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(54) **ACCOMMODATING INTRA-OCULAR LENS SYSTEM**

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5,203,788	A	4/1993	Wiley	
5,800,530	A	9/1998	Rizzo, III	
6,096,078	A	8/2000	McDonald	
6,120,538	A	9/2000	Rizzo, III et al.	
6,511,508	B1 *	1/2003	Shahinpoor et al.	623/4.1
6,618,208	B1	9/2003	Silver	
6,797,004	B1	9/2004	Brady et al.	
7,041,133	B1	5/2006	Azar	
7,060,094	B2	6/2006	Shahinpoor et al.	
7,118,596	B2	10/2006	Zadno-Azizi et al.	
7,198,640	B2	4/2007	Nguyen	

(Continued)

Related U.S. Patent Documents

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USPC 623/6.22, 6.37, 4, 24, 25, 4.1
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,373,218	A *	2/1983	Schachar	623/6.13
4,585,457	A	4/1986	Kalb	
4,816,031	A	3/1989	Pfaff	
5,108,429	A	4/1992	Wiley	
5,171,266	A	12/1992	Wiley et al.	

OTHER PUBLICATIONS

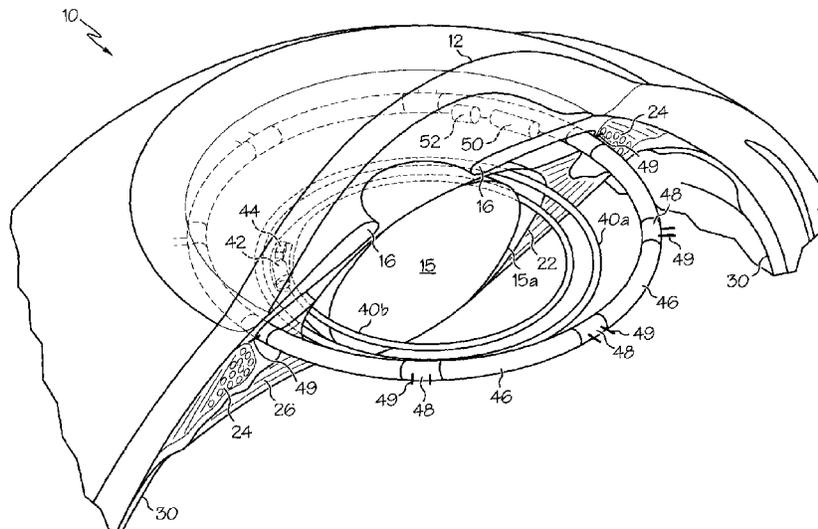
PCT/US2013/021663 International Search Report and Written Opinion dated Apr. 25, 2013 (12 pages).
(Continued)

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(74) *Attorney, Agent, or Firm* — Grasso PLLC

(57) **ABSTRACT**

An implantable, compressible, accommodating intra-ocular lens (IOL) coupled to at least one sensor which detects a signal created by the ciliary muscle. A ciliary sulcus ring can house the at least one sensor, and the sensor can include miniaturized electrodes (ciliary muscle probes) for implanting into the ciliary muscle of the subject. A potentiometer/microcomputer can modulate the ciliary muscle signal detected by the sensor(s) into an electrical signal, and a transmitter sends this electrical signal to a micromotor, which causes compression of the IOL via an annular support ring system, causing a change in the IOL shape. The IOL can be part of an IOL complex including a compressible, accommodating IOL, an external lens membrane, and an annular support ring system. The annular support ring system provides a foundation for the micromotor to compress the IOL.

20 Claims, 5 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

7,238,201 B2 7/2007 Portney et al.
 7,261,736 B1* 8/2007 Azar 623/6.22
 7,309,943 B2 12/2007 Henderson et al.
 7,326,246 B2 2/2008 Brady et al.
 7,334,892 B2 2/2008 Goodall et al.
 7,390,088 B2 6/2008 Goodall et al.
 7,416,562 B2 8/2008 Gross
 7,486,988 B2 2/2009 Goodall et al.
 7,591,849 B2 9/2009 Richardson
 7,795,782 B2 9/2010 Wischnewskij et al.
 7,857,850 B2* 12/2010 Mentak A61F 2/1627
 623/6.13
 7,941,201 B2 5/2011 Chiou et al.
 7,964,833 B2 6/2011 Holladay
 8,425,599 B2 4/2013 Shaddock
 8,574,295 B2 11/2013 Roholt
 8,778,002 B2 7/2014 Blum
 8,900,298 B2 12/2014 Anvar et al.
 8,919,953 B1 12/2014 Ho
 8,968,396 B2 3/2015 Matthews et al.
 9,036,264 B2 5/2015 Gupta et al.
 9,052,528 B2 6/2015 Pugh
 9,084,561 B2 7/2015 Etzkorn
 9,084,673 B2 7/2015 Dell
 9,111,473 B1 8/2015 Ho
 9,113,829 B2 8/2015 Etzkorn
 9,125,736 B2 9/2015 Kahook et al.
 9,155,614 B2 10/2015 Blum et al.
 9,220,590 B2 12/2015 Beer
 9,277,987 B2 3/2016 Smiley et al.
 9,364,318 B2 6/2016 Beer
 9,456,895 B2 10/2016 Shaddock
 2006/0122530 A1 6/2006 Goodall et al.
 2006/0122531 A1* 6/2006 Goodall et al. 600/546
 2006/0136055 A1 6/2006 Michel
 2007/0005136 A1 1/2007 Richardson
 2007/0142909 A1 6/2007 Peyman
 2008/0177170 A1 7/2008 Roberts et al.
 2010/0331974 A1 12/2010 Schaper, Jr.
 2010/0331977 A1 12/2010 Schaper, Jr.
 2011/0040378 A1 2/2011 Werblin
 2011/0177393 A1 7/2011 Park et al.
 2012/0046744 A1 2/2012 Woods et al.
 2013/0184815 A1 7/2013 Roholt

2013/0261744 A1 10/2013 Gupta et al.
 2014/0227437 A1 8/2014 DeBoer et al.
 2015/0173893 A1 6/2015 Portney

