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(71) Applicant: **NEXISVISION, INC.** [US/US]; 191 Jefferson Drive, Menlo Park, California 94025 (US).

(72) Inventors: **DE JUAN, Eugene, Jr.**; San Francisco, California (US). **REICH, Cary, J.**; Los Gatos, California (US). **ALSTER, Yair**; Palo Alto, California (US). **CLARKE, Matt**; Mountain View, California (US). **TUAN, Kuang-mon, Ashley**; Mountain View, California (US). **LEVY, Brian**; New York, New York (US). **LUM, Raymond**; El Cerrito, California (US). **ALEJANDRO, Jose, D.**; Sunnyvale, California (US).

(74) Agents: **LAMBERT, William, R.** et al.; Kilpatrick Townsend & Stockton LLP, Two Embarcadero Center, Eighth Floor, San Francisco, California 94111 (US).

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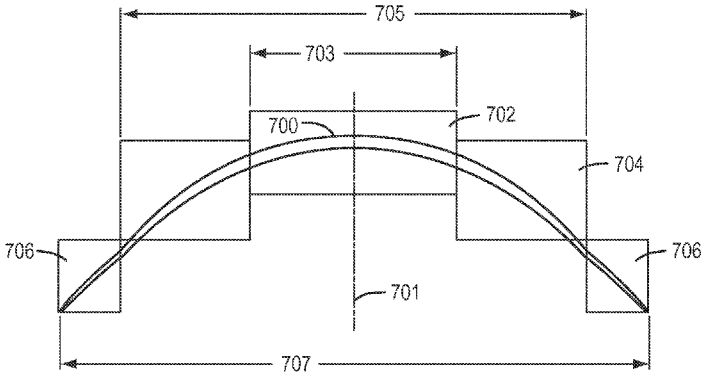

FIG. 7

(57) Abstract: Ophthalmic lenses for correcting refractive error of an eye are disclosed. Ophthalmic lenses include a deformable inner portion and a deformable peripheral portion. When disposed over the optical region of an eye, the inner portion is configured so that engagement of the posterior surface against the eye deforms the posterior surface so that the posterior surface has a shape diverging form the refractive shape of the epithelium when viewing with the eye through the ophthalmic lens. The rigidity of the inner portion is greater than the rigidity of the peripheral portion and the ophthalmic lenses are configured to allow movement relative to the eye upon blinking of the eye and to be substantially centered on the optical region of the cornea following the blinking of the eye. Methods of correcting refractive errors of an eye such as astigmatism or spherical aberration using the ophthalmic lenses are also disclosed.

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CONTACT LENSES FOR REFRACTIVE CORRECTION

[0001] This application claims benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 61/636,404 filed on April 20, 2012, which is incorporated by reference in its entirety.

FIELD

[0002] The disclosure relates to ophthalmic lenses for correcting refractive error of an eye are disclosed. Ophthalmic lenses include a deformable inner portion and a deformable peripheral portion. When disposed over the optical region of an eye, the inner portion is configured so that engagement of the posterior surface against the eye deforms the posterior surface so that the posterior surface has a shape diverging form the refractive shape of the epithelium when viewing with the eye through the ophthalmic lens. The rigidity of the inner portion is greater than the rigidity of the peripheral portion and the ophthalmic lenses are configured to allow movement relative to the eye upon blinking of the eye and to be substantially centered on the optical region of the cornea following the blinking of the eye. The disclosure further relates to methods of correcting refractive errors of an eye such as astigmatism or spherical aberration using the ophthalmic lenses.

BACKGROUND OF THE INVENTION

[0003] The eye includes several tissues that allow patients to see. The cornea of the eye is an anterior tissue of the eye that is clear in healthy eyes and refracts light so as to form an image on the retina. The retina is a posterior tissue of the eye that senses light from the image formed thereon and transmits signals from the image to the brain. The cornea includes an outer layer of tissue, the epithelium, which protects the underlying tissues of the cornea, such as Bowman's membrane, the stroma, and nerve fibers that extend into the stroma and Bowman's membrane. The healthy eye includes a tear film disposed over the epithelium. The tear film can smooth small irregularities of the epithelium so as to provide an optically smooth surface and maintain eye health. The tear film is shaped substantially by the shape of the underlying epithelium, stroma, and Bowman's membrane, if present. The tear film comprises a liquid that is mostly water and does include additional components, such as mucoids and lipids. The many nerve

fibers of the cornea provide sensation to promote blinking that can cover the cornea with the tear film. The never fibers also sense pain so that one will normally avoid trauma to the cornea and also avoid direct contact of an object to the cornea so as to protect this important tissue.

[0004] Work in relation to embodiments of the present invention suggests that at least some of the prior contact lenses and therapeutic coverings can be less than ideal in at least some instances. Many contact lenses and therapeutic coverings can be left in the eye for less than ideal time, as the patient removing and replacing the contact lens or therapeutic covering can be somewhat cumbersome and in at least some instances patients may leave the contact lens or therapeutic covering in the eye for a time that can be longer than would be ideal. Although extended wear lenses can be left in the eye for somewhat longer time, the time such lenses can be left in the eye can be less than ideal. Work in relation to embodiments of the present invention also suggests that tear flow of the prior contact lenses can be less than ideal, and that less than ideal tear flow may be related to the potential complications and can limit the amount of time such lenses can be left in the eye.

[0005] In the healthy cornea, the proper amount of hydration of the cornea, sometimes referred to as dehydration of the cornea, is maintained such that the cornea remains clear. The cornea includes a posterior endothelial layer that pumps water from the cornea into the adjacent anterior chamber. The epithelium inhibits flow of water from the tear liquid into the cornea, such that the corneal stroma can be maintained with the proper amount of hydration with endothelial pumping. The endothelial pumping of water from the cornea to maintain the proper hydration and thickness of the eye is referred to as deturgescence. When the corneal epithelium heals, the layer of cells forming over the defect can be at least somewhat irregular in at least some instances, such that the vision of the patient can be less than ideal.

[0006] Following corneal surgery, such as refractive keratectomy, the post-ablation cornea may have a complex shape, and many of the prior commercially available lenses may not fit the ablated cornea as well as would be ideal, and in at least some instances fitting of lenses can be time consuming and awkward. Commercially available contact lenses having a rigid gas permeable (RGP) central portion and a soft peripheral skirt can be difficult and/or time consuming to fit to the ablated cornea and may not fit very well in at least some instances. The ablated cornea may comprise an abrupt change in curvature near the edge of the ablation, and in

at least some instances it can be difficult to fit such lenses near the edge of the ablation. Also, at least some of the commercially available contact lenses may not be suitable for extended wear and may be removed each day, which can be somewhat awkward for a patient and can result in lack of compliance and lenses remaining in the eye longer than would be ideal in at least some instances.

[0007] Hybrid contact lenses, lenses having a rigid central proton and a soft skirt are also used to correct refractive error of the eye such as astigmatism. Current products such as RGP and soft toric lenses for correcting refractive error include a cylindrical component in addition to any spherical corrective component that must be determined for each patient and oriented with respect to the optical region of the cornea to maintain optimal vision correction. Features are incorporated into the lens to maintain centration and radial orientation of the lens of the eye during wear. Because of the need to fit and orient the cylindrical corrective component, a large number of lenses must be maintained in inventory and individually fit and selected for each patient.

[0008] In light of the above, it is desirable to provide improved contact lenses for vision correction and coverings for treatments related to epithelial defects of the cornea, such as epithelial defects following PRK. Ideally, these contact lenses and coverings would provide treatments that improve tear flow and avoid at least some of the deficiencies of known techniques while providing improved patient comfort and/or vision. It is also desirable to provide improved contact lenses for correcting refractive error that only requires a spherical fit and provide comfort and vision correction as good as or better than current toric lens products.

BRIEF SUMMARY OF THE INVENTION

[0009] Embodiments of the present invention provide improved ophthalmic devices that provide improved vision for extended amounts of time and can be used to treat normal eyes or eyes having an epithelial defect, such as an epithelial defect subsequent to refractive surgery such as PRK. The device may comprise a contact lens and can provide improved tear flow such that the device can be left on the eye to correct vision for an extended time. Devices may comprise a water inhibiting layer and one or more structures to pump tear liquid under the water inhibiting layer of the device such that the device can remain in the eye and correct vision for an extended amount of time. Alternatively or in combination, the device may comprise a silicone or

hydrogel layer extending along a posterior surface of the device coupled to fenestrations to provide hydration and patient comfort. The silicone or hydrogel layer may fluidly couple the cornea to the fenestrations so as to pass tear liquid and therapeutic agents from an anterior surface of the device through the fenestrations and silicone or hydrogel to the cornea. In certain embodiments, the device comprises a material having fenestrations and an outer portion shaped to contact the conjunctiva to pump tear liquid when the eye blinks. The device may comprise a deflectable outer portion having a resistance to deflection such that a chamber is formed when the device is placed on the eye and the eye is open with the eyelids separated. A silicone or hydrogel layer coupled to the fenestrations may extend along a lower surface of the device at least a portion of the chamber. The resistance to deflection of the deflectable outer portion can be configured such that the outer portion deflects inward toward the cornea when the eyelid closes to pump tear liquid. The fenestrations can draw tear liquid into the chamber located under the device when the eye opens and the chamber can expands. The fenestrations may extend through the silicone or hydrogel layer to provide pumping. Alternatively or in combination, the silicone or hydrogel layer may cover the posterior end of the fenestrations and the deflection of the outer portion can encourage movement of liquid and medicament along the silicone or hydrogel. The outer portion of the device comprises a sclera coupling portion shaped to contact the conjunctiva to define the chamber when the device is placed on the eye. The fenestrations and sclera coupling portion of the device can pass tear liquid away from the chamber when the eye closes and pressure of one or more eyelids urges the device toward the cornea such that the chamber volume decreases. In certain embodiments, opening of the eye so as to separate the eyelids reduces pressure on the outer portion of the device such that the outer portion of the device over an outer portion of the cornea can separate from the outer portion of the cornea so as to draw liquid through the fenestrations and into the chamber located under the device. The sclera coupling portion of device may contact the conjunctiva to inhibit the flow of tear liquid under the sclera coupling portion when the eye opens and tear liquid is drawn through the fenestrations, for example with formation of a seal where the device contacts the conjunctiva. When the eye blinks subsequently, the pressure of the one or more eyelids can urge the device toward the cornea such that tear liquid can pass through the fenestrations, and the sclera coupling portion may separate slightly from the conjunctiva to pass tear liquid under the sclera coupling portion, so as to rinse the cornea, the limbus, the conjunctiva and the underside of the device

with the pumped tear liquid. The device may comprise a material having high oxygen permeability such as silicone such that the device may provide improved tear flow and high oxygen permeability. This improved flow of tear liquid can allow the device such as a contact lens to be worn for an extended time of at least about one week, for example thirty days or sixty days or more. The improved tear flow can improve healing and vision of eyes with epithelial defects, for example epithelial defects following PRK. Improved tear flow can also maintain health of the eye and facilitate longer wear.

[0010] In certain embodiments, a device comprises an inner optical component for vision, such as a lens, and an outer coupling component to hold the inner component in relation to the pupil to improve vision. The coupling component may comprise a deflectable material that inhibits passage of the tear liquid through the material such that the tear liquid passes through the fenestrations when the eye blinks and an eyelid exerts pressure on the optical component. The outer coupling component may comprise the fenestrations to pass the tear liquid and the outer sclera coupling portion to contact the conjunctiva. The optical component may comprise a first material and first thickness corresponding to a first rigidity. The coupling component may comprise a second material and a second thickness corresponding to a second rigidity. The second material can be softer than the first material and the second thickness can be less than the first thickness such that the coupling component can be deflected with the eyelid, and such that the coupling component can be deflected by an amount greater than the optical component when the eyelids close to cover the first component and the second component. The optical component can be more rigid than the coupling component, such that the optical component can provide vision when the outer portion is deflected with one or more eyelids.

[0011] The alignment of the optical component to the pupil provided with the coupling to the conjunctiva and underlying sclera can be beneficial for vision. In certain embodiments, the optical component can be held at a substantially fixed location in relation to the pupil so as to provide improved vision such as presbyopia correction and vision correction of aberrations that may depend on location of the pupil such as measured wavefront aberrations, spherical aberration, coma, and trefoil.

[0012] The optical component and the coupling component can be helpful to improve vision and regeneration of the epithelium in eyes with epithelial defects. The optical component can

smooth the cornea and may smooth irregularities of the epithelium and ablated stroma. The coupling component can support the optical component so as to resist sliding movement of the optical component and provide an environment to promote regeneration of the epithelium. The pumping of the tear liquid may improve tear flow to the regenerating epithelium near the epithelial defect so as to promote regeneration of the epithelium over the defect. The pumping of the tear liquid can also promote delivery of a medicament, for example a steroid, to the ablated region so as to inhibit corneal infiltrates and haze.

[0013] In a first aspect, ophthalmic lens for correcting a refractive error of an eye are provided, the eye having a cornea with an epithelium providing a refractive shape extending across an optical region of the eye, the ophthalmic lens comprising: an inner optic portion configured to be disposed over the optical region of the cornea; a posterior surface extending along the inner portion adjacent the eye when the inner portion is disposed over the optical region, the inner portion configured so that engagement of the posterior surface against the eye deforms the posterior surface and so that the posterior surface has a shape diverging from the refractive shape of the epithelium when viewing with the eye through the ophthalmic lens; a peripheral portion of the ophthalmic lens disposed radially outward of the inner portion; and an anterior surface of the ophthalmic lens extending along the inner portion opposite the posterior surface so that viewing with the eye through the ophthalmic lens mitigates the refractive error.

[0014] In a second aspect, methods for selecting an ophthalmic lens for correcting a refractive error of an eye of a patient are provided, the eye having a cornea with an epithelium providing a refractive shape, the method comprising: determining a desired spherical power so as to mitigate any spherical component of the refractive error; and identifying, from among a plurality of alternative ophthalmic lenses having differing spherical powers, a selected ophthalmic lens so as to provide: an anterior surface corresponding to the desired spherical power, the anterior surface extending along an inner portion of the ophthalmic lens, wherein the inner portion of the ophthalmic lens is characterized by a thickness from about 100 μm to about 900 μm and a peripheral portion of the ophthalmic lens has a rigidity lower than a rigidity of the inner portion; wherein the ophthalmic lens is configured to allow movement relative to the eye upon blinking of the eye and to be substantially centered on the optical region of the cornea following the blinking of the eye.

[0015] In a third aspect, methods for correcting a refractive error of an eye are provided, the eye having a cornea with an epithelium providing a refractive shape extending across an optical region of the cornea, the method comprising: positioning an ophthalmic lens on the eye so that an inner portion of the ophthalmic lens is disposed over the optical region of the cornea, wherein a posterior surface of the positioned ophthalmic lens extends adjacent the eye and is deformed by the epithelium of the eye; and viewing with the eye through an anterior surface of the ophthalmic lens while a shape of the posterior surface diverges from the refractive shape of the epithelium so that the ophthalmic lens mitigates the refractive error.

[0016] In a fourth aspect, sets of alternatively selectable ophthalmic lenses for correcting refractive errors of eyes in a population of patients are provided, each eye having a cornea with an epithelium providing a refractive shape, the set comprising: a plurality of alternative ophthalmic lenses having differing spherical powers, each ophthalmic lens comprising: an anterior surface corresponding to an associated desired spherical power, the anterior surface extending along an inner portion of the ophthalmic lens, wherein the inner portion of the ophthalmic lens is deformable; and a peripheral portion of the ophthalmic lens extending radially outward from the inner portion, the peripheral portion characterized by a rigidity lower than a rigidity of the inner portion and configured for engaging tissue outside an optical region of the eye so as to support the inner portion in alignment with the optical region.

[0017] In a fifth aspect, ophthalmic lens for correcting a refractive error of an eye are provided, the eye having a cornea with an epithelium providing a refractive shape extending across an optical region of the eye, the ophthalmic lens comprising: an inner optic portion configured to be disposed over the optical region of the cornea; a posterior surface extending along the inner portion adjacent the eye when the inner portion is disposed over the optical region, the inner portion configured so that engagement of the posterior surface against the eye deforms the posterior surface and so that the posterior surface has a shape diverging from the refractive shape of the epithelium when viewing with the eye through the ophthalmic lens; a peripheral portion of the ophthalmic lens disposed radially outward of the inner portion; and an anterior surface of the ophthalmic lens extending along the inner portion opposite the posterior surface so that viewing with the eye through the ophthalmic lens mitigates the refractive error; wherein the inner optic portion is characterized by a thickness from 100 μm to 900 μm , and by a modulus from about 10

MPa to about 1,000 MPa, and a rigidity from about 4E8MPa-μm^3 to about 1.2E10MPa; and wherein the anterior surface is characterized by a spherical profile without a cylindrical component.

[0018] In a sixth aspect, embodiments of the present invention provide a device to treat an eye of a patient. The eye has a tear liquid, a pupil, a cornea, and a conjunctiva. The device comprises an optical component to correct vision of the eye and a coupling component. The optical component comprises a first rigidity sufficient to resist deformation when placed on the eye. The coupling component contacts the cornea and the conjunctiva and supports the optical component in relation to the pupil. The coupling component comprises an outer portion sized to contact the conjunctiva, an inner portion to couple to the optical component, and an intermediate portion extending between the inner portion and the outer portion. One or more of the optical component or the coupling component comprises a plurality of fenestrations to pump the tear liquid when the eye blinks.

[0019] In certain embodiments, a device comprises an inner portion comprising the optical component and an outer portion comprising the coupling component. An outer portion of the device may comprise an intermediate portion of a coupling component and an outer portion of the coupling component.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 shows an eye suitable for use with an ophthalmic device as described herein, in accordance with embodiments of the present invention.

[0021] FIG. 1-1A shows an ablated eye immediately following refractive surgery resulting in an epithelial defect, suitable for remediation in accordance with embodiments of the present invention.

[0022] FIG. 1A1 shows a device positioned on an eye and blinking of the eye, in accordance with embodiments of the present invention.

[0023] FIG. 1A2 shows the device of FIG. 1A1 that is capable of pumping tear liquid under the device, in accordance with embodiments of the present invention.

[0024] FIG. 1A3 shows a schematic illustration of the devices of FIG. 1A1 and FIG. 1A2 pumping tear liquid when the eye closes, in accordance with embodiments of the present invention.

[0025] FIG. 1A4 shows a schematic illustration of the device of FIG. 1A1 and FIG. 1A2 pumping tear liquid when the eye opens, in accordance with embodiments of the present invention.

[0026] FIG. 1B1 shows a device having a tricurve profile to fit the sclera of an eye, which device may be used to fit an ablated cornea, in accordance with embodiments of the present invention.

[0027] FIG. 1B2 shows a device having a tricurve profile to fit the sclera of an eye with slopes of the curved profiles aligned so as to inhibit ridges at the boundaries of the curved portions, in accordance with embodiments of the present invention.

[0028] FIG. 1B2-1 shows alignment of the slope of the lower surface of the corneal contacting portion with the slope of the lower surface of the sclera coupling portion, such that pressure to the limbus is decreased substantially, in accordance with embodiments of the present invention.

[0029] FIG. 1B3 shows a tapered edge of the device of FIG. 1B1, in accordance with embodiments of the present invention.

[0030] FIG. 1B4 shows a plan view device having a tricurve profile to fit the cornea, limbus, and sclera with slopes of the curved profiles aligned so as to inhibit ridges at the boundaries of the curved portions, in accordance with embodiments of the present invention.

[0031] FIG. 1B5 shows a side sectional view of the device of FIG. 1B4 and corresponding curved portions to couple to the cornea, limbus, and sclera, in accordance with embodiments of the present invention.

[0032] FIG. 1B6 shows a side sectional view of the device of FIG. 1B4 and corresponding curved portions of the upper surface, in accordance with embodiments of the present invention.

[0033] FIG. 1B7 shows a tapered edge of the device of FIG. 1B4, in accordance with embodiments of the present invention.

[0034] FIG. 1C shows a device comprising a single piece of material having an inner thickness greater than an outer thickness, in accordance with embodiments of the present invention.

[0035] FIG. 1C1 shows a device as in FIGS. 1-2A to 1B2 having an inner portion comprising an inner thickness and an inner material and an outer portion comprising an outer thickness and an outer material, in which the inner thickness is greater than the outer thickness, in accordance with embodiments of the present invention.

[0036] FIG. 1C2 shows a device as in FIGS. 1-2A to 1B2 having an inner portion comprising an inner thickness and an inner material and an outer portion comprising an outer thickness and an outer material, in which the inner thickness is greater than the outer thickness and the outer material extends around the inner material, in accordance with embodiments of the present invention.

[0037] FIG. 1C2A shows a device as in one or more of FIGS. 1-2A to 1B7 having a layer of silicone or hydrogel material on a posterior surface of the device, in accordance with embodiments of the present invention.

[0038] FIG. 1C2B shows a device as in one or more of FIGS. 1-2A to 1B7 having a layer of silicone or hydrogel material on a posterior surface of the device extending less than a maximum distance across the device such that end portions of the device are configured to engage the epithelium of the eye away from the silicone or hydrogel layer and inhibit movement of the device when placed on the eye, in accordance with embodiments of the present invention.

[0039] FIG. 1C2C shows a device as in one or more of FIGS. 1-2A to 1B7 having an annular layer of silicone or hydrogel material on a posterior surface of the device such that an inner portion of the device contacts the cornea away from the silicone or hydrogel layer and an outer portion of the device contacts the cornea away from the device when placed on the eye, in accordance with embodiments of the present invention.

[0040] FIG. 1C3 shows a shows a device having a tricurve profile to fit sclera with slopes of the curved profiles aligned so as to inhibit ridges at the boundaries of the curved portions as in FIG. 1B2 and having a layer of silicone or hydrogel material on a lower surface, in accordance with embodiments of the present invention.

[0041] FIG. 1C4 shows a plan view device having a tricurve profile to fit the cornea, limbus, and sclera with slopes of the curved profiles aligned so as to inhibit ridges at the boundaries of the curved portions as in FIG. 1B4 and having a silicone or hydrogel material on a lower surface extending less than a maximum distance across the device to engage the conjunctiva with the device away from the silicone or hydrogel material, in accordance with embodiments of the present invention.

[0042] FIG. 1C5 shows a fenestration having a posterior end covered with a layer of silicone or hydrogel extending along the posterior surface of the device, in accordance with embodiments of the present invention.

