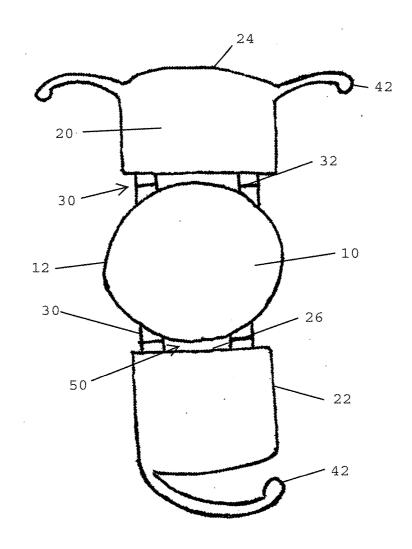


Figure 1

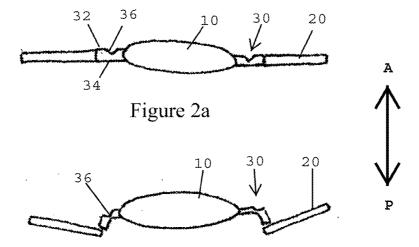
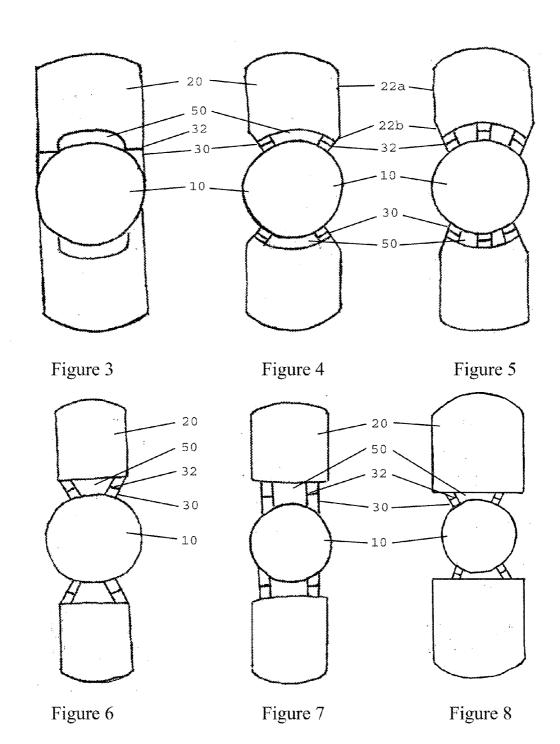


Figure 2b



TILT STABILIZING ACCOMMODATING INTRAOCULAR LENS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is based on and claims the benefit of the filing of U.S. Provisional Patent Application No. 61/398,107 filed Jun. 21, 2010; U.S. Provisional Patent Application No. 61/398,098 filed Jun. 21, 2010; U.S. Provisional Patent Application No. 61/398,115, filed Jun. 21, 2010; and U.S. Provisional Patent Application No. 61/398,099, filed Jun. 21, 2010, the contents and disclosure of which are fully incorporated herein by reference.

[0002] This application is related to U.S. Non-Provisional patent application Ser. No. 13/017,189, filed Feb. 14, 2011; and U.S. Non-Provisional patent application Ser. No. 13/092, 359, filed Apr. 22, 2011, the contents and disclosure of which are fully incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0003] Accommodating Intraocular Lenses were developed in the early 1900's and have been sold in Europe for the last ten years and later in the U.S. They function by means of forward movement of the optic upon constriction of the ciliary muscle which increases the intraocular vitreous pressure. The forward movement of the lens optic enables the patient implanted with the lens to automatically change their vision from distance vision, to see at intermediate and near distances. The increase in pressure in the posterior part of the eye is accompanied by a simultaneous decrease in pressure in the front part of the eye. The reverse pressure changes take place upon relaxation of the ciliary muscle, resulting in the backwards movement of the lens for distance vision.

[0004] The currently marketed accommodating plate haptic intraocular lenses provide excellent distance and intermediate vision but sometimes require weak, +1.00, reading glasses for prolonged reading, for seeing small print, or reading in dim lighting conditions.