OTHER PUBLICATIONS

PCT/US2013/021663 International Preliminary Report on Patent-ability dated Jul. 22, 2014 (6 pages).
 PCT/US2013/021663 International Publication No. WO 2013/109579, with ISR, published Jul. 25, 2013 (28 pages).
 EP Application 13738060.6 European Patent Office Communication, with extended European Search Report, dated Jun. 8, 2015 (7 pages).
 PCT/F12009/050622 International Publication No. WO 2010/004094, with ISR, published Jan. 14, 2010 (28 pages).
 DeLuca, Carlos J., Surface Electromyography: Detection and Recording. Delsys, Inc, 2002.
 Mettingvanrijn, A.C. et al., Low-cost Active Electrode Improves the Resolution in Biopotential Recordings, Academic Medical Center, Medical Physics Department, Meibergdreef 15 1105 AZ Amsterdam, The Netherlands, Oct.-Nov. 1996.
 Marques, E.F., et al. Clinical Performance of a New Aspheric Dual-Optic Accommodating Intraocular Lens, Dove Press Journal, Clin Ophthalmology, Nov. 19, 2014.
 Bausch + Lomb, Crystalens Advanced Optics (AO) Accommodating IOL, WWW.bausch.com.
 Karavitaki, AE, et al. Long-term Visual Outcomes after Crystalens HD intraocular lens implantation, Clinical Ophthalmology, May 22, 2014.
 Larkin, Howard, Dual-Optic IOL, Eurotimes, vol. 16; Issue 5, 2011.
 U-M Kellogg Eye Center, Kellogg Resident Creates New Intraocular Power Source, www.kellogg.umich.edu, 2014.
 EW Supplement: Crystalens AO: Outstanding Vision Quality Across a More Natural Range; ASCRS—EyeWorld, Mar. 2012.
 EP 13 73 8060.6, Search Opinion & Supplementary EP Search Report, May 28, 2015.
 PCT/US2013/021663, International Preliminary Report on Patent-ability, Jul. 22, 2014.
 PCT/US2013/021663, International Search Report, Apr. 25, 2013.
 PCT/US2016/052400, International Search Report & Written Opinion, Dec. 29, 2016.
 WO 2010/004094 A1, Published Jan. 14, 2010, with ISR (28 pages).

