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(54) Title: VISUAL ENHANCEMENT THROUGH REFRACTIVE PUPILLARY CONTROL

(57) Abstract: A method for improving visual acuity of a patient is provided. The method includes fixing to an eye of the patient an active element so as to be capable of controlling an amount of light entering the eye. An electrical signal is applied to the active element, typically so as to modulate a diameter of the pupil of the eye.

VISION ENHANCEMENT THROUGH REFRACTIVE PUPILLARY CONTROL

Field Of The Invention

The present invention relates generally to the improvement of vision, and specifically to invasive methods and apparatus for improvement of visual acuity.

background of the invention

Because of the importance of vision in enabling people to interact with their environment, significant efforts are continually being made to improve eyesight and to correct or compensate for physiological conditions which reduce visual acuity. Other than in instances of traumatic damage to the eye, most of the more common factors which reduce visual acuity are inherent in the physiology of the eye of the individual. Widespread vision problems such as myopia (nearsightedness), hyperopia (farsightedness), presbyopia (inability to focus properly for near vision), and astigmatism (uneven focus in different meridians) are caused by conditions of the eye which are present at birth, or by those which slowly develop with aging, lifestyle, or the environment in which the individual lives and works.

For most of recorded history, people were limited to the visual acuity inherent in the physiology of their own eyes. With the increase of mankind's knowledge of optics, corrective lenses were developed which, when placed in front of the eye, could compensate for natural deficiencies of the ocular system. Further development led to more sophisticated corrective lenses, such as bifocals and trifocals, in order to compensate for varying refraction of an eye at different distances.

Eyeglasses, although a significant step in the improvement of vision, suffer from deficiencies such as discomfort due to improper fit and weight, dislodgement, and other drawbacks. As a result of these shortcomings, efforts were made to develop lenses which would fit directly onto the eye. Contact lenses were thus introduced in the 1940's, and over the next several decades, the physical size of contact lenses was reduced. Ongoing improvements in material technology have led to lenses which are lighter, smaller, softer and more suitable to different eye shapes and conditions. Contact lenses typically require more care than eyeglasses, however, and are generally only suitable for those patients with the coordination, education, and discipline to safely adhere to their instructions for use.

Eye surgery is yet another method used to correct defects in visual acuity. To a large extent, surgical correction of the refractive properties of the eye involves making modifications in the cornea and lens. These techniques include radial keratotomy, lamellar refractive surgery, and phakic IOL implantation. Radial keratotomy is a surgical operation on the cornea for the correction of myopia, which involves flattening the central cornea through the making of a series of incisions in a radial pattern resembling the spokes of a wheel. Lamellar refractive surgery involves the removal of corneal tissue, so as to reduce the extent of the cornea's curvature. This, in turn, reduces the refractive effect of the cornea, typically resulting in at least partial correction of myopia, hyperopia, and astigmatism. The first technique developed in this area was myopic keratomileusis (MKM), which had certain drawbacks that were corrected by the development of better techniques and instrumentation. More recently, advances in computer technology have lead to a device which is essentially an automated scalpel, and was used in a surgical procedure called automated lamellar keratoplasty (ALK).

Another surgical procedure for corrective eye surgery is the excimer laser technique, in which the surface of the cornea is irradiated by a laser beam. The beam is controlled to etch away surface corneal tissue and to alter the curvature of the cornea, in order to treat myopia, hyperopia, and astigmatic conditions. Yet another surgical procedure is laser assisted intrastromal keratomileusis (LASIK). In this procedure, laser light is used to sculpt the cornea's interior, so as to obtain a modified corneal curvature. LASIK is typically used to correct hyperopia, myopia, or astigmatism.

The lens of the eye has also been the subject of research, leading to the development of various surgical and implantation techniques for the correction of vision. US Patents 4,373,218 to Lieberman et al., 4,816,031 to Pfoff, 5,171,266 and 5,108,429 to Wiley et al., 5,800,530 to Rizzo, 4,601,545 to Kern, 4,373,218 to Schachar, and 5,728,155 to Anello, which are incorporated herein by reference, describe methods and apparatus for implanting and adjusting intraocular lens assemblies (IOLs) for refractive purposes.

The eye is a particularly sensitive organ, and the space available for placement of instrumentation and devices is extremely limited. Therefore, the introduction and growth in the last half century of technologies and techniques such as electronics, microelectronics, solid state devices, micro-miniaturization and laser technology have played a significant role in the

development and implementation of apparatus for improving vision. Thus, for example, some of the cited US patents incorporated herein include miniaturized electromechanical circuitry, micromotors, micro DC storage cells, microsolar power cells, microprocessors, thermionic devices, optically-active molecular materials, magnets, piezoelectric devices, and other apparatus, which are shown to be feasible for use in the eye as components of systems designed for vision improvement.

Recently, major innovations have occurred in the approach to understanding the physiology of vision. These have arisen from the ability to apply new and more accurate techniques for measuring optical aberrations in an eye, and, in turn, to apply known technologies to eliminate the effects of these aberrations. Wavefront sensors, for example, are used to measure the aberrations in the eye, and adaptive optics are applied to minimize the aberrations and thereby improve visual resolution.

Higher order optical aberrations that are present mainly in the mid-periphery area of the cornea, in the lens, and in the retina, have been found to occur even in the eyes of people whose vision is satisfactory enough not to require corrective lenses or other vision aids. Elimination of these higher order aberrations will enable vision improvement above the level of 20/20, which has until now been considered the optimal level achievable in most of the population. Modification of the optics associated mainly with the mid-periphery area of the cornea can be accomplished in several ways. The shape of the cornea can be modified by the laser methods previously described. This approach, however, has a number of inherent drawbacks. For example, the required accuracy of corneal ablation is on the order of several microns, and the effect of the treatment may be lost or unpredictably distorted because treated areas tend to thicken in the process of recovery from surgery. Another potential problem is that correction of distance vision causes an increase in near vision aberrations that may seriously affect visual acuity after accommodation, thus having a deleterious effect upon near and mid-distance vision. Pharmaceuticals are commonly used to cause changes in pupil size for diagnostic and therapeutic purposes. Mydriatics and cycloplegics are used for pupillary dilation, and miotics are used to induce constriction. The effect of these pharmaceuticals varies depending on the physiological condition of the eye. For example, differences in eye color or age of the patient produce

corresponding differences in the extent and duration of the change in the pupil's diameter. In addition, the effect of the applied pharmaceutical diminishes in a non-linear way with time. US Patent 5,824,072 to Wong, which is incorporated herein by reference, describes the use of biocompatible ocular implants to provide long-term sustained release of a pharmaceutical product.

US Patent 5,481,393 to Kashima et al., which is incorporated herein by reference, describes a pupil modulation optical system, which includes passive filters and lenses to achieve contrast enhancement or other effects.

summary of the invention

It is an object of some aspects of the present invention to provide improved apparatus and methods for enhancing visual acuity.

