

ACCOMMODATING INTRAOCULAR LENS (AIOL), AND AIOL ASSEMBLIES INCLUDING SAME

Field of the Invention

The invention pertains to accommodating intraocular lenses (AIOLs), and
5 AIOL assemblies including same.

Background of the Invention

Commonly owned PCT International Application No. PCT/IL02/00693
entitled Accommodating Lens Assembly and published under PCT International
Publication No. WO 03/015669 illustrates and describes accommodating
10 intraocular lens (hereinafter AIOL) assemblies, the contents of which are
incorporated herein by reference. The AIOL assemblies include a haptics system
adapted to be securely fixed in a human eye's annular ciliary sulcus at at least
two spaced apart stationary anchor points so that it may act as a reference plane
for an AIOL of continuously variable diopter strength affected by a human eye's
15 capsular diaphragm acting thereagainst from a posterior direction and under the
control of its sphincter-like ciliary body. WO 03/015669's Figures 1 and 2 show
an AIOL assembly 2 designed to replicate a human eye's natural crystalline lens.
The AIOL assembly 2 has a lens 6 made of a rigid material and a natural
spherical shaped silicone ball 10 both having a refractive index greater than that
20 of water. A human eye's capsular diaphragm directly bears against the silicone
ball 10 from a posterior direction for resiliently elastically deforming it to a
compressed flattened shape on relaxation of a human eye's ciliary body for
decreasing its natural positive diopter strength for distance vision in a similar
fashion to a human eye's natural crystalline lens. However, a human eye, and
25 particularly an aging human eye, may be too weak to apply sufficient force to
overcome such a silicone ball's inherent tendency to retain its natural shape
thereby precluding accommodation.

Exemplary AIOLs are illustrated and described in US Patent No. 4,254,509 to Tennant, US Patent No. 4,409,691 to Levy, US Patent No. 4,888,012 to Horn et al., US Patent No. 4,892,543 to Turley, US 4,932,966 to Christie et al., US Patent No. 5,476,514 to Cumming, US Patent No. 5,489,302 to Skottun, US Patent No. 5,496,366 to Cumming, US Patent No. 5,522,891 to Klaas, US Patent No. 5,674,282 to Cumming, US Patent No. 6,117,171 to Skottun, US Patent No. 6,197,059 to Cumming, US Patent No. 6,299,641 to Woods, US Patent No. 6,342,073 to Cumming et al., US Patent No. 6,387,126 to Cumming, US Patent No. 6,406,494 to Laguette et al., US Patent No. 6,423,094 to Sarfarazi, US Patent No. 6,443,985 to Woods, US Patent No. 6,464,725 to Skotton, US Patent No. 6,494,911 to Cumming, US Patent No. 6,503,276 to Lang et al., US Patent No. 6,638,306 to Cumming, US Patent No. 6,645,245 to Preussner, and US Patent Application Publication No. US 2004/0169816 to Esch.

Summary of the Invention

One aspect of the present invention provides an accommodating intraocular lens (AIOL) comprising:

- (a) a cup shaped casing having a leading surface, a trailing surface with an aperture, and at least one elastically deformable shape memory optical element;
 - (b) a carriage having a base plate and an aperture lens, and being slidably mounted on said casing with said base plate lateral to said trailing surface for reciprocation between a first extreme position with said base plate adjacent said trailing surface and a second extreme position with said base plate distanced from said trailing surface relative to said first extreme position; and
 - (c) a biasing mechanism for urging said carriage relative to said casing towards said second extreme position for deforming said at least one shape memory optical element to at least partially bulge through said aperture to afford the AIOL a natural positive diopter strength for near vision,
- said carriage being driven to said first extreme position on application of an external force to said base plate in an opposite direction to said urging direction to allow said at least one shape memory optical element to revert to its natural shape to decrease the AIOL's natural positive diopter strength for distance vision.

An alternate aspect of the present invention provides an accommodating intraocular lens (AIOL) assembly for implantation in a human eye having a visual axis, a sclera of tough connective tissue, an annular ciliary sulcus and a sphincter-like ciliary body for tensioning a capsular diaphragm in an anterior direction along the visual axis on its relaxation from a contracted ciliary body state to a relaxed ciliary body state, the AIOL assembly comprising:

(a) a haptics systems having a longitudinal axis intended to be deployed co-directional with the human eye's visual axis, and a main body with at least two haptics extending therefrom in a plane perpendicular to said haptics system's longitudinal axis, each haptics having at least one pointed penetrating member for penetrating the tough connective tissue of the human eye's sclera for self-anchoring the AIOL assembly at at least two spaced apart stationary anchoring points in the human eye's ciliary sulcus; and

(b) an AIOL according to any one of Claims 1 to 8 wherein the human eye's capsular diaphragm applies said external force to said base plate on relaxation of its ciliary body.