* cited by examiner

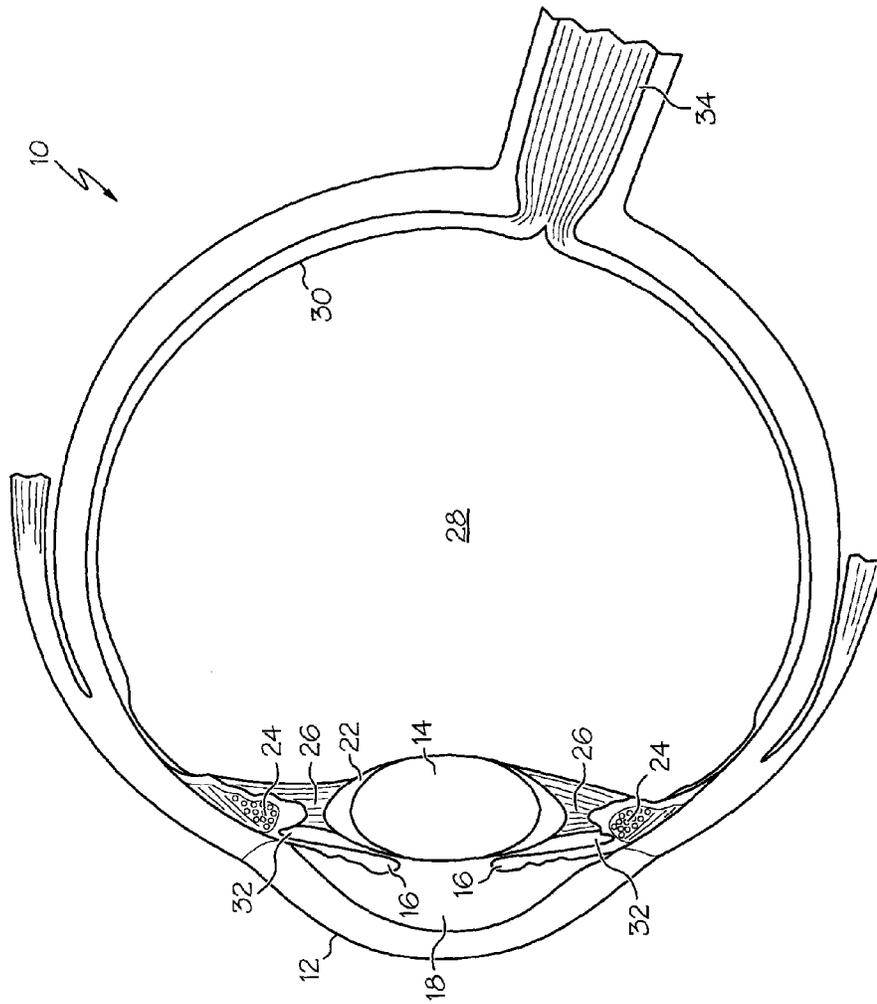


FIG. 1

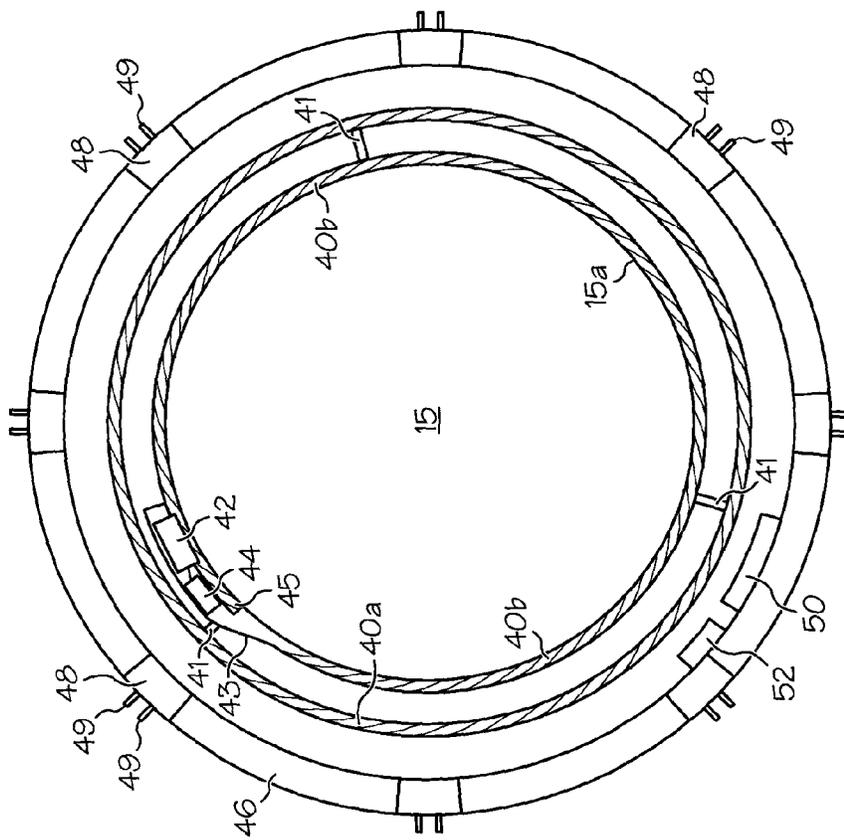
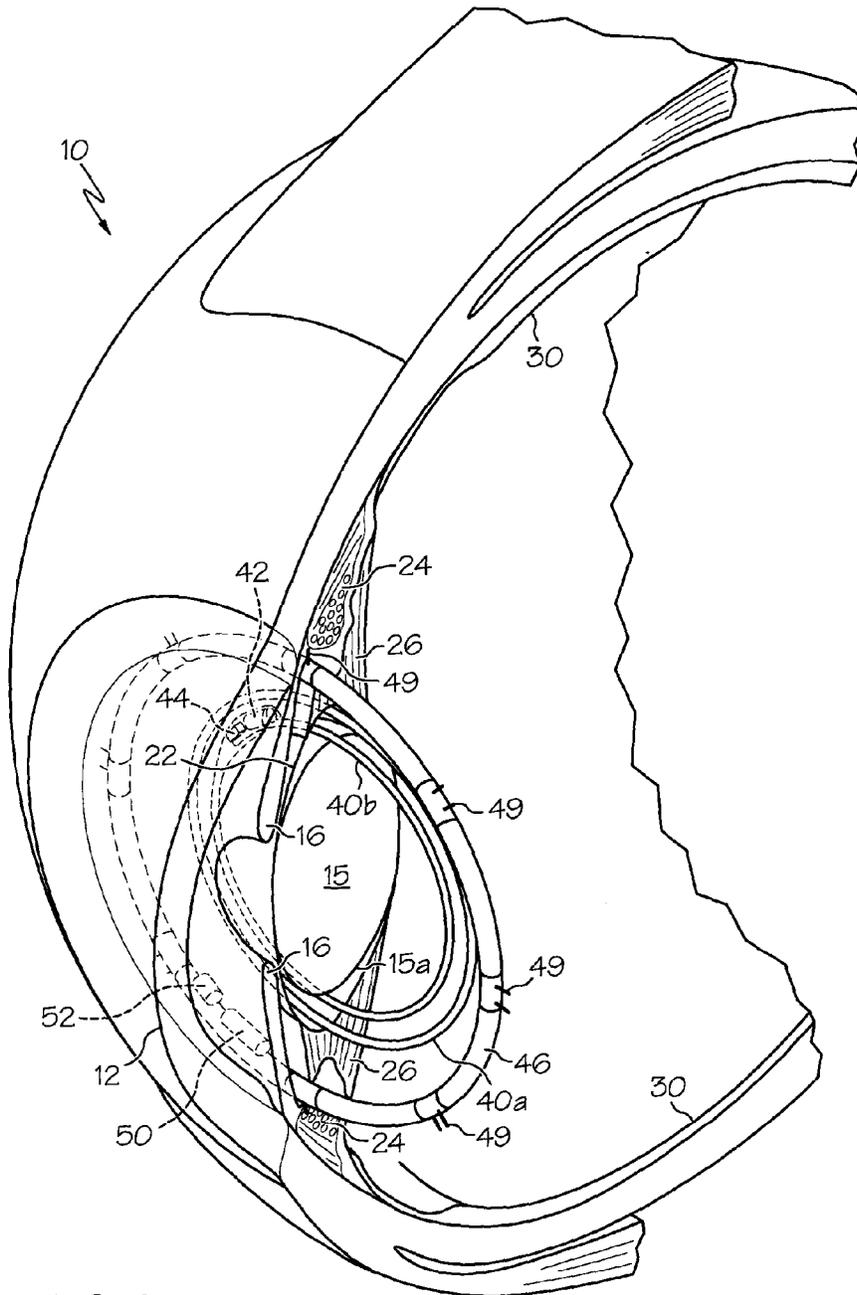


FIG. 2



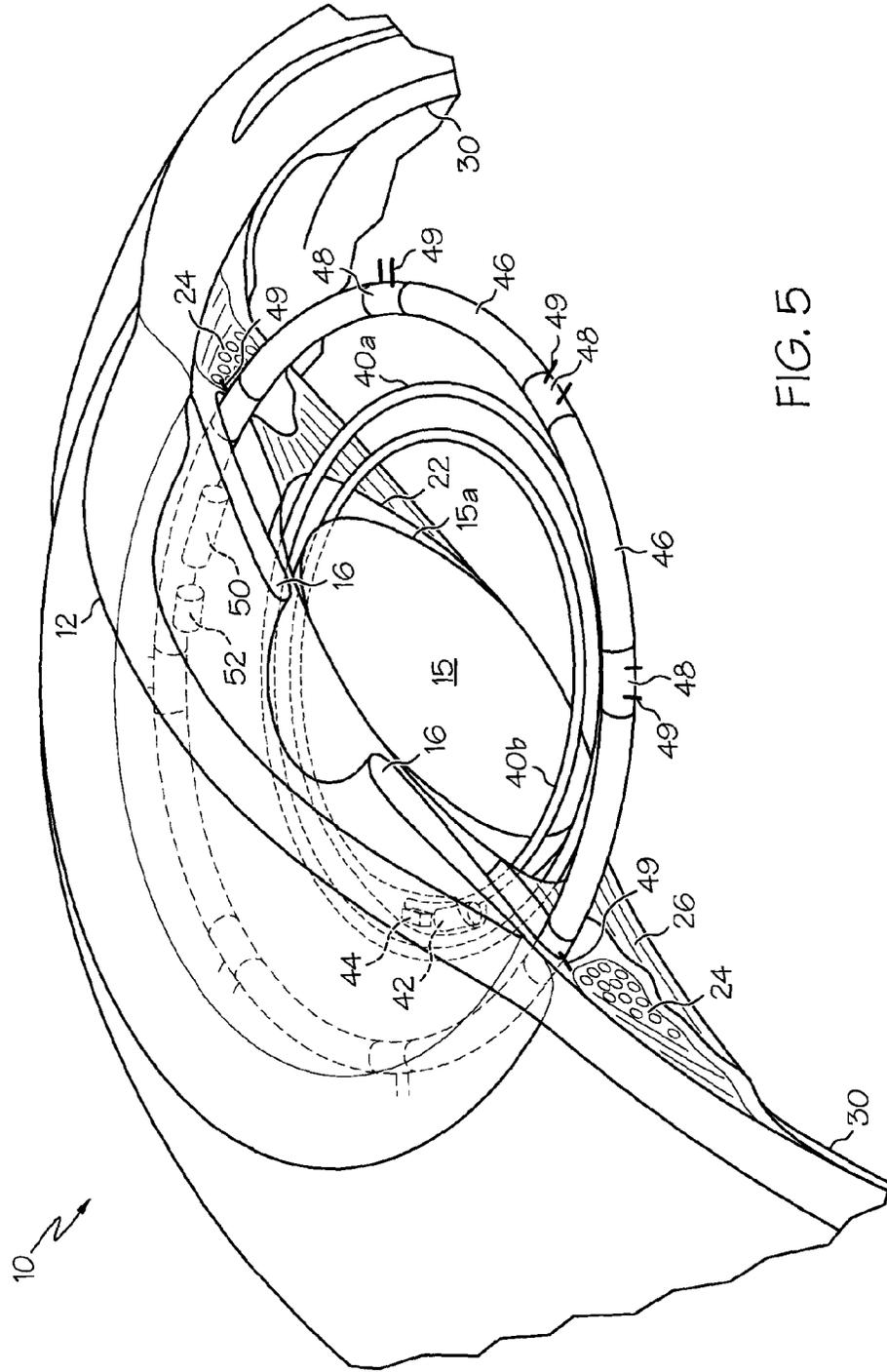


FIG. 5

ACCOMMODATING INTRA-OCULAR LENS SYSTEM

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

FIELD OF THE INVENTION

The present invention relates generally to the correction and/or cure of presbyopia, and more particularly to the reliable transduction of an accommodative impulse of the ciliary muscle to an accommodating intra-ocular lens (IOL).