It is also an object of some aspects of the present invention to provide apparatus and methods for resolving vision difficulties caused by higher order optical aberrations.

It is a further object of some aspects of the present invention to provide apparatus and methods for accurate regulation of the diameter of the pupil.

It is yet a further object of some aspects of the present invention to provide apparatus and methods which enable controlled pupillary response to variations in ambient lighting conditions.

It is still a further object of some aspects of the present invention to provide apparatus and methods for controlling pupillary dilation and constriction which can be adapted to a particular physiological condition of a patient's eye.

It is also an object of some aspects of the present invention to provide apparatus and methods for controlling pupillary dilation and constriction responsive to an environmental condition.

It is an additional object of some aspects of the present invention to provide apparatus and methods which enable regulation of pupillary diameter for controllable time periods.

It is yet an additional object of some aspects of the present invention to provide surgically implantable and/or surgically removable apparatus, and methods for using the apparatus, in order to enable regulation of pupillary diameter.

It is yet an additional object of some aspects of the present invention to provide implantable apparatus which can be activated following implantation to control pupil diameter, and which can also be deactivated while still implanted.

It is still an additional object of some aspects of the present invention to provide apparatus and methods for programmably regulating pupillary diameter.

In preferred embodiments of the present invention, apparatus for improving visual acuity comprises one or more active elements, which are implanted in the eye, and a control unit which actuates the active elements so as to constrict or dilate the pupil. Alternatively or additionally, the desired improvements in visual acuity are achieved by other means. For example, the active elements may comprise a diaphragm with a hole of variable size passing therethrough. The control unit preferably modulates the diameter of the hole in order to achieve analogous optical effects to those which occur responsive to changes in pupillary diameter. Alternatively, the active elements comprise a pharmaceutical substance able to modulate pupillary diameter, and the control unit or another mechanism regulates the release of the substance in order to actively control pupillary diameter. In many applications, the elements are actuated to constrict the pupil in order to minimize aberrations in the patient's vision. Use of these embodiments typically yields significant improvements in the patient's near and far vision.

Although many embodiments of the present invention are described herein with respect to constricting the patient's pupil, the scope of the present invention includes applying analogous techniques, mutatis mutandis, in order to dilate the pupil. For example, in older patients, the pupil is often excessively constricted, thereby preventing sufficient light from striking the retina and decreasing the quality of the patient's vision. Similarly, it is to be understood that pupillary constriction and dilation may not necessarily preserve the typically circular shape of the pupil. Asymmetrical constriction or dilation may, in some instances, be an unintended but harmless result of the use of a relatively small number of active elements. For some applications, however, asymmetrical pupillary shape changes may be intentionally induced.

It is also to be appreciated that although some preferred embodiments of the present invention are described, by way of illustration and not limitation, with respect to modifying the diameter of the pupil itself, the scope of the present invention also includes other optically analogous means, such as implanted diaphragms, active contact lenses, and other apparatus

which a person of ordinary skill in the art would think to use having read the disclosure of the present patent application.

Typically, the active elements are regulated by the patient by means of a user control device, located, for example, on the patient's watch. The patient is preferably enabled to press buttons on an interface unit of the control device in order to instruct the control unit to actuate the elements to cause pupillary constriction or dilation, or to terminate or otherwise modify the operation of the active elements. Further preferably, the patient can direct the control unit to apply varying levels of pupillary constriction, e.g., in steps of 0.1 mm, until a desired level of focus is achieved.

Alternatively or additionally, the control unit operates in an automatic mode, modulating the diameter of the pupil based on a schedule programmed into a memory of the control unit. For some applications, the control unit modulates the pupillary diameter based on other factors, such as a detected ambient light level, a change in ambient lighting, or a change in a physiological condition of the patient. For example, the control unit may be programmed to determine the onset and termination of the patient's sleep periods, or changes in the patient's heart rate or focus. In some preferred embodiments of the present invention, the user control device is calibrated and intermittently recalibrated by the patient's ophthalmologist, in order to ensure that the control parameters are appropriate to the physiological and optical characteristics of the eye of the patient. Moreover, if the ophthalmologist deems it appropriate, the active elements may intermittently be replaced with other active elements, or removed entirely at the end of a treatment period. This is in clear contrast to many surgical vision treatment techniques, the effects of which are generally irreversible once performed.

There is therefore provided, in accordance with a preferred embodiment of the present invention, a method for improving visual acuity of a patient, including:

fixing to an eye of the patient an active element so as to be capable of controlling an amount of light entering the eye; and

applying an electrical signal to the active element.

Preferably, applying the electrical signal to the element includes configuring the signal to change a mechanical disposition of the element. Alternatively or additionally, applying the

electrical signal to the element includes driving current through the element into tissue of the patient so as to induce modification of a state of a muscle.

In a preferred embodiment, fixing the active element to the eye includes incorporating into the active element a pharmaceutical substance capable of modulating a diameter of the pupil.

In another preferred embodiment, fixing the active element to the eye includes fixing to the eye an element having an aperture through which light may pass when the element is fixed to the eye. Preferably, applying the electrical signal to the active element includes configuring the electrical signal such that application thereof reduces an effective size of the aperture.

For some applications, the method includes removing the element from the eye subsequent to a treatment period.

Fixing the element to the eye typically includes implanting the element in the eye. For example, implanting the element in the eye may include implanting the element in contact with the iris of the eye. Moreover, fixing the element to the eye typically includes fixing the element so as to be capable of controlling a diameter of the pupil of the eye. In a preferred application, fixing the element to the eye includes fixing the element to the eye so as to be capable of constricting the pupil. Alternatively or additionally, fixing the element to the eye includes fixing the element to the eye so as to be capable of dilating the pupil.

Preferably, the method includes:

receiving a sensor signal; and

analyzing the sensor signal,

wherein applying the electrical signal includes applying the electrical signal responsive to the analysis.

In a preferred embodiment, receiving the sensor signal includes measuring an amount of light entering the eye. Alternatively or additionally, receiving the sensor signal includes receiving the sensor signal responsive to a physiological characteristic of the patient. Thus, for example, analyzing the sensor signal may include determining an onset of sleep of the patient or determining a change in a level of focus of the eye. For some applications, analyzing the sensor signal includes analyzing a change in an ambient light level.

Typically, the method includes receiving an instruction from the patient, wherein applying the electrical signal to the element includes applying the electrical signal responsive to the instruction. Preferably, receiving the instruction includes receiving a designation of a time, and applying the electrical signal includes applying the signal responsive to the designation of the time. Alternatively or additionally, receiving the instruction includes receiving a designation of a desired change in a level of the electrical signal, and applying the electrical signal includes modifying the signal responsive to the designation of the change in the level.

There is further provided, in accordance with a preferred embodiment of the present invention, apparatus for improving visual acuity of a patient, including:
at least one electrically-controlled active element adapted to be fixed to an eye of the patient so as to be capable of controlling an amount of light entering the eye; and
a control unit, adapted to apply an electrical signal to the active element.