Commonly owned PCT International Application No. PCT/IL2005/000456 entitled Accommodating Intraocular Lens Assemblies and Accommodation Measurement Implant illustrates and describes such a discrete haptics system, and a unitary construction including a haptics system with plastically deformable haptics and integrally formed with an AIOL both enabling *in situ* AIOL displacement, the contents of which are incorporated herein by reference.

Brief Description of the Drawings

In order to understand the invention and to see how it can be carried out in practice, preferred embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings in which similar parts are likewise numbered, and in which:

Fig. 1 is a cross section of an anterior part of a human eye in its natural near vision condition in an axial plane of the human body;

Fig. 2 is a cross section of an anterior part of a human eye in its natural distance vision condition in an axial plane of the human body;

Fig. 3 is a perspective view of a dissembled two component AIOL assembly including a first preferred embodiment of an AIOL in accordance with the present invention;

Fig. 4 is a perspective view of a unitary AIOL assembly integrally formed with the first preferred embodiment of an AIOL in accordance with the present invention;

Fig. 5 is an exploded view of Figure 3's AIOL;

Fig. 6 is a longitudinal cross section of Figure 3's AIOL in its near vision state;

Fig. 7 is a longitudinal cross section of Figure 3's AIOL in its distance vision state;

Fig. 8 is a cross section of an anterior part of a human eye implanted with Figure 3's AIOL in its near vision state in an axial plane of the human body;

Fig. 9 is a cross section of an anterior part of a human eye implanted with Figure 3's AIOL in its distance vision state in an axial plane of the human body;

Fig. 10 is a perspective view of a second preferred embodiment of an AIOL in accordance with the present invention; and

Fig. 11 is a perspective view of a third preferred embodiment of an AIOL in accordance with the present invention.

Detailed Description of Preferred Embodiments of the Present Invention

Figures 1 and 2 are cross sections of an anterior part of a human eye 10 having a visual axis VA in its natural near and distance vision conditions, respectively, in an axial plane of the human body. The human eye 10 has a cornea 11 peripherally connected to a spherical exterior body made of tough connective tissue known as the sclera 12 at an annular sclero-corneal juncture 13. An iris 14 inwardly extends into the human eye 10 from its root 16 at the sclero-corneal juncture 13 to divide the human eye's anterior part into an anterior chamber 17 and a posterior chamber 18. A sphincter-like peripheral structure known as the ciliary body 19 includes ciliary processes housing ciliary muscles 21 fired by parasympathetic nerves. The ciliary muscles 21 are connected to zonular fibers 22 which in turn are peripherally connected to the equatorial edge of a membrane known as the capsular bag 23 with an anterior capsule 24 and a posterior capsule 26 enrobing a natural crystalline lens 27. The iris's root 16 and the ciliary body 19 delimit a portion of the interior surface of the sclera 12 at the sclero-corneal juncture 13 known as the ciliary sulcus 28. Remnants of the

anterior capsule 24 which may remain after extraction of the natural crystalline lens 27 and the intact posterior capsule 26 are referred to hereinafter as the capsular diaphragm 29. Contraction of the ciliary body 19 allows the lens 27 to thicken to its natural thickness T1 along the visual axis VA for greater positive optical power for near vision (see Figure 1). Relaxation of the ciliary body 19 tensions the zonular fibers 22 which draws the capsular bag 23 radially outward as shown by arrows A for compressing the lens 27 to shorten its thickness along the visual axis VA to $T2 < T1$ for lower positive optical power for distance vision (see Figure 2).

10 Figure 3 shows an AIOL assembly 31 for self-anchoring implantation in a human eye's ciliary sulcus 28 for enabling spectacle free vision over the nominal range of human vision. The AIOL assembly 31 includes a discrete haptics system 32 for selectively retaining a discrete AIOL 33 therein. The haptics system 32 is made from suitable bio-compatible material such as PMMA, and the
15 like. The haptics system 32 includes a tubular main body 34 with a longitudinal axis 36 and an axial length L1 (see Figure 6), and a pair of diametrically opposite haptics 37 tangentially extending therefrom in opposite directions in a front view of the haptics system 32. The haptics 37 have a pair of parallel and opposite attachment plates 38 with pointed penetrating members 39 of sufficient strength
20 for forced penetration into the tough connective tissue of a human eye's sclera 12. The penetrating members 39 are preferably dimensioned so as to penetrate slightly more than half of a sclera's thickness of about 1mm. Further details regarding the haptics system 32 are illustrated and described in the aforementioned PCT International Application No. PCT/IL2005/000456 in
25 general, and Figures 3-5 in particular.