BACKGROUND OF THE INVENTION

The human eye possesses natural accommodation capability, which involves relaxation and constriction of the circular ciliary muscle of the eye, and zonules controlled by the ciliary muscle, by the brain to provide the eye with near and distant vision. This ciliary muscle action is automatic, and varies the shape of the natural crystalline lens to an appropriate optical configuration for focusing light rays entering the eye on the retina. Ciliary muscle relaxation, which is the normal state of the muscle, shapes the human crystalline lens for distant vision. Ciliary muscle contraction deforms the lens for near vision, and the extent of contraction changes the focal length of the lens to the desired endpoint. This change in effective focal length in order to focus on nearby objects is known as accommodation.

Normally the human eye loses its ability to accommodate as individuals reach the age of 40. This condition, known as presbyopia, is typically due to a progressive loss in the elasticity of the lens of the eye, such that the ciliary muscle can no longer exert the necessary deformation of the lens' shape. In addition, the human eye is susceptible to disorders and diseases which attack the crystalline lens, such as cataracts.

Cataracts causing partial or complete blindness are typically treated by removing the crystalline lens and replacing it with an intra-ocular lens (IOL). While conventional IOL's have had great success at restoring vision, they have limited ability for accommodation. The conventional solution to the problem of presbyopia is a prescription for reading glasses or, for individuals who already require glasses to correct other refractive errors such as myopia or astigmatism, a prescription of bifocal or multifocal glasses. This is necessary for the subject's eye to have clear vision of objects at different distances.

Alternative attempts in the art to overcome presbyopia focus on providing implantable IOL's with accommodation ability. Accommodative IOL's have been introduced, for example, which change the shape of the IOL by physically deforming the lens to become more convex for focusing on nearby objects, similar to the way the body's natural crystalline lens focuses. Other accommodative IOL's work by moving the IOL along its optical axis within the orbit of the eye. However, synthetic IOLs implanted in subjects for the treatment of cataracts typically do not have the ability to change shape as do natural lenses. Thus, subjects with synthetic accommodating IOL's still have presbyopia and cannot adequately focus on proximate visual targets due to the reduced flexibility of the IOL relative to the tractive

capabilities of the ciliary muscle. Therefore, such subjects experience a degradation of their ability to accommodate.

It is believed that the neuromuscular activity of the ciliary muscle correlates with a person's effort to adjust the focus of the eye. Previously, enhancement of the physical movement of the ciliary muscle has been utilized for IOL accommodation. For example, U.S. Pat. No. 7,060,094 to Shahinpoor et al discloses a circularly distributed assembly of synthetic muscles in the form of mini-bridges for augmenting the contraction force of the ciliary muscle transmitted to the lens. However, it has been difficult to capture the action potential of the ciliary muscle and transfer it with enough force to cause IOL deformation, even when various multipliers such as micropumps or levers are used.

Other inventions aimed at improving the accommodative abilities of implantable IOLs include the following: U.S. Pat. No. 7,334,892 to Goodall et al discloses an adjustable lens system which detects a neural signal and then generates a control signal to drive actuation of an adjustable IOL.

U.S. Pat. No. 5,800,530 to Rizzo, III discloses an implantable and deformable IOL having microelectronic components implanted thereon, in which a micromotor controlled by a distance measuring apparatus changes tension in a band encircling the periphery of the lens to vary its focal length.

U.S. Pat. No. 5,203,788 to Wiley discloses micromotors powered by EMG or ultrasound to change the lens shape, in which each micromotor is responsive to an externally generated control signal for selectively changing the circumference and/or axial position of the lens. The changes made to the lens are not automatic and are not under the control of the subject.

U.S. Pat. No. 4,373,218 to Schacar discloses an expandable intra-ocular lens filled with liquid crystal material which could be activated by an electrical signal originated from the action potential of the ciliary muscle, sensed by an electrode which is sent to a microprocessor by miniature wiring.

While such prior art devices and methods for the surgical correction of presbyopia may be useful for their intended purposes, those developed to date have generally achieved limited success because they are unable to provide adequate accommodation when compared to a healthy natural crystalline lens, are too complex to be practical to construct, or fail to accurately and reliably focus on demand.

As such, it would be beneficial in the art to provide a system and method that provides an enhanced capacity for accommodation of implanted IOLs. It would also be beneficial to detect a signal, such as an action potential, created by the ciliary muscle and to convert this signal to activate micromotors and/or nanomotors implanted into the eye for creating accommodative forces. It would also be advantageous to mimic the force of contraction created by the ciliary muscle onto a native lens, thereby causing an accommodating shape change in an implanted IOL. It would also be advantageous to provide an IOL system that can detect and capture the action of the ciliary muscle and transfer it with enough force to cause adequate IOL deformation and accommodation.

SUMMARY OF THE INVENTION

The present invention relates to a device which causes a change in the shape of a compressible, accommodating intra-ocular lens (IOL) that has previously been implanted to replace the original crystalline lens of a subject, and which typically includes an internal deformable lens having an external membrane, as is known in the art. The IOL is

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coupled to a sensor, such as an electromyographic (EMG) receiver (or a series of EMG receivers), which detects a signal created by the ciliary muscle around the eye. The receiver then transmits the signal to a signal processor such as a transducer or microprocessor which generates an electrical signal. A transmitter then sends the resultant electrical signal to a micromotor which creates a force of contraction which acts on the IOL. The force of contraction created by the micromotor can mimic that created by the ciliary muscle onto a native lens, thereby causing a shape change in the IOL.

A first aspect of the invention provides a system for causing a change in the shape of a compressible, accommodating intra-ocular lens (IOL) of a subject, the system comprising: (a) an IOL complex comprising a compressible, accommodating IOL; (b) at least one sensor for detecting a signal from the subject's ciliary muscle; (c) a signal processor for receiving and processing the ciliary muscle signal to generate a corresponding electrical signal; (d) a transmitter for transmitting the electrical signal; and (e) at least one micromotor for receiving the transmitted electrical signal and causing a change in shape of the IOL.

A second aspect of the invention provides a system for causing a change in the shape of a compressible, accommodating intra-ocular lens (IOL), the system comprising: (a) an IOL complex comprising a compressible, accommodating IOL, an external lens membrane, and an annular support ring system for providing a means to cause a change in shape of the IOL; (b) at least one sensor for detecting a signal from the subject's ciliary muscle; (c) a microcomputer for modulating the ciliary muscle signal into an electrical signal; (d) a transmitter for transmitting the electrical signal; and (e) at least one micromotor for receiving the transmitted electrical signal and causing the annular support ring system to compress the IOL.