In a preferred embodiment, the active element includes an electrode adapted to be coupled to muscle tissue of the eye.

Alternatively or additionally, the active element includes a pharmaceutical substance capable of modulating a diameter of the pupil.

Further alternatively or additionally, the active element includes a contact lens.

Still further alternatively or additionally, the active element includes a diaphragm having an aperture adapted to permit passage of light therethrough when the element is fixed to the eye, and the control unit is adapted to modulate the electrical signal applied to the active element so as to regulate a level of the light.

Yet further alternatively or additionally, the active element includes a band adapted to be mechanically coupled to induce constriction of the pupil of the eye responsive to the electrical signal.

Alternatively or additionally, the active element includes an electromagnet.

In a preferred embodiment, the active element is adapted to be removed from the eye subsequent to a treatment period.

For some applications, the active element is adapted to change a mechanical disposition thereof responsive to application of the electrical signal, so as to apply a force to the eye. For example, the active element may include a piezoelectric element, an inductive coil, an

electrically-sensitive polymer, or a solenoid. Optionally, the active element may include first and second elements, and the control unit may be adapted to apply the electrical signal so as to generate a magnetic field between the first and second elements that changes a disposition of the first and second elements with respect to each other.

In a preferred embodiment, the active element includes an inflatable member including a fluid (e.g., a liquid or a gas), and wherein the active element is adapted to change the mechanical disposition thereof responsive to a change in pressure of the fluid.

Preferably, the active element is adapted for implantation in the eye, for example, in contact with the iris of the eye. Typically, the active element is adapted to modify a diameter of the pupil of the eye responsive to the electrical signal.

In a preferred embodiment of the present invention, the apparatus includes a sensor adapted to generate a sensor signal, the control unit is adapted to apply the electrical signal responsive to the sensor signal. For example, the sensor may be adapted to measure an amount of light entering the eye. Alternatively or additionally, the control unit may be adapted to apply the electrical signal responsive to a change in an ambient light level.

For some applications, the sensor is adapted to sense a physiological characteristic of the patient. For example, the sensor may include an electromyographic electrode. Alternatively or additionally, the sensor is adapted to generate the sensor signal responsive to a level of focus of the eye.

In a preferred embodiment, the apparatus includes a user control device, adapted to receive an instruction from the patient, and the control unit is adapted to apply the electrical signal to the active element responsive to the instruction. For example, the user control device may be adapted to receive from the patient a designation of a time, and the control unit may be adapted to apply the electrical signal responsive to the designation of the time. Alternatively or additionally, the user control device is adapted to receive a designation of a desired change in a level of the electrical signal, and the control unit is adapted to modify the electrical signal responsive to the designation of the change in the level.

There is still further provided, in accordance with a preferred embodiment of the present invention, apparatus for improving visual acuity of a patient, including:

at least one active element adapted to be fixed to an eye of the patient so as to be capable of controlling an amount of light entering the eye; and

a control unit, adapted to generate a magnetic field which modifies a disposition of the active element.

There is yet further provided, in accordance with a preferred embodiment of the present invention, a method for improving visual acuity of a patient, including:

fixing to an eye of the patient an active element so as to be capable of controlling an amount of light entering the eye; and

generating a magnetic field which modifies a disposition of the active element.

There is also provided, in accordance with a preferred embodiment of the present invention, a method for improving visual acuity, including:

making a dose of a pupil-modulating pharmaceutical substance which engenders a desired change in visual acuity of an eye to which the substance is applied; and

providing the dose for administration to a patient so as to modulate a diameter of a pupil of an eye of the patient, thereby changing visual acuity of the eye of the patient.

There is additionally provided, in accordance with a preferred embodiment of the present invention, a method for improving visual acuity of a patient, including:

fixing to an eye of the patient an active element so as to be capable of controlling a diameter of the pupil of the eye; and

applying a signal to the active element.

There is still additionally provided, in accordance with a preferred embodiment of the present invention, apparatus for improving visual acuity of a patient, including:

at least one active element adapted to be fixed to an eye of the patient so as to be capable of controlling a diameter of the pupil of the eye; and

a control unit, adapted to apply a signal to the active element.

There is yet additionally provided, in accordance with a preferred embodiment of the present invention, apparatus for treating glaucoma of a patient, including:

at least one active element adapted to be fixed to an eye of the patient in a vicinity of the iridocorneal angle; and

a control unit, adapted to apply a signal to the active element configured such that the active element applies a force to the eye responsive to the signal.

In a preferred embodiment, the active element includes at least one electromagnet. Preferably, the control unit is adapted to configure the signal such that the active element applies the force to open trabecular meshwork of the eye responsive to the signal.

There is also provided, in accordance with a preferred embodiment of the present invention, a method for treating glaucoma of a patient, including:

fixing to an eye of the patient in a vicinity of the iridocorneal angle at least one active element; and

applying a signal to the active element configured such that the active element applies a force to the eye responsive to the signal.

The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings, in which:

Brief Description Of The Drawings

Fig. 1 is a cross-sectional side view of a human eye, showing an implanted active element for regulation of pupillary diameter, in accordance with a preferred embodiment of the present invention;

Figs. 2 and 3 are schematic pictorial illustrations showing implanted active elements, which enable regulation of pupil diameter, in accordance with respective preferred embodiments of the present invention; and

Fig. 4 illustrates a control unit which actuates the active elements shown in Figs. 1-3, in accordance with a preferred embodiment of the present invention.

Detailed Description Of Preferred Embodiments

Fig. 1 shows a cross-sectional side view of a patient's eye 10, coupled to pupillary control apparatus 30, in accordance with a preferred embodiment of the present invention. Typically, apparatus 30 comprises (a) at least one active element 26 implanted in the eye or fixed in a vicinity of the eye, and (b) a control unit 28, preferably external to the eye, which drives the active element to regulate pupillary diameter. The eye includes a cornea 12 covering an opening

in a generally spherical sclera 14. Adjacent to the cornea, in the opening of the sclera 14, is an iris 16 having an opening, the pupil 18. Behind the pupil is a lens 20, which focuses light that enters through the pupil onto a retina 22 on the interior surface of the eye. The retina, in turn, is connected by an optic nerve 24 to the brain (not shown). Active element 26 in this embodiment is coupled to iris 16, and is driven by control unit 28 to cause pupil 18 to constrict, in order to improve the accuracy with which eye 10 conveys information about an object in the patient's visual field to the brain. Control unit 28 is preferably, but not necessarily, in wireless communication with active element 26.

Reference is now made to Figs. 2 and 3, which are schematic illustrations showing different configurations of pupil control apparatus 30, in accordance with respective preferred embodiments of the present invention. In Fig. 2, an active element 32 is preferably coupled to or in a vicinity of the anatomical sphincter 34 encircling pupil 18. Alternatively or additionally, one or more active elements 36 are coupled to or in a vicinity of the dilator muscles 35 of iris 16. Active elements 32 and 36 are preferably driven by control unit 28 to change their own shape, or to modify their position, so as to apply mechanical pressure on the iris in order to constrict or dilate pupil 18.