[0043] FIG. 1C6 shows a fenestration extending through a layer of silicone or hydrogel extending along the posterior surface of the device, in accordance with embodiments of the present invention.

[0044] FIG. 1D shows a device comprising channels extending radially outward along a lower surface of the device, in accordance with embodiments.

[0045] FIG. 1E shows a device comprising channels extending radially inward along a lower or posterior surface of the device, in accordance with embodiments.

[0046] FIG. 1F shows a test apparatus to measure deflection of a portion of a lens in response to a load, in accordance with embodiments.

[0047] FIG. 2A shows a device comprising a contact lens placed on the eye with the eyelids separated, in accordance with embodiments.

[0048] FIG. 2B shows a profile view of the device of FIG. 2A with the eyelids closing, in accordance with embodiments.

[0049] FIG. 2C shows a front view the device of FIG. 2A with the eyelids closing, in accordance with embodiments.

[0050] FIG. 2D shows side profile of the device of FIG. 2A with the eyelids opening, in accordance with embodiments.

[0051] FIG. 2E shows a device comprising a contact lens placed on the eye such that the device is supported with an inner portion of the cornea and the conjunctiva with the device separated from an outer portion of the cornea so as to define a chamber when the eyelids are separated, in accordance with embodiments.

[0052] FIG. 2F shows a profile view of the device of FIG. 2E with the eyelids closing, in accordance with embodiments.

[0053] FIG. 2F1 shows a profile view of the device of FIG. 2F with rotation of the eye when the lids close such that sliding of the device along the epithelium is inhibited when tear liquid is pumped, in accordance with embodiments.

[0054] FIG. 2G shows a profile view of the device of FIG. 2E with the eyelids opening, in accordance with embodiments.

[0055] FIG. 2H shows a profile view of the device of FIG. 2E with the eyelids located at an intermediate location such that the chamber comprises an intermediate volume, in accordance with embodiments.

[0056] FIG. 2I shows a profile view of the device of FIG. 1C4 placed on the eye with silicone or hydrogel contacting the eye, in accordance with embodiments.

[0057] FIG. 3A shows a device positioned on cornea an eye having an epithelial defect, in accordance with embodiments.

[0058] FIG. 3B shows a device in a first configuration prior to placement on cornea of an eye having an epithelial defect, in accordance with embodiments.

[0059] FIG. 3C shows the device of FIG. 3B placed on the eye having a second configuration, in accordance with embodiments.

[0060] FIG. 4A shows a mold suitable to form an optical component of a device.

[0061] FIG. 4B shows a mold suitable to form a device comprising the optical component of FIG. 4A.

[0062] FIG. 4C shows a mold suitable to form a device comprising the optical component of FIG. 4A and a layer of a soft material of the device.

[0063] FIG. 4D shows a mold to form a device and having a solid inner component comprising the rigid material placed therein prior to injection of a flowable material, in accordance with embodiments of the present invention.

[0064] FIG. 4E shows formation of fenestrations in a device with energy, in accordance with embodiments of the present invention.

[0065] FIG. 4F shows spin coating of a silicone or hydrogel material on a posterior surface of the device, in accordance with embodiments of the present invention.

[0066] FIG. 4G shows chemical vapor deposition on the device having the silicone or hydrogel material formed thereon, in accordance with embodiments of the present invention.

[0067] FIG. 4H shows a device comprising the silicone or hydrogel material packaged in a container, in accordance with embodiments of the present invention.

[0068] FIG. 5 shows a device in accordance with certain embodiments.

[0069] FIG. 6A shows views of radials for an example of a hard lens positioned on an astigmatic eye.

[0070] FIG. 6B shows views of radials for an example of a soft lens positioned on an astigmatic eye.

[0071] FIG. 6C shows views of radials for an example of a device according to certain embodiments of the present invention positioned on an astigmatic eye.

[0072] FIG. 7 shows a cross-sectional view of an ophthalmic device according to certain embodiments of the present disclosure.

[0073] FIG. 8A shows the average spherical lens corrected visual acuity (LogMAR) for a population of patients having eyes with 1.25DC to 2.00DC uncorrected cylindrical error and wearing an ophthalmic lens provided by the present disclosure characterized by different thickness of the inner optical region.

[0074] FIG. 8B shows the percent of patients in a population of patients having a visual acuity of less than 20/25 or less than 20/20 when wearing ophthalmic lenses provided by the present

disclosure having different thicknesses and where the patients have eyes with uncorrected cylindrical error of 1.25DC to 2.00DC.

[0075] FIG. 9A shows the average spherical lens corrected visual acuity (LogMAR) for a population of patients having eyes with 2.25DC to 3.00DC of uncorrected cylindrical error and wearing an ophthalmic lens provided by the present disclosure characterized by different thickness of the inner optical region.

[0076] FIG. 9B shows the percent of patients in a population of patients having a visual acuity of less than 20/25 or less than 20/20 when wearing ophthalmic lenses provided by the present disclosure having different thicknesses and where the patients have eyes with uncorrected cylindrical error of 2.25DC to 3.00DC.

[0077] FIG. 10A shows a comparison of the comfort score for patients wearing an ophthalmic lens provided by the present disclosure having different thicknesses of the inner optical portion compared to the comfort score for patients wearing commercially available toric contact lenses for astigmatic correction.

[0078] FIG. 10B shows histograms of the percent of patients having a comfort score equal to or greater than 8 and a comfort score equal to or greater than 9 after wearing an ophthalmic lens provided by the present disclosure with different inner optical region thickness for 30 minutes.

[0079] FIG. 11 shows the experimental configuration for measuring flexure of the inner portion of an ophthalmic lens according to ISO 18369-4.

[0080] FIG. 12 is a graph showing the force (gm) required to flex certain embodiments of an inner portion of an ophthalmic lens provided by the present disclosure having different cross-sectional thicknesses.

[0081] FIG. 13 is a histogram comparing the force (gm) required to flex an inner portion of ophthalmic lenses provided by the present disclosure by 1% with two commercially available lenses used to correct refractive error.

[0082] FIGS. 14A-14C shows cross-sectional profiles for three examples of ophthalmic lenses provided by the present disclosure.

[0083] FIGS. 15A and 15B shows perspective and cross-sectional views, respectively, of an ophthalmic lens for correcting refractive error according to certain embodiments.

[0084] Reference is now made in detail to embodiments provided by the present disclosure. The disclosed embodiments are not intended to be limiting of the claims.

DETAILED DESCRIPTION OF THE INVENTION

[0085] Embodiments of the present invention as described herein can be combined with a therapeutic e device for pain management and vision as described in U.S. Application No. 12/384, 659, filed on April 6, 2009, the full disclosure of which is incorporated by reference and is suitable for combination in accordance with some embodiments of the present invention as described herein.

[0086] An ophthalmic device or device encompasses both ophthalmic coverings and ophthalmic lenses. As used herein, a covering is used to refer to an ophthalmic device that covers an eye of a patient and that does not by itself provide refractive vision correction. Ophthalmic devices that provide refractive correction are referred to herein as contact lenses or ophthalmic lenses. A lens may include certain features as disclosed herein for coverings and coverings may include certain features as disclosed herein for lenses.

[0087] The embodiments described herein can be used to treat eyes in many ways with a device such as a contact lens. A device described herein can be used for long term vision correction with extended wear contact lenses that inhibit swelling of the cornea when the device is positioned on the eye for an extended period, and may also be combined with many forms of ocular surgery, such as photorefractive keratectomy.

[0088] As used herein, mathematical equations and scientific notation can be used to identify values in many ways understood by a person of ordinary skill in the art, for example so as to express data in accordance with notations used in many commercially available spreadsheets such as Excel™ commercially available from Microsoft. As used herein the symbol "E" can be used to express an exponent in base 10, such that 1E1 equals about 10, 2E1 equals about 20, and 4E2 equals about 400. As used herein the symbol "^" can be used to express an exponent, such that A^B equals A^B. Units can be expressed in many ways and as would be understood by a

person of ordinary skill in the art, for example "m" as meters, "Pa" as the Pascal unit for pressure, "MPa" as Mega Pascal.

[0089] As used herein, a siloxane bond encompasses a covalent –Si–O–Si– bond, for example of a silicone elastomer.

[0090] As used herein, an on K fit of a device such as a contact lens encompasses fitting the contact lens to the flattest meridian of the cornea and the on K fit can be flatter than the flattest meridian within about 1.5 D. For example, for a cornea having keratometer values (hereinafter "K's") of about 44D axis 90 and 43D axis 180, the on K fit would provide a device having a curvature corresponding to an optical power within a range from about 43D to about 41.5 D for the region of the eye measured. The on K fit as described herein can allow for tear liquid to form under the device such that the tear liquid can be pumped in accordance with embodiments as described herein.

[0091] The optical power of the cornea in Diopters ("D") can be related to the radius R of curvature of the cornea with the formula D = (1.3375-1)/R, where 1.3375 corresponds to the index of refraction of the aqueous humora. The curvature of the cornea is inversely related to the radius of curvature R such that as the radius of curvature increases the curvature of the cornea decreases and such that as the radius of curvature decreases, the curvature of the cornea increases.

[0092] As used herein the terms outer portion of a lens and peripheral portion of a lens are used interchangeably. The outer or peripheral portion is disposed radially around and connected to the inner portion of a covering or lens. In general, the outer or peripheral portion tapers from a thickness at the interface with the inner portion toward the outer or peripheral edge of the covering or lens. The outer or peripheral portion may be further characterized by sub-portions characterized by, for example, different radii of curvature, thickness, rigidity, and material. Furthermore, the outer or peripheral portion is typically disposed outside the optical region of the corneas with the covering or lens is centered on the cornea of an eye. The inner portion is also referred to herein as the inner or optical component or button. The outer portion is also referred to herein as the outer or coupling component.

[0093] FIG. 1 shows an eye 2 suitable for use with the device 100 (not shown) as described herein. In certain embodiments, device 100 comprises a contact lens. The eye has a cornea 10 and a lens 4 configured to form an image on the retina 5, and the image can form on a fovea 5F corresponding to high visual acuity. The cornea can extend to a limbus 6 of the eye, and the limbus can connect to a sclera S of the eye. The eye 2 has a pars plana PP located near limbus 6. A conjunctiva C of the eye can be disposed over the sclera. The lens can accommodate to focus on an object seen by the patient. The eye has an iris 8 that defines a pupil 9 that may expand and contract in response to light. The eye also comprises a choroid CH disposed the between the sclera 7 and the retina 5. The eye has a vitreous humor VH extending between the lens and the retina. The retina 5 senses light of the image and converts the light image to neural pulses that are processed and transmitted along an optic nerve ON to the brain of the patient.

[0094] FIG. 1-1A shows an ablated eye immediately following refractive surgery, for example PRK surgery resulting in an epithelial defect. The device comprising a contact lens as described herein can be placed over the ablated cornea and coupled to the conjunctiva to provide improved vision. The eye 2 comprises an iris 8 that defines a pupil 9, through which light passes such that the patient can see. Cornea 10 includes an epithelium 12 disposed over a stroma 16. The epithelium 12 comprises a thickness 12T that can be about 50 μm. A tear liquid covers the anterior surface of epithelium 12. In at least humans, primates and some birds, a Bowman's membrane 14 is disposed between epithelium 12 and stroma 16. Bowman's membrane 14 comprises an acellular substantially collagenous tissue with a thickness of about 5 to 10 microns. Stroma 16 comprises a substantially collagenous tissue with keratocytes disposed therein. In some animals, Bowman's membrane may be absent and the epithelium may be disposed adjacent to the stromal layer. An endothelium 18 is disposed under stroma 16. Endothelium 18 comprises a layer of cells that pump water from cornea 10 toward iris 8. Tear liquid also covers surfaces of the cornea that are exposed by the epithelial defect, such as an exposed surface of Bowman's membrane and an exposed stromal surface.

[0095] With refractive surgery, for example PRK, the epithelium can be removed to ablate a refractive correction into Bowman's membrane 14 and/or stroma 16. An initial profile of the anterior surface of stroma and/or Bowman's membrane is ablated to an ablated profile 20 to correct the patient's vision. The profile of tissue removed to correct vision is described in U.S.

Patent No. 5,163,934, entitled "Photorefractive keratectomy", the disclosure of which may be suitable for combination in accordance with some embodiments of the present invention described herein. Ablated profile 20 generally comprises an optical zone that extends across the cornea to correct refractive error of the eye and may correct aberrations of the eye, for example wavefront aberrations. Ablated profile 20 is bounded by boundary 20B that may circumscribe the ablated profile. The ablation profile 20 comprises a maximum dimension across, for example a diameter 20D.

[0096] The epithelium may comprise an inner boundary that moves centripetally inward as indicated by arrows 30.

[0097] In certain embodiments as described herein, irregularities of the cornea are decreased when the epithelium regenerates so as to provide one or more of improved vision or comfort. The devices as described herein can be configured so as to decrease an effect on vision of corneal irregularities.

[0098] FIG. 1A1 shows device 100 positioned on a blinking eye. An upper lid and a lower lid can blink over the eye. Work in relation to embodiments suggests that the upper lid can exert a downward movement 22A and that the lower lid can exert an upper movement 22B on the eye. The downward movement 22A can be greater than the upper movement 22B. The wettable coating material as described herein can decrease force and movement transferred from the lids to the device so as to inhibit motion of the device.

[0099] FIG. 1A2 shows the device of FIG. 1A1 that is capable of pumping tear liquid under the device. The device 100 has inner portion 110 and outer portion 120, and fenestrations 100F extending through the thickness of the device on the outer portion so as to allow tear liquid TL to move through the device, which may comprise a medicament. The medicament may comprise an anesthetic, an analgesic, or other medication, for example.

[0100] The device 100 comprises an optical component 100A and a coupling component 100B. The optical component 100A may comprise an inner portion 110 of device 100 and the coupling component 100B may comprise an outer portion 120 of device 100. The optical component 100A comprises rigidity sufficient to resist deformation such that the optical component 100 can correction vision of the eye. The optical component 100A may comprise a

single layer of material, or a plurality of layers of materials. The coupling component 100B may comprise a rigidity less than optical component 100A, such that the coupling component can one or more of deflect or elastically deform so as to conform to the cornea when covered with the eyelid. The coupling component 100B may comprise an inner component 100B1 to couple to the optical component, an outer portion 100B3 to couple to the sclera, and an intermediate portion 100B2. The intermediate portion 100B2 can extend between the inner component 100B1 and the outer component 100B3 so as define a chamber when placed on the eye.

[0101] The optical component 100A and the coupling component 100B can pump tear liquid to the cornea when the eye closes and opens, for example when the eye blinks. The outer component 100B comprising outer portion 120 may comprise fenestrations 100F. For example, the intermediate portion 100B2 may comprise fenestrations 100F. The outer portion 120 may comprise outer portion 100B3 comprising a sclera coupling portion 130 to contact the conjunctiva over the sclera and peripheral portion 120P. The sclera coupling portion 130 may comprise a thin flange portion extending to the peripheral portion 120P. The sclera coupling portion may comprise a thin elastic portion capable of elastic deformation when the eye blinks to allow the optical component to move downward. Alternatively or in combination, the outer portion 120 may comprise a rigidity sufficient to deflect when the eye blinks.

[0102] FIG. 1A3 shows a schematic illustration of the device of FIGS. 1A1 and 1A2 pumping tear liquid when the eye closes, in accordance with certain embodiments of the present invention.

[0103] When placed on the eye, the device 100 can define a chamber with the lower surface of the device extending along the cornea, the limbus and conjunctiva over the sclera. When the eyelids are separated, the device 100 is held loosely on the eye with slight pressure from the eyelids extending under the outer portion of the device. When the eye blinks, the lids extend over the outer portion 120 of the device and inner portion 110 so as to exert pressure on the device such that the device is urged downward toward the cornea and the volume of the chamber under the device is decreased. The downward movement of the optical component 100A of the inner portion 110 of the device 100 can move the device downward so as to pass pumped tear liquid 100TL through the fenestrations, and in certain embodiments the pumped tear liquid 100TL can pass under the peripheral portion 120P.

[0104] FIG. 1A4 shows a schematic illustration of the device of FIG. 1A1 and 1A2 pumping tear liquid when the eye opens, in accordance with embodiments of the present invention.

[0105] When the eyelids open, the pressure on the device is decreased, such that the device can move away from the cornea and increase the volume of the chamber. The movement of the optical portion 100A away from the cornea can draw pumped tear liquid 100TL into the device through the fenestrations, and contact of the peripheral portion 120P and sclera coupling portion 130 with the conjunctiva can inhibit flow of tear liquid under the peripheral portion 120P. In certain embodiments, the peripheral portion 120P and sclera coupling portion 130 can contact the conjunctiva so as to form a seal when the eyelids open and the optical portion 100A moves away from the cornea.

[0106] The fenestrations 100F can be located away from the optical component, for example about 3.5 mm to about 4.5 mm from a center of the optical component to decrease optical artifacts of the fenestrations 100F. However, the fenestrations may be located within the optical component when of a sufficiently small diameter and sufficiently few so as to not produce perceptible visual artifacts. The fenestrations may comprise a pattern to indicate the orientation of the device 100 on the cornea. For example the upper fenestrations and lower fenestrations may indicate a 90 degree axis on the patient and horizontal fenestrations can be provided to indicate the location of the 180 degree axis on the eye of the patient. The fenestrations may comprise additional fenestrations to be located inferiorly to indicate that the device is not flipped by 180 degrees on the patient, for example upside down. The additional inferior fenestrations may also couple to the rivulet comprising tear liquid that forms near the lower lid, so as to facilitate pumping of tear liquid. For example, when the eye blinks the lower lid may extend over the inferior fenestrations and the upper lid may extend downward to couple to the lower rivulet. When the eye opens and the eyelids separate the upper eyelid can draw tear liquid of the rivulet over the upper fenestration and the lower eyelid can move inferiorly so as to pass the rivulet over the inferior rivulets.

[0107] A device may comprise one or more of many optically clear materials, for example synthetic materials or natural material such as collagen-based materials, and combinations thereof, such as described in U.S. Publication No. U.S. 2010/0036488. For example, a device may comprise a naturally occurring material, such as collagen-based material. Alternatively or

in combination, a device material may comprise a known synthetic material, for example hydroxyethyl methacrylate (HEMA) hydrogel, hydrogel, silicone hydrogel, silicone, for example hydrated silicone and derivatives thereof. For example the optically clear material may comprise one or more of silicone, silicone hydrogel, silicone comprising resin, silicone comprising silicate, acrylate, collagen, or a combination of any of the foregoing. The cured silicone may comprise silicone that is two-part, heat-curable and RTV (room temperature vulcanized). For example, polydimethyl siloxane such as NuSil, or poly(dimethyl) (diphenyl) siloxane may be used to mold the device, for example with less than 10% water content so as to increase oxygen diffusion through the device. A device may comprise perfluoropolyethers or fluorofocal. The material may comprise, for example, silicone elastomer having optically clear silicate disposed therein and a water content of no more than about 10%, for example no more than about 5%, or no more than about 1%, such that the device has a very high Dk exceeding 150 and in certain embodiments exceeding 300, and the silicone lens comprising silicate can be treated to provide a wettable surface. A device may comprise hydrogel, for example silicone hydrogel, or silicone and can be formed with a water content within a range from about 5% to about 35% and a modulus within a range or a combination of ranges from about 0.1 MPa to about 40 MPa, such that the device conforms at least partially to the anterior surface of the cornea. In certain embodiments, devices provided by the present disclsoure do not contain water and provide a barrier for the flow of fluid across the device. For example, when applied to the cornea, devices minimize or prevent the flow of fluid from the cornea and the flow of fluid such as tea fluid from the outer surface of the device to the cornea. The devices provide a fluid seal and the material or materials forming a device are selected to minimize or prevent moisture transport across the device thickness.

[0108] In certain embodiments, the materials forming devices provided by the present disclosure are characterized by a high oxygen permeability (Dk, $cm^2 \cdot mL\ O_2/sec \cdot mL \cdot mm\ Hg$) such as from 100 to 500, from 200 to 500, from 250 to 450, from 300 to 400, and in certain embodiments, about 350. In certain embodiments, devices provided by the present disclosure are characterized by a high oxygen permeability (Dk) such as at least about 250, at least about 300, at least about 350, and in certain embodiments, at least about 400.

[0109] A device may comprise silicone or silicone hydrogel having a low ionoporosity. For example, a device may comprise silicone hydrogel or silicone comprising a low ion permeability, and the range of water can be from about 5% to about 35%, such that the Dk is 100 or more. In certain embodiments, the low ion permeability may comprise an Ionoton Ion Permeability Coefficient of no more than about 0.25×10^{-3} cm^2/sec, for example no more than about 0.08×10^{-3} cm^2/sec. In certain embodiments, the low ion permeability comprises an Ionoton Ion Permeability Coefficient of no more than about 2.6×10^{-6} mm^2/min, for example no more than about 1.5×10^{-6} mm^2/min.

[0110] A device 100 may comprise a wettable surface coating 134 disposed on at least the upper side (anterior surface) of the device, such that the tear film of the patient is smooth over the device and the patient can see. The wettable surface coating may comprise a lubricious coating for patient comfort, for example to lubricate the eye when the patient blinks. The wettable coating may comprise a contact angle no more than about 80 degrees. For example the coating may comprise a contact angle no more than about 70 degrees, and the contact angle can be within a range from about 55 to 65 degrees to provide a surface with a smooth tear layer for vision. For example, the wettable coating can be disposed both an upper surface and a lower surface of the device. The upper surface may comprise the wettable coating extending over at least the inner portion 110.

[0111] A wettable coating 134 may comprise one or more of many materials. For example, the wettable coating 134 may comprise polyethylene glycol (PEG), and the PEG coating can be disposed on Parylene™. Alternatively, the wettable coating 134 may comprise a plasma coating, and the plasma coating may comprise a luminous chemical vapor deposition (LCVD) film. For example, the plasma coating comprises at least one of a hydrocarbon, for example CH_4, O_2 or fluorine containing hydrocarbon, for example CF_4 coating. Alternatively or in combination, the wettable coating may comprise a polyethylene glycol (PEG) coating or 2-hydroxyethylmethacrylate (HEMA). For example, the wettable coating may comprise HEMA disposed on a Parylene™ coating, or the wettable coating may comprise N-vinylpyrrolidone (NVP) disposed on a Parylene™ coating.

[0112] The device 100 may comprise a base radius R1 of curvature corresponding to a curvature of a central portion of the cornea. The device 100 comprises a first configuration

100C1 when placed on the cornea and the eyelids are spaced apart and a second configuration 100C2 when placed on the cornea and the blinks such that the eyelids. The first configuration 100C1 and the second configuration 100C2 pump tear liquid under the device 100.