A third aspect of the invention provides a method for causing a change in shape of a compressible, accommodating intra-ocular lens (IOL) in a subject, the method comprising the steps of: (a) implanting at least one sensor for detecting a signal from a subject's ciliary muscle into an eye of the subject; (b) detecting a ciliary muscle signal with the at least one sensor; (c) transforming the ciliary muscle signal into an electrical signal; and (d) transmitting the electrical signal to at least one micromotor, wherein the micromotor causes a change in shape of an IOL upon receipt of the transmitted electrical signal.

The ciliary muscle signal can be in the form of a neuro-electrical impulse, a muscle action potential, a muscle contractile force, a chemical signal, or a combination of these means. The nature and advantages of the present invention will be more fully appreciated after reviewing the accompanying drawings, detailed description and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings illustrate embodiments of the invention and, together with a general description of the invention given above, and the detailed description given below, serve to explain the principles of the invention.

FIG. 1 is a side view illustrating the anatomy of the human eye.

FIG. 2 is a perspective frontal view of one embodiment of the system of the invention.

FIG. 3 is a partial cross-sectional view of the human eye showing the embodiment of FIG. 2 after implantation into the eye.

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FIG. 4 is a side view illustrating the embodiment of FIG. 2 as positioned within the human eye.

FIG. 5 is a partial cross-sectional view of the human eye showing the embodiment of FIG. 2 after implantation into the eye.

DETAILED DESCRIPTION OF THE INVENTION

As defined herein, the term "ciliary muscle" means a ring of striated smooth muscle encircling the eye that controls accommodation for viewing objects at varying distances. The ciliary muscle also regulates the flow of aqueous humor into Schlemm's canal, and has parasympathetic and sympathetic innervation. The terms "ciliary body" and "ciliary complex" are structures that include the ciliary muscle.

The term "ciliary muscle signal" means an action detected at the subject's ciliary muscle, and more specifically means an action relating to the ciliary muscle in the form of a neuroelectrical pulsation, a muscle action potential, a muscle contractile force or movement, a chemical signal, or a combination of these means. The ciliary muscle signal can be electrical/neuroelectrical or chemical/neurochemical in nature, or it can be initiated by mechanical movement of the ciliary muscle.

FIG. 1 illustrates a human eye 10, which has an anterior chamber 18 between the cornea 12 and iris 16, a posterior chamber behind the iris containing a bi-convex natural crystalline lens 14, a vitreous chamber 28 behind the lens 14 containing vitreous humor, and a retina 30 at the rear of the vitreous chamber 28. Light is focused by the eye 10 by being refracted through the cornea 12 and then refracted again through the lens 14 and upon the retina 30 for transmission to the brain by the optic nerve 34. The lens 14 is encased in a native lens capsule or capsular bag 22, which is attached about its equator or periphery to the ciliary muscle 24 by zonular fibers 26, called zonules of Zimm. Between the iris 16 and the ciliary muscle 24 is an annular crevice-like space called the ciliary sulcus 32.

While the cornea 12 provides a significant portion of the refractive power of the eye, the capacity for accommodation is primarily contributed by the lens 14, because of its inherent elastic properties. The inner ends of the zonules 26 are attached to the lens capsule 22, and the outer ends are attached to the ciliary muscle 24. The ciliary muscle 24 is part of a sphincter-like ciliary body, which opens when it is relaxed, thereby generating tension on the zonular fibers 26. The ciliary muscle 24 is relaxed in the unaccommodated eye, and the ciliary body therefore assumes its largest inner diameter, which in turn causes a tension on the zonules 26. In this state, the zonules 26 are caused to pull radially outward on the lens capsule 22, flattening and making the lens 14 less convex. Thus, when the ciliary muscle 24 is relaxed, the refractive power of the lens is relatively low and the eye is focused for clear vision of distant objects. The lens capsule 22 is comprised of membrane-like, elastic, optically clear anterior and posterior walls or capsules. When the ciliary muscle 24 contracts the lens capsule moves forward and inward, thereby relaxing the outward pull of the zonules 26 on the equator of the lens capsule 22 and reducing the zonular tension on the lens 14. The lens 14 becomes more rounded, so that the eye is focused for clear vision of nearby objects. Therefore, for near vision, the ciliary muscle contracts and releases tension on the zonular fibers 26, allowing the lens 14 to elastically rebound and thicken, and, in a manner of speaking, "relax" back to its more convex and spherical natural state.

Modern cataract surgery typically involves removing the cloudy contents of the eye's natural lens **14** while leaving the clear outer membrane or capsule **22** (also referred to as a capsular bag) to hold a new, artificial intra-ocular lens (IOL) in place. As illustrated in FIGS. 2-5, a synthetic IOL **15** intended for use in the present invention replaces the natural crystalline lens **14**. The IOL can be part of an IOL complex, which can include an internal compressible accommodating IOL **15** which incorporates a flexible, elastic external lens membrane **15a** about its periphery, and an annular support ring system **40**. The annular support ring system provides a means to cause a change in shape of the IOL. The annular support ring system typically consists of two (2) concentric, adjacent encircling elements: an outer annular support ring **40a** and an adjacent inner annular support ring **40b**. The inner annular ring **40b** encircles, and is attached to, the external lens membrane **15a**, which encases the IOL **15**. The IOL **15**, external lens membrane **15a** and the annular support ring system **40a**, **40b** are all positioned within the native capsular bag **22**, which previously encased the (now removed) natural crystalline lens **14** of FIG. 1. The capsular bag **22** and its supporting zonular ligaments **26** serve as a support structure for the IOL complex and the annular support ring system.

As illustrated in FIG. 2, the inner annular ring **40b** encircles the external lens membrane **15a** and provides a foundation/housing for a micromotor **42** to cause tightening/shortening of the inner annular support ring **40b**, which results in a change in shape of the IOL **15**. The micromotor **42** is typically powered by a miniaturized power source such as a rechargeable battery **44**. A ciliary sulcus ring **46**, which can be implanted in the ciliary sulcus **32** via intra-ocular endosurgery (now commonly and easily performed in a procedure called endocyclophotocoagulation), can communicate with the inner annular support ring **40b** via a transmitter **50** (FIG. 2). The ciliary sulcus ring **46** supports at least one and typically a series of ciliary muscle signal sensors **48**, illustrated here in the form of electromyographic (EMG) receivers for detecting ciliary muscle contraction. Each EMG receiver **48** can include contacts or miniaturized electrodes in the form of ciliary muscle probes **49**, typically in pairs, for entering the ciliary muscle **24** (FIG. 3). However, the invention can employ sensors known in the art that can detect a ciliary muscle signal by electrical/neuroelectrical means, chemical/neurochemical means, mechanical movement of the ciliary muscle, or a combination of these means.

Alternatively, the ciliary muscle signal sensors can be in the form of a first sensor positioned within the ciliary sulcus, typically on the ciliary sulcus ring **46**, and a companion sensor positioned on the outer annular support ring **40a**. Movement of the first sensor relative to the companion sensor provides the ability to detect ciliary muscle movement in response to the accommodative reflex. Further, a series of ciliary muscle sensors can be supported on both the ciliary sulcus ring **46** and the outer annular support ring **40a**, and the degree of movement of these sensors relative to one another can provide very sensitive means for detecting an accommodative signal from the ciliary muscle.