[0005] It is important for intraocular lenses to have a consistent location along the axis of the eye to provide good uncorrected distance vision and to center in the middle of the vertical meridian of the eye. Without excellent uncorrected distance vision there is no point in implanting an accommodating lens. With the advent of the new premium lenses, not only are the above requirements important but also the vision is likely to be better if the lens after implantation and centration, is without any tilt which can reduce the quality of vision particularly if the lens optic has a toric component or is a multifocal.

[0006] The word "haptic" has been used to describe an attachment to intraocular lenses. The original intraocular lens consisted of a single optic. These single optic lenses, without any attachments, were first implanted in London by Harold Ridley in 1949. These lenses frequently de-centered and it was discovered that there was a need to center and fixate the lens optic in the vertical meridian of the eye.

[0007] The first attachments to the optic were called "haptics". They consisted of multiple flexible loops of various designs, J loops, C loops, closed loops and flexible radial arms.

[0008] Later, these loops which became commonly referred to as "haptics" were replaced in some lens designs with oblong, flat, flexible plates, called "plate haptics". It is

necessary to fixate and center the plate haptics within the capsular bag and so "loops", "fingers", or "flexible arms" may be extended from the distal lateral ends of the plate haptics. These can be of the same material as the plate or integrally molded into the plate lens design during manufacturing, and can be made of polymide, prolene PMMA or titanium. These plate haptics are solid, flat, flexible and approximately between 3.0 and 6.0 mm in width, 0.20 to 0.75 mm thick, and may have tapered rounded or parallel sides.

[0009] When the accommodating lens plate haptic is fibrosed into the capsular bag of an eye after cataract surgery, sometimes several weeks or months following the surgery, a complication can occur. The lens can deform to a "Z" dislocated shape. This occurs when there is little sandwiching of the distal tip of the plate haptics between the remaining anterior and the posterior walls of the capsular bag.

[0010] The current accommodating lenses utilize an oblong lens body design having plate haptics connected to the lens optics by a single transverse hinge across the plate haptic. This promotes accommodation by allowing the optic to move forwards and backwards relative to the outer, or distal, ends of the plates. Such accommodating lenses are found in U.S. Pat. No. 5,476,514 and U.S. Pat. No. 5,496,366, both to Cumming, the disclosures of which are herein incorporated by reference. However, these designs do not permit adequate movement of the optic to a change in vitreous cavity pressure to allow many patients to read comfortably at near without glasses.

[0011] In order to increase the movement of the optic to respond to the increase in vitreous cavity pressure that occurs during constriction of the ciliary muscle, the transverse hinge may be weakened by elongating the hinge base or reducing the width of the hinge. However, elongating the hinge base would destabilize the lens optic, and making the hinge narrower would make it prone to tilting.

BRIEF SUMMARY PREFERRED EMBODIMENTS

[0012] An accommodating intraocular lens design according to an embodiment of the present invention is described that overcomes the deficiencies of present designs noted above.

[0013] An accommodating intraocular lens (AIOL) is provided whereby an optic is coupled to opposing plate haptics by a plurality of spaced apart flexible connecting members.

[0014] One feature of the presently described AIOL is that the connecting members operate to stabilize the optic with respect to the plate haptics. Coupling the haptics to the optics with spaced apart connecting members permits pressure to be distributed more evenly along more of the circumference of the optic and thus increases optic stability. Whereas a single narrow connecting member on opposing sides of the optic may cause the lens to tilt easily during fibrosis.

[0015] Another feature of the presently described AIOL is that the connecting members improve near vision by reducing the resistance to pressure changes on the optic with contraction and relaxation of the ciliary muscle. This occurs because the spaces between the connecting members do not allow the connecting members to 'share' force. Furthermore, the connecting members preferably comprise one or more grooves or hinges on one or more opposing surfaces. These grooves or hinges further decrease the resistance of the connecting member to pressure changes caused by the contracting and relaxing ciliary muscle.

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[0016] Still another feature of the presently described AIOL is that further stabilization of the optic is achieved by the plate haptics being at least as wide as the optic. In a two diametrically opposed or oblong design, this would form a longitudinal lens body.