 Figure 4 shows an AIOL assembly 41 for self-anchoring implantation in a human eye's ciliary sulcus 28 for enabling spectacle free vision over the nominal range of human vision. The AIOL assembly 41 includes a haptics system 42 integrally formed with an AIOL 43 similar in construction and operation as the
30 discrete AIOL 33. The haptics system 42 is similar in construction as the haptics

system 32 but differs therefrom insofar that it includes plastically deformable haptics 44 with regions 46 impregnated with radiation sensitive bio-compatible chemicals, for example, Infra Red (IR) sensitive indocyanine green (ICG), and the like, such that the haptics 44 are plastically deformable on heating to a so-called glass transition temperature. Further details regarding the haptics system 42 are illustrated and described in the aforementioned PCT International Application No. PCT/IL2005/000456 in general, and Figures 12-16 in particular.

Figures 5-7 show the AIOL 33 includes a cup shaped casing 51 made from a suitable rigid bio-compatible material such as PMMA, and the like, and having an axial length L2 along a longitudinal axis 52, a leading surface 53, a stepped external surface 54 with a wide diameter leading portion 56 for secure clamping in the main body 34 and a narrow diameter trailing portion 57, a right cylindrical internal surface 58, and a trailing surface 59 formed with an annular flange 61 defining an aperture 62. The casing's axial length L2 is longer than the main body's axial length L1 such that the main body 34 is capable of contacting the casing 51 along an adjustment stroke longer than the main body's axial length L1. The leading portion 56 is formed with three peripherally disposed longitudinally directed grooves 63 formed with cutouts 64 in the leading surface 53. The casing 51 has a natural disc-like shape optical element 66 made of suitable elastically deformable bio-compatible material, such as, polymeric gel, hydrogel, and the like, having a refractive index greater than that of water. Suitable polymeric gels include silicone gel commercially available from NuSil Technology LLC., USA (www.nusil.com). The optical element 66 begins to undergo elastic deformation along its longitudinal axis on application of a minimum deformation force F_{OE} .

A rigid carriage 67 is slidably mounted on the casing 51 from the exterior and includes an annular base plate 68 formed with an aperture 69 and three longitudinally directed struts 71 having free ends 72 each formed with an aperture 73, and an aperture lens 74 having a leading portion 76 and a trailing portion 77 formed with three equispaced radially directed protrusions 78 for snap

fitting into the apertures 73. The base plate 68 is preferably formed from a suitable rigid bio-compatible material such as PMMA, and the like. The aperture lens 74 is preferably formed from a suitable rigid bio-compatible material such as PMMA, and the like. The aperture lens 74 preferably has sufficient positive
5 diopter strength, say, in the range of between about +10 to about +30, for basic eyesight correction. The struts 71 are slidably received in the grooves 63 such that the aperture lens 74 is lateral to the leading surface 53 and the base plate 68 is lateral to the trailing surface 59. The carriage 67 reciprocates through a stroke S between a first extreme position in which the base plate 68 is adjacent the
10 trailing surface 59 and a second extreme position in which the base plate 68 is distanced from the trailing surface 59 relative to the first extreme position. A biasing mechanism 79 constituted by a compression spring is disposed between the trailing portion 57 and the struts 71 for urging the carriage 67 to its second extreme position. The biasing mechanism 79 applies a deforming force F_{BM}
15 where $F_{BM} = F_{OE} + \Delta$ for deforming the optical element 66 to bulge through the aperture 62 to afford the AIOL 33 with a high positive diopter strength for near vision (see Figure 6). The biasing mechanism 79 is designed such that an accommodation force F_{CD} applied against the base plate 68 in an anterior direction on relaxation of the ciliary body 19 satisfies the condition that $F_{OE} +$
20 $F_{CD} > F_{BM}$ such that the carriage 67 assumes its first extreme position for allowing the optical element 66 to revert to its natural disc-like shape to decrease the AIOL's natural positive diopter strength for distance vision (see Figure 7).