[0113] The device 100 may comprise a lower surface corresponding to one or more of many suitable shapes to fit the device to the cornea, such as a natural unablated cornea or an ablated cornea following refractive surgery such as PRK. The lower surface of the inner portion 110 of the device 100 may correspond to base radius of curvature. With post-ablation corneas, the device can resist deformation and smooth the epithelium over about 3 mm and may deflect so as conform substantially to the ablated cornea over a larger dimension such as 6 mm. The device may comprise a second curve in combination with a first curve, such that the lower surface comprises a bicurve surface. Alternatively, the lower surface may correspond to an aspheric surface. For example an aspheric surface may comprise an oblate shape and conic constant to fit a post PRK eye. The curved and aspheric surfaces as described herein can fit non- ablated eyes and the device can be selected by based on the curvature of an un-ablated central region of the cornea. Also, it may be helpful to identity a device that fits the cornea, for example with selection of one device from a plurality of sizes.

[0114] A device 100 may comprise an inner portion 110 having an optical component 1 100A. The optical component 100A may comprise an inner portion 110 of the device 100. The optical component may have a modulus within a range from about 5 MPa to about 40 MPa, and a thickness within a range from about 100 μm to about 300 μm such that the central portion can have sufficient rigidity to resist deformation and smooth irregularities and correct vision. A device may comprise an elastomeric stretchable material such that the device can stretch to fit the cornea, for example. A device having the modulus within a range from about 4 MPa to about 40 MPa can be formed in many ways as described herein. For example, the device may comprise a single piece of material having a non-uniform thickness extending across the cornea. A device can be shaped in many ways and may comprise a single piece of one material, or may comprise a single piece composed of two similar materials, or may comprise a plurality of materials joined together.

[0115] FIG. 1B1 shows device 100 having a tricurve profile to fit a sclera and cornea. The tricurve profile can be used to fit an unablated natural eye, in which the base curvature R1

corresponds to the optically used central portion of the cornea. For ablated corneas, the base curvature R1 may correspond to the ablated cornea. The tricurve device may comprise an inner portion with an inner lower surface having radius of curvature R1 and an outer portion comprising an outer lower surface having radius of curvature R1B. The outer portion 130 may comprise the sclera coupling portion 130 having a third radius of curvature R1C sized to fit the conjunctiva located over the sclera and contact the conjunctiva so as to inhibit sliding movement of inner portion 110. Work in relation to embodiments suggests that coupling to the sclera may improve alignment of the lens on the cornea.

[0116] The device 100 having the tricurve profile may comprise dimensions sized to fit the cornea and sclera of the eye 2. The device 100 having the at least a tricurve profile may comprise an inner portion 110 and an outer portion 120 as described herein. The outer portion 120 may comprise the third sclera coupling portion 130 having curvature R1C shaped to fit the sclera of the eye, for example shaped so as to contact the conjunctiva of the eye such that the conjunctiva is located between the sclera and the sclera coupling portion 130. The inner portion 110 may comprise a dimension 102 and the outer portion 120 may comprise a dimension 104 as described herein. The device 100 may comprise a sag height 105 extending between an upper location of the inner portion 110 and the outer boundary of outer portion 120 shaped to fit the cornea. The sclera coupling portion 130 may comprise a dimension across 103.

[0117] The dimension 102, the dimension 104, the dimension 103, the dimension 105 and the dimension 105S can be sized to the eye based on measurements of the eye. The dimension 103 may correspond to an annular region of the sclera extending from the limbus to the outer boundary of the sclera coupling portion across a distance within a range from about 1 to 4 mm, for example within a range from about 1.5 to 2 mm. The size of the limbus of the eye can be measured so as to correspond to dimension 104, for example, and can be within a range from about 11 to 13 mm. The dimension 105 may correspond to a height of the eye from the vertex of the cornea to the limbus, and the dimension 105S may correspond to the sag height were the outer location of the device couples to the conjunctiva device the sclera.

[0118] The dimension 102 may correspond to an inner region of the natural cornea or the dimension across an ablation. Dimension 102 may correspond to the more rigid inner portion 110 can be sized about 0.5 to about 2 mm less than the dimension across the ablation zone, such

that the soft and less rigid outer portion 120 contacts the eye near the edge of the ablation and the epithelial debridement.

[0119] The radius of curvature R1C of portion 130 can be determined so as to fit the eye, and can be within a range from about 12 mm ± 3 mm. The radius R1B of the outer portion can be fit to within about ±0.5 mm, for example to within about ±0.25 mm.

[0120] The dimensions of the device 100 can be determined in many ways, for example with topography measurements of the cornea and sclera. The corneal and scleral topography can be measured with many instruments, such as with the OrbscanTM topography system commercially available from Bausch and Lomb, and the PentacamTM Scheimpflug camera system commercially available from Oculus, and commercially available optical coherence tomography (OCT). The ablation profile can be combined with the topography to determine the shape of the eye.

[0121] The dimensions of device 100 can be sized to one or more of the cornea and sclera based on tolerances that may be determined clinically.

[0122] The outer portion 120 and sclera coupling portion 130 may comprise a silicone or hydrogel material, for example a silicone or silicone hydrogel material, and the inner portion 110 may comprise the rigid material 110M, for example second layer 110L2 and second material 110M2 between first layer 110L1 of first material 110M1 and third layer 110L3 of third material 110M3 as described herein.

[0123] The portions of devices as described herein, for example the inner portion and the outer portion, may comprise a junction wherein a first portion connects with a second portion, and the junction may have the modulus as described herein. A device may comprise a contact lens having a central lens portion having a center stiffness of at least about 2 psi-mm^2 coupled to an outer lenticular junction portion having a lenticular junction stiffness of at least about 5 psi-mm^2.

[0124] FIG. 1B2 shows device 100 having a tricurve profile to fit sclera with slopes of the curved profiles aligned so as to inhibit ridges at the boundaries of the curved portions, in accordance with embodiments of the present invention. An inner portion 110 comprises the optical component 100A and the outer portion 120 comprises the coupling component 100B. A coupling component 100B may comprise a thin layer of material 120M extending under the

optical component 100A for improved comfort and support of the optical component. An outer portion 120 comprising coupling component 100B may comprise fenestrations 100F as described herein. An inner portion 120 comprises first radius R1 along the lower surface and a first anterior radius R1A along the upper surface. An outer portion 120 couples to the inner portion with a second radius R1B aligned with the first radius R1A at a boundary corresponding to dimension 102. The outer portion 120 has a second anterior radius R1BA extending along the anterior surface. The outer portion 120 comprising second radius R1B along the lower surface to contact the cornea may couple to sclera coupling portion 130 at a location corresponding to the limbus of the eye, for example along a boundary corresponding to dimension 104. Work in relation to embodiments suggests that formation of a ridge near the boundary of the cornea contacting portion and sclera coupling portion may decrease epithelial cell migration somewhat more than would be ideal, and the alignment of the curved profiles to inhibit ridge formation can provide a smooth transition over the limbus and may decrease mechanical pressure to the limbus. The sclera contacting portion 130 comprises an upper surface having an anterior radius of curvature R1CA.

[0125] The inner portion 110 can be curved to fit an ablated eye or a non-ablated eye. The modulus and thickness of the sclera coupling portion can be configured in many ways to fit may eyes with comfort and so as to resist movement of the inner portion 120. The modulus of sclera coupling portion 130 may be no more than about 5 MPa and the thickness no more than about 200 μm, for example no more than 100 μm, so as to stretch substantially for comfort and resist movement of the inner portion when the placed on the sclera.

[0126] The dimension 103 of sclera coupling portion 130 may correspond to an annular region of the sclera extending from the limbus to the outer boundary of the sclera coupling portion across a distance within a range from about 1 to 4 mm, such that the dimension 103 can be from about 12 mm to about 16 mm, for example from about 14 mm to about 16 mm.

[0127] The radius of curvature R1C, thickness and modulus of the portion 130 can be configured so as to fit the eye to resist movement of inner portion 110 and with comfort. The radius of curvature R1C can be sized less than the radius of curvature of the sclera and conjunctiva. For example, the radius of curvature R1C can be no more than about 10 mm, for example no more than about 9 mm when the curvature of the sclera portion of the eye is at least

about 12 mm for example. The third relative rigidity may comprise no more than about 4E-5 Pa-m^3 so as to stretch substantially for comfort and resist movement of the inner portion when the outer portion is placed on the sclera.

[0128] The thickness of the sclera coupling portion having radius of curvature R1C can vary, for example from a thickness of about 100 μm to a tapered edge.

[0129] FIG. 1B2-1 shows alignment of the slope of the lower surface of the corneal contacting portion comprising second radius R1B with the slope of the lower surface of the sclera coupling portion 130 comprising radius R1C, such that pressure to the limbus is decreased substantially. The second slope corresponding to second radius R1B is given by a height R1BY and a length R1BX, and the third slope corresponding to third radius R1C is given by height R1CY and width R1CX. The second slope is aligned with the third slope such that no substantial ridge is formed at the location corresponding to the limbus. For example, the first slope can be substantially equal to the second slope. The slope of the inner portion 110 can be aligned with the slope of the second portion 120 at a location corresponding to dimension 102 in a similar manner.

[0130] FIG. 1B3 shows a tapered edge of the device of FIG. 1B1 having a tricurve profile to fit sclera and cornea. The sclera coupling portion 130 may comprise a flange 120F having a narrowing taper extending a distance 120FW to a chamfer 120FE. The chamfer 120FE can be defined along an outer rim where a first convexly curved lower surface joins a second convexly curved upper surface. The convex surfaces along the outer rim allow the device to slide along the conjunctiva and the narrowing taper permits the sclera coupling portion of the device to stretch substantially and couple to the sclera and conjunctiva with decreased resistance for comfort.

[0131] The dimensions of the device 100 can be determined in many ways, for example with one or more topography measurements or tomography measurements of the cornea and sclera. The corneal and sclera topography can be measured with many instruments, such as with the OrbscanTM topography system commercially available from Bausch and Lomb, and the PentacamTM Scheimpflug camera system commercially available from Oculus. The tomography can be measured with optical coherence tomography (hereinafter "OCT") so as to determine the sag height of the limbus and conjunctiva, for example with OCT measurement

systems commercially available from Zeiss/Humphrey. The ablation profile can be combined with the topography to determine the shape of the eye.

[0132] FIG. 1B4 shows a plan view device 100 having a multi-curve profile to fit the cornea, limbus and sclera with slopes of the curved profiles aligned so as to inhibit ridges at the boundaries of the curved portions, in accordance with embodiments of the present invention. The device 100 comprises fenestrations 100F and optical component 100A for vision correction and outer coupling component 100B that may pump tear liquid as described herein.

[0133] FIG. 1B5 shows a side sectional view of the device of FIG. 1B4 and corresponding curved portions to couple to the cornea, limbus, and sclera, in accordance with embodiments of the present invention.

[0134] The inner portion 110 comprises optical component 100A, which may comprise material 110M. The outer portion 120 comprises coupling component 100B, which may comprise outer material 120M. The inner portion 110 is coupled to the outer portion along a boundary corresponding to dimension 102. The lower surface of inner portion 110 has a shape profile corresponding to a first radius R1. The outer portion 120 couples to the inner portion with a first outer radius R1B1 of curvature, such that the slopes are aligned as described herein at a location corresponding to dimension 102. The outer portion 120 comprises a second outer radius R1B2 of curvature coupled to the first outer radius of curvature R1B1. The first outer radius R1B1 of curvature is coupled to the second outer radius R1B2 of curvature with the slopes aligned as described herein at a location corresponding to dimension 104A. The outer portion 120 comprises a third outer radius R1B3 of curvature coupled to the second outer radius of curvature R1B2. The second outer radius R1B2 of curvature is coupled to the third outer radius R1B3 of curvature with the slopes aligned as described herein at a location corresponding to dimension 104B.

[0135] The first outer radius of curvature R1B1, the second outer radius of curvature R1B2, and the third outer radius of curvature R1B3 may comprise values determined from a patient population. The first radius of curvature R1 may comprise a value determined based on the patient population. Alternatively or in combination, the first radius of curvature R1 may correspond to a post ablation profile.

[0136] The first outer radius of curvature R1B1, the second outer radius of curvature R1B2, and the third outer radius of curvature R1B3 can be combined or replaced with an aspheric surface such as a conic surface. The conic surface can be determined in accordance with the first outer radius of curvature R1B1, the second outer radius of curvature R1B2, and the third outer radius of curvature R1B3, such that the conic surface corresponds to values determined from a patient population.

[0137] The sclera coupling portion 130 may have a lower surface comprising a first sclera coupling radius R1C1 of curvature and a second sclera coupling portion having a second sclera coupling radius R1C2 of curvature. The first sclera coupling portion comprising radius R1C1 can be aligned to the third radius R1B3 at a location corresponding to dimension 104. The second sclera coupling portion comprising radius R1C2 can be aligned to the first sclera coupling portion having radius R1C1 at a location corresponding to dimension 120FW corresponding to an inner boundary of tapering flange 120F.

[0138] FIG. 1B6 shows a profile view of the device of FIG. 1B4 and corresponding curved portions of the upper surface, in accordance with embodiments of the present invention. The upper surface may comprise an inner anterior radius of curvature R1A, a first outer anterior radius of curvature R1B1A, a second outer anterior radius of curvature R1B2A. The sclera coupling portion 130 may comprise a first anterior radius R1C1A of curvature and a second anterior coupling radius R1C2A of curvature.

[0139] FIG. 1B7 shows a tapered edge of the device of FIG. 1B4, in accordance with embodiments of the present invention.

[0140] Fig. 1C shows device 100 comprising a device molded with a homogeneous material, in which the outer portion comprises a thickness configured to conform to the surface of the cornea and in which the inner portion 110 comprises thickness configured to smooth the epithelium and cornea. The inner portion 110 comprises optical component 100A, and the outer portion 120 comprises coupling component 100B. The inner portion 110 may comprise a thickness of no more than about 300 microns, for example no more than about 200 microns. Many materials can be used as described herein, and the device may comprise one or more materials. For example, the device may comprise a single piece of material such as silicone having a water content within

a range from about 0.1 % to about 10%, for example no more than about 1%, and a hardness Shore A durometer parameter within a range from about 5 to about 90, for example within a range from about 40 to about 85.

[0141] FIG. 1C1 shows a device 100 having an inner portion 110 comprising an inner thickness and an inner material 110M and an outer portion 120 comprising an outer thickness and an outer material 120M, in which the inner thickness is greater than the outer thickness. The inner material 110M may comprise many materials and may comprise an optically clear silicone, for example silicone with resin. The inner material may comprise silicone positioned in a mold with the outer portion 120 formed around the inner portion. The inner portion may comprise a hardness similar to the outer portion. The outer material 120M of the outer portion 120 may comprise a material similar to the inner portion. For example the outer material 120M may comprise silicone and the inner material 110M may comprise silicone. This use of similar materials on the inner and outer portion can improve adhesion of the inner portion to the outer portion. The outer material 120M may extend along the inner portion 110, for example along the underside of the inner portion 110, such that the inner material 110M is held in a pocket of the outer material 120M. Alternatively, the inner material 110M may extend substantially across the thickness of the inner portion 110, such that the outer material 120M comprises a substantially annular shape with the inner material 110M comprising a disc shaped portion disposed within the annulus and extending substantially from the upper surface coating to the lower surface coating when present.

[0142] FIG. 1C2 shows device 100 having inner portion 110 comprising an inner thickness and inner material 110M and outer portion 120 comprising an outer thickness and outer material 120M, in which the inner thickness can be greater than the outer thickness and the outer material 120M extends around the inner material 110M. The inner portion 110 comprises the optical component 100A and the outer portion 120 comprises the coupling component 100B. The device 100 may comprise at least a bicurve device having at least a second radius R1B. The inner portion 110M may comprise three layers of material, a first layer 110L1 of a first material 110M1, a second layer 110L2 of a second material 110M2 and a third layer 110L3 of a third material 110M3. The second material 110M2 may comprise a rigid material, for example one or more of a rigid gas permeable material, a rigid silicone, or a rigid silicone acrylate. The first

material 110M1 and the third material 110M3 may comprise a soft material, for example a soft elastomer, soft hydrogel, or soft silicone such as one or more of a soft optically clear silicone or a soft silicone hydrogel. The first material, the third material, and the outer material 120M may comprise similar materials, such that the second layer of rigid material 110M2 is encapsulated with the first soft material 110M1, the third soft material 110M3 and on the perimeter with the soft outer material 120M. In certain embodiments, the second rigid material 110M2 comprises a material similar to each of the first material 110M1, the third material 110M3 and the outer material 120M, for example each may comprise silicone, such that the corresponding portions of the device 100 can be bonded together with the silicone similar silicone elastomer material, for example. In certain embodiments, the device 100 can be formed in a mold with rigid second material 110M2 placed in the mold and encapsulated within a single piece of material comprising first material 110M1, third material 110M3 and outer material 120M, such that first material 110M1, third material 110M3 and outer material 120M comprise substantially the same material, for example silicone elastomer. The rigid second material 110M2 may comprise silicone bonded to each of first material 110M1, third material 110M3 and the outer material 120M, for example with curing such that first material 110M1, third material 110M3 and outer material 120M comprise the same soft silicone material bonded to the second material 110M2 comprising rigid silicone.

[0143] The soft material comprising soft outer portion 120 composed of soft material 120M, first layer 110L1 composed of soft material 110M1 and third layer 110L3 composed of soft material 120M3 can provide improved comfort and healing for the patient, and can extend the amount of time the device can be worn in the eye when combined with the fenestrations 100F and sclera coupling component 130 and peripheral portion 120P and flange 120F as described herein. The soft material can deflect, bend or indent so as to conform at least partially to the tissue of the eye when the rigid portion comprising rigid material 110M2 corrects vision of the patient. The dimension 102 across inner portion 110 can be sized to substantially cover one or more of the entrance pupil of the eye or ablation zone. With ablated eyes, the dimension 102 can be sized slightly smaller than the ablation dimensions, such as ablation diameter 20D, so that the epithelium can grow inward and contact the layer 110L1 of soft first material 110M1 without substantial disruption from the rigid material 120M2 when the inner portion 110M corrects vision with the layer of rigid material 110M2. The eyelid can also move over the third layer

110M3 for improved comfort. The soft first material 110M1 and soft third material 110M3 may comprise soft elastomer, soft hydrogel, or soft silicone, for example, and may each comprise the same material so as to encapsulate the second layer 110L2 of rigid second material 110M2.

[0144] The soft material comprising soft outer portion 120 composed of soft material 120M, first layer 110L1 composed of soft material 110M1 and third layer 110L3 composed of soft material 120M3 can have a modulus within a range from about 1 to 20 MPa, for example within a range from about 1 to 5 MPa.

[0145] The material inner material 120M and 120M2 of second layer 120L2 can have a modulus within a range from about 5 MPa to about 35 MPa or more, for example as set forth in Table A below. For example, when material 120M comprises silicone elastomer or layer 110L2 of material 120M2 comprises silicone elastomer, the modulus can be within a range from about 5 MPa to about 35 MPa, for example within a range from about 20 MPa to about 35 MPa.

[0146] The layers of device 100 can comprise dimensions so as to provide therapeutic benefit when placed on eye 2. The thickness of layer 110L1 can be from about 5 μm to about 50 μm, for example, within a range from about 10 μm to 30 μm, such that the layer 110L1 can provide a soft at least partially conformable material to receive the lens. The middle layer 110L2 can be from about 20 μm to about 150 μm, for example, and material M2 can have a modulus greater than first material 110M1 of first layer 110L1, so as to deflect the epithelium of the eye when the middle layer is deflected. The third layer 110L3 can be within a range from about 5 μm to 50 μm, for example within a range from about 10 μm to about 30 μm, and can cover second layer 110L2 so as to retain the second layer in the inner portion 110 of the device 100.

[0147] The therapeutic device 100 may comprise a first inner material 110M and a second outer material 120M, in which the outer portion 120 comprises a hardness configured to stretch elastically and conform with one or more of epithelium of the cornea or the conjunctiva, and in which the inner portion 110 comprises second hardness configured to smooth the cornea to provide optical benefit. The outer material 120M may comprise many materials as herein. The Shore A hardness of each of the inner portion and the outer portion can be within a range from about 5 to about 90. For example, the outer material 120M may comprise silicone having a hardness Shore A durometer from about 20 to about 50, for example from about 20 to about 40,

and the inner material 110M may comprise silicone having a Shore A hardness from about 40 to about 90, for example from about 50 to about 90. The outer portion comprises a perimeter 120P, and the perimeter may comprise a peripheral and circumferential edge structure to abut the epithelium to form a seal with the epithelium, for example when the base radius of the device is less than the cornea. The peripheral and circumferential edge structure can be shaped in many ways to define an edge extending around the perimeter to abut the epithelium, for example with one or more of a taper of the edge portion extending to the perimeter, a bevel of the edge portion extending to the perimeter or a chamfer of the edge portion extending to the perimeter. The inner portion 110 may comprise inner thickness and inner material 110M and the outer portion 120 may comprise an outer thickness and outer material 120M, in which the inner thickness is substantially similar to the outer thickness.

[0148] The peripheral edge structure to abut the epithelium can be used with many configurations of the inner portion as described herein. For example, the inner portion may comprise an RGP lens material having a lower rigid surface to contact and smooth the cornea and an upper rigid optical surface. Alternatively, the inner portion may conform to the cornea as described herein. The outer portion may comprise a skirt, and the skirt may comprise the peripheral edge structure to abut and seal the cornea, such as the chamfer. The rigidity of the outer portion comprising the edge structure can be determined to seal the cornea with one or more of hardness and thickness, as described herein.

[0149] FIG. 1C2A shows a device as in one or more of FIGS. 1-2A to 1B7 having a layer of silicone or hydrogel material on a posterior surface of the device. The device 100 may comprise a wettable surface coating 134 disposed on at least the upper side of the device as described herein. The layer of silicone or hydrogel material may comprise an inner portion of the layer of silicone or hydrogel material 110MHG and an outer portion of the layer of silicone or hydrogel material 120MHG. The layer of silicone or hydrogel material extends to the fenestration so as to couple the silicone or hydrogel material to the fenestration. The silicone or hydrogel material can be coupled to the fenestration in many ways. For example, the layer of silicone or hydrogel material may cover the fenestration, or the fenestration 100F may extend through the silicone or hydrogel material. The fenestration 100F extending through the layer of silicone or hydrogel material can encourage pumping of the tear liquid as described herein. Alternatively or in

combination, the layer of silicone or hydrogel material device a posterior surface of the fenestration 100F to couple the fenestration 100F to the silicone or hydrogel layer may encourage movement of a therapeutic agent along the silicone or hydrogel layer toward a central portion of the cornea for example. The silicone or hydrogel may extend along a deflectable portion of the device so as to exert at least some pressure on the silicone or hydrogel layer to encourage movement of one or more of tear liquid or the therapeutic agent along the silicone or hydrogel layer when the patient blinks, for example.