[0017] Other features and advantages of the present invention will become apparent from the following more detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the presently described apparatus and method of its use.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[0018] Illustrated in the accompanying drawing(s) is at least one of the best mode embodiments of the present invention In such drawing(s):

[0019] FIG. 1 illustrates a top view of a tilt stabilizing AIOL according to an embodiment of the present invention;

[0020] FIG. 2 illustrates a side view of a tilt stabilizing AIOL according to an embodiment of the present invention;

[0021] FIGS. 3-8 illustrate top views of exemplary tilt stabilizing AIOLs according to various embodiments of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED **EMBODIMENTS**

[0022] The above described drawing figures illustrate the described invention and method of use in at least one of its preferred, best mode embodiment, which is further defined in detail in the following description. Those having ordinary skill in the art may be able to make alterations and modifications to what is described herein without departing from its spirit and scope. Therefore, it should be understood that what is illustrated is set forth only for the purposes of example and should not be taken as a limitation on the scope of the present apparatus and its method of use.

[0023] FIG. 1 illustrates a tilt stabilizing AIOL according to a preferred embodiment. As illustrated, a lens optic 10 is flexibly coupled to a plurality of opposing plate haptics 20 via a plurality of spaced apart coupling members 30. The tilt stabilizing AIOL is operable to be inserted into an eye having a ciliary body, and is responsive to vitreous pressure changes in the eye such that an increase in vitreous pressure caused by a contraction of the ciliary muscle about the plate haptics 20 causes the lens optic 10 to be displaced in a substantially anterior direction A so as to accommodate near vision, and the a decrease in vitreous pressure caused by a relaxation of the ciliary muscle about the plate haptics 20 causes the lens optic 10 to be displaced in a substantially posterior direction P for distance vision, as shown in FIGS. 2b and 2a.

[0024] Returning to FIG. 1, at least one pair of diametrically opposed plate haptics 20 are longitudinally coupled to the lens optic 10 periphery 12 via the coupling members 30. In at least one embodiment, the lens optic 10 is stabilized by plate haptics 20 having a width equal to or greater than the diameter of the lens optic 10. In some embodiments, the width of the plate haptic 20 is between 5.0 and 6.0 mm, and the thickness of the plate haptic is between 0.15 and 0.4 mm.

[0025] In some embodiments, the lens optic 10 is further stabilized by plate haptics 20 having parallel sides 22. In other embodiments, the lens optic 10 may be stabilized by plate haptics 20 having sides which have parallel portions 22a and non-parallel portions 22b. In at least one embodiment, the non-parallel portions 22b may be substantially convergent, as shown in FIGS. 4 and 5, but divergent non-parallel portions are specifically contemplated. The plate haptic is preferably made of substantially of silicone, hydrogel, acrylic, or similar material.

[0026] A plurality of spaced apart connecting members 30 flexibly couple the lens optic 10 to each plate haptic 20, forming at least one aperture 50 defined by the lens optic 10, the plate haptic 20 and the spaced apart coupling members 30. In order to aid in lens optic 10 stabilization, in at least one embodiment, the connecting members 30 extend radially from the lens optic 10 to the haptic 20. However, other embodiments stabilize the lens optic 10 with connecting members 30 that extend longitudinally from the plate haptic 20 to the lens optic 10. The connecting members are preferably narrow, thin straps, but may be any structure permitting longitudinal flexion. In at least one embodiment, the connecting member is between 0.5 to 2.0 mm in width.

[0027] As illustrated in FIG. 1, two or more straps 30 are preferably used to couple each haptic 20 to the lens optic 10. The straps 30 are preferably equidistant from a longitudinal axis of the AIOL and the space between them defines the aperture 50 along with the lens optic 10 and the plate haptic 20. While preferred embodiments illustrate multiple straps 30, at least one embodiment is contemplated that comprises a single strap 30 that may be of varying thickness.

[0028] FIG. 3 illustrates an embodiment wherein at least two straps 30 couple each haptic 20 to the lens optic 10. Straps 30 extend longitudinally from each haptic 20 to the lens optic 10 so as to couple each haptic 20 to the lens optic 10. As shown in FIG. 3, the connecting members 30 may be wholly or partially formed as right triangles of flexible material with their hypotenuses fixed to the lens periphery 12. The groove 32 may also be substantially adjacent the proximal end 26 of the haptic, as shown.