Figures 8 and 9 show the AIOL assembly 31 self-anchored in a human eye's ciliary sulcus at peripherally disposed stationary anchor points AP in its
25 near vision and far distance states, respectively. The AIOL assembly 31 is implanted in a human eye 10 such that the capsular diaphragm 29 lightly bears against the base plate 68 in the contracted state of the human eye's ciliary body 19 such that on its relaxation, the capsular diaphragm 29 urges the AIOL 33 from its near vision state to its distance vision state.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention can be made within the scope of the appended claims. For example, the biasing mechanism 79 can be implemented by
5 longitudinally compressible flex elements 81 (see Figure 10), leaf springs 82 (see Figure 11), and the like. Also, basic eyesight correction can be effected by a circular base plate instead of the aperture lens. Furthermore, the carriage can be assembled using non-mechanical techniques, for example, gluing, welding, and the like.

- 9 -

Claims:

1. An accommodating intraocular lens (AIOL) comprising:

(a) a cup shaped casing having a leading surface, a trailing surface with an aperture, and at least one elastically deformable shape memory optical element;

(b) a carriage having a base plate and an aperture lens, and being slidably mounted on said casing with said base plate lateral to said trailing surface for reciprocation between a first extreme position with said base plate adjacent said trailing surface and a second extreme position with said base plate

distanced from said trailing surface relative to said first extreme position; and

(c) a biasing mechanism for urging said carriage relative to said casing towards said second extreme position for deforming said at least one shape memory optical element to at least partially bulge through said aperture to afford the AIOL a natural positive diopter strength for near vision,

said carriage being driven to said first extreme position on application of an external force to said base plate in an opposite direction to said urging direction to allow said at least one shape memory optical element to revert to its natural shape to decrease the AIOL's natural positive diopter strength for distance vision.

2. The AIOL according to Claim 1 wherein said biasing mechanism is disposed between said trailing surface and said base plate.

3. The AIOL according to Claim 2 wherein said biasing mechanism is a compression spring.

4. The AIOL according to any one of Claims 1 to 3 wherein said aperture lens has a diopter strength in the range of about +10 to about +30 for basic eyesight correction.

- 10 -

5. The AIOL according to any one of Claims 1 to 4 wherein said base plate is annular.

6. The AIOL according to any one of Claims 1 to 5 wherein said aperture lens is lateral to said leading surface.

7. The AIOL according to any one of Claims 1 to 6 wherein said carriage is externally mounted on said casing.

8. The AIOL according to any one of Claims 1 to 7 wherein said at least one shape memory optical element has a natural disc-like shape.

9. An accommodating intraocular lens (AIOL) assembly for implantation in a human eye having a visual axis, a sclera of tough connective tissue, an annular ciliary sulcus and a sphincter-like ciliary body for tensioning a capsular diaphragm in an anterior direction along the visual axis on its relaxation from a contracted ciliary body state to a relaxed ciliary body state, the AIOL assembly comprising:

(a) a haptics systems having a longitudinal axis intended to be deployed co-directional with the human eye's visual axis, and a main body with at least two haptics extending therefrom in a plane perpendicular to said haptics system's longitudinal axis, each haptics having at least one pointed penetrating member for penetrating the tough connective tissue of the human eye's sclera for self-anchoring the AIOL assembly at at least two spaced apart stationary anchoring points in the human eye's ciliary sulcus; and

(b) an AIOL according to any one of Claims 1 to 8 wherein the human eye's capsular diaphragm applies said external force to said base plate on relaxation of its ciliary body.

- 11 -

10. The AIOL assembly according to Claim 9 wherein said haptics system is a discrete component for selectively retaining a discrete AIOL therein.

11. The AIOL assembly according to Claim 10 wherein said AIOL has a main body with an axial length L1 along its longitudinal axis and said AIOL's casing has an axial length L2 along its longitudinal axis where $L2 > L1$ such that said main body is capable of clamping said AIOL's casing along an adjustment stroke longer than said main body's axial length.

12. The AIOL assembly according to Claim 9 wherein said haptics system is integrally formed with said AIOL and said at least two haptics each have a plastically deformable radiation sensitive region for enabling *in situ* manual selective displacement of said AIOL along the human eye's visual axis relative to said at least two stationary anchor points.

13. The AIOL assembly according to Claim 12 wherein said radiation sensitive regions are adjacent said AIOL and remote from their respective pointed penetrating members.

14. The AIOL assembly according to any one of Claims 9 to 13 wherein each said haptics has a thin profile in a plane perpendicular to said haptics system's longitudinal axis such that each said haptics is sufficiently flexible for encircling around said main body in said plane perpendicular to said haptics system's longitudinal axis, and a wide profile along said haptics system's longitudinal axis such that each said haptics is rigid against a compression force therealong.

15. The AIOL assembly according to Claim 14 wherein said wide profile tapers from a haptics' proximal end adjacent said main body towards its distal end remote therefrom.