As appropriate, the active elements may comprise any of a number of materials or components known in the art for changing their shape or position in response to a stimulus. For example, active elements 32 and/or 36 may comprise certain polymer gels that are widely known for changing their volume or shape in the presence of an applied electrical or magnetic field. Alternatively or additionally, the active elements comprise piezoelectric components, electromagnets, wire coils, a micro-solenoid, or other elements known for transducing a signal into a change in mechanical disposition. If appropriate, apparatus 30 includes circuitry (e.g., band-pass filters) or shielding elements to prevent ambient magnetic or electrical fields from adversely affecting the performance of apparatus 30. For the purposes of this embodiment of the present invention, when pupillary constriction is desired, a voltage is preferably applied to active element 32 in order to reduce its volume. Correspondingly, when dilation is desired, a voltage is applied to active elements 36.

For some applications, active elements 32 and/or 36 comprise electrodes, which are driven by control unit 28 to apply current to one or more muscles in the eye in order to stimulate

the muscles to contract and to thereby modulate pupillary diameter. Typically, regardless of whether mechanical or electrical means are used, pupillary response times of less than one second may be obtained.

In a preferred embodiment, active element 32 comprises a diaphragm having a hole passing therethrough. Control unit 28 preferably actuates element 32 to modify the diameter of the hole in the diaphragm (which is analogous to modifying pupillary diameter), typically so as to achieve enhanced visual acuity. As appropriate, active element 32 may be implanted in the eye, or integrated into an external fitting, such as a contact lens 27 worn on the eye (Fig. 1). A range of techniques are known in the art which may be adapted for the purpose of controlling the size of the hole. Alternatively or additionally, active element 32 is substantially transparent, and comprises liquid crystals or other means which are actuated by control unit 28 in order to obscure a desired portion of the pupil and thereby attain the increased focus typically achieved by pupillary constriction.

In another preferred embodiment of the present invention, active element 32 comprises a pharmaceutical pupillary constrictor or dilator, which is preferably contained in a polymer or other structure which control unit 28 can actuate (e.g., by application of an electric field), so as to induce the release of a desired quantity of the pharmaceutical. For some applications, apparatus and methods described in US Patent 5,824,072 to Wong, which is incorporated herein by reference, are adapted for use with these embodiments of the present invention. If appropriate, active element 32 containing the pharmaceutical product may be integrated into an easily-replaceable pouch, which is typically placed by the patient or a healthcare provider under an eyelid, and actuated by the control unit to apply regulated doses of constricting or dilating eye drops.

Alternatively or additionally, the pharmaceutical product may be administered in standard eye-drop form, by the patient, in accordance with physician's instructions, in order to enhance visual acuity by modulation of the diameter of the pupil. Thus, by contrast to prior art use of pupil-constricting and pupil-dilating pharmaceuticals for therapeutic purposes (e.g., in the treatment of glaucoma) and for enabling an ophthalmologist to examine the retina, this embodiment of the present invention uses pharmaceutical to yield essentially immediate improvements in a patient's visual acuity. Preferably, dosages are determined for each patient,

taking into account eye color, age, weight, gender, and other factors which influence the magnitude of the pupillary response to the administration of the pharmaceutical product. Further preferably, the effect of the pharmaceutical product in the patient's eye has a half-life between about 30 minutes and 6 hours, and the product is re-administered as appropriate to provide a suitable enhanced-vision period in accordance with the patient's needs (e.g., during waking hours, working hours, or while driving). By way of illustration and not limitation, pilocarpine (2%) administered four times a day, tropicamide (0.5%) administered three times a day, and phospholine iodide (0.125%) administered twice a day, are appropriate for some applications of the present invention.

Fig. 3 illustrates an alternate embodiment of the present invention, wherein a band 38 is preferably coupled to iris 16. Typically, methods and apparatus described in the above-cited US Patent 5,800,530 to Rizzo are adapted for use with this embodiment, in order to enable control unit 28 to increase and decrease the diameter of pupil 18. One end of band 38 is preferably engaged by a micromotor 42, which is driven by control unit 28 to increase or decrease tension in the band. This, in turn, induces corresponding increases or decreases in the pressure on iris 16, causing the desired precise changes in the diameter of pupil 18. For some applications, micromotor 42 is driven in cooperation with active elements 36 (Fig. 2), in order to provide active dilation and constriction of the pupil. It will be appreciated by those skilled in the art that micromotor 42 may be replaced by other apparatus, for example, by a piezoelectric actuator or by an electrically-sensitive biocompatible polymer gel.

In a preferred embodiment, band 38 comprises a tube, which partially or completely encircles pupil 18. Preferably, micromotor 42 or other driving apparatus modulates the pressure of a gas or liquid within the tube, in order to induce a shape change of the tube, and, in turn, apply a force to the iris in order to modulate the diameter of the pupil.

Alternatively or additionally, band 38 comprises a plurality of electromagnetic actuator bodies 46. The bodies are preferably actuated by control unit 28 to attract each other, in order to cause constriction of pupil 18, or, alternatively, the bodies are magnetized to repel, causing band 38 to expand and to cause dilation of the pupil. For some applications, voltages are also applied to active elements 32 or 36 (Fig. 2) in order to enhance the contraction or dilation. It is to be understood that in some configurations, the band generally only serves the function of a housing,

and can therefore be eliminated if electromagnetic actuator bodies 46 are directly implanted in the eye. If appropriate, methods and apparatus described with respect to configuring artificial lenses within the eye, disclosed in the above-cited US Patent 5,171,266 to Wiley et al., may be adapted for use with this embodiment of the present invention.

In a particular preferred embodiment of the present invention, at least one actuator body 46 comprises two elements, oriented in a generally radial direction with respect to pupil 18. One or both of the elements preferably comprises an electromagnet which, when driven by current from control unit 28, causes repulsion or attraction of the two elements in the radial direction, in turn causing the pupil to constrict or dilate. As appropriate, one such actuator body 46 could be implanted in the eye, or three actuator bodies could be disposed around the pupil, as shown in Fig. 3. It is noted that in embodiments of the present invention in which the actuator body comprises two elements, as described, it is not generally necessary for different actuator bodies to generate any mutual attraction or repulsion.

Fig. 4 is a block diagram of control unit 28 of pupil control apparatus 30, in accordance with a preferred embodiment of the present invention. A user control device 50 is typically operated by the patient to send instructions to an input/output block 52 of control unit 28. For example, user control device 50 may be integrated into a watch worn by the patient, who is preferably enabled to press buttons on the watch in order to enter any one or more of the following instructions:

Decrease (increase) pupil diameter by one step (e.g., 0.1 mm or 0.2 mm).

Induce minimum (maximum) pupil diameter.

Turn off all active elements.