[0029] FIG. 4 illustrates an embodiment wherein connecting members 30 extend substantially radially from the optic periphery 12 to couple the optic 10 to a curved proximal end 26 of the haptic 20 that is substantially parallel to the optic periphery 12. Additionally, the haptic is shown to have substantially converging non-parallel sides 22b adjacent the proximal end 26. While the proximal end 26 is shown as curving so as to run parallel with the optic periphery 12, the proximal end 26 may also be substantially straight so as to run tangential to the optic periphery 12 and/or the proximal end 26.

[0030] FIG. 5 illustrates an embodiment wherein at least three connecting members 30 extend radially from the lens optic periphery 12 to the haptic proximal end 26. The connecting members 30 comprise at least one opposing pair of outer connecting members 30a and a central connecting member 30b. The outer connecting members 30a making up an opposing pair are preferably equidistant from the longitudinal axis of the AIOL, and extend radially from the optic periphery 12 to the proximal end 26 of the haptic. The outer connecting members may comprise a plurality of opposing pairs of connecting members 30a, or a single opposing pair of connecting members 30a. The central connecting member 30b is aligned with the longitudinal axis of the AIOL and extends radially from the optic periphery to the proximal end of the haptic.

[0031] FIGS. 6-8 illustrate connecting member 30 placement according to various embodiments. FIG. 6 shows conUS 2011/0313525 A1 Dec. 22, 2011 3

necting members 30 extending radially from parallel sides 22 of the plate haptic 20 whose width is less than the diameter of the lens optic 10. FIG. 7 shows connecting members 30 extending radially from parallel sides 22 of the plate haptic whose width is greater than the diameter of the lens optic 10. FIG. 8 shows connecting members 30 extending longitudinally from the plate haptic 20 to the lens optic 10, the plate haptic 20 being substantially the same width as the lens optic 10, the connecting members 30 being substantially parallel.

[0032] As shown, for example, in FIG. 2, each connecting member 30 preferably comprises a first surface 32 and a second surface 34 opposed thereto. The first surface 32 may comprise a groove, channel or hinge 36 that weakens the connecting member 30 and increases flexion at the hinge 36. The groove 36 preferably traverses the connecting member 30 in at least one of: a lateral direction, as in FIG. 1; parallel to the optic periphery, as in FIG. 5; tangential to the optic periphery, as in FIG. 3; parallel to the haptic proximal end; and tangential to the haptic proximal end, but may also traverse the connecting member through non-parallel, nonlateral, or non-linear paths. Thus, the groove 36 may be straight, curved or any combination thereof. In at least some embodiments, the second surface 34 may also comprise a groove, channel or hinge 36 to further weaken the connecting member 30. The hinge 36 may have a thickness that is half the thickness of the plate haptic, or preferably a thickness of $0.10\,$ to 0.30 mm. In at least one embodiment, multiple grooves 36 are present on at least one of the first 32 and second 34

[0033] Returning now to FIG. 1, preferably, each plate haptic 20 comprises a distal end 24 having a centration fixation component 42. The centration fixation component 42 is preferably T-shaped, and comprises a pair of curved loops 42 extending in an arc from either lateral side of the distal end 24 of the haptic 20. In at least one embodiment, the loop 42 curves substantially towards the lens optic 10. However, in at least one other embodiment, the centration fixation component 42 comprises a single curved loop extending in an arc from one lateral side of the distal end 24 of the haptic to the other lateral side of the distal end 24 of the haptic. It is important to note that each plate haptic may comprise a different centration fixation component, for example, as show in FIG. 1, or none at all. In one embodiment, the length of the tilt stabilizing AIOL without the centration fixation component 42 is 10.5 to 11.0 mm, while the length of the tilt stabilizing AIOL with the cetnration fixation component 42 is 11.5 to 12.5 mm. The flexible loops 42 are preferably compressible centrally to fix and center the AIOL within the capsular while minimizing tilt.