Looking at FIG. 2 it can be appreciated that the inner annular support ring **40b** houses the micromotor **42**. Activation of the micromotor **42** causes the inner ring **40b** to slide upon itself and tighten, thereby shortening the inner ring **40b** in both circumference and diameter and exerting a compressive force on the IOL **15** to change the IOL shape. The outer annular support ring **40a** can typically be manufactured to be more rigid and adapted to resist compressive,

fibrotic contraction forces of the native capsular bag **22**. Also, the outer annular ring **40a** can include attachments of optical, electrical or magnetic sensors (not shown) with corresponding sensors/receivers located on the ciliary sulcus ring **46**. The sensors on the ciliary sulcus ring **46** and the outer annular ring **40a** would allow detection of the ciliary muscle action by the relative movement of the two components (**40a,46**) during accommodation.

As noted above, modern cataract surgery typically involves removing the natural lens while leaving the clear outer capsule **22** to hold the new intraocular lens in place. The capsule **22** that remains has epithelial cells on it which can continue to produce lens fibers. These fibers cannot be laid down in an organized manner and will form little beads or "pearls" on the lens capsule **22**, forming a secondary membrane. When these pearls accumulate in the pupil, they cause a blurring of vision similar to that experienced with a cataract. This occurs approximately 30-40% of the time and can appear at any time after cataract surgery, even as much as five or more years later.

Thus, there is a risk that the surrounding capsular bag **22** will scar down, bind, compress, contract and otherwise reduce the effectiveness of a single annular ring. This can be avoided by employing a double ring system as disclosed above, which includes the outer annular support ring **40a** and the inner annular support ring **40b** of the present invention. With this double annular support ring configuration, the outer annular support ring **40a** can protect the inner annular support ring **40b** from the contractile forces of a fibrotic capsular bag **22**. For example, in FIG. 2 the outer ring **40a** is attached to the inner ring **40b** via attachment **41** near the location of the micromotor **42** and battery **44** housed on the inner ring **40b**. The annular support rings **40a** and **40b** can also be connected to one another by attachments **41** at intervals along their lengths as shown, if needed for stability, such as every one-third to one-fourth of the way around their circumference. The attachments **41** between the outer ring **40a** and the inner ring **40b** would likely be via mini-welds or clips.

As shown in FIG. 2, the inner ring **40b** includes a free end or distal portion **45** that can fit within the micromotor housing or proximal portion **43**, thereby allowing the distal end **45** to slide within itself at the proximal end **43**. The housing of the micromotor **42** is typically continuous with the proximal end **43** of the inner ring **40b**. This sliding of the inner ring **40b** within itself serves to decrease both the diameter and circumference of the inner ring **40b**, resulting in a compressive force being exerted upon the IOL. In the embodiment shown in FIG. 2 the inner ring **40b** is in a partially compressed position with the distal end **45** located to some extent within the proximal end **43** of the inner ring **40b**.

It should be noted, however, that the inner ring **40b** cannot have a connection or attachment at its sliding distal end **45** because then the distal end of the inner ring **40b** would not be able to slide into its proximal end **43**. That is, a sliding inner ring **40b** as described here must have a free, unattached segment at its distal end **45**, the amount determined by the degree of compression needed as the inner ring **40b** is shortened when it slides.

The outer ring **40a** not only can provide rigidity to the inner ring **40b** in the face of scarring, thereby protecting the inner ring, but as noted above it also can include sensors for detecting relative motion of the ciliary sulcus ring **46**. This will allow detection of ciliary muscle action by the relative movement of the two components (**40a, 46**) during accommodation. In this manner, a first sensor (or series of sensors)

can be positioned on the ciliary sulcus ring **46**, and a companion sensor (or series of sensors) can be located on the outer annular support ring **40a**, in order to detect relative motion of the ciliary sulcus ring **46** following ciliary muscle movement. Companion sensors can also be placed on the iris or other ocular tissue.

Looking again at FIG. 2, the ciliary muscle sensors **48** can be flat or tubular areas contiguous with the main body of the ciliary sulcus ring **46**, and can provide electrical, mechanical or chemical recognition of a ciliary muscle signal via miniaturized electrode probes or contacts **49**. A microcomputer and/or micropotentiometer **52** acts as a signal processor and modulates the ciliary muscle signal detected by the sensor **48** and converts it to an electrical signal. This electrical signal created by the microcomputer **52** is then sent to the micromotor **42** via the transmitter **50**. Typically a single microcomputer/transmitter system is needed for a ciliary sulcus ring **46**; however, it can be appreciated that it may become feasible to attach another set as backup in case of a failure of one of the components. The transmitter **50** can be directly wired to the micromotor **42**, or it can work via radio frequency (RF) transmission. The micromotor **42** then creates a tightening of the inner annular ring **40b**, and this tightening compresses the compressible IOL **15**.

As noted above, the ciliary muscle sensor **48** can be a myoelectrical sensor such as an EMG receiver known in the art for detecting muscle action potentials for taking clinical EMG measurements. With EMG-type sensors, miniaturized electrode probes or contacts **49** are incorporated onto the ciliary sulcus ring **46** and implanted into the ciliary muscle via intra-ocular endosurgery (i.e. via endocyclophotocoagulation). Known EMG electrodes or probes that may be useful as a sensor supported on the ciliary sulcus ring of the invention include those disclosed in U.S. Pat. No. 7,941,201 to Chiou et al., which is incorporated by reference herein in its entirety, disclosing a microprobe array structure suitable for electromyography which detects a neuroelectrical signal through skin.

The ciliary sulcus ring **46** is a generally circular ring which is implanted into the ciliary sulcus **32** of a subject. The ciliary sulcus ring **46** may be made of polymethylmethacrylate, with or without a collamer coating, or a combination of biocompatible metals having conductive plates. If a ciliary sulcus ring includes such conducting plates, the plates can serve as the sensors/EMG contacts **48**, and may include fine wire appendages as probes **49** for entering the ciliary muscle. The composition of the probes **49** should be a metal material or an alloy that is both biocompatible and conductive.

Regarding capturing ciliary muscle contraction by mechanical means rather than electrical means, there may be several ways of doing this. For example, a sensor could be fixed to any ocular tissue adjacent the ciliary muscle, near the ciliary sulcus ring, where the relative movement of the companion sensors would be maximized. This could include the outer annular support ring **40a**, but can also include the posterior iris base, the external sclera or episclera, or ciliary zonular fibers. Such sensors could detect the relative movement of a companion sensor located on the ciliary sulcus ring.

The diameter of the ciliary sulcus ring **46** may be changed by ciliary muscle contraction, which could be sensed by electrical methods within the ring itself. In one embodiment, the ciliary sulcus ring **46** can be fashioned as a complete circle. Alternatively, in order to facilitate insertion and/or movement, the ciliary sulcus ring can include a space or gap between the ends. Sensors on the ciliary sulcus ring **46** and

the outer annular ring **40a** would allow detection of the ciliary muscle action by the relative movement of these two components during accommodation.