Reduce pupil diameter to pre-programmed setting "A" between 9 am and 5 pm, and to setting "B" from 5 pm until sleep begins (e.g., when eyes are closed for at least ten minutes).

Change pupil size to minimum in response to detected rapid ambient lighting transitions from dark to bright light.

Change pupil size to maximum in response to detected rapid ambient lighting transitions from bright light to dark.

Change pupil size to setting "A" when a sensor coupled to eye 10 detects near focusing, and to setting "B" when the sensor detects far focusing.

Increase by one step the rate of administration of a pharmaceutical product which induces constriction or dilation of the pupil.

Alternatively, some or all of the above instructions may be pre-programmed in a processor 54 of control unit 28, and executed automatically by the processor in appropriate circumstances. Processor 54 may additionally be pre-programmed with a range of overall physiological characteristics of the patient (e.g., age, gender) as well as particular characteristics or pathologies of the patient's eye (e.g., eye color, eyeglasses prescription, presence of glaucoma, cataract, or astigmatism), so as to allow processor 54 to optimally enhance the patient's vision. Operational parameters of processor 54 are preferably initially determined by the patient's ophthalmologist, based on the results of an examination of the patient, and are subsequently adjusted responsive to changes in the patient's condition, either as determined during follow-up visits in a medical facility or based on self-calibration. For example, the patient may indicate via user control device 50 that a pre-programmed setting of pupil control apparatus 30 no longer provides the desired enhancement of visual acuity, in which case processor 54 preferably initiates a recalibration program designed to determine optimal protocols for driving one or more active elements 60 to regulate pupillary diameter. Active elements 60 coupled to processor 54 preferably comprise one or more of active elements 26 (Fig. 1), active elements 32 or 36 (Fig. 2), micromotor 42 (Fig. 3), or other apparatus described in the above-cited patents or otherwise known in the art for their ability to control tissue of the eye.

For some applications, input/output device 52 is additionally enabled to download information concerning the condition of the eye and/or usage of pupil control apparatus 30 to user control device 50, for review by the patient's ophthalmologist. If appropriate, the ophthalmologist may alter operational parameters of processor 54 responsive to this review. Typically, an energy source 56 coupled to control unit 28 is adapted for implantation in the patient's body or for operation outside of the patient's body. The energy source is selected so as to be compatible with the particular type of active element chosen by the patient's ophthalmologist for use in apparatus 30, and may comprise, as appropriate, a battery, a miniature power supply having an output coupled to a coil so as to generate a magnetic field, a source of ultrasonic energy, a photovoltaic solar cell, or a combination of the above. In a preferred embodiment, a coil is fixed to the patient's eyeglasses or is placed under the patient's lower

eyelid, and is driven by a battery to generate a magnetic field which inductively supplies the control unit and/or active elements 60 with the energy necessary to perform the functions described herein. Additionally, appropriate circuitry in energy source 56 is preferably configured to regulate the output of the source, in order to assure that the active elements operate within limits dictated by the patient's ophthalmologist.

In a preferred embodiment, one or more sensors 58 provide information to processor 54 indicative of a characteristic of eye 10, an overall physiological characteristic of the patient, or of an environmental parameter. Processor 54 preferably modulates parameters used to drive active elements 60 responsive to analyzing the outputs of sensors 58, or saves the outputs for later downloading and analysis. For example, sensors 58 may comprise a light sensor implanted in the eye and coupled in a feedback loop with active elements 60 such that a desired level of pupillary constriction or dilation is attained. Alternatively or additionally, sensors 58 comprise a light sensor adapted to measure ambient light levels, and processor 54 increases pupillary constriction responsive to high light levels, and increases pupillary dilation responsive to low light levels. Further alternatively or additionally, sensors 58 comprise an electromyographic electrode, coupled to detect, for example, prolonged periods of non-blinking or other occurrences indicative of sleeping. Still further alternatively or additionally, sensors 58 comprise an implanted sensor adapted to generate a signal responsive to a state of the patient's focus, e.g., for near-, middle-, or far-vision.

It is to be understood that the numbers and positions of the various components of pupil control apparatus 30 are shown in the figures and described herein by way of illustration and not limitation, and that the scope of the present invention includes placement of different types and different numbers of active elements at other locations on, in, or coupled to the patient's eye. In a preferred embodiment, a plurality of active elements are implanted at or near the iridocorneal angle of the anterior chamber of the eye, and are driven to induce a shape change in the eye so as to treat glaucoma or another condition of the eye. For example, the active elements may comprise electromagnets, which act on each other in order to apply tension to the iris and open the trabecular drainage meshwork. In this manner, the increased intraocular pressure caused by insufficient flow of aqueous humor and associated with glaucoma is typically relieved, as normal flow is restored. This embodiment of the present invention may be utilized in

combination with or separately from the embodiments described herein for enhancing visual acuity.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

Claims

1. A method for improving visual acuity of a patient, comprising:
fixing to an eye of the patient an active element so as to be capable of controlling an amount of light entering the eye; and
applying an electrical signal to the active element.

2. A method according to claim 1, wherein applying the electrical signal to the element comprises configuring the signal to change a mechanical disposition of the element.

3. A method according to claim 1, wherein applying the electrical signal to the element comprises driving current through the element into tissue of the patient so as to induce modification of a state of a muscle.

4. A method according to claim 1, wherein fixing the active element to the eye comprises incorporating into the active element a pharmaceutical substance capable of modulating a diameter of the pupil.

5. A method according to claim 1, wherein fixing the active element to the eye comprises fixing to the eye an element having an aperture through which light may pass when the element is fixed to the eye, and wherein applying the electrical signal to the active element comprises configuring the electrical signal such that application thereof reduces an effective size of the aperture.

6. A method according to claim 1, and comprising removing the element from the eye subsequent to a treatment period.

7. A method according to claim 1, wherein fixing the element to the eye comprises implanting the element in the eye.

8. A method according to claim 7, wherein implanting the element in the eye comprises implanting the element in contact with the iris of the eye.

9. A method according to claim 1, wherein fixing the element to the eye comprises fixing the element so as to be capable of controlling a diameter of the pupil of the eye.

10. A method according to claim 9, wherein fixing the element to the eye comprises fixing the element to the eye so as to be capable of constricting the pupil.

11. A method according to claim 9, wherein fixing the element to the eye comprises fixing the element to the eye so as to be capable of dilating the pupil.

12. A method according to claim 1, and comprising:
receiving a sensor signal; and
analyzing the sensor signal,
wherein applying the electrical signal comprises applying the electrical signal responsive to the analysis.

13. A method according to 12, wherein receiving the sensor signal comprises measuring an amount of light entering the eye.

14. A method according to claim 12, wherein analyzing the sensor signal comprises analyzing a change in an ambient light level.

15. A method according to claim 12, wherein receiving the sensor signal comprises receiving the sensor signal responsive to a physiological characteristic of the patient.

16. A method according to claim 15, wherein analyzing the sensor signal comprises determining an onset of sleep of the patient.