[0034] The centration fixation component 42 may be of the same material as the plate haptic 20 and/or the lens optic 10, or may be polymide, prolene, polymethylmethanylate (PMMA), titanium or similar material. In one embodiment, the projection comprises a homogenous integral part of the plate haptic. In another embodiment, the projection comprises a distinct unit set into the plate haptic during molding. Preferably, the projections measure from 2.0 to 4.0 mm in length extending from the distal end of the haptic and are flexible extending to a transverse diameter that exceeds the diameter of the capsular bag.

[0035] The lens optic 10 is preferably a solid refractive single vision optic, however other optics are contemplated. For example, the lens optic 10 may be at least one of: solid, single vision, multifocal, Fresnell, spheric, aspheric, toric,

biconvex, plano-convex, liquid filled, diffractive or refractive. Additionally, the lens optic 10 is preferably constructed of a flexible optical material such as silicone, hydrogel or acrylic material, but may be made of any similar material. In at least one embodiment, the lens optic has a diameter of 5.0 mm.

[0036] According to one embodiment, when the AIOL is implanted into the capsular bag of the eye, the plate haptics 20 and its loops 42 contact the periphery of the capsular bag and operate to support the optic 10 within the eye and to substantially align and fix the lens into the capsular bag, thereby centering the lens optic 10 along the optical axis of the eye. The flexible projections 42 extend beyond the diameter of the capsular bag. Lateral and distal end extensions (not shown) may be provided to contact the periphery of the capsular bag, increasing the contact area of the lens within the bag and provide additional fixation and support to for the lens within the capsular bag.

[0037] As illustrated in FIGS. 2a and 2b, during accommodation the ciliary muscle exerts radial pressure on the ends of the haptics 20. The plate haptics 20, which naturally vault backwards when placed into the capsular bag, are thus moved centrally and posterior, towards the optic 10. The haptic 20 resists bending to the radial force exerted by the ciliary muscle. However, the stretchable thin hinge 32 across the flexible connecting members 30 is less resistant to the pressure from the vitreous cavity, and therefore stretches and flexes on application of the pressure. The separation of multiple connecting members 30 ensures the transferred pressure is uniform. With this increase in vitreous cavity pressure, the optic 10 is thus pushed forward along the axis of the eye by the stretching of the thin base of the hinge 32, the optic 10 moving forward relative to both the proximal 26 and distal ends 24 of the plate haptics 20, resulting in accommodation.

[0038] The enablements described in detail above are considered novel over the prior art of record and are considered critical to the operation of at least one aspect of the invention and to the achievement of the above described objectives. The words used in this specification to describe the instant embodiments are to be understood not only in the sense of their commonly defined meanings, but to include by special definition in this specification: structure, material or acts beyond the scope of the commonly defined meanings Thus if an element can be understood in the context of this specification as including more than one meaning, then its use must be understood as being generic to all possible meanings supported by the specification and by the word or words describing the element.

[0039] The definitions of the words or drawing elements described herein are meant to include not only the combination of elements which are literally set forth, but all equivalent structure, material or acts for performing substantially the same function in substantially the same way to obtain substantially the same result. In this sense it is therefore contemplated that an equivalent substitution of two or more elements may be made for any one of the elements described and its various embodiments or that a single element may be substituted for two or more elements in a claim.

[0040] Changes from the claimed subject matter as viewed by a person with ordinary skill in the art, now known or later devised, are expressly contemplated as being equivalents within the scope intended and its various embodiments. Therefore, obvious substitutions now or later known to one with ordinary skill in the art are defined to be within the scope of the defined elements. This disclosure is thus meant to be understood to include what is specifically illustrated and described above, what is conceptually equivalent, what can be obviously substituted, and also what incorporates the essential ideas.

[0041] The scope of this description is to be interpreted only in conjunction with the appended claims and it is made clear, here, that the named inventor believes that the claimed subject matter is what is intended to be patented.

What is claimed is:

1. An intraocular lens for insertion into a capsular bag of an eye, the intraocular lens comprising:

an optic;

a plurality of opposing plate haptics coupled to the optic; at least one flexible coupling member associated with each plate haptic, each coupling member coupling the associated plate haptic to the optic;

wherein the coupling members substantially stabilize the optic with respect to the haptics.