The micromotor **42** activates the annular support ring system including the inner annular ring **40b** around the compressible IOL **15**. Since the micromotor **42** is responding to a signal which originated in the ciliary muscle, the action of the micromotor **42** converts the signal created by the ciliary muscle to act on the IOL, causing an accommodation change in the IOL shape. The motor mechanism can be via friction drive, or it can be a sealed, geared motor having a clutch/brake release. Such a micromotor/annular ring combination that may be useful in the present invention is that disclosed in U.S. Pat. No. 5,800,530 to Rizzo, III, incorporated herein by reference in its entirety, which changes tension in a band encircling the periphery of the lens to vary its focal length in response to a distance measuring apparatus. Also, newly developed motors such as piezoelectric motors having a simple, reversible, sliding action, or micromotors such as those disclosed in U.S. Pat. No. 7,309,943 to Henderson, or U.S. Pat. No. 7,795,782 to Wischniewskij et al. may be used, both of which are incorporated herein by reference in their entirety.

As noted above, the micromotor **42** causes the inner annular support ring **40b** to compress the IOL **15** and its external membrane **15a**, either through piezoelectric action or a geared mechanism. The inner annular ring **40b** can accomplish this by sliding upon itself, or into itself, if it is tubular as shown in FIG. 2, to tighten and overlap itself, thereby decreasing in both circumference and diameter. Regarding a tubular embodiment, the ring can be a tapered tube in which the circumference of the sliding end is smaller than the opposite end of the ring, so that the sliding, smaller end can fit inside the larger, stationary end as it slides; alternatively, the sliding end can be larger than the other end of the ring, so that the sliding end can envelop the stationary end as it slides.

The natural accommodative response involves a rapid ciliary muscle contraction, followed by sustained contraction until the accommodative effort is voluntarily released. The mechanisms are not completely understood, but there is presumably an ongoing, continued recruitment of components of the ciliary muscle, such that the ciliary muscle becomes "locked" into place until released. This natural accommodated state is easily maintained, generally without fatigue, until relaxation occurs. When released, the non-accommodated state is attained rapidly, typically in less than 1/2 sec. In light of this, it is preferred that the micromotor/annular ring combination of the present invention has the ability to release almost instantaneously to the non-accommodated state, and preferably within 0.1 seconds to 0.5 seconds, in order to match the natural speed of accommodation. That is, it is preferable that the inner ring **40b** quickly releases the lens **15** so that the lens can return to its original circumference soon after the inner ring **40b** undergoes shortening.

Typically the sensor **48**, the signal processor **52** and the micromotor **42** are powered by a rechargeable battery **44**. Power for the system can be obtained by long-lasting implantable batteries, such as miniature lithium-ion batteries and batteries having lives of up to 50 years, by light-charged batteries through the pupil, or by ciliary complex-activated or ciliary complex-charged batteries. Composite materials for electrochemical storage that may be useful in such a miniature, long-lasting, rechargeable battery of the present invention are disclosed in Published U.S. App. No. 2011/0177393 to Park et al., which is incorporated by reference

herein in its entirety. However, any source of electrical power known in the art can be used to run the system.

The method of implanting the device of the invention is technically difficult but can be successfully performed by a skilled ophthalmic surgeon. While the ciliary sulcus ring is relatively easy to implant, since it does not have to be a complete circle, the external annular ring 40a may initially have to include a detachable end that can be directed through a small incision for placement, and then clipped together, making it a complete, rigid circle. The inner ring 40b of course needs to be more flexible so it can be deformed to pass through a 3-5 mm incision. Thus, the inner annular ring 40b, the lens 15 and the flexible membrane 15a can be collapsed and the lens filled by cannula with a low-viscosity refractive polymer after the insertion. After the inner ring and lens complex is inserted, the detachable ends of the outer ring 40a are then clipped together, and the now circular outer ring 40a is then clipped onto the inner ring 40b. Both rings 40a, 40b are typically individually inserted into the anterior chamber, anterior to the iris, and subsequently the entire complex including the rings 40a and 40b and the lens elements 15 and 15a can be easily slipped into the native capsular bag.

In another embodiment of the invention, a thin acrylic circular plate can be implanted first onto the back surface of the native capsular bag 22 prior to implanting the other components of the IOL complex, and would serve as a platform to the other parts of the IOL complex which would be implanted anterior to the acrylic plate. This is done in case a YAG (Yttrium Aluminum Garnet) laser capsulotomy would need to be done due to a secondary cataract. As noted above, continued epithelial proliferation and fibrosis of the lens capsule 22 is a common occurrence with IOLs following cataract surgery. A YAG laser capsulotomy can easily clear the blurred vision produced by a scarred capsular bag 22. The placement of an acrylic circular plate onto the back surface of the native capsular bag 22 would protect the thin, flexible, posterior portion of the external IOL membrane 15a from rupture.

Alternatively, in another embodiment of the invention, the posterior surface of the IOL 15 itself can be made of acrylic. In this embodiment, the posterior surface of the IOL has a fixed curvature, and only the anterior portion of the external IOL membrane 15a is flexible enough to alter the power of the lens 15. These concepts arise because, although some materials are resistant to the YAG pulses, a highly flexible membrane such as that intended for the external IOL membrane 15a may not be. Thus, it is believed that if sufficient compression and shape change of the IOL 15 can be accomplished with only the anterior portion of the external IOL membrane 15a, the posterior portion can be acrylic, which is currently the material commonly used for fixed IOLs.

Taking this concept one step further, another embodiment of the invention can include two separate acrylic plates, one acting as a posterior portion of the lens and the other as the anterior lens. These acrylic plates can replace the IOL 15 (which is typically a fluid- or copolymer-filled bag) and its surrounding flexible membrane 15a. However, the posterior and anterior plates can be connected by a circumferential flexible membrane similar to the IOL membrane 15a, wherein the membrane is acted upon by an intervening movable dual annular support ring system, as described above for the present invention. The acrylic refractive surfaces can be separated by the annular support ring system, and the distance between the plates (lenses) can be changed by the micromotor/ring system, for example by causing the

anterior, forward plate to shift forward, thereby adjusting the focus. Examples of inventions utilizing this dual plate technology are disclosed in U.S. Pat. No. 7,118,596 to Zadno-Azizi at al., and U.S. Pat. No. 7,198,640 to Nguyen, both of which are incorporated by reference herein in their entirety.

The present invention utilizes recent advances in micro-technology, including micromotors and/or nanomotors, to convert signals created by the ciliary muscle into contractile forces acting on an implanted IOL. Other advantages of the invention include easy implantability, exceptional optical characteristics, high accommodative range, and excellent natural controllability of refractive effect by accommodative effort and resistance to the natural fibrotic and proliferative forces of the healing capsular bag and intra-capsular epithelium.

While the present invention has been illustrated by the description of embodiments thereof in considerable detail, it is not intended to restrict or limit the scope of the appended claims to such detail. Additional advantages and modifications will be readily apparent to those skilled in the art. Accordingly, departures may be made from such details without departing from the scope or spirit of the invention.