[0150] The silicone or hydrogel layer as described herein may encourage regeneration of the epithelium and may provide a soft surface to contact the epithelium regenerating over the ablation so as to encourage epithelial regeneration under the optical component as described herein, and the optical component can resist deformation so as to protect the epithelium and provide an environment to encourage regeneration of the epithelium.

[0151] The silicone or hydrogel material may comprise one or more of the silicone or hydrogel materials as described herein. The silicone or hydrogel material extending along the lower surface can increase comfort of the device when placed on the eye. The silicone or hydrogel material may comprise a substantially uniform thickness within a range from about 1 μm to about 100 μm, for example from about 2 μm to about 50 μm and in certain embodiments within a range from about 5 μm to about 20 μm. The silicone or hydrogel material extending along the posterior surface may comprise one or more of the silicone or hydrogel materials as described herein combined with one or more of materials 110M, 110M1, 110M2, 110M3 or 120M as described herein. For example the one or more of materials 110M, 110M1, 110M2, 110M3 or 120M may comprise silicone such as silicone elastomer comprising siloxane, and the silicone or hydrogel may comprise a silicone or hydrogel such as silicone or hydrogel material as described herein.

[0152] FIG. 1C2B shows a device as in one or more of FIGS. 1-2A to 1B7 having a layer of hydrogel material on a posterior surface of the device extending less than a maximum distance across the device such that end portions of the device are configured to engage the epithelium of the eye away from the hydrogel layer and inhibit movement of the device when placed on the eye. In certain embodiments, the material 120M can couple to the surface of the eye, for example the epithelium so as to inhibit movement of the device. The material 120M may

comprise a sticky tacky hydrophobic material such as silicone to engage the epithelium to inhibit movement, and the material 120M may be coated with one or more coatings as described herein, for example with vapor deposition. The silicone or hydrogel material can be coupled to the fenestration in many ways. For example, the layer of silicone or hydrogel material may cover the fenestration, or the fenestration 100F may extend through the silicone or hydrogel material.

[0153] FIG. 1C2C shows a device 100 as in one or more of FIGS. 1-2A to 1B7 having an annular layer of silicone or hydrogel material 120MHG on a posterior surface of the device such that an inner portion of the device contacts the cornea away from the silicone or hydrogel layer and an outer portion of the device contacts the cornea away from the device when placed on the eye. Work in relation to embodiments suggests that the annular silicone or hydrogel layer can provide an environment to encourage growth of the epithelium along the posterior surface of inner material 110M1 as described herein, and the lower surface of material 110M1 can be coated with a material having a thickness less than the silicone or hydrogel, for example.

[0154] FIG. 1C3 shows a device having a tricurve profile to fit sclera with slopes of the curved profiles aligned so as to inhibit ridges at the boundaries of the curved portions as in FIG. 1B2 and having a layer of silicone or hydrogel material 120MHG on a lower surface. The silicone or hydrogel material 120M may extend substantially across the posterior surface of the device. A silicone or hydrogel material may extend along the lower surface a distance less than a distance across the device so as to provide a portion of the device without the silicone or hydrogel to engage the eye, for example the epithelium of the eye that may comprise one or more of the corneal epithelium or the conjunctival epithelium. Alternatively, a silicone or hydrogel material may extend substantially along the posterior surface of the device corresponding to the distance across the device so as to provide a portion of the device with a silicone or hydrogel material over the outer portion of the device that engages the eye.

[0155] FIG. 1C4 shows a plan view of a device having a tricurve profile to fit the cornea, limbus, and sclera with slopes of the curved profiles aligned so as to inhibit ridges at the boundaries of the curved portions as in FIG. 1B4 and having a silicone or hydrogel material on a lower surface extending less than a maximum distance across the device to engage the conjunctiva with the device away from the silicone or hydrogel material. Alternatively, the silicone or hydrogel material may extend substantially along the posterior surface of the device

corresponding to the distance across the device so as to provide the silicone or hydrogel material over the outer portion of the device that engages the eye. The silicone or hydrogel device may comprise an annular shape extending along the lower surface as described herein.

[0156] FIG. 1C5 shows a fenestration 100F having a posterior end 100FPE covered with a layer of silicone or hydrogel material 29MHG extending along the posterior surface of the device 100, in accordance with embodiments of the present invention.

[0157] FIG. 1C6 shows fenestration 100F extending through a layer of silicone or hydrogel material 120MHG extending along the posterior surface of the device 100, in accordance with embodiments of the present invention.

[0158] FIG. 1D shows a device comprising channels 100FC extending radially outward from fenestrations 100F along a lower surface of the device, in accordance with embodiments.

[0159] FIG. 1E shows a device comprising 100FC channels extending radially inward from fenestrations 100F along a lower surface of the device, in accordance with embodiments.

[0160] FIG. 1F shows a test apparatus 190 to measure deflection of a portion of a lens in response to a load. The load deflection of the devices and composite layers as described herein can be used to determine the deflection of the device and corresponding pumping. Work in relation to embodiments suggests that one or more of the inner device or the outer device contacting the epithelium may comprise a rigidity such that blinking of the eye deflects the device sufficiently with elastic deformation so as to urge tear liquid from beneath the device as described herein. For example, the inner portion 120 of the devices suited to cover the ablated cornea and provide pumping as described herein are also well suited to cover natural unablated corneas to provide vision correction with pumping of the tear liquid. The outer portion 120 may comprise a rigidity as described herein sufficient to deflect when the eye blinks and provide elastic deformation that may pump tear liquid under the device such as a contact lens.

[0161] The test apparatus 190 may comprise a rigid support having an aperture 192, such that deflection of the device 100 through the aperture 192 can be measured. The aperture 192 has a dimension across 194 that can be sized smaller than the dimension across inner portion 110, so as to measure a deflection 110D of the inner portion 110 in response to a load 196. The deflection 110D may comprise a peak deflection, for example a distance. The load 196 may

comprise a point load or a load distributed over an area corresponding to diameter 104, for example a pressure from a gas or liquid on the lower side of the device. The device may comprise a first configuration C1 corresponding to the shape of the device prior to placement on the eye, and the device may comprise a second configuration C2 when placed on the eye, and the amount of force and/or pressure to deflect device 100 can be determined such that device 100 can be deflected without substantially degrading vision and so as to smooth the epithelium. For example, the device may deflect slightly so as to decrease vision no more than about 1 or 2 lines of visual acuity and such that the device can smooth the epithelium and provide environment 100E as described herein.

[0162] The modulus and thickness of the device can be used to determine an amount of relative rigidity of the device 100, the corresponding amount of force to deflect the device 100 across a distance, and the corresponding amount pressure to smooth the epithelium with the deflected device as described herein.

[0163] The amount of relative rigidity can be determined based on the modulus multiplied with cube of the thickness. The amount of deflection corresponds to the sixth power of the deflected span across the device, the modulus, and the cube of the thickness. The approximately fourth order relationship of the span to the deflection can allow the devices as described herein to conform at least partially to the ablation profile within a range from about 4 mm to 6 mm, and inhibit substantially irregularities having diameters of about 3 mm or less, for example.

[0164] The deflection can be approximated with the following equation:

$$\text{Deflection} \approx (\text{constant}) \times (\text{Load} \times \text{Span}^4) / (\text{Modulus} \times \text{thickness}^3)$$

[0165] The above approximation can be useful to understand the properties of device 100, for example with a substantially uniform thickness of the inner portion. The substantially uniform thickness may comprise a thickness that is uniform to within about ±25%, for example to within about ±10%, such that the device can conform substantially to at least a majority of the surface area of an ablation zone and inhibit irregularities over a smaller portion of the ablation zone corresponding to no more than a minority of the surface area of the ablation. In certain embodiments, a device conforms over an area having diameter of at least about 4 mm and inhibits irregularities over an area having a diameter of no more than about 4 mm, for example

less inhibits irregularities over an area of no more than about 3 mm. For example, based on the above equations, the deflection is related to the fourth power of the span, such that for a comparable load, a 2 mm span will have about $1/16^{h}$ the deflection of a 4 mm span. Similarly, a 3 mm span will have a deflection that is about $1/16^{h}$ the deflection of a 6 mm span. As the deflection is related to the cube of the thickness, doubling the thickness can decrease the deflection by about a factor of 8. The above approximations can be combined with clinical testing to determine thicknesses and moduli suitable for incorporation in accordance with embodiments as described herein.

[0166] The equations for deflection of an unsupported circular span of a material having a substantially uniform thickness are:

$$E_c = E_1\left(\frac{t_1}{t_1 + t_2}\right) + E_2\left(\frac{t_2}{t_1 + t_2}\right)$$

$$\text{"Relative" Rigidity} = E_c(t_1 + t_2)^3$$

$$y = \frac{3wR^4}{16Et^3}(5 + v)(1 - v)$$

$$w = \frac{y16Et^3}{(5 + v)(1 - v)3R^4}$$

where:

W = evenly distributed load over the surface, Pressure (Pa);

R=span of unsupported material (m);

E=Young's Modulus (Pa);

t=Thickness (m);

v=Poisson's Ratio (unit-less, assumed to be constant among materials); and

y= Deflection (m).

[0167] The equations for deflection are described in Theory and analysis of elastic plates, Junuthula Narasimha Reddy, p. 201 equation 5.3.43 (1999).

[0168] Although the above equations describe relative rigidity for a substantially flat surface, the equations can approximate a curved surface and a person of ordinary skill in the art can determine the deflection load and relative rigidity empirically based on the teachings described herein, for example with finite element modeling.

[0169] Table A1. Material, modulus, thickness, relative rigidity Dk/and deflection load of inner portions of devices as described herein.

Button Material	Uniform Button Thickness (um)	Button Thickness (m)	Flexural Modulus (MPa)	Flexural Modulus (Pa)	Relative Rigidity (Pa*m^3)	Material Dk	Dk/t
Rigid Silicone	250	2.50.E-04	35	35000000	5.47E-04	600	240
Rigid Silicone	200	2.00.E-04	35	35000000	2.80E-04	600	300
Rigid Silicone	150	1.50.E-04	35	35000000	1.18E-04	600	400
Rigid Silicone	100	1.00.E-04	35	35000000	3.50E-05	600	600
Rigid Silicone	50	5.00.E-05	35	35000000	4.38E-06	600	1200
Exemplary Silicone	293	2.93.E-04	20	20000000	5.03E-04	600	205
Exemplary Silicone	272	2.72.E-04	20	20000000	4.02E-04	600	221
Exemplary Silicone	250	2.50.E-04	20	20000000	3.13E-04	600	240
Exemplary Silicone	215	2.15.E-04	20	20000000	1.99E-04	600	279
Exemplary Silicone	200	2.00.E-04	20	20000000	1.60E-04	600	300
Exemplary Silicone	175	1.75.E-04	20	20000000	1.07E-04	600	343
Exemplary Silicone	150	1.50.E-04	20	20000000	6.75E-05	600	400
Exemplary Silicone	100	1.00.E-04	20	20000000	2.00E-05	600	600
Exemplary Material	50	5.00.E-05	20	20000000	2.50E-06	600	1200
enflufocon	25	2.50.E-05	1900	1900000000	2.97E-05	18	72

Button Material	Uniform Button Thickness (um)	Button Thickness (m)	Flexural Modulus (MPa)	Flexural Modulus (Pa)	Relative Rigidity (Pa*m^3)	Material Dk	Dk/t
A (Boston ES)							
enflufocon A	50	5.00.E-05	1900	1900000000	2.38E-04	18	36
enflufocon A	150	1.50.E-04	1900	1900000000	6.41E-03	18	12
hexafocon B (Boston XO2)	25	2.50.E-05	1160	1160000000	1.81E-05	141	564
hexafocon B	50	5.00.E-05	1160	1160000000	1.45E-04	141	282
hexafocon B	150	1.50.E-04	1160	1160000000	3.92E-03	141	94

[0170] As shown in Table A1, an RGP material such as an enflufocon or hexafocon having a thickness of about 50 μm can have a relative rigidity suitable for epithelial smoothing and so as to conform at least partially to the ablated stroma. The rigid silicone having a modulus of about 20 MPa and a thickness of about 250 μm will provide a relative rigidity 3E-4 and deflection under load similar to the RGP material having a thickness of about 50 μm and modulus of about 1900 MPa so as to provide a relative rigidity of about 2.4E-4. Commercially available RGP lens materials as shown in Table A1 can be combined in accordance with embodiments as described herein so as to provide device 100. Based on the teachings described herein, a person of ordinary skill in the art can determine the thickness of the device based on the modulus and the intended relative rigidity.

[0171] Work in relation to embodiments in accordance with clinical studies as described herein has shown that the inner portion 110 of the device 100 having the relative rigidity of about 3E-4 (3×10^{-4}Pa-m^3) can be effective so to improve vision and conform at least partially of the eye so as to provide at least some comfort and improve fitting. Many eyes have been measured with many devices and work in relation to embodiments indicates that an inner portion 110 having a relative rigidity within a range from about 1E-4 to about 5E-4 (Pa-m^3) can allow the device to conform to the ablation and smooth the epithelium as described herein. For example, inner

portion 110 may a relative rigidity within a range from about 2E-4 to about 4E-4, and the eye can be fit accordingly based on the deflection of the device 100.

[0172] The relative rigidity can be related to the amount of deflection of the device 100 on the eye. Work in relation to embodiments indicates that a relative rigidity of inner portion 110 about 3E-4 can deflect about ± 2D when placed on the eye so as to conform to an ablation to within about ± 2D across the approximately 5 mm or 6 mm ablation diameter when an inner diameter of about 2 mm or 3 mm is smoothed. A device 100 having a relative rigidity of about 1.5 E-4 can deflect about ±4D when placed on the eye so as to conform to an ablation to within about ±4D across an approximately 5 mm or 6 mm diameter when an inner diameter of about 2 mm or 3 mm is smoothed.

[0173] The o-n, for example for coverings having a plurality of layers having a plurality of materials.

Table A3. Relative Rigidity of Layered Devices

Total Thickness	Layered Material	Material 1 (Rigid)		Material 2 (Soft)		Composite		Relative Rigidity (Pa-m^3)
		Thickness (m)	Modulus (Pa)	Thickness (m)	Flexural Modulus (Pa)	Thickness (m)	Composite Modulus (Pa)	
270 µm thick	Exemplary Silicone Shield	2.40E-04	2.00E+07	3.00E-05	2.00E+06	2.70E-04	1.80E+07	3.54E-04
	Soft and Hard are Equal	1.35E-04	2.00E+07	1.25E-04	2.00E+06	2.70E-04	1.13E+07	1.99E-04
150 µm thick	Exemplary Silicone Shield	1.20E-04	2.00E+07	3.00E-05	2.00E+06	1.50E-04	1.64E+07	5.54E-05
	Soft and Hard w/ Equal thickness	7.50E-05	2.00E+07	7.50E-05	2.00E+06	1.50E-04	1.10E+07	3.71E-05

[0174] When two or more materials are combined so as to provide two or more layers, the relative rigidity of each layer can be combined so as to determine a total composite rigidity. For example, the combined rigidity can be determined for a device having first layer 110L1 of first material, a second layer 110L2 of second material M2 and third layer 110L3 of third material 110L3, in which the first and third materials can be the same material.

[0175] A weighted average system can be used to treat the two layers as one material. The relative amounts of each material and the moduli of the two materials can be combined to determine a composite modulus based on the weight average of the thickness of each layer. For example, with 90 μm of 20 MPa material layer and a 10 μm of 5 MPa material layer can be combined so as to determine the composite modulus as

$$20\text{MPa}\times 0.9 + 5\ \text{MPa}\times 0.1 = 18.5\ \text{MPa}$$

[0176] The equations described herein accommodate many layers of different materials and thicknesses.

[0177] Based on the composite modulus, one can multiply the composite modulus by the overall thickness cubed, in the present example 18.5 MPa $\times 100^3$. Although these calculations can be based on approximations, a person of ordinary skill in the art can conduct simulations, for example finite element modeling simulations, so as to determine the amount of relative rigidity, pressures and deflection forces and pressures as described herein.

[0178] The index of refraction of one or more layers of device 100 may correspond substantially to the index of refraction of the cornea.

[0179] One or more of the materials 110M1, 110M2 or 110M3 may comprise an index of refraction within a range from about 1.38 to about 1.43 so as to match the index of refraction of the cornea to within about ± 0.05. For example the materials 110M1 and 110M3 may comprise an optically transparent soft silicone elastomer having an index of refraction of about 1.41 and the material M2 may comprise an optically transparent rigid silicone elastomer having an index of refraction of about 1.43, for example available from NuSil. Alternatively, material 110M1 and material 110M3 may comprise silicone silicone or hydrogel and material 110M2 may silicone, for example.

[0180] While the device may comprise similar materials such as a more rigid silicone combined with a softer silicone, the device may comprise dissimilar materials. For example, an RGP material can be combined with a silicone or hydrogel, such as the bicurve or tricurve embodiments as described herein. The device can extend at least to the limbus for stability. The RGP material may comprise the second layer 110L2 of the second material 110M2, for example in accordance with Table A1, and the hydrogel may comprise the first layer 110L1 of the first

material 110M1 and the third layer 110L3 of the third material 110M3. The hydrogel may have an index of refraction from about 1.38 to about 1.42 so as to match the index of refraction of the cornea of about 1.377 to within about 0.05 and may comprise one or more of HEMA, NVP, GMA, MMA, SiH, TRS, HEMA/NVP, MMA/NVP, HEMA/GMA, or SiH/TRS, commercially available from Vista Optics, UK, for example. The hydrogel comprising HEMA/NVP, MMA/NVP, or HEMA/GMA may have a water content within a range from about 40% to about 70% so as to provide an index of refraction within a range from about 1.38 to about 1.43. A water content of about 40% corresponds to an index of refraction of about 1.43 and a water content of about 70% corresponds to an index of refraction of about 1.38. A hydrogel comprising SiH/TRS may comprise water content within a range from about 20% to about 70% so as to provide an index of refraction within a range from about 1.38 to about 1.43. With these SiH hydrogels a water content of about 20% corresponds to an index of refraction of about 1.43 and a water content of about 70% corresponds to an index of refraction of about 1.38.

[0181] FIG. 2A shows a device 100 comprising a contact lens placed on the eye with the eyelids separated, in accordance with certain embodiments. A device 100 is placed on the eye such that the tear liquid TL extends under at least a portion of the device between the device and the cornea so as to provide a chamber 100C. The device 100 can be fit on K or slightly flatter than the cornea so as to provide chamber 100C. Alternatively or in combination, the flange 120F and sclera coupling portion 120S of the outer portion 120 may comprise an angle steeper than the conjunctiva such the device is urged away from the cornea near inner portion 110 so as to provide chamber 100C. The device 100 comprises a sag height 105S1 corresponding to the elevation distance from the center of the device to the outer perimeter 120P of the sclera coupling portion 130. The eyelids can be separated for the patient to see an object.

[0182] FIG. 2B shows a profile view of the device of Fig. 2A with the eyelids closing.

[0183] FIG. 2C shows a front view the device of Fig. 2A with the eyelids closing, in accordance with embodiments. The eyelids can close with a downward movement 22A of the upper eyelid and an upward movement 22B of the lower eyelid. The closing of the eyelids exerts pressure on the device 100 such that device 100 comprises second configuration 100C2. The second configuration 100C2 comprises the sag height 105 decreased to second sag height 105S2 such that the volume of chamber 100C decreases and urges pumped tear fluid 100TL from under

the device. The pumped tear liquid 100TL flows radially outward under the outer portion 120P and through fenestrations 100F such as fenestrations not covered by the eyelid. The pressure of the eyelid can urge the device 100 toward cornea 100 so as to decrease the volume of chamber 100C. The volume of chamber 100C can decrease substantially when the outer portion 120 comprising flange 120F deflects with elastic deformation. Alternatively or in combination, the outer portion 120 corresponding to the cornea can deflect so as to decrease the volume of chamber 100C. In certain embodiments, the inner portion 110 comprising optical component 100A may deflect with pressure of the eyelid so as to decrease the volume of chamber 100.

[0184] FIG. 2D shows a side profile of the device of FIG. 2A with the eyelids opening, in accordance with embodiments. When the eyelids retract with upward movement 22C of the upper eyelid and downward movement 22D of the lower eyelid, the device 100 can return to the first configuration 100C1 having first sag height 105S1, such that the volume of the chamber increases. The outer portion 120 comprising flange 120F and peripheral portion 120F of the sclera coupling portion 130 may contact the conjunctiva so as to form a contact seal with the conjunctiva. The contact seal with the conjunctiva encourages flow of the tear liquid TL through the fenestrations 100F and into the chamber 100C, such that pumped tear liquid 100TL can be located between the cornea and the device 100.

[0185] The tear rivulet of the lower lid can move upward when the eyes close so as to provide tear liquid on the surface of the eye, and at least a portion of the rivulet can couple to the upper lid when the lids contact each other. When the upper lid moves upward with movement 22C and the lower lid moves downward with movement 22D, the upper lid provide tear liquid TL near the upper fenestrations to pass through the upper fenestrations and the lower lid can provide tear liquid TL near the lower fenestrations to move through the lower fenestrations.

[0186] Repeated blinking of the eye may occur naturally, so as to pump tear liquid under the covering and rinse the cornea and conjunctiva under the device. This pumping and rinsing provided by the device can extend the amount of time the device can be worn by a patient such as a patient having a normal unablated eye, and may encourage epithelial regeneration in post-PRK eyes, for example.