17. A method according to claim 15, wherein analyzing the sensor signal comprises determining a change in a level of focus of the eye.

18. A method according to claim 1, and comprising receiving an instruction from the patient, wherein applying the electrical signal to the element comprises applying the electrical signal responsive to the instruction.

19. A method according to claim 18, wherein receiving the instruction comprises receiving a designation of a time, and wherein applying the electrical signal comprises applying the signal responsive to the designation of the time.

20. A method according to claim 18, wherein receiving the instruction comprises receiving a designation of a desired change in a level of the electrical signal, and wherein applying the electrical signal comprises modifying the signal responsive to the designation of the change in the level.

21. Apparatus for improving visual acuity of a patient, comprising:
at least one electrically-controlled active element adapted to be fixed to an eye of the patient so as to be capable of controlling an amount of light entering the eye; and
a control unit, adapted to apply an electrical signal to the active element.

22. Apparatus according to claim 21, wherein the active element comprises an electrode adapted to be coupled to muscle tissue of the eye.

23. Apparatus according to claim 21, wherein the active element comprises a pharmaceutical substance capable of modulating a diameter of the pupil.

24. Apparatus according to claim 21, wherein the active element comprises a contact lens.

25. Apparatus according to claim 21, wherein the active element comprises a diaphragm having an aperture adapted to permit passage of light therethrough when the element is fixed to the eye, and wherein the control unit is adapted to modulate the electrical signal applied to the active element so as to regulate a level of the light.

26. Apparatus according to claim 21, wherein the active element comprises a band adapted to be mechanically coupled to induce constriction of the pupil of the eye responsive to the electrical signal.

27. Apparatus according to claim 21, wherein the active element is adapted to be removed from the eye subsequent to a treatment period.

28. Apparatus according to claim 21, wherein the active element comprises an electromagnet.

29. Apparatus according to claim 21, wherein the active element is adapted to change a mechanical disposition thereof responsive to application of the electrical signal so as to apply a force to the eye.

30. Apparatus according to claim 29, wherein the active element comprises a piezoelectric element.

31. Apparatus according to claim 29, wherein the active element comprises an inductive coil.

32. Apparatus according to claim 29, wherein the active element comprises first and second elements, and wherein the control unit is adapted to apply the electrical signal so as to generate a magnetic field between the first and second elements that changes a disposition of the first and second elements with respect to each other.

33. Apparatus according to claim 29, wherein the active element comprises an electrically-sensitive polymer.

34. Apparatus according to claim 29, wherein the active element comprises a solenoid.

35. Apparatus according to claim 29, wherein the active element comprises an inflatable member comprising a fluid, and wherein the active element is adapted to change the mechanical disposition thereof responsive to a change in pressure of the fluid.

36. Apparatus according to claim 21, wherein the active element is adapted for implantation in the eye.

37. Apparatus according to claim 36, wherein the active element is adapted for implantation in contact with the iris of the eye.

38. Apparatus according to claim 21, wherein the active element is adapted to modify a diameter of the pupil of the eye responsive to the electrical signal.

39. Apparatus according to claim 38, wherein the active element is adapted to constrict the pupil responsive to the electrical signal.

40. Apparatus according to claim 38, wherein the active element is adapted to dilate the pupil responsive to the electrical signal.

41. Apparatus according to claim 21, and comprising a sensor adapted to generate a sensor signal, wherein the control unit is adapted to apply the electrical signal responsive to the sensor signal.

42. Apparatus according to 41, wherein the sensor is adapted to measure an amount of light entering the eye.

43. Apparatus according to claim 42, wherein the control unit is adapted to apply the electrical signal responsive to a change in an ambient light level.

44. Apparatus according to claim 41, wherein the sensor is adapted to sense a physiological characteristic of the patient.

45. Apparatus according to claim 44, wherein the sensor comprises an electromyographic electrode.

46. Apparatus according to claim 44, wherein the sensor is adapted to generate the sensor signal responsive to a level of focus of the eye.

47. Apparatus according to claim 21, and comprising a user control device, adapted to receive an instruction from the patient, wherein the control unit is adapted to apply the electrical signal to the active element responsive to the instruction.

48. Apparatus according to claim 47, wherein the user control device is adapted to receive from the patient a designation of a time, and wherein the control unit is adapted to apply the electrical signal responsive to the designation of the time.

49. Apparatus according to claim 47, wherein the user control device is adapted to receive a designation of a desired change in a level of the electrical signal, and wherein the control unit is adapted to modify the electrical signal responsive to the designation of the change in the level.

50. Apparatus for improving visual acuity of a patient, comprising:

at least one active element adapted to be fixed to an eye of the patient so as to be capable of controlling an amount of light entering the eye; and

a control unit, adapted to generate a magnetic field which modifies a disposition of the active element.

51. A method for improving visual acuity of a patient, comprising:

fixing to an eye of the patient an active element so as to be capable of controlling an amount of light entering the eye; and

generating a magnetic field which modifies a disposition of the active element.

52. A method for improving visual acuity, comprising:

making a dose of a pupil-modulating pharmaceutical substance which engenders a desired change in visual acuity of an eye to which the substance is applied; and

providing the dose for administration to a patient so as to modulate a diameter of a pupil of an eye of the patient, thereby changing visual acuity of the eye of the patient.

53. A method for improving visual acuity of a patient, comprising:

fixing to an eye of the patient an active element so as to be capable of controlling a diameter of the pupil of the eye; and

applying a signal to the active element.

54. Apparatus for improving visual acuity of a patient, comprising:

at least one active element adapted to be fixed to an eye of the patient so as to be capable of controlling a diameter of the pupil of the eye; and

a control unit, adapted to apply a signal to the active element.

55. Apparatus for treating glaucoma of a patient, comprising:

at least one active element adapted to be fixed to an eye of the patient in a vicinity of the iridocorneal angle; and

a control unit, adapted to apply a signal to the active element configured such that the active element applies a force to the eye responsive to the signal.

56. Apparatus according to claim 55, wherein the active element comprises at least one electromagnet.

57. Apparatus according to claim 55, wherein the control unit is adapted to configure the signal such that the active element applies the force to open trabecular meshwork of the eye responsive to the signal.

58. A method for treating glaucoma of a patient, comprising:

fixing to an eye of the patient in a vicinity of the iridocorneal angle at least one active element; and

applying a signal to the active element configured such that the active element applies a force to the eye responsive to the signal.

59. A method according to claim 58, wherein applying the signal comprises inducing a magnetic field in a vicinity of the active element.

60. A method according to claim 58, wherein applying the signal comprises configuring the signal such that the active element applies the force to open trabecular meshwork of the eye responsive to the signal.