- 2. The intraocular lens of claim 1, wherein the coupling members substantially promote displacement of the optic along a normal axis of the eye in response to a vitreous pressure change.
- 3. The intraocular lens of claim 1, wherein the coupling members comprise a plurality of spaced apart, flexible straps.
- **4**. The intraocular lens of claim **3**, wherein each of the straps is equidistant from a longitudinal axis of the intraocular lens.
- 5. The intraocular lens of claim 1, wherein the coupling members further comprise at least one groove traversing the coupling member substantially tangential to and partially circumscribing the optic.
- **6**. The intraocular lens of claim **5**, wherein the groove substantially promotes displacement of the optic along a normal axis of the eye in response to vitreous pressure change.
 - 7. The intraocular lens of claim 5,
 - wherein the coupling members further comprise a first surface, and a second surface opposed thereto;
 - wherein the groove is defined by at least one of: the first surface and the second surface.
- **8**. The intraocular lens of claim **1**, wherein each coupling member extends substantially radially from the optic to the haptic.
- 9. The intraocular lens of claim 1, wherein at least one coupling member is substantially parallel to at least one other coupling member.
- 10. The intraocular lens of claim 1, further comprising at least one aperture associated with each plate haptic, the aperture defined by at least: the optic, the associated plate haptic, and the coupling members.
- 11. The intraocular lens of claim 10, wherein the aperture substantially promotes displacement of the optic along a normal axis of the eye in response to vitreous pressure change.
 - 12. The intraocular lens of claim 1,

wherein each plate haptic comprises a distal end, and wherein at least one centration fixation component extends from the distal end to engage the capsular bag.

13. The intraocular lens of claim 1, wherein the optic comprises a periphery; wherein each plate haptic comprises:

- a proximal end coupled to the optic via the coupling members:
- a distal end opposite the proximal end; and
- a pair of laterally opposing sides therebetween; and
- wherein the coupling members further comprise at least one groove parallel to at least one of: the optic periphery, and the proximal end.
- **14**. The intraocular lens of claim **1**, wherein the optic is at least one of: biconvex, refractive, diffractive, plano-convex, Fresnel, spheric, toric, multifocal or aspheric.
- **15**. An accommodating intraocular lens for providing improved vision, the lens comprising:
 - a plurality of opposing plate haptics coupled to an optic;
 - a plurality of flexible coupling members associated with each plate haptic, each coupling member coupling the associated plate haptic to the optic;
 - wherein the coupling members substantially stabilize the optic with respect to the haptics; and
 - wherein the coupling members substantially promote displacement of the optic along a normal axis of the eye in response to a vitreous pressure change.
 - 16. The intraocular lens of claim 15,
 - wherein the coupling members comprise at least one groove traversing the coupling member substantially tangential to and partially circumscribing the optic; and
 - wherein the at least one groove substantially promotes displacement of the optic along a normal axis of the eye in response to the vitreous pressure change.
 - 17. The intraocular lens of claim 15, further comprising: at least one aperture associated with each plate haptic, the aperture defined by at least: the optic, the associated plate haptic, and the coupling members;
 - wherein the aperture substantially promotes displacement of the eye along a normal axis of the optic in response to vitreous pressure change.
- 18. A method of substantially increasing the response of an intraocular lens to a vitreous pressure change of a capsular bag of an eye, the method comprising:

providing an intraocular lens having:

an optic having a periphery;

- a plurality of opposing plate haptics, each plate haptic having a proximal edge coupled to the optic periphery by a plurality of spaced apart flexible coupling members:
- at least one groove associated with each coupling member, the at least one groove traversing the coupling member substantially tangential to and partially circumscribing the optic periphery;
- at least one aperture defined by the optic periphery, the proximal edge, and the plurality of coupling members; and

causing the plate haptics to engage the capsular bag.

19. The method of claim 15, wherein causing the plate haptics to engage the capsular bag comprises at least one centration fixation component extending from the plate haptic to engage the capsular bag.

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