[0187] FIG. 2E shows a device comprising a contact lens placed on the eye such that the device is supported with an inner portion of the cornea and the conjunctiva with the device separated from an outer portion of the cornea so as to define a chamber when the eyelids are separated, in accordance with embodiments. The device 100 may contact the cornea at an inner portion of the cornea, for example at a central location. The inner portion 110 can be sized to fit the cornea centrally as described herein, for example with on K fitting. The outer portion of the device 120 comprising flange 120F and sclera coupling portion 130 can be sized to contact the conjunctiva when the inner portion 110 contacts the sclera centrally, such that chamber 100C is formed over the outer portion of the cornea with a gap extending between the outer portion of the cornea and the device. The outer portion 120 of the device extending over the outer portion of the cornea may have a curvature less than the cornea, such that the outer portion 120 over the outer portion of the cornea can form chamber 100C when the inner portion 110 is supported with the cornea and the outer portion 120 comprising flange 120F is coupled to the conjunctiva. The fenestrations 100F can be located on the device to correspond with a location of chamber 100C and the gap when the eyelids are open. The outer portion 120 comprises a resistance to deflection sufficient to form chamber 100C when the eyelids are open an insufficient to resist deflection when the eyelids move over the outer portion such that the outer portion moves toward the cornea and decrease the gap distance when the eyelids close.

[0188] The device 100 can be fit to the cornea to encourage formation of the chamber 100C and such that device 100 comprises an initial configuration 100C1 with chamber 100C formed beneath. The cornea may comprise a limbus sag height 105L corresponding to an elevational distance extending from a vertex of the cornea to the limbus. The limbus may be located a radial distance 105RL from a measurement axis of the eye. The eye may comprise a conjunctiva sag height 105C at a radial distance 105RC from the axis of the eye. The device may comprise a limbus sag height 105LC at a location corresponding to the radial distance RL to the limbus. The device may comprise a conjunctiva sag height 105CC at a conjunctiva contacting location corresponding to the radial distance 105RC of the conjunctiva, for example along flange 120F. In certain embodiments, the sag height 105LC of the device at the location corresponding to the limbus is no more than the limbus sag height 105L, and the sag height 105CC of the device at the location corresponding to the conjunctiva is no more than the conjunctiva sag height 105C, such that pressure to the limbus is decreased. When the device is placed on the eye, the conjunctiva

coupling portion 130 comprising flange portion 120F can deflect such that the sag height of the conjunctiva contacting portion is decreased from 105CC the sag height of the conjunctiva to the sag height of the conjunctiva 105C, such that the sag height of the device comprises a sag deflected sag height 105S2.

[0189] FIG. 2F shows a side sectional view of the device of Fig. 2E with the eyelids closing such that device 100 comprises a configuration 100C2 with chamber 100C having a decreased volume. When the eyelids close, the upper and lower lids exert pressure on the device such that the device is urged toward the outer portion of cornea and the conjunctiva. The outer portion of the device over the outer portion of the cornea may not have sufficient resistance to deflection such that the outer portion of the device is deflected downward toward the outer portion of the cornea. The gap distance extending between the outer portion of the device over the outer portion of the cornea is decreased, such that the volume of chamber 100C decreases and pumped tear liquid 100TL flow from chamber 100C through fenestrations 100F and under the conjunctiva contacting portion 130 comprising flange portion 120F. The upper eyelid can extend across the pupil so as to cover inferior and superior fenestrations 100F. The upper eyelid may contact the lower eyelid so as to draw the tear liquid of the rivulet superiorly when the eye opens, such that tear liquid of the rivulet can be drawn into the chamber through the inferior and superior fenestrations.

[0190] The deflection of the outer portion of the device over the outer portion of the cornea can be provided with a device having a relative rigidity within a range from about 1.0 E-6 Pa-m^3 to about 6 E-4 Pa-m^3, for example from about 2.5 E-6 Pa-m^3 to about 5 E-4 Pa- m^3. Table A2 shows values suitable of relative rigidity and corresponding ranges of outer portion 120 corresponding to the outer portion of the cornea that can be determined based on the teachings described herein so as to determine the relative rigidity of the outer portion of the device to provide resistance to deflection and form the chamber with the gap when the eyelid is away from the portion of the device and so as to deflect toward the cornea and decrease the gap and corresponding chamber volume when the eyelid covers the portion of the device.

[0191] The deflection of the sclera contacting portion 130 to couple to the conjunctiva can be provided with the sclera contacting portion 130 comprising a relative rigidity of no more than about 2 E-4 Pa-m^3, for example no more than about 1 E-4 Pa-m^3, and in certain embodiments no

more than about 2 E-5 Pa-m^3. Table A2 shows values suitable of relative rigidity and corresponding ranges of sclera coupling portion 130 that can be determined based on the teachings described herein so as to determine the relative rigidity of the sclera coupling portion of the device to provide resistance to deflection and form the chamber with the gap when the eyelid is away from the portion of the device and so as to deflect toward the cornea and decrease the gap and corresponding chamber volume when the eyelid covers the outer portion of the device over the outer portion of the cornea.

[0192] The deflection of the flange portion 120F to couple to the conjunctiva can be provided with the flange portion 130 comprising a relative rigidity of no more than about 1 E-4 Pa-m^3, for example no more than about 2 E-5 Pa-m^3, and in certain embodiments no more than about 2.5 E-6 Pa-m^3. Table A2 shows values suitable of relative rigidity and corresponding ranges of outer flange portion 120F that can be determined based on the teachings described herein so as to determine the relative rigidity of the flange portion 120F of the device to provide resistance to deflection and form the chamber with the gap when the eyelid is away from the portion of the device and so as to deflect toward the cornea and decrease the gap and corresponding chamber volume when the eyelid covers the outer portion of the device over the outer portion of the cornea.

[0193] FIG. 2F1 shows a profile view of the device of Fig. 2F with rotation of the eye when the lids close such that sliding of the device along the epithelium is inhibited when tear liquid is pumped, in accordance with certain embodiments. The axis of the eye can rotate superiorly such that the device slides along the upper lid and the lower lid. The axis of the eye may comprise one or more known axis of the eye and can be determined in many ways by a person of ordinary skill in the art.

[0194] FIG. 2G shows a profile view of the device of Fig. 2E with the eyelids opening, in accordance with embodiments. The opening of the eyelids decreases pressure and allows the outer portion of the device above the outer portion of the cornea to move away from the cornea. The tear liquid TL may pass through fenestrations 100F and into the chamber 100C. The outer portion of the device comprising portion 130 and flange 120F can contact the conjunctiva to inhibit tear flow and may seal the device.

[0195] FIG. 2H shows a profile view of the device of Fig. 2E with the eyelids located at an intermediate location such that the chamber comprises an intermediate configuration 100C12 volume, in accordance with embodiments. The optical component 100A comprising inner portion 110 may comprise sufficient rigidity and resistance to deflection so as to provide vision for the patient when the device comprises intermediate portion 100C12 having outer portion 120 deflected so as to decrease volume of chamber 100C. For example, the patient can close the eyelids to the pupil margin to deflect the outer portion and the optical component 100B and inner portion 110 can remain substantially undeflected such that the patient can have vision of 20/20 or better (metric 6/6 or better) with a portion of one or more eye lids contacting the inner portion 110. Opening of the eyelids can increase the chamber volume and pump tear liquid and closing of the eyelids can decrease chamber volume and pump tear liquid.

[0196] FIG. 2I shows a side view sectional view of the device of Fig. 1C4 placed on the eye with silicone or hydrogel contacting the eye. The device 100 comprises the layer of silicone or hydrogel material 120MHG extending along the posterior surface of the device so as to contact the eye with at least a portion of the silicone or hydrogel layer. The device 100 can be dimensioned to form chamber 100C defined at least in part with the layer of silicone or hydrogel material. Fenestrations may extend through the silicone or hydrogel layer so as to provide pumping as described herein. Alternatively or in combination, the posterior end of the fenestrations can be covered with the silicone or hydrogel material to couple the cornea to the fenestrations with the layer of silicone or hydrogel material. Fenestrations covered with the layer of silicone or hydrogel material 120MHG can be located along the deflectable portion of the device so as to encourage movement of water and therapeutic agents along the silicone or hydrogel material, for example when the eye blinks. The silicone or hydrogel layer may comprise a medium to pass liquid and therapeutic agent from the fenestrations to a desired location of the cornea, for example with wicking of the liquid and therapeutic agent to a central location of the cornea. The device comprising the silicone or hydrogel layer extending along the lower surface as described herein can be fit to an unablated eye to provide refractive correction or fit to an ablated eye as described herein.

[0197] Clinical testing in accordance with embodiments has shown that the curved portions of the device can be fit with on K values in accordance with corneal curvatures and sag heights and limbus sag heights and conjunctiva sag heights of a patient population.

[0198] Appendix I shown herein below provides dimensions and fit parameters for device 100 in accordance with embodiments and teachings as described herein. The devices may comprise one or more of the materials in the Series A Tables shown herein, for example. The dimensions and fit parameters of the devices can provide pumping of the tear liquid when placed on the cornea in accordance with embodiments described herein. The tables of Appendix I identify the devices for use with steep K corneas, medium K corneas and flat K corneas, for example. The K values listed can be based on population norms, such that the devices provide pumping as described herein when placed on the eye. The devices can be used with non-ablated eyes or ablated eyes, and the device can be identified at least in part based on the first inner curvature R1.

[0199] Table B1 shows device 100 having a diameter of approximately 14 mm across and can be fit on K or flatter, for example as described herein. The table lists R1 corresponding to the center ablated portion of the cornea. The inner portion 110 comprising optical component 100A and inner coupling component 100B1 has dimension R1 extends about 5 mm across, and the ablation zone can be larger, for example about 6 mm. The portion corresponding to radius R1B1 has dimensions of about 5-7 mm across, and the curvature can be expressed with keratometry values (K-values) corresponding to the optical power of the eye in Diopters (D). The portion corresponding to radius R1B2 has dimensions of about 7-9 mm across. The portion corresponding to radius R1B3 has dimensions of about 9-11 mm across. The portion corresponding to R1C1 can extend from about 11 to 13.5 mm across, and may comprise curvature having one or more values between portion R1B3 and portion R1C2, for example a radius of curvature between about 8 mm and about 12 mm such as about 10 mm. The portion corresponding to R1C2 can extend from about 13.5 to 14 mm across. The sag height of the portion R1C2 can be from about 3.1 to about 3.4 mm, for example. The portion corresponding to R1C1 can be fit to the cornea in many ways as described herein, for example with the tangent of portion R1C1 aligned with R1B3 on the inner boundary and R1C2 along an outer boundary so as to inhibit ridge formation as described herein.

[0200] Table B2 shows device 100 having a diameter of approximately 14 mm across and can be fit on K or flatter, for example as described herein. The table lists R1 corresponding to the center ablated portion of the cornea. The inner portion 110 comprising optical component 100A and inner coupling component 100B1 has dimension R1 extends about 5 mm across, and the ablation zone can be larger, for example about 6 mm. The portion corresponding to radius R1B1 has dimensions of about 5-7 mm across, and the curvature can be expressed with keratometry values (K-values) corresponding to the optical power of the eye in Diopters (D). The portion corresponding to radius R1B2 has dimensions of about 7-9 mm across. The portion corresponding to radius R1B3 has dimensions of about 9-11 mm across, and these values range from about 35.75 to about 40, such that each value is somewhat flatter at the peripheral portion than corresponding values of Table B1. For example, Table B1 lists the values for R1B3 as having a range from about 36.75 to about 41 D. The portion corresponding to R1C1 can extend from about 11 to 13.5 mm across. The portion corresponding to R1C2 can extend from about 13.5 to 14 mm across. The sag height of the portion R1C2 can be from about 3.1 to about 3.4 mm, for example. The portion corresponding to R1C1 can be fit to the cornea in many ways as described herein, for example with the tangent of portion R1C1 aligned with R1B3 on the inner boundary and R1C2 along an outer boundary so as to inhibit ridge formation as described herein.

[0201] Table B3 shows device 100 having a diameter of approximately 16 mm across and can be fit on K or flatter, for example as described herein. The table lists R1 corresponding to the center ablated portion of the cornea. The inner portion 110 comprising optical component 100A and inner coupling component 100B1 has dimension R1 extends about 5 mm across, and the ablation zone can be larger, for example about 6 mm. The portion corresponding to radius R1B1 has dimensions of about 5-7 mm across, and the curvature can be expressed with keratometry values (K-values) corresponding to the optical power of the eye in Diopters (D). The portion corresponding to radius R1B2 has dimensions of about 7-9 mm across. The portion corresponding to radius R1B3 has dimensions of about 9-10.5 mm across, and these values range from about 36.75 to about 41. The portion corresponding to R1C can extend from about 13 to about 16 mm across. The sag height of the portion R1C2 can be less than about 3.6 mm, for example, such that portion R1C2 can be deflected when placed on the eye. The portion corresponding to R1C1 can be fit to the cornea in many ways as described herein.

[0202] Table B4 shows device 100 having curvatures for use with non-ablated eyes so as to pump tear liquid as described herein, for example with an extended wear contact lens. Device 100 has a diameter of approximately 14 mm across and can be fit on K or flatter, for example as described herein. The table lists R1 corresponding to the center ablated portion of the cornea. The inner portion 110 comprising optical component 100A and inner coupling component 100B1 has dimension R1 extends about 5 mm across. The curvatures of the inner portion corresponding to R1 have curvature values corresponding to optical powers from about 39 D to about 48D, which can be based on population data for unablated eyes and combined with the curvatures for portions R1B1 to R1B3 and R1C1 and R1C2, for example. The portion corresponding to radius R1B1 has dimensions of about 5-7 mm across, and the curvature can be expressed with keratometry values (K-values) corresponding to the optical power of the eye in Diopters (D). The portion corresponding to radius R1B2 has dimensions of about 7-9 mm across. The portion corresponding to radius R1B3 has dimensions of about 9 mm to 11 mm across. The portion corresponding to R1C1 can extend from about 11 mm to about 13.5 mm across. The portion corresponding to R1C2 can extend from about 13.5 mm to 14 mm across. The sag height of the portion R1C2 can be from about 3.1 mm to about 3.4 mm, for example. The portion corresponding to R1C1 can be fit to the cornea in many ways as described herein, for example with the tangent of portion R1C1 aligned with R1B3 on the inner boundary and R1C2 along an outer boundary so as to inhibit ridge formation as described herein.

[0203] Although Tables B1-B4 list specific curvature values by way of example, a person of ordinary skill in the art can determine many curvature values based on the teachings and embodiments described herein and one or more of the curvatures can be combined with an aspheric surface, for example an aspheric surface having a conic constant.

[0204] FIG. 3A shows a device 100 positioned on cornea 10 an eye 2 having an epithelial defect 11. The device may comprise a curved body, for example a curved contact lens body shaped to fit the cornea.

[0205] The device 100 can be sized to cover the ablated profile and epithelial defect. The inner portion 110 comprises a dimension across 102 that can be sized to extend across a majority of the ablation, and the outer portion 120 comprises a dimension across 104 sized to extend across at least the epithelial defect and contact the epithelium on opposite sides of the defect.

[0206] The dimension 102 extending across a majority of the ablation may extend about 6 to 8 mm, for example, and may be sized larger than the ablation. The dimension 104 may comprise about 12 mm to 14 mm across, for example so as to extend to the limbus and can be sized to the limbus of the patient for example. Work in relation to embodiments suggests that the device sized to extend to the limbus and circumferentially around the limbus can be centered on the cornea. The device may extend such that the outer rim of the device contacts the conjunctiva disposed above the sclera peripheral to the limbus, for example, and that such configurations may center the lens on the cornea, for example.

[0207] The thickness of the device can be sized and shaped in many ways. The inner portion 110 of the device comprises a thickness 106 and the outer portion 120 of the device comprises a thickness 108. The thickness 106 of the inner portion may comprise a substantially uniform thickness such that the inner portion comprises an optical power of no more than about ± 1D prior to placement on the eye, for example when held in front of the eye and separated from the cornea by a distance. Alternatively, the thickness of the inner portion may vary so as comprise optical power, for example optical power to correct vision of the patient.

[0208] A smooth layer 12S of regenerated epithelium 12R may substantially cover an ablated profile. The environment 100E is configured to guide epithelial regeneration and smooth the regenerated epithelium. The regenerating epithelium comprises a thickness profile 12RP.

[0209] The epithelium grows centripetally from circumscribing boundary 12E toward the center of ablated profile 20 to cover the exposed stroma, as indicated by arrows 30.

[0210] The device 100 may comprise an inner portion 110 and an outer portion 120. The outer portion 110 can be configured to form a seal 100S with the cornea near the edge of the ablation and the epithelial defect, for example with a soft conformable material such as silicone elastomer or silicone hydrogel. The inner portion 120 is positioned over the pupil and configured for the patient to see, and may comprise a rigidity greater than the outer portion, so as to smooth irregularities of the epithelium when the cornea heals. Alternatively, the inner portion may comprise rigidity equal to or less than the rigidity of the outer portion as well. For example, the inner portion may comprise silicone and the outer portion may comprise silicone, and the inner portion may comprise one or more of a more rigid silicone or a greater thickness such that the

inner portion can be more rigid than the outer portion so as to smooth the epithelium. Although the inner portion can be more rigid than the outer portion, the inner portion can be sufficiently soft, flexible and conformable so as to conform at least partially to the ablated profile 20 in the stroma, such that the patient receives the benefit of the vision correction with the ablation profile 20 when the patient looks through the inner portion and the inner portion smoothes the epithelium. Work in relation to embodiments of the present invention suggests that the regenerating epithelium is softer than the underlying stroma of ablation profile 20, such that the inner portion can be configured to conform to the shape of the ablation profile 20 when the inner portion smoothes the epithelium disposed under the inner portion, for example with deflection pressure as described herein.

[0211] FIG. 3B shows device 100 in a first configuration prior to placement on the cornea of an eye having an epithelial defect, such as an eye having a PRK ablation. The device 100 comprises fenestrations 100F. The fenestrations 100F can be located on the device such that the fenestrations are located away from the epithelial defect to pump tear liquid under the device as described herein. The device 100 may comprise inner portion 110 having a base radius R1 of curvature, and the base radius of curvature may be slightly longer than the ablated cornea such that the device can be flatter than the cornea prior to placement on the cornea. The outer portion 120 comprising sclera coupling portion 130 may comprise a portion steeper than the cornea to reduce pressure to the limbus. For example flange portion 120F can be steeper than the corresponding portions of conjunctiva and sclera so as to decrease pressure of the device on the limbus.

[0212] The base radius R1 can be sized to the cornea in many ways. For example, the base radius R1 may have a radius corresponding to the post ablated eye.

[0213] The device 100 may comprise a modulus within a range from about 4 MPa to about 35 MPa, such that central portion can conform at least partially to the ablated stroma and so that the device can smooth corneal irregularities and stromal irregularities of the ablated cornea. The device may comprise an elastomeric stretchable material such that the device can stretch to fit the cornea, for example. The device having the modulus within a range from about 4 MPa to about 35 MPa can be formed in many ways as described herein. For example, the device may comprise a single piece of material having a substantially uniform thickness extending across the

ablated cornea and at least a portion of the unablated cornea, and the single piece of material may comprise an elastic material such as a silicone elastomer or a hydrogel. Alternatively, the device may comprise a single piece of material having a non-uniform thickness extending across the ablated cornea and at least a portion of the unablated cornea. The device can be shaped in many ways and may comprise a single piece of one material, or may comprise a single piece composed to two similar materials, or may comprise a plurality of materials joined together.

[0214] The device 100 may comprise one or more outer portions extending outside the inner portion as described herein.

[0215] FIG. 3C shows the device of FIG. 3B placed on the eye having a second configuration 100C2 conforming to ablated stromal tissue and smoothing the epithelium over the ablated stroma, such that the device can pump tear liquid as described herein. The cornea comprises an ablated surface 20 to correct vision that may have a corresponding radius of curvature, for example radius R2. The ablated profile 20 may comprise additional, alternative, or combinational shapes with those corresponding to radius R2, such as aberrations ablated into the cornea to correct aberrations of the eye and astigmatism ablated into the cornea, and the inner portion 110 of device 100 can conform to these ablated profiles of the cornea such that the patient can receive the benefit of the ablative vision correction when the device is positioned on the cornea. For example, the cornea ablation profile 20 may correspond to radius of curvature R2, and the inner portion 110 can flatten from configuration 100C1 corresponding to radius of curvature R1 prior to placement to a second configuration 100C2 corresponding substantially to the ablated profile 20, such the patient can see with the benefit of ablation profile 20. For example, the second configuration 100C2 can comprise a conforming radius of curvature R12 that corresponds substantially to radius of curvature R2. The profile corresponding to the first configuration 100C1 of the device 100 is shown positioned over cornea 10 to illustrate the change in profile of the device from configuration 100C1 prior to placement to conforming configuration 100C2 of the device 100 when positioned on the cornea.

[0216] The conformable device 100 comprises sufficient rigidity so as to smooth the epithelium when device 100 is positioned on the cornea over the ablation profile 20. The epithelium comprises a peripheral thickness 12T that may correspond substantially to a thickness of the epithelium prior to debridement of the epithelium to ablate the cornea. The epithelium

also comprises regenerating epithelium 12R disposed over the ablation profile 20. The device 100 can smooth the epithelium 12R when conforming to the cornea in the second configuration 12C2. For example, irregularities 12I of the regenerating epithelium 12R disposed over the ablation can be smoothed when the epithelium regenerates along the inner portion of device 100, such that the irregularities 12I of the regenerating epithelium 12R are thinner than the thickness 12T of the peripheral epithelium.

[0217] Work in relation to the embodiments as described herein indicates that an at least partially conformable device having a modulus within a range from about 4 MPa to about 35 MPa can conform at least partially to the ablated stroma and smooth irregularities of the epithelium and stroma so as to improve vision as described herein. The device having the modulus within the range from about 4 MPa to about 35 MPa can be formed in many ways as described herein.

[0218] FIGS. 4A to 4H show a method 400 of manufacturing a device 100 and apparatus for manufacturing the device as described herein.

[0219] FIG. 4A shows a mold 600A to form an optical component 100A of a device 100 comprising material 110M as described herein. The optical component 100A may comprise an optically transparent material such as a silicone, for example. The optical component may comprise a modulus and thickness and corresponding rigidity as described herein, so as to provide vision and smoothing of the cornea. The mold 600A may comprise an optical correction on one surface and a base curvature on the opposite surface, for example. With a step 410, the optical component 100A can be formed in mold 600A.