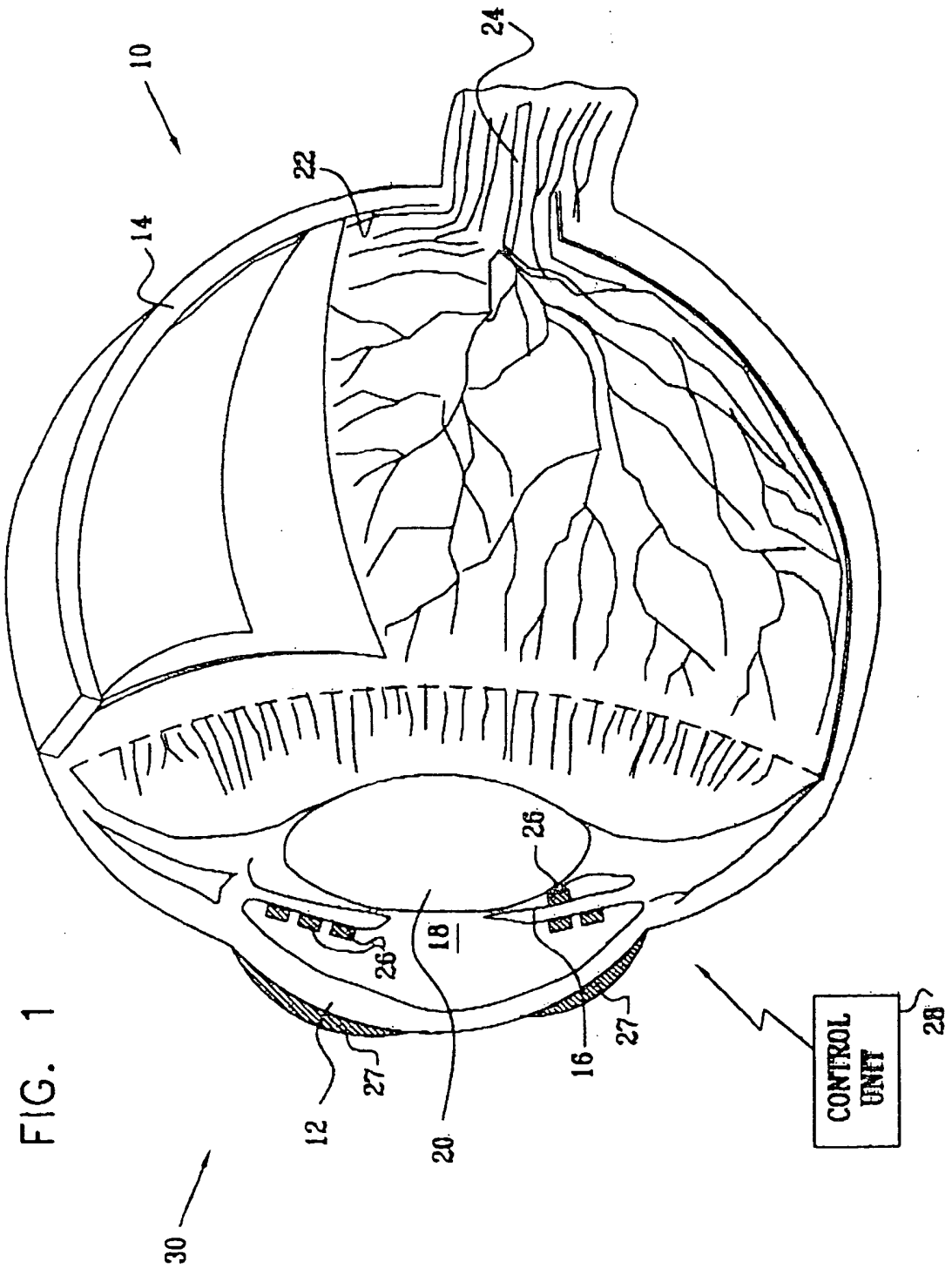
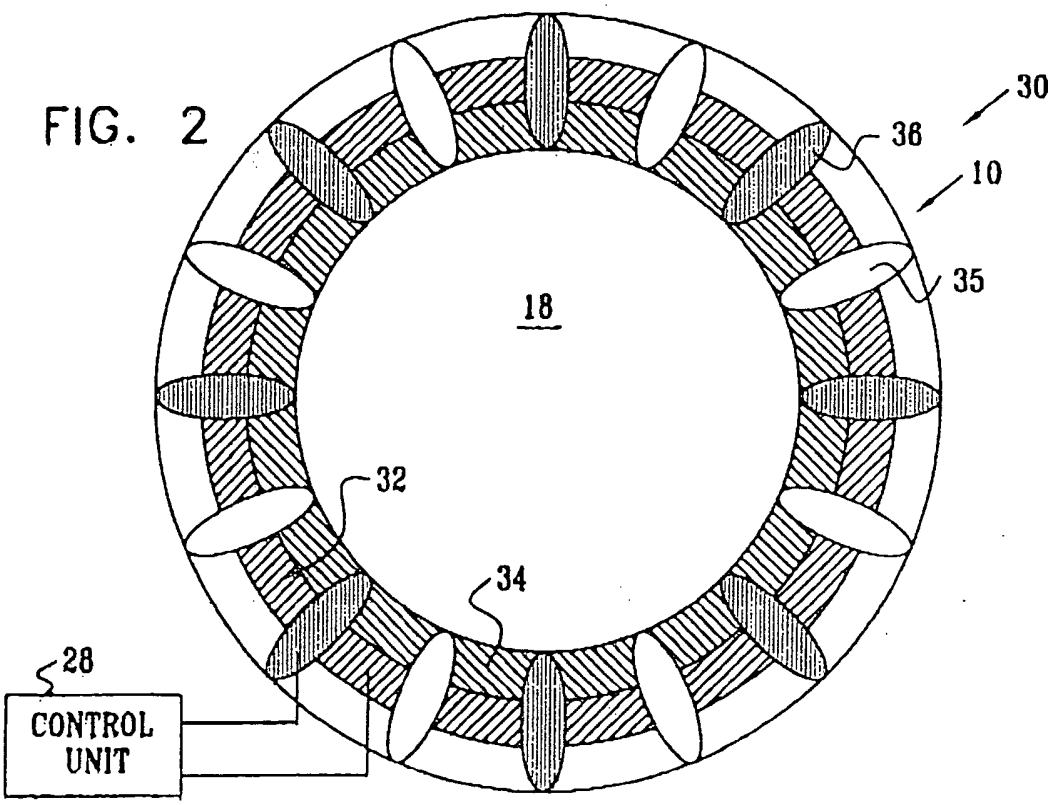