What is claimed is:

1. A system for causing a change in the shape of a compressible, accommodating intra-ocular lens (IOL) of a subject, the system comprising:

- a) an IOL complex comprising a compressible, accommodating IOL;
- b) at least one sensor for detecting a signal from the subject's ciliary muscle;
- c) a signal processor for receiving and processing the ciliary muscle signal to generate a corresponding electrical signal;
- d) a transmitter for transmitting the electrical signal; [and]
- e) at least one micromotor for receiving the transmitted electrical signal and causing a change in shape of the IOL, the IOL complex further comprising an external lens membrane and an annular support ring system for providing a means to cause a change in shape of the IOL, wherein the annular support ring system comprises two concentric rings including an outer annular ring and an inner annular ring, the outer annular ring being rigid for resisting compressive forces of the native capsular bag, the inner annular ring encircling the external lens membrane and providing a foundation for the at least one micromotor to cause a change in shape of the IOL; and
- f) a ciliary sulcus ring adapted for implantation in the ciliary sulcus of the subject and adapted to be positioned around the IOL complex.

2. The system of claim 1, wherein the at least one micromotor causes a change in shape of the IOL by causing the inner annular ring to shorten in circumference and diameter about the IOL, thereby compressing the IOL.

3. The system of claim 1, [further including a ciliary sulcus ring adapted for implantation into the ciliary sulcus of the subject,] wherein the at least one sensor is an electromyography (EMG) receiver for detecting the muscle action potential of the ciliary muscle, the EMG receiver being positioned on the ciliary sulcus ring and having miniaturized electrodes for implanting into the ciliary muscle.

4. The system of claim [3] 1, wherein the at least one sensor is a series of EMG receivers positioned about the ciliary sulcus ring, and wherein the signal processor and the transmitter are also positioned about the ciliary sulcus ring.

5. The system of claim 1, wherein the ciliary muscle signal [comprises] is in a form comprising a signal selected

from the group consisting of a neuro-electrical pulsation, a muscle action potential, a muscle contractile force or movement, and a chemical signal, *or a combination of these signal forms.*

6. The system of claim 1, wherein the signal processor is selected from the group consisting of a micropotentiometer and a microcomputer.

7. [A] *An implantable system for [causing a change in the shape of a compressible, accommodating intra-ocular lens (IOL),] correction of presbyopia, the system, implantable at an eye of a subject, comprising:*

a) [an IOL complex comprising a compressible, accommodating IOL, an external lens membrane, and an annular support ring system for providing a means to cause a change in shape of the IOL] *a synthetic intra-ocular lens (IOL) sized and configured for implantation at an eye of a subject;*

b) at least one sensor *configured* for detecting a ciliary muscle signal from [the subject's] *a ciliary muscle, the signal detected at an eye of a subject;*

c) a microcomputer for modulating the ciliary muscle signal into an electrical signal, *the electrical signal used for IOL accommodation;*

[d] *a transmitter for transmitting the electrical signal; and*
e) at least one micromotor for receiving the transmitted electrical signal and causing the annular support ring system to compress the IOL, *the system further including]*

d) *a ciliary sulcus ring for implanting into the ciliary sulcus of a subject, the ciliary sulcus ring adapted for supporting at least one [of the at least one] sensor, the ciliary sulcus ring configured to pass through an incision in the eye of a subject and configured to be proximate to the IOL when implanted at the eye of a subject such that the microcomputer can receive wired or wireless communications from the at least one sensor.*

8. The system of claim 7, wherein the at least one sensor is an electromyography (EMG) receiver *configured* for detecting the muscle action potential of the ciliary muscle, the EMG receiver being positioned on the ciliary sulcus ring and having miniaturized electrodes for implanting into the ciliary muscle.

9. The system of claim 8, wherein the at least one sensor is a series of EMG receivers positioned about the ciliary sulcus ring.

10. The system of claim 7, *wherein*

the ciliary sulcus ring is part of an annular support ring system adapted to cause a change in focus of the IOL, wherein the annular support ring system comprises two concentric rings including an outer annular ring and an inner annular ring, the outer annular ring being rigid for resisting compressive forces [of the native capsular bag, the inner annular ring encircling the external lens membrane and providing a foundation for the at least one micromotor to cause a change in shape of the IOL] developed at a target implant site.

11. The system of claim 10, [further including a ciliary sulcus ring for implanting into the ciliary sulcus of a subject, and] wherein the at least one sensor includes a first sensor positioned on the ciliary sulcus ring and [a companion sensor] *at least one companion sensor* located on the outer annular support ring.

12. The system of claim 11, wherein the first sensor is a series of sensors and the companion sensor is a series of sensors.

13. *The system of claim 7 wherein the ciliary sulcus ring is a complete circle or is not a complete circle.*

14. *A system for causing a change in the shape of a compressible, accommodating intra-ocular lens (IOL), the system comprising:*

an (IOL) complex comprising a compressible, accommodating IOL, an external lens membrane, and an annular support ring system for providing a means to cause a change in shape of the IOL;

at least one sensor positioned on a ciliary sulcus ring, the sensor for detecting a ciliary muscle signal from a subject's ciliary muscle at an eye of the subject;

a microcomputer for modulating the ciliary muscle signal into an electrical signal;

a transmitter for transmitting the electrical signal; and

at least one micromotor for receiving the transmitted electrical signal and causing the annular support ring system to compress the IOL, wherein the annular support ring system comprises two concentric rings including an outer annular ring and an inner annular ring, the outer annular ring being rigid for resisting compressive forces of an implant subject's native capsular bag, the inner annular ring encircling an implant subject's external lens membrane when implanted and providing a foundation for the at least one micromotor to cause a change in shape of the IOL.

15. *A system for transduction of an accommodating signal of a ciliary muscle to an accommodating intraocular lens, the system comprising:*

one or more ciliary muscle accommodating signal sensors,

one or more of the sensors configured to detect a ciliary muscle accommodating signal, the accommodating signal reflected in the form of a neuro-electrical pulsation, a muscle action potential, a chemical signal or a combination thereof,

the one or more ciliary muscle accommodating signal sensors positioned on a ring, the ring configured to surround an intraocular lens, and configured to permit placement of the ring through an incision in the eye of a patient.

16. *The system of claim 15 wherein the signal sensors are sized to be implanted in the eye of a patient and wherein the ring is circular.*

17. *The system of claim 15 wherein the signal sensors are sized to be implanted in the eye of a patient and wherein the ring is a complete circle or is not a complete circle.*

18. *The system of claim 15 wherein the accommodating signal is reflected in the form of at least one of: a neuro-electrical pulsation or a muscle action potential or a chemical signal.*

19. *The system of claim 15 wherein one or more of the signal sensors are positioned about an implantable synthetic intra ocular lens (IOL).*

20. *The system of claim 15 further comprising: a plurality of muscle probes, the muscle probes positioned and sized for contact with a ciliary muscle of a patient when implanted in the eye of a patient.*