[0220] FIG. 4B shows a mold 600B to form a device comprising the optical component of FIG. 4A and the coupling component 100B. The optical component 100A can be placed in the mold and the flowable material 120M of the coupling component injected into the mold so as to form the device. The solid inner component comprising a rigid material placed therein prior to injection of a flowable material. The mold 600B may comprise inner material 110M positioned within the mold as a solid piece of material and outer material 120M comprising a flowable material injected into mold 600B and cured around the preformed piece comprising inner material 120M. The flowable material can be injected around the inner material 100M in many

ways. For example, the inner material 110M may comprise a second layer 110L2 of rigid material 110M2 of the inner portion 110 as described herein, and the flowable material can be injected around the upper and lower surfaces of second material 110M2 so as to form a first layer 110L1 of first material 110M1 and a third layer 110L3 of the third material 110M3 with the flowable material such that the first material 110M1, the third material 110M3 and the outer material 120M each comprise substantially the same soft material when cured. With a step 420, the device comprising the optical component 100A and the coupling component 100B can be formed.

[0221] FIG. 4C shows a mold 600C to form a device comprising the optical component of FIG. 4A and a layer of a soft material of the device, such that the optical component can be located between two layers of the coupling component. The optical component 100M can be removed from the mold as shown in FIG. 4A and placed in the mold 600C. The flowable material M3 corresponding to layer 110L3 can be injected into the mold and cured. The partially formed inner component comprising layer 110L2 and layer 110L3 can be removed from mold 600C. With a step 430, the portion of the device comprising the two layers can be formed.

[0222] FIG. 4D shows a mold 600D to form a device and having a solid inner component comprising the rigid material placed for injection of a flowable material, in accordance with embodiments of the present invention. The mold 600 may comprise inner material 110M positioned within the mold as a solid piece of material and outer material 120M comprising a flowable material injected into mold 600 and cured around the preformed piece comprising inner material 600. The mold may comprise an upper portion and a lower portion. In certain embodiments, the device 100 can be formed in a mold with rigid second material 110M2 placed in the mold and encapsulated within a single piece of material comprising first material 110M1, third material 110M3 and outer material 120M, such that first material 110M1, third material 110M3 and outer material 120M comprise the same material, for example silicone. The rigid second material 110M2 may comprise silicone bonded to each of first material 110M1, third material 110M3 and the outer material 120M, for example with curing such that first material 110M1, third material 110M3 and outer material 120M comprise the same soft silicone material bonded to the second material 110M2 comprising rigid silicone. With a step 440, the device

comprising the solid inner component between first material 110M1 and third material 110M3 can be formed.

[0223] FIG. 4E shows formation of fenestrations in the device with energy. With a step 450 the device as described in FIG. 4B or FIG. 4D can be treated with energy 650, for example mechanical energy or electromagnetic energy such as light energy to form the fenestration extending through the device. For example, the fenestration can be removed from the mold and mechanically punched or ablated with laser light energy to form the fenestration.

[0224] FIG. 4F shows spin coating of a silicone or hydrogel material on a posterior surface of the device. An amount of a curable silicone or hydrogel forming material 660 as described herein can be deposited on the posterior surface of the device and spun with rotation 662 at rate such that the coating moves away from a center of the device toward and outer boundary of the silicone or hydrogel material. The outer boundary of the silicone or hydrogel material can be determined based on the amount of curable material 660 and spin rate, and the curable silicone or hydrogel material can be formulated to provide the desired thickness as described herein, for example a substantially uniform thickness within a range from about 1 μm to about 100 μm when fully hydrated. With a step 460, the curable silicone or hydrogel forming material 660 can be cured so as to provide the layer of silicone or hydrogel material on the lower surface of the device 100.

[0225] FIG. 4G shows chemical vapor deposition on the device having the silicone or hydrogel material formed thereon. The device 100 can be placed in a chemical vapor deposition chamber 670, and treated with one or more forms of chemical vapor deposition as described herein. With a step 460, the device 100 can be coated with the CVD to provide the wettable material on the surface of the device.

[0226] FIG. 4H shows the device comprising 100 the silicone or hydrogel material 120HG packaged in a container 680. The device can be sterilized, and can be packaged wet or dry, or combinations thereof in container 680. For example, the device can be placed with a fluid comprising saline in the container. Alternatively, the device 100 can be dry packaged in container 680, for example. With a step 480, the device 100 can be placed on container 680 and the container sealed.

[0227] It should be appreciated that the specific steps illustrated in method 400 provide a particular method of manufacturing a device, according to an embodiment of the present invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

[0228] A method 500 of manufacturing device 100 comprising a contact lens to pump tear liquid may comprise one or more of the following steps:

505- Provide first mold for optical component
510- Inject first flowable material into first mold
515- Cure first flowable material to form first optical component
520- Remove first optical component from first mold
525- Place first optical component in second mold
530- Inject second curable material into second mold
535- Cure second flowable material to form second component
540- Remove second component from second mold
545- Place second component in third mold
550- Inject third flowable material into third mold
555- Cure third flowable to form device
560- Remove device
565- Drill fenestrations
570- Coat with wettable material

[0229] The rigidity and hardness of the molded device can be determined by one or more of the material hardness, the modulus or the thickness. The molded device may comprise a device with an inner center more rigid than the outer periphery, for example, and the center can be thicker than edge. For example, the device may comprise a single piece device with an inner portion thicker than the outer portion such that the inner portion is more rigid than the outer

portion. Alternatively or in combination, an optically clear inner portion can be molded; the inner portion placed in the mold, and the device molded to form the outer portion around the inner portion. For example, the molded inner portion comprising layer 110L2 of material 110M2 as described herein, and one or more of layers 110L1 or 110L3 molded around layer 110L2.

[0230] It should be appreciated that the specific steps illustrated in Method 500 provide a particular method of manufacturing a device, according to an embodiment of the present invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

[0231] Clinical studies have been undertaken and are contemplated to show the pumping of the tear under the lens with blinking of the eye in accordance with the embodiments described herein. A person of ordinary skill in the art can determine empirically the properties of device 100 as described herein so as to provide pumping of the tear fluid under the device to provide one or more of an extended wear contact lens or a device for placement on the cornea following PRK to improve vision and promote reepithelialization.

[0232] As used herein, like reference characters indicate like structures that can be combined in accordance with the teachings and embodiments described herein.

[0233] In certain embodiments, methods for selecting ophthalmic lenses are provided. The methods may be used to correct a refractive error of an eye of a patient, the eye having a cornea with an epithelium providing a refractive shape. In certain embodiments, methods for selecting ophthalmic lenses comprise determining a desired spherical power so as to mitigate any spherical component of the refractive error of the eye of the patient; and identifying, from among a plurality of alternative ophthalmic lenses having differing spherical powers, the ophthalmic lens corresponding to the desired spherical power. The identified ophthalmic lens may then be selected and applied to the eye of the patient to correct the spherical refractive error. The

identified ophthalmic lens has an anterior surface corresponding to the desired optical power, and the anterior surface extends along an inner portion of the ophthalmic lens.

[0234] The ophthalmic lenses have an inner portion for correcting spherical refractive error and a peripheral portion for contacting an optical tissue. The inner portion of the ophthalmic lens is deformable and the peripheral portion of the ophthalmic lens is deformable. The inner portion of the ophthalmic lens has a modulus and a rigidity that is higher than the modulus and the rigidity of the peripheral portion. The peripheral portion of the ophthalmic lens has a shape suitable for engaging the eye outside the optical region so as to support the inner portion in alignment with an optical region of the eye. In certain embodiments, the peripheral portion is configured to engage a tissue of the eye such as the epithelium and to prevent or minimize motion of the ophthalmic device with respect to the optical region of the eye. In certain embodiments, the inner portion, the peripheral portion, or both the inner and peripheral portions may deform or deflect upon blinking of the eye.

[0235] In certain embodiments, the refractive shape of the epithelium extends across the optical region of the eye such that the refractive error comprises astigmatism and/or a high-order optical aberration. In such embodiments, the posterior surface extending across the optical region adjacent the eye may or may not comprise a refractive shape so as to mitigate the astigmatism and/or high-order aberration. Selection of a desired ophthalmic lens is performed so that the peripheral portion of the ophthalmic lens has a suitable shape to maintain a lenticular volume between the posterior surface of the ophthalmic device and the surface of the eye such as the epithelium. Before, during, and/or following positioning of the ophthalmic device on the eye, the lenticular volume fills with tear fluid such that the anterior shape of the ophthalmic lens corrects the refractive error. Accordingly, in certain methods, selecting an ophthalmic lens is performed so that the peripheral portion has a suitable shape such that tear fluid will fill a lenticular volume between the posterior surface and the refractive shape of the eye so as to mitigate the astigmatism and/or high-order aberration. Where tear fluid is disposed between the contact lens and the eye, and where the lens has a refractive index sufficiently close to that of the tear fluid, the refraction of the eye may be largely independent of the shape the posterior surface and/or lenticular volume, at least when the posterior surface initially contacts the lens and/or the contact lens remains disposed on the eye. In certain methods, identifying an ophthalmic lens is

independent of as least one member of the group a power of the astigmatism; and orientation of the astigmatism about an optical axis of the eye, and/or as strength of the high-order aberration and/or a type of high-order aberration. As a consequence of the lenticular volume as defined by posterior surface of the eye and the refractive shape being filled with tear fluid, it is not necessary to orient an axis or position of the ophthalmic device with the eye.

[0236] Ophthalmic lens provided by the present disclosure may also be used for treating presbyopia. Methods for treating presbyopia comprise, for example, positioning an ophthalmic lens on an eye so that an inner portion of the ophthalmic lens is disposed over the optical region of the cornea of the eye, and supporting the inner portion of the ophthalmic lens by engagement between a peripheral portion of the ophthalmic lens and a tissue of the eye outside the optical region. The inner portion of the ophthalmic lens and the peripheral portion of the ophthalmic lens can be deformable such that the inner portion has a modulus and rigidity that is greater than the modulus and rigidity of the peripheral portion. To correct for presbyopia, the inner portion comprises a presbyopia-mitigating refractive shape. In certain embodiments, a presbyopia-mitigating shape is selected from an add region, a multifocal shape, an aspherical shape, and a combination of any of the foregoing. In certain embodiments, the peripheral portion comprises one or more radius of curvature configured to engage a tissue of the eye such as the epithelium so as to prevent or minimize motion of the inner portion with respect to the optical region of the cornea. The anterior portion of ophthalmic lens and the posterior surface of the eye define a lenticular volume that is configured to fill with tear fluid. To facilitate filling and/or flow of the tear fluid a plurality of fenestrations extending through the thickness of the peripheral region may be disposed in the peripheral region. The fenestrations are disposed so as to facilitate, in conjunction with motion of the ophthalmic lens, transfer of tear fluid through the lenticular volume. Such methods of treating presbyopia using an ophthalmic lens provided by the present disclosure may not require precise alignment of the ophthalmic lens with respect to the eye.

[0237] Similarly, methods for correcting a refractive error of an eye, such as astigmatism and/or spherical aberration, where the eye has a cornea with an epithelium providing a refractive shape extending a cross an optical region of the eye are also provided. Methods for correcting a refractive error comprise positioning an ophthalmic lens on the eye so that an inner portion of the ophthalmic lens is disposed over the optical region of the cornea, wherein a posterior surface of

the positioned ophthalmic lens extends adjacent the eye and has shape diverging from the refractive shape of the epithelium so that a lenticular volume is disposed between the posterior surface and the epithelium. A peripheral portion of the ophthalmic lens may comprise a plurality of fenestrations extending through the thickness of the peripheral portion and allowing passage of tear fluid between the lenticular volume and the posterior (outer) surface of the ophthalmic lens. In such embodiments, the inner portion of the positioned ophthalmic lens is supported by engagement of a peripheral portion of the ophthalmic lens and a tissue of the eye such as the epithelium outside the optical region. The peripheral portion is configured to support the inner portion of the ophthalmic lens, to prevent or minimize motion of the inner portion with respect to the optical region of the eye, and to facilitate filling of the lenticular volume with tear fluid.

[0238] Fenestrations may be disposed outside the optical region of the ophthalmic lens and inward of a region of engagement between the peripheral portion of the ophthalmic lens and a tissue of the eye. The inner portion and the peripheral portion of the ophthalmic lens are deformable, for example, deformable upon motion of an eyelid and/or over locally protruding epithelial regions so as to inhibit pain, such that the inner portion has a modulus and rigidity that is higher than the modulus and rigidity of the peripheral portion. In certain embodiments, the deformability of the inner portion and the outer portion of the ophthalmic lens are configured so that blinking of the eye induces flow of tear fluid through the fenestrations into and out of the lenticular volume, and that when the eye is not blinking the inner portion retains a shape that corrects the refractive error of the eye.

[0239] In certain embodiments, the peripheral portion comprises one or more radius of curvature configured to engage a surface of the eye and thereby resist motion of the inner portion with respect to the optical region of the eye. For example, in certain embodiments, a peripheral portion comprises a plurality of radii of curvature wherein the radii of curvature become smaller from the center of the ophthalmic lens toward the periphery. In certain embodiments, the engagement between the peripheral portion and the tissue surface of the eye along the engagement region inhibits lateral movement of the inner portion relative to the cornea during blinking.

[0240] In certain embodiments, methods of correcting refractive error provided by the present disclosure can, for example, mitigate the refractive error, when viewing with the eye through the

anterior surface, substantially independent of a shape of the lenticular volume throughout a range of astigmatic errors of at least about 0.5 D, at least about 1.0 D, and in certain embodiments, at least bout 1.5 D, and is independent of a rotational orientation of the ophthalmic lens about a viewing axis of the eye.

[0241] Methods provided by the present disclosure further comprise methods of remodeling the shape of the epithelium of an eye. In certain embodiments, methods for optically remodeling the relative shape of the epithelium comprise positioning an ophthalmic lens on the eye so that an inner portion of the ophthalmic lens is disposed over the optical region of the cornea, wherein a posterior surface of the positioned ophthalmic lens extends adjacent the eye and has a shape diverging from the refractive shape of the epithelium so that a lenticular volume is disposed therebetween; and supporting the inner portion of the ophthalmic lens by engagement between a peripheral portion of the ophthalmic lens and the eye outside the optical region so that fluid fills the lenticular volume and viewing with the eye through an anterior surface of the ophthalmic lens mitigates the refractive error. In methods of remodeling the shape of the epithelium to correct refractive error of the eye, the ophthalmic lens may (though not always) does not comprise fenestrations. The posterior surface of the ophthalmic lens defines a refractive shape for correcting spherical power and when positioned on the eye defines a lenticular volume with the surface of the eye. Over time, the epithelium and/or underlying tissue of the eye may fill or otherwise occupy some, most, or all of the lenticular volume disposed over the optical region. As with certain other embodiments, an ophthalmic lens for use in remodeling the shape of the epithelium comprises a deformable inner portion and a deformable peripheral portion such that the inner portion has a higher modulus and rigidity than that of the peripheral portion and the peripheral portion is configured to engage a tissue surface of the eye and to inhibit lateral movement of the inner portion with respect to the optical region of the cornea.

[0242] In certain embodiments, methods of remodeling the refractive shape of the epithelium mitigate the refractive error when viewing with the eye through the anterior surface, substantially independent of a shape of the lenticular volume throughout a range of astigmatic errors of at least about 0.5 D, at least about 1.0 D, and in certain embodiments, at least bout 1.5 D, and is independent of a rotational orientation of the ophthalmic lens about a viewing axis of the eye.

[0243] Furthermore, when the ophthalmic lens is removed from the eye the optical remodeling of the epithelium mitigates the refractive error of the eye by at least about 1 ½ D at least about 8 hours, at least about 24 hours, and in certain embodiments, at least about 48 hours, after removal of the ophthalmic lens from the eye.

[0244] Certain embodiments provided by the present disclosure comprise sets of alternatively selectable ophthalmic lenses for correcting refractive errors of eyes of a population of patients. Such sets of ophthalmic lenses may be used in the methods disclosed herein. The plurality alternative ophthalmic lenses have differing spherical powers representing different refractive corrections. Each of the plurality of alternative ophthalmic lenses comprises an anterior surface corresponding to an associated desired spherical power, the anterior surface extending along an inner portion of the ophthalmic lens, wherein the inner portion of the ophthalmic lens is deformable; and a peripheral portion of the ophthalmic lens extending radially outward from the inner portion, the peripheral portion having a rigidity lower than that of the inner portion and configured for engaging tissue outside the optical region so as to support the inner portion in alignment with an optical region.

[0245] In certain embodiments, ophthalmic lenses suitable for use in methods provided by the present disclosure comprise an inner portion configured to be disposed over the optical region of the cornea of an eye, and a peripheral portion configured to support the inner portion of the ophthalmic lens by engagement between the peripheral portion of a tissue of an eye such as an epithelium disposed outside the optical region. The inner portion and the peripheral portion are deformable such that the modulus and rigidity of the inner portion is higher than that of the peripheral portion. In certain embodiments, the peripheral portion comprises one or more radii of curvature whereby the peripheral portion engages a surface tissue of an eye to prevent or mitigate motion of the inner portion with respect to the optical region of the cornea during blinking.

[0246] For treatment of presbyopia, the inner portion of the ophthalmic lens comprises a surface extending along the inner portion comprising a presbyopia-mitigating refractive shape.

[0247] For treatment of spherical refractive error the surface extending along the inner portion of the ophthalmic lens comprises a shape configured to correct spherical refractive error.

[0248] In certain embodiments, the inner portion may be configured to correct non-spherical refractive errors such as astigmatic error, multifocal error, higher order aberrations, and custom optically corrective functions such as pin holes.

[0249] Certain embodiments provided by the present disclosure include devices comprising an optical component and a coupling component, the optical component comprising a first material having a first modulus, and the coupling component comprising a second material having a second modulus, wherein the first modulus is greater than the second modulus. FIG. 5 shows device 500, comprising optical component 501 and coupling component 502.

[0250] In certain embodiments, device 500 has a diameter 510 from about 9 mm to about 16 mm, in certain embodiments, from about 10 mm to about 15 mm, and in certain embodiments, from about 12 mm to about 14 mm.

[0251] In certain embodiments, optical component 501 comprises a center thickness from about 150 μm to about 500 μm, from about 200 μm to about 400 μm, and in certain embodiments, from about 250 μm to about 350 μm.

[0252] In certain embodiments, optical component 501 comprises a first material having a first thickness 505 and a second material having a second thickness 503. In such embodiments, the second material may be disposed on the inner surface of optical component 501, e.g., the surface facing the cornea, and may be the same material as the material forming coupling component 502. The second material may have a thickness 503 from about 5 μm to about 60 μm, from about 10 μm to about 50 μm, and in certain embodiments, from about 20 μm to about 40 μm. In such embodiments, where optical component 501 comprises two materials, the total thickness of the optical component may be from about 100 μm to about 550 μm, from about 200 μm to about 450 μm, and in certain embodiments, from about 250 μm to about 350 μm.

[0253] In certain embodiments, optical component 501 comprises an optically clear material having a modulus from about 10 MPa to about 70 MPa, from about 20 MPa to about 60 MPa, from about 20 MPa to about 50 MPa, and in certain embodiments from about 30 MPa to about 40 MPa.

[0254] Optical component 501 may be configured to correct vision or may not be configured to correct vision.

[0255] In certain embodiments, optical component 501 comprises a material selected from silicone, silicone hydrogel, and a combination thereof. In certain embodiments, optical component 501 comprises silicone, in certain embodiments, silicone hydrogel, and in certain embodiments a combination of silicone and silicone hydrogel.

[0256] In certain embodiments, optical component 501 comprises a center thickness from about 150 μm to about 500 μm, a diameter from about 3 mm to about 9 mm, a radius of curvature from about 7 mm to about 12 mm, and a modulus from about 20 MPa to about 50 MPa.

[0257] In certain embodiments, coupling component 502 extends from optical component 501 to an outer periphery 504, where the thickness at the juncture with optical component 501 is the same as or similar to that of optical component 502, and gradually tapers toward outer periphery 504, wherein the thickness of the coupling component at the periphery us from about 5 μm to about 60 μm, from about 10 μm to about 50 μm, and in certain embodiments, from about 20 μm to about 40 μm.

[0258] In certain embodiments, coupling component 502 comprises at least one radius of curvature 512. For example, in certain embodiments, coupling component 502 comprises a single radius of curvature, and in certain embodiments, coupling component 502 comprises more than one radius of curvature such as two, three, four, five, six, or more than six radii of curvature. The at least one radius of curvature can be, for example, from about 5 mm to about 15 mm, from about 6 mm to about 13 mm, from about 7 mm to about 12 mm, and in certain embodiments, from about 6 mm to about 10 mm. The one or more radius of curvature 512 characterizing coupling component 502 are less than the radius of curvature of optical component 501.

[0259] In certain embodiments, coupling component 502 comprises a material having a modulus from about 0.05 MPa to about 4 MPa, from about 0.1 MPa to about 3 MPa, from about 0.1 MPa to about 2 MPa, and in certain embodiment from about 0.2 MPa to about 1.5 MPa.

[0260] In certain embodiments, coupling component 502 comprises a material selected from silicone, silicone hydrogel, and a combination thereof. In certain embodiments, coupling component comprises silicone, in certain embodiments, silicone hydrogel, and in certain embodiments a combination of silicone and silicone hydrogel.

[0261] In certain embodiments, coupling component 502 comprises a plurality of fenestrations 509 extending through the thickness of the coupling component. Coupling component 502 may comprise, for example, from 1 to about 30 fenestrations, from 1 to about 20 fenestrations, and in certain embodiments, from about 1 to about 10 fenestrations. Fenestrations 509 may have any suitable shape to provide egress of tear fluid. Suitable shapes include, for example, circular, elliptical, oval, rectangular, square, slot, or combination of any of the foregoing. Each of the plurality of fenestrations 509 may have the same shape or at least some of the fenestrations may have different shapes. In certain embodiments, the fenestrations have a maximum dimension (hole size) from about 50 μm to about 700 μm, from about 100 μm to about 500 μm, and in certain embodiments, from about 200 μm to about 400 μm. Each of the fenestrations may have the same maximum dimension or at least one of the fenestrations may have a different dimension.

[0262] In certain embodiments, coupling component 502 does not include fenestrations.

[0263] In certain embodiments, coupling component 502 comprises a thickness tapering from the thickness of optical component 501 to a thickness of about 30 μm at the periphery 504 of the coupling component; a plurality or radius of curvature from about 7 mm to about 12 mm; and comprises a material having a modulus from about 0.1 MPa to about 2 MPa. In embodiments in which coupling component 502 comprises a plurality of radii of curvatures 512, the radius of curvature decreases from the optical component toward the periphery.

[0264] The device, including optical component 501 and coupling component 502, is configured to provide a seal to a tissue of an eye such as an epithelium to thereby resist movement of the optical component on an eye.