FIG. 1

FIG. 2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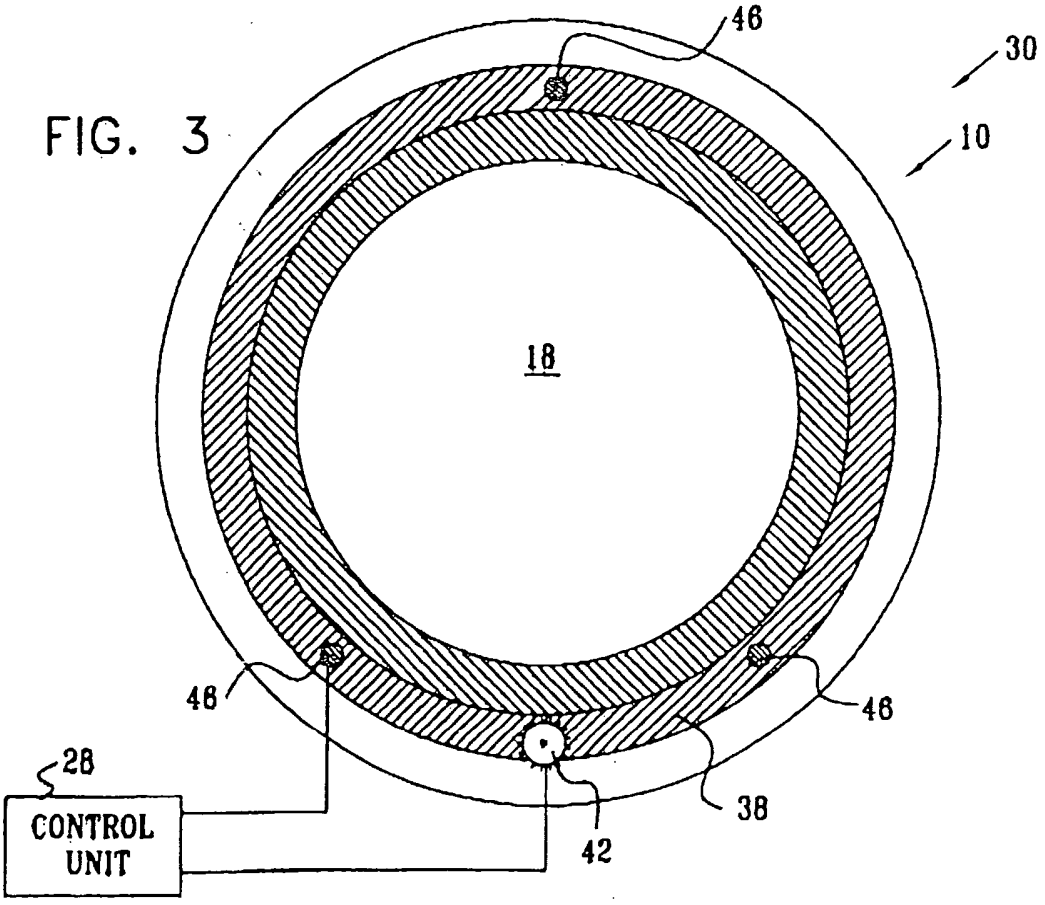
10
35
18
32
34
28
CONTROL UNIT

FIG. 3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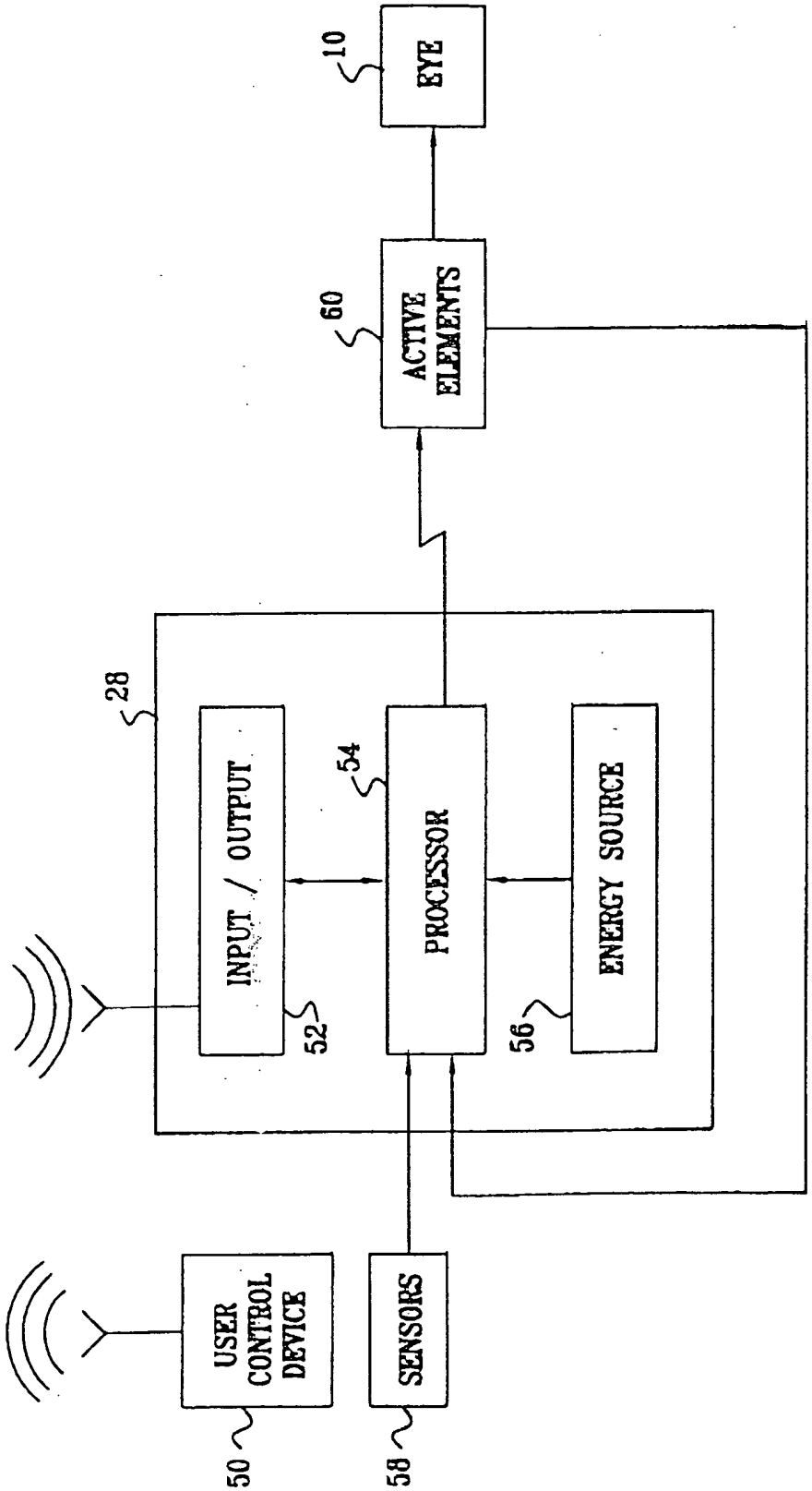
10
18
46
46
28
CONTROL UNIT
38
42

FIG. 4


10
EYE
60
ACTIVE ELEMENTS
28
INPUT / OUTPUT
52
54
PROCESSOR
56
ENERGY SOURCE
USER CONTROL DEVICE
50
SENSORS
58