[0265] FIGS. 6A-6C show various lenses positioned on an astigmatic eye. For each of FIGS. 6A-6C, the left image shows the configuration of the first radial and the right image shows the configuration of the second radial corresponding to the aspheric projection 608. In FIG. 6A, the configuration corresponding to the first radial includes the optical surface of the eye 601 and soft refractive lens 603, which provides a focus on retina 605. In the right image of FIG. 6A, the second radial direction corresponds to a different refractive shape 602 that does not focus on the retina. Soft, conformable ophthalmic lens 604 conforms to shape 602 and thereby fails to correct

the non-spherical aberration. FIG. 6B shows aspheric correction using a hard, non-conformable ophthalmic lens 606. Again, the first radial and the second radial correspond to different optical shapes 601 and 602, respectively. Although hard ophthalmic lens 606 corrects vision, the lens must be oriented to correct the asymmetric profile of the eye. FIG. 6C schematically shows correction of non-spherical aberration using ophthalmic lenses and methods provided by the present disclosure (with the peripheral portion of the eye and lens outside the optical region omitted for simplicity). Ophthalmic lenses provided by the present disclosure have a modulus and rigidity that is configured to provide a lenticular volume between the optical surface of the eye 602 and the ophthalmic lens 607. For correction of presbyopia, the ophthalmic lens is configured such that the lenticular volume fills with tear fluid. As can be appreciated, it is not necessary to orient ophthalmic lens 607 to correct non-spherical optical aberrations.

[0266] Devices provided by the present disclosure may be used as platforms in a number of ophthalmic applications including, for example, epithelium healing, spherical correction of astigmatism, presbyopic solutions, epithelial reshaping, and dry eye.

[0267] In certain embodiments, devices may be used to facilitate epithelial healing. Epithelial defects can occur, for example, as the result of PRK, filamentary keratitis, evaporative dry eye, or physical injury to the eye. In these and other applications, including applications in which vision is corrected,

[0268] When positioned on the eye of a patient, the inner surface of the device and the outer surface of the eye, which may include, for example, the cornea, Bowman's membrane, and /or epithelium, can define a chamber to facilitate healing and/or growth of the epithelium. In such applications it is desirable that a device control moisture content and exhibit a high Dk to facilitate extended wear. Using devices and methods provided by the present disclosure, complete epithelial regrowth following PRK surgery can occur within about 48 hours, about 72 hours, 96 hours, and in for certain patients, within about 1 week following PRK.

[0269] When used for spherical correction of corneal astigmatism, devices and methods provided by the present disclosure exhibit the advantages of improved comfort compared to gas permeable lenses, enhanced vision compared to soft contact lenses, and reduced fitting time compared to toric and GP lenses. Devices and methods can, in certain embodiments, correct

greater than 95% of astigmatic errors, irregular astigmatism such as induced by trauma or RK, and early kerotoconus.

[0270] In certain embodiments, a device comprises an optical component that corrects vision. Thus, in addition to spherical correction, the optical component can be configured to support multifocal, higher order aberration or custom optical designs such as pin holes.

[0271] In epithelial reshaping applications, devices and methods provided by the present disclosure can be used to reshape the epithelial during wear, and correct vision for a period of time after the device is removed from the eye. For example, to correct myopia, a device can be used to guide the epithelium toward the periphery of the eye and to create a flatter center curve. To correct hyperopia, a device may be used to guide the epithelium toward the center of the eye and to create a steeper center curve. In certain embodiments, a device can be used to induce mulitfocality for vision correction by guiding the epithelium toward a desired location or locations on a cornea by molding with an aspheric optic. The induction of mulitfocality through epithelial resphaping can be useful to correct vision in presbyopia and myopia.

[0272] In certain embodiments, ophthalmic lenses provided by the present disclosure are configured to correct refractive error such as astigmatism. The lenses provide a smooth spherical anterior surface and minimize lens-induced distortions by reducing flexure of the inner optical portion and by maintaining lens centration during wear. Reduced flexure of the inner optical portion can in part be accomplished by increasing the rigidity of the inner portion and by creating a tear lens. Centration of the inner optical portion minimizes astigmatic and prismatic effects caused by tilting of the optic and also minimizes edge distortion.

[0273] Ophthalmic lenses provided by the present disclosure can achieve visual correction at least equivalent to that of soft toric contact lenses and achieve a superior comfort level compared to soft toric contact lenses. Furthermore, because the ophthalmic lenses provided by the present disclosure are radially symmetric, fitting to an eye of the patient involves only accommodating the spherical correction and an inventory of lenses for correcting cylindrical error is not required.

[0274] Ophthalmic lenses provided by the present disclosure include an inner optic portion configured to be disposed over the optical region of the cornea and a peripheral or outer portion that is disposed radially outward of the inner portion. An ophthalmic lens includes a posterior

surface that extends along the inner portion of the lens and is adjacent an eye when applied to an eye of a patient. An ophthalmic lens also includes an anterior surface that extends along the outer surface of the lens and opposite the posterior surface. In general, the inner portion of a lens is configured to improve vision and the peripheral portion is configured to improve comfort. However, the configuration of the inner portion can play a role in determining patient comfort, and the peripheral portion, at least in part, by maintaining centration of the inner optical portion on the optical portion of the cornea during wear enhances the visual outcome.

[0275] The inner optical portion of a lens is configured so that engagement of the posterior surface against the eye deforms the posterior surface so that the posterior surface of the inner portion has a shape diverging from the refractive shape of the epithelium and optical portion of the cornea. The anterior surface of the inner portion of the ophthalmic lens provides a spherical surface to correct a patient's vision.

[0276] In certain embodiments, the inner optical portion of a lens is characterized by a diameter from about 5 mm to about 10 mm, from about 7 mm to about 9 mm, from about 7.5 mm to about 8.5 mm, from about 7.8 mm to about 8.2 mm, and in certain embodiments, about 8 mm. The anterior inner portion of a lens is characterized by a substantially spherical profile without a cylindrical component. In certain embodiments, an inner portion is characterized by a thickness from about 100 μm to about 900 μm, from about 200 μm to about 900 μm, from about 300 μm to about 700 μm, 500 μm to 900 μm, from 550 μm to 850 μm, from 600 μm to 750 μm, from 600 μm to 800 μm, from 600 μm to 725 μm, and in certain embodiments, from 600 μm to 700 μm. In comparison, commercially available toric contact lenses for correcting refractive error are characterized by a thickness from about 150 μm to about 250 μm.

[0277] In certain embodiments, the inner portion comprises a first layer of material forming the posterior surface of the lens and a second layer of material forming the anterior surface of the lens. The first layer is thin and can be formed from the same material as that of the peripheral portion. In certain embodiments, first layer is from 10 μm to 60 μm, from 20 μm to 50 μm, and in certain embodiments from about 25 to about 35 μm thick. The first layer retains the inner portion. In certain embodiments, an inner portion comprises a third layer overlying the anterior surface of the second layer. Again, as with the first layer, the third layer is thin, having for example a similar thickness to that of the first layer, can be formed from the same material as the

material forming the peripheral region, and retains the second layer, which is also referred to as the button. The second layer or button provides the bulk of the thickness of the inner portion of a lens.

[0278] The inner optical portion of a lens is characterized by a rigidity where the rigidity of the inner portion is greater than the rigidity of the peripheral portion of the lens. In certain embodiments, the inner portion is characterized by a rigidity from about 8E8 MPa-μm^3 to about 2 E10 MPa-μm^3. As disclosed herein, the rigidity is a function of the thickness and the modulus of the material. Ophthalmic lenses provided by the present disclosure employ a soft, low modulus material for the inner portion and achieve increased rigidity by increasing the cross-sectional thickness. For example, in certain embodiments, the modulus of the material forming the inner optical portion is from about 10 MPa to about 100 MPa. It is believed that the soft, low modulus material improves patient comfort.

[0279] In certain embodiments, the rigidity of the inner portion of the device is greater than the rigidity of the outer portion. For example, in certain embodiments, a device can have an inner rigidity from about 1.2E-6 Pa-m^3 to about 3.1E-3 Pa-m^3, from about 1E-5 Pa-m^3 to about 1E-3 Pa-m^3, and in certain embodiments, from about 1E-4 Pa-m^3 to about 1E-3 Pa-m^3.

[0280] In certain embodiments, a device can have an outer rigidity from about 5.4E-9 Pa-m^3 to about 1.5E-4 Pa-m^3, from about 1E-8 Pa-m^3 to about 1E-4 Pa-m^3, from about 1E-7 Pa-m^3 to about 1E-5 Pa-m^3, and in certain embodiments, from about 1E-6 Pa-m^3 to about 1E-5 Pa-m^3.

[0281] The rigidity of a portion of the device can be increased by increasing the thickness of a single material, using a material having a higher modulus for the same thickness, or by combining materials having different moduli and thicknesses.

[0282] The rigidity of a portion of a device is approximated by the modulus of the material comprising the portion multiplied by the cube of the thickness. When a portion comprises more than one material, the rigidity can be approximated based on the average modulus of the portion multiplied by the thickness cubed of the portion. For example, a portion comprising a first material with a modulus of 20 MPa and a thickness of 90 μm and a second material with a modulus of 5 MPa and a thickness of 10 μm will have an average modulus of 18.5 MPa. The rigidity of the portion can then be approximated by multiplying the average modulus times the

cube of the thickness, which for the present example is determined to be $18.5E^{-6}$ Pa-m^3. Although these calculations can be based on approximations, a person skilled in the art can conduct simulations, for example finite element modeling simulations, so as to more accurately estimate relative rigidity and/or can measure pressures and deflection forces to determine rigidities of the various portions of the device.

[0283] In certain embodiments, an inner portion of a device is further characterized by an index of refraction that may correspond substantially to the index of refraction of the cornea, for example the index of refraction may be within a range from about 1.38 to about 1.43 so as to match the index of refraction of the cornea to within about ± 0.05. In certain embodiments, the inner portion and the outer portion are characterized by an index of refraction from about 1.38 to about 1.43 so as to match the index of refraction of the cornea to within about ±0.05.

[0284] In certain embodiments, for example, where the device provides vision correction, the inner portion may be characterized by an index of refraction that is different than the refractive index of the cornea.

[0285] In certain embodiments, an inner portion comprises an optically clear material having a modulus from about 10 MPa to about 100 MPa, 10 MPa to about 70 MPa, from about 20 MPa to about 60 MPa, from about 20 MPa to about 50 MPa, and in certain embodiments from about 30 MPa to about 40 MPa. In certain embodiments, the inner portion comprises a material characterized by a modulus from about 20 MPa to about 30 MPa, from about 22 MPa to about 28 MPa and in certain embodiments about 25 MPa.

[0286] In certain embodiments, the inner portion of a device comprises a single material having a modulus from about 1.2 MPa to about 25 MPa, a thickness from about 100 μm to about 500 μm, and a rigidity from about $1.2E^{-6}$ Pa-m^3 to about $3.1E^{-3}$ Pa-m^3. In certain embodiments, the outer portion of a device comprises a single material having a modulus from about 0.2 MPa to about 1.4 MPa, a thickness from about 30 μm to about 500 μm (e.g., tapering from the thickness of the inner portion), and a rigidity from about $5.4E^{-9}$ Pa-m^3 to about $1.5E^{-4}$ Pa-m^3. In certain embodiments, the inner portion of a device comprises a single material having a modulus from about 1.2 MPa to about 25 MPa, a thickness from about 100 μm to about 500 μm, and a rigidity from about $1.2E^{-6}$ Pa-m^3 to about $3.1E^{-3}$ Pa-m^3; and the outer portion of a device

comprises a single material having a modulus from about 0.2 MPa to about 1.4 MPa, a thickness from about 30 μm to about 500 μm (e.g., tapering from the thickness of the inner portion), and a rigidity from about $5.4E^{-9}$ Pa-m^3 to about $1.5E^{-4}$ Pa-m^3.

[0287] In certain embodiments, an inner portion comprises a material selected from silicone, silicone hydrogel, a hydrogel, and a combination of any of the foregoing. In certain embodiments, an inner portion comprises silicone, in certain embodiments, silicone hydrogel, in certain embodiments, a hydrogel, and in certain embodiments a combination of silicone and silicone hydrogel.

[0288] FIG. 7 shows a cross-section view of a device according to certain embodiments of the present invention. The device shown in FIG. 7 has a least a tri-curve profile including a central curvature, a mid-periphery curvature, and a peripheral curvature. The central curvature refers to the curvature of the inner portion of the device spanning an approximately 3 mm diameter region in the center of the device. The mid-periphery curvature refers to the curvature in a radial region about 5 mm from the center of the device. The peripheral curvature refers to the curvature toward the edge of the device. In certain embodiments, as shown for example in FIG. 7, the transition from the peripheral curvature region to other parts of the device may not be smooth and may be characterized by an angle. FIG. 7 shows a centerline 701 of devices 700 provided by the present disclosure, having a central region 702 and mid-peripheral regions 704 on either side of the central region 702. In certain embodiments, the diameter 703 of central region 702 is from about 5 mm to about 7 mm, from about 5.5 mm to about 6.5 mm, and in certain embodiments is about 6 mm. In certain embodiments, the mid-peripheral regions 704 extend form the edge diameter of center region 702 to about 5 mm from centerline 701. Accordingly, the diameter of the mid-peripheral region can be from about 7 mm to about 11 mm, from about 7 mm to about 10 mm, from about 6.5 mm to about 11 mm, from about 6.5 mm to about 10 mm, and in certain embodiments, from about 6 mm to about 10 mm. In certain embodiments, the peripheral diameter 707 of a device can be from about 11 mm to about 16 mm, from about 12 mm to about 15 mm, and in certain embodiments, about 14 mm. As referred to herein, the outer portion comprises the mid-peripheral regions, which are also referred to as intermediate portions, and the peripheral portion.

[0289] In certain embodiments, an outer portion comprises a material having a modulus from about 0.05 MPa to about 4 MPa, from about 0.1 MPa to about 3 MPa, from about 0.1 MPa to about 2 MPa, and in certain embodiment from about 0.2 MPa to about 1.5 MPa. In certain embodiments, the outer portion comprises a material characterized by a modulus from about 0.9 MPa to about 1.5 MPa, from about 1 MPa to about 1.4 MPa, and in certain embodiments, about 1.2 MPa. In certain embodimetns, the material forming the peripheral portion is characterized by a moduls from about 0.01 MPa to about 10 MPa, from about 0.01 MPa to about 8 MPa, from about 0.01 MPa to aobut 5 MPa, and in certain embodiments, from about 0.01 MPa to about 2 MPa. In certain embodiments, a device comprises an inner portion formed from a material such as a silicone polymer, silicone hydrogel, or hydrogel characterized by a modulus of about 25 MPa, and an outer portion formed from a material such as a silicone polymer or silicone hydrogel characterized by a modulus of about 1.2 MPa.

[0290] In certain embodiments, an outer portion comprises a material selected from silicone, silicone hydrogel, a hydrogel, and a combination of any of the foregoing. In certain embodiments, coupling component comprises silicone, in certain embodiments, silicone hydrogel, a hydrogel, and in certain embodiments a combination of silicone, silicone hydrogel, and/or a hydrogel.

[0291] In certain embodiments, the material forming a device including both the inner and outer portions have low water content and is characterized by low water or ion permeability. In certain embodiments, the water content is less than about 5%, less than about 4%, and in certain embodiments, less than about 3%. In certain embodiments, the material forming a device has a water content less than about 1%, less than about 0.6%, and in certain embodiments, less than about 0.3%. In certain embodiments, the material less than about 0.4×10^{-6} cm^2/sec, less than about 0.2×10^{-6} cm^2/sec, and in certain embodiments, less than about 0.1×10^{-6} cm^2/sec..

[0292] In certain embodiments, the inner portion comprises a different material than the outer portion. In certain embodiments, the inner portion and the outer portion comprise the same material. In embodiments in which the inner portion and the outer portion comprise the same material, the different moduli may be realized by the detailed chemistry of the polymer used, such as characterized by different crosslinking densities.

[0293] In certain embodiments, the inner portion of a device and the outer portion of a device comprise a first material characterized by a first modulus and extending along a lower surface of the device; and the inner portion comprises a second material characterized by a second modulus disposed anteriorly to the first material, the second modulus being greater than the first modulus. In such embodiments, the first material is a thin layer that is configured to promote comfort of the device when applied to the cornea by cushioning between the anterior surface of the cornea and the layer of the first material. The second material is configured to promote a beneficial optical shape of an anterior surface of the applied device over the eye.

[0294] As a measure reflecting the rigidity of the inner portion, the flexure of the inner portion can be determined using the ISO 18369-4 flexure test method. The flexure of inner portions or buttons was determined for various thicknesses of a silicone material having a modulus of about 25 MPa.

[0295] A peripheral portion is radially disposed radially outward of the inner portion of an ophthalmic lens. In general, the peripheral portion retains the inner portion and is characterized by approximately the same thickness as the inner portion at the interface between the inner and peripheral portions, and the thickness of the peripheral portion tapers toward the peripheral edge. In certain embodiments, the diameter of the peripheral edge is from about from about 12 mm to 16 mm, 13 mm to about 16 mm, from about 13.5 mm to about 15.5 mm, from about 14 mm to about 15 mm, and in certain embodiments, from about 14.2 mm to about 14.8 mm.

[0296] The peripheral portion is characterized by a lower rigidity than the inner portion and can be formed from a material having a lower modulus than that of the inner portion. In certain embodiments, the material forming the peripheral portion is characterized by a modulus from about 0.5 MPa to about 2.0 MPa, from about 0.8 MPa to about 1.7 MPa, from about 1.0 MPa to about 1.4 MPa, and in certain embodiments, about 1.2 MPa.

[0297] The peripheral portion is configured to provide tear flow between the anterior surface of the device and the epithelium. In certain embodiments, the peripheral portion comprises a plurality of fenestrations extending from the anterior to the posterior surface of the peripheral portion. In certain embodiments, the plurality of fenestrations are disposed at a radius from a central optical axis of the ophthalmic lens such as for example, at a radius proximate to the

interface between the inner portion and the peripheral portion. The plurality of fenestrations may be symmetrically or asymmetrically disposed. The fenestrations may be configured to pump tear liquid between the peripheral portion and the epithelium when the eye blinks so as to maintain a tear layer between the posterior surface of the lens and the epithelium and/or across the anterior surface of the lens. In certain embodiments, the plurality of fenestrations may be configured to facilitate removal of the lens from the eye. In certain embodiments, the plurality of fenestrations may be configured to facilitate air dissipation if airbubbles are trapped underneath the lens, In certain embodiments, the plurality of fenestrations facilitates the removal of air bubble entrapped within any lenticular volumes following application of a lens to a patient's eye. The plurality of fenestrations may facilitate both removal of the lens form the eye and dissipation of air bubbles. In certain embodiments, the plurality of fenestrations improves the reproducibility of visual outcome in a population of patients wearing the lens compared to the visual outcome in a population of patients wearing a comparable lens without fenestrations.

[0298] In certain embodiments, the inner portion, the peripheral portion, or both the inner and peripheral portions of an ophthalmic lens provided by the present disclosure are radially symmetric. In certain embodiments, the anterior surface of the inner portion and the posterior surface of the inner portion are radially symmetric.

[0299] In certain embodiments of ophthalmic lenses provided by the present disclosure, the inner portion and the peripheral portion are configured to allow movement of the lens relative to the eye in response to blinking of the eye. In such embodiments, an ophthalmic lens is configured such that the inner optical portion centers on the optical portion of the cornea following blinking. During blinking the inner portion, the peripheral portion, or both the inner and peripheral portions may deform and/or move with respect to the center optical axis of the cornea. When an ophthalmic lens is worn by a patient, depending at least in part by the shape of the patient's eye and the configuration of the lens, the ophthalmic lens may move during blinking or may exhibit only micro-movement. However, in certain embodiments, a lens is not configured to resist movement such that, for example, the peripheral edge of the lens is not configured to fixedly engage the epithelium or sclera such that the inner portion resists movement relative the cornea.

[0300] In certain embodiments of ophthalmic lenses provided by the present disclosure, the inner portion and the peripheral portion are configured to provide a tear fluid flow between the peripheral portion of the ophthalmic lens and the epithelium.

[0301] In certain embodiments, an ophthalmic lens provided by the present disclosure includes a reinforcement ring disposed toward the interface between the inner portion and the peripheral portion. FIGS. 15A and 15B show perspective and cross-sectional views of an ophthalmic device provided by the present disclosure incorporating a reinforcement ring. FIGS. 15A and 15B show an ophthalmic lens having a central optic portion 1501, a peripheral portion or skirt 1502, mechanically coupled to the inner portion 1501, in part by thin layer 1706 disposed along the posterior surface of the inner portion. Inner portion 1501 is characterized by a substantially uniform thickness 1507 and a rigidity that is greater than the rigidity of peripheral portion 1702. Peripheral portion 1502 includes a heal 1505 and a peripheral edge 1504. Reinforcement ring 1503 is disposed toward the interface between the central optic portion 1501 and the peripheral portion 1502 and in the embodiment shown in FIGS. 15A and 15B the reinforcement ring 1503 is embedded within central optic portion 1701. In FIG. 15A the different elevations of the central optic portion and the peripheral portion are intended to show that these portions may have one or more radius of curvature. A reinforcement ring may be disposed or embedded within the inner portion, disposed or embedded within the peripheral portion, or disposed at the interface between the inner and peripheral portions. A reinforcement ring is configured to prevent or minimize flexure of the inner optic portion from forces on the eye and/or forces of the eye lids such as during blinking. A reinforcement ring is disposed at a radial location such that the ring does not interfere with vision. A reinforcement ring may be a radially symmetric ring and can be configured to facilitate centering of the ophthalmic lens on the optical region of the cornea during wear. In certain embodiments, a reinforcement ring may be made from a material having a higher modulus than that of the materials forming the inner portion and the peripheral portion of the lens. In certain embodiments, a reinforcement ring may be made from a rigid, optically opaque or translucent material such as, for example, polyimide, polyether ether ketone, polyetherimide, polysulfone, or a combination of any of the foregoing. In certain embodiments a reinforcement ring may be made of a transparent rigid gas permeable polymer such as, for example, polymethylmethacrylate, fluorosilicone acrylate, a silicone acrylate or a combination of any of the foregoing. In certain embodiments, a reinforcement ring may be made from a metal

such as, for example, titanium, stainless steel, cobalt steel, or a combination of any of the foregoing. In certain embodiments, the material forming the reinforcement ring has the same index of refraction as that of the material forming the inner portion. In certain embodiments, a reinforcement ring may have, for example, an inner diameter from about 4 mm to about 12 mm, from about 6 mm to about 12 mm, from about 8 mm to about 12, and in certain embodiments, from about 8 mm to about 10 mm. In certain embodiments, a reinforcement ring may have, for example, a width from about 0.1 mm to about 5 mm, from about 1 mm to about 4 mm, from about 2 mm to about 3 mm, and in certain embodiments, from about 0.5 mm to about 2 mm. In certain embodiments, a reinforcement ring may have, for example, a thickness from about 0.05 mm to about 0.5 mm, from about 0.1 mm to about 0.4 mm, from about 0.2 mm to about 0.3 mm, and in certain embodiments from about 0.2 mm to about 0.4 mm. A reinforcement ring may or may not include features to enhance adhesion of the ring to the material forming the center optic portion and/or the material forming the peripheral portion of the lens. For example, a reinforcement ring may include concave and/or convex surfaces, indentations, partial through-holes, full through-holes, perforations, serrated or irregular edges, or a combination of any of the foregoing.

[0302] The peripheral portion of a lens can be tapered toward the peripheral edge. The taper may be continuous or discontinuous. The peripheral portion may be flared outward toward the peripheral edge and is referred to as a modified heeled configuration. A cross-sectional profile of a lens is determined by the inner portion characterized by a substantially constant thickness and the shape of the taper of the peripheral portion. Examples of cross-section lens profiles are shown in FIGS. 14A-14C. In general, the cross-sectional shape of an ophthalmic lens is configured to correct refractive error of any eye, center the lens on the optical portion of the cornea, facilitate motion of the lens with respect to the eye, provide flow of tear liquid between the posterior surface of the lens and epithelium, and to provide comfort to a patient wearing the lens. The ability of the lens to move, provide a fluid layer, and exchange tear fluid facilitates eye health and improves comfort for extended wear.

[0303] The flexure of the inner portion of lenses provided by the present disclosure is presented in Table 1. Table 1 provides the force (gm) required to flex an inner portion having thicknesses from 200 μm to 850 μm a certain percent of the un-flexed diameter. For thicknesses

of 200 μm, 325 μm, and 550 μm, the force required to displace the inner portion by 1% was too small for the instrument to measure accurately. The results for a 150 μm-thick inner portion of a standard RGP toric lens and for a 250 μm-thick hybrid toric lens, used to correct refractive error are also presented in Table 1. As is shown by the results presented in Table 1, significantly more force is required to flex the toric lenses than ophthalmic lenses provided by the present disclsoure having a similar thickness. This is at least in part the consequence of the toric lenses being made of a material having a much higher modulus than that of the present design.

Table 1.

Lens Design	Thickness (μm)	Force (gm) to flex		
		1%	10%	20%
NXV Rigid Silicone	200	N/A	1.2	1.6
	325	N/A	4.9	6.7
	550	N/A	20	25
	600	8	35	36
	725	15	65	69
	850	20	101	96
RGP	150	6.4	29	39
Soft Toric	250	16	116	167

[0304] In certain embodiments, the force required to flex the inner portion using the ISO 18369-4 flexure test method by 1% is from aobut 0.5 gm to about 50 gm, from about 1 gm to about 40 grm, and in certain embodiments, from about 5 gm to about 25 gm.

[0305] In certain embodiments, the inner portion is characterized by a rigidity from about 5.0E10 Pa-μm^3 to about 5.0E8 Pa-μm^3, 2.0E10 MPa-μm^3 to about 8E9 MPa-μm^3, from about 1.8E10 MPa-μm^3 to about 8.5E9 MPa-μm^3, from about 1.6E10 MPa-μm^3 to about 8.8E9 MPa-μm^3, and in certain embodiments, from about 1.5E10 MPa-μm^3 to about 9E9 MPa-μm^3. In certain of such embodiments, the thickness of the inner portion is from about 650 μm to about 850 μm, in certain embodiments, from 200 μm to 800 μm, and in certain embodiments, from 400 μm to 800 μm. And, in certain of such embodiments, the modulus of the material forming the inner portion is from about 20 MPa to about 30 MPa, from about 23 MPa to about 27 MPa, and in certain embodiments, about 25 MPa. This can be compared to soft toric lenses having a

central optic thickness of about 70 μm, a modulus of 1.7 MPa, and a rigidity of about 5.8E5 MPa-μm^3. This can also be compared to a RGP lens having a center optic thickness of 150 um, a modulus of 1,200 MPa and rigidity of 4E9 MPa-μm^3. Compared to a soft toric lens, in certain embodiments, ophthalmic lenses provided by the present disclosure have a relative rigidity of the central optic portion that is from about 10,000 to 30,000 times greater than the rigidity of the central portion of a soft toric lens.

[0306] In certain embodiments, the inner portion is characterized by a rigidity from 4E8 MPa-μm^3 to 1E10 MPa- μm^3, from 6E8 MPa-μm^3 to 1E10 MPa-μm^3, from 8E8 MPa-μm^3 to 1E10 MPa-μm^3, from 1E9 MPa-μm^3 to 1E10 MPa-μm^3 from 2E9 MPa-μm^3 to 1E10 MPa-μm^3, from 4E9 MPa-μm^3 to 1E10 MPa-μm^3, and in certain embodiments, from 6E9 MPa-μm^3 to 1E10 MPa-μm^3. In certain of such embodiments, the thickness of the inner portionis from about 100 μm to 900 μm, in certain embodiments, from 200 μm to 800 μm, and in certain embodiments, from 400 μm to 800 μm. And, in certain of such embodiments, the modulus of the material forming the inner portion is from about 20 MPa to about 30 MPa, from about 23 MPa to about 27 MPa, and in certain embodiments, about 25 MPa.

[0307] In certain embodiments, ophthalmic lenses provided by the present disclosure are characterized by a center rigidity of at least about 6E9 MPa-μm^3, at least about 8E9 MPa-μm^3, at least about 1E10, at least about 1.2E10 MPa-μm^3 and in certain embodiments, at least about 1.4E10 MPa-μm^3. The center rigidity can be selected based on the modulus and thickness of the material or materials used to form the center optical portion of a lens. In general, the rigidity of the central portion of a lens is selected to maintain a spherical anterior surface during use. In certain embodiments, the thickness of the center of the optical portion is at least 200 μm, at least 300 μm, at least 400 μm, at least 500 μm, at least 600 μm, at least 700 μm, and in certain embodiments at least 800 μm. In certain embodiments, the thickness of the center of the optical portion is from 100 μm to 900 μm, from 200 μm to 900 μm, from 300 μm to 900 μm, from 400 μm to 900 μm, from 500 μm to 900 um, from 600 μm to 700 μm, from 700 μm to 800 μm, and in certain embodiments at least 300 μm to 600 μm. In general, lenses with a thinner central thickness are more comfortable to wear. In certain embodiments, the inner portion of an ophthalmic lens is formed from a material characterized by a modulus less than 1,000 MPa, less

than 750 MPa, less than 500 MPa, less than 250 MPa, less than 200 MPa, less than 100 MPa, less than 50 MPa, less than 30 MPa, less than 20 MPa, and in certain embodiments, less than 10 MPa. In certain embodiments, an ophthalmic lens is characterized by a center rigidity of at least about 6E9 MPa-μm^3, a thickness from 200 μm to 900 μm, and a modulus from 10 MPa to 1,000 MPa, and in certain embodiments a modulus from 10 MPa to 200 MPa.

[0308] In certain embodiments, an inner optic portion is characterized by a thickness from 100 μm to 900 μm, by a modulus from about 10 MPa to about 1,000 MPa, and a rigidity of at least about 4E8MPa-μm^3. In certain embodiments, an inner optic portion is characterized by a thickness from 100 μm to 900 μm, by a modulus from about 10 MPa to about 600 MPa, and a rigidity of at least about 4E8MPa-μm^3. In certain embodiments, an inner optic portion is characterized by a thickness from 100 μm to 900 μm, by a modulus from about 10 MPa to about 300 MPa, and a rigidity of at least about 4E8MPa-μm^3. In certain embodiments, an inner optic portion is characterized by a thickness from 100 μm to 900 μm by a modulus from about 10 MPa to about 100 MPa, and a rigidity of at least about 4E8MPa-μm^3.

[0309] In certain embodiments, an inner portion of an ophthalmic lens is characterized by a center rigidity of at least about 1E9 MPa-μm^3, a thickness from 100 μm to 800 μm, and a modulus from 10 MPa to 800 MPa, and in certain embodiments a modulus from 10 MPa to 200 MPa. In certain embodiments, an ophthalmic lens is characterized by a center rigidity of at least about 5E8 MPa-μm^3, a thickness from 100 μm to 800 μm, and a modulus from 10 MPa to 800 MPa, and in certain embodiments a modulus from 10 MPa to 200 MPa.

[0310] In certain embodiments and depending at least in part on the shape of a patient's cornea, the posterior surface of an ophthalmic lens may not completely conform to the surface of the epithelium during wear. Thus, at least a portion of the inner portion, the peripheral portion, or both the inner and peripheral portions by form a vault over at least certain portions of the underlying epithelium to form one or more lenticular volumes. The lenticular volumes may be filled with tear liquid. The ability of the lens to move on the eye during blinking and any fenestrations if present can circulate tear fluid the lenticular volume and exchange tear fluid with other parts of the eye.

[0311] In certain embodiments, the inner portion and the peripheral portion are formed from silicone, a silicone hydrogel, a hydrogel, or a combination of any of the foregoing.

[0312] FIG. 8A shows the average spherical lens corrected visual acuity (LogMAR) in a population of patients having uncorrected 1.25DC to 2.00DC cylindrical error (low to moderate astigmatism) when wearing a lens of the present disclosure. The average spherical lens visual acuity (LogMAR) for each thickness of lens is shown above the minimum and maximum values. The number of patients tested is also indicated in the figure. Soft toric contact lenses suitable for correcting low to moderate astigmatism provide 20/20 vision (Toric SCL) 0.00 LogMAR with a standard deviation of ±0.15 (±1SD). Similar corrected visual acuities are obtained with lenses provided by the present disclosure in which the thickness of the inner portion is from 600 μm to 800 μm and a modulus of 25 MPa. As reflected by the minimum and maximum for the lenses provided by the present disclosure, the deviation in the corrected visual acuities are less than those for the toric soft contact lens product tested.

[0313] The results presented in FIG. 8A are represented in a different format in FIG. 8B to show the percent of patients having equal to or better than 20/25 vision or having equal to or better than 20/20 vision when wearing a lens having a central thickness of 600 μm, 725 μm, or 850 μm, provided by the present disclsoure. Prior to wearing the lens, the patients had an uncorrected cylindrical error from 1.25DC to 2.00DC. As shown in FIG. 8B, 100% of patients had 20/25 vision or better for each thickness tested. Also, the percent of patients seeing 20/20 or better increased with the thickness of the inner portion of the lens.

[0314] In certain embodiments, devices for correcting refractive error in patients having low to moderate astigmatism corresponding to an uncorrected cylindrical error from about 1.25DC to about 2.00DC when worn by a patient provide at least 20/25 vision or 20/20 vision.

[0315] FIG. 9A and FIG. 9B show results similar to those provided in FIG. 8A and FIG. 8B for patients having uncorrected cylindrical error of 2.25DC to 3.00DC consistent with moderate to high astigmatism. The average sperhical lens visual acuity (LogMAR) for each thickness of lens is shown above the minimum and maximum of the measure values. The number of patients tested is also indicated in the figure. For patients with moderate to high astigmatism, soft toric lenses provide an average spherical lens corrected visual acuity (LogMAR) of 0.15 ±0.15

(±1SD). As shown in FIG. 9A, ophthalmic lenses provided by the present disclosure having a central thickness from 600 μm to 850 μm and a modulus of 25 MPaprovide an average spherical lens corrected visual acuity that is equivalent to or better than that of the tested toric soft contact lens. The histogram in FIG. 9B shows that for patients having moderate to severe astigmatism, the percent of patients seeing 20/25 or better and 20/20 increases with increasing thickness of the inner portion of the lens.

[0316] In certain embodiments, devices for correcting refractive error in patients having moderate to high astigmatism corresponding to an uncorrected cylindrical error from about 2.25DC to about 3.00DC when worn by a patient provide at least 20/25 vision or 20/20 vision.

[0317] In certain embodiments, when wearing an ophthalmic lenses provided by the present disclosure an average corrected visual acuity in a population of patients having from 2.25DC to 3.00DC cylindrical error is 0.1 ± 0.15 LogMAR or better.

[0318] In certain embodiments, when wearing an ophthalmic lenses provided by the present disclosure an average corrected visual acuity in a population of patients having from 1.25DC to 2.00DC cylindrical error is 0.0 ± 0.15 LogMAR or better.

[0319] Ophthalmic lenses provided by the present disclosure are configured to provide refractive correction equivalent to or better than RGP and soft toric lens, and to provide enhanced comfort. The comfort of lenses provided by the present disclosure is compared to that of commercially available soft toric contact lenses in FIG. 10A. A comfort score was determined by asking patients to rate the level of comfort experienced while wearing a particular lens on a scale from 1 to 10 with a score of 10 reflecting extreme comfort. The average comfort score for each thickness of lens is shown above the error bars for ±1SD. The number of patients tested is also indicated in the figure. The average (±1SD) comfort scores for patients wearing lenses of the present disclosure having an inner thickness from 275 μm to 850 μm are compared with the comfort score for five (5) different soft toric contact lens designs A-E. The results for the present lenses were obtained within 30 minutes after a lens was applied to an eye. For a 275 μm-thick lens, the comfort was also determined at the end of one day. The results for the soft toric contact lens were determined either one week or at the end of one day following application to the eye. The best soft toric contact lens provided a mean comfort score of 8.3 (±1.12) after

one week of wearing. The lenses provided by the present disclosure provided an enhanced comfort score with thinner lenses exhibiting greater comfort.

[0320] In certain embodiments, devices for correcting refractive error exhibit a mean comfort level in a population of patients of at least 6.5, at least 7.5, at least 8, or at least 9 following wearing the device for at least one day or for at least one week. In certain embodiments, devices for correcting refractive error exhibit a mean comfort level in a population of patients of at least 6.5, at least 7.5, at least 8, or at least 9 following wearing the device for at least 30 minutes.

[0321] The percent of patients experiencing a comfort level equal to or greater than 8 or a comfort level equal to or greater than 9 for inner region thicknesses of 600 μm, 725 μm, and 850 μm are presented in FIG. 10B. The results generally demonstrate that the percent of patients experiencing high comfort increases for lenses having a thickness around 725 μm and less.

[0322] In certain embodiments, ophthalmic lenses provided by the present disclosure do not increase the risk of contact lens-related adverse events such as corneal ulcers, microbial keratitis, and iritis.

[0323] FIG. 11 is a schematic diagram of instrumentation for testing the flexure of an inner portion or button of a contact lens consistent with ISO 18369-4.

[0324] FIG. 12 is a graph showing the relationship between thickness and flexure for certain ophthalmic lenses provided by the present disclsoure. The force (gm) required to flex a central portion or button of a lens having a thickness from 200 μm to 800 μm by 10% is shown in FIG. 12.

[0325] FIG. 13 is a histogram showing the force (gm) required to flex an inner portion or button of a lens by 1%. The flexure of lenses provided by the present disclosure (NXV) having a central thickness from 600 μm to 850 μm is compared to the flexure of a rigid gas permeable (RGP) lens and a soft toric contact lens (A) used for treating astigmatic error.

[0326] Devices and methods provided by the present disclosure can also be used to address dry eye. In such applications, the device material comprises a material such as silicone that has a low water content and low water absorption, water evaporation from the eye can be controlled and a tear or lubricant reservoir maintained.

EXAMPLES

[0327] Embodiments provided by the present disclosure are further illustrated by reference to the following examples, which describe the use of certain ophthalmic devices provided by the present disclosure. It will be apparent to those skilled in the art that many modifications, both to materials, and methods, may be practiced without departing from the scope of the disclosure.

Example 1

[0328] A subject requiring an optical correction of -2.63 Diopters (OD) and -2.13 Diopters (OS) characteristic for a subject having myopia wore ophthalmic lenses on both eyes for (very roughly) about 40 hours. The inner and peripheral radii of curvature for the ophthalmic devices are provided in Table 1. After about 40 hours, the ophthalmic lenses were removed and the amount of optical correction (Diopters) need to correct vision was determined at various times. The amount of optical correction (Diopters) needed after the ophthalmic lens was removed from the subjects is presented in Table 2

Table 2. Amount of optical correction (Diopters) needed after wearing an ophthalmic lens.

		Radii of curvature for ophthalmic lens		Time following ophthalmic lens removal						
	Amount of correction needed (prior to shield wear)	Inner Curve (degrees)	Peripheral Curve (degrees)	5 min	2 hr	4 hr	8 hr	24 hr	30 hr	48 hr
Subject #1 OD	-2.63	39.5	43.0	-0.63	+0.13	+0.13	NM	-0.50	-0.75	-1.25
Subject #1 OS	-2.13	39.5	41.5	-0.63	-0.13	NM	NM	0.00	0.00	-2.38

*NM = No Measurement

Example 2

[0329] A subject requiring an optical correction of +0.13 Diopters (OD) and +0.25 Diopters (OS) characteristic for a subject having hyperopia wore ophthalmic lenses on the right eye for (very roughly) about 35 hours, and on the left eye for (very roughly) about 17. The inner and peripheral radii of curvature for the ophthalmic devices are provided in Table 2. After about the specified number of hours, the ophthalmic lenses were removed and the amount of optical correction (Diopters) need to correct vision was determined at various times. The amount of optical correction (Diopters) needed after the ophthalmic lens was removed from the subjects is presented in Table 3.

Table 3. Amount of optical correction (Diopters) needed after wearing an ophthalmic lens.

		Radii of curvature for ophthalmic lens		Time following ophthalmic lens removal						
	Amount of correction needed (prior to shield wear)	Inner Curve (degrees)	Peripheral Curve (degrees)	5 min	2 hr	4 hr	8 hr	24 hr	30 hr	48 hr
Subject #2 OD	+0.13	39.5	43.0	-2.38	-3.13	-3.37	-2.00	NM	NM	NM
Subject #2OS	+0.25	39.5	41.5	-1.00	-1.25	NM	NM	0.00	NM	NM

*NM = No Measurement

[0330] While the exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, those of skill in the art will recognize that a variety of modifications, adaptations, and changes may be employed. Hence, the scope of the present invention should be limited solely by the appended claims.

APPENDIX 1.

TABLE B1

14mm multicurve designs	R1 center BC (D)	R1B1 5-7mm K (D)	R1B2 7-9mm K (D)	R1B3 9-11mm K (D)	R1 C2 13.5-14mm K (D)	SAG mm	DIA
Steep K	36.5	43.50	42.25	39.50	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Medium	36.5	42.00	40.75	38.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Flat K	36.5	40.50	39.25	36.75	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Steep K	38.5	44.25	43.00	40.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Medium	38.5	42.75	41.50	39.00	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Flat K	38.5	41.25	40.00	37.50	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Steep K	40.5	45.00	43.75	41.00	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Medium	40.5	43.50	42.25	39.75	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Flat K	40.5	42.00	40.75	38.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm

TABLE B2

Flatter periphery design

14mm multicurve designs	R1 Center BC (D)	R1B1 5-7mm K (D)	R1B2 7-9mm K (D)	R1B3 9-11mm K (D)	R1 C2 13.5-14mm K (D)	SAG (mm)	DIA
Steep K	36.5	43.50	42.25	38.50	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Medium	36.5	42.00	40.75	37.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Flat K	36.5	40.50	39.25	35.75	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Steep K	38.5	44.25	43.00	39.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Medium	38.5	42.75	41.50	38.00	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Flat K	38.5	41.25	40.00	36.50	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Steep K	40.5	45.00	43.75	40.00	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Medium	40.5	43.50	42.25	38.75	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
Flat K	40.5	42.00	40.75	37.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm

TABLE B3.

Large shield (16mm) multicurve designs	R1 center BC	R1B1 5-7mm K (D)	R1B2 7-9mm K (D)	R1B3 9-10.5mm K (D)	10.5-13mm K (D)	13-16mm*	SAG (mm)	DIA
Steep K	36.5	43.50	42.25	39.50	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
Medium	36.5	42.00	40.75	38.25	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
Flat K	36.5	40.50	39.25	36.75	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
Steep K	38.5	44.25	43.00	40.25	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
Medium	38.5	42.75	41.50	39.00	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
Flat K	38.5	41.25	40.00	37.50	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
Steep K	40.5	45.00	43.75	41.00	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
Medium	40.5	43.50	42.25	39.75	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
Flat K	40.5	42.00	40.75	38.25	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm

* may not tangent with previous curve (may insert an outer curve to help it flare)

TABLE B4.

	Multicurve CL designs	R1 center BC (D)	R1B1 5-7mm K (D)	R1B2 7-9mm K (D)	R1B3 9-11mm K (D)	R1C 13.5-14mm K (D)	SAG (mm)	DIA
CL central curve 1	**Steep K**	40	41.75	39.00	39.00	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
	Medium	40.00	39.75	37.25	37.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
	Flat K	40.00	37.75	35.25	35.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
CL central curve 2	**Steep K**	42.00	43.75	41.00	41.00	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
	Medium	42.00	41.75	39.25	39.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
	Flat K	42.00	39.75	37.25	37.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
CL central curve 3	**Steep K**	44.000	44.75	42.00	42.00	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
	Medium	44.00	43.25	40.75	40.75	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
	Flat K	44.00	41.75	39.25	39.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
CL central curve 4	**Steep K**	46.00	46.75	44.00	44.00	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
	Medium	46.00	45.25	42.75	42.75	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm
	Flat K	46.00	43.75	41.25	41.25	<12mm BC (140micron thick)	3.1-3.4	13.8-14.1mm

CLAIMS

WHAT IS CLAIMED IS:

1. An ophthalmic lens for correcting a refractive error of an eye, the eye having a cornea with an epithelium providing a refractive shape extending across an optical region of the eye, the ophthalmic lens comprising:

an inner optic portion configured to be disposed over the optical region of the cornea;

a posterior surface extending along the inner portion adjacent the eye when the inner portion is disposed over the optical region, the inner portion configured so that engagement of the posterior surface against the eye deforms the posterior surface and so that the posterior surface has a shape diverging from the refractive shape of the epithelium when viewing with the eye through the ophthalmic lens;

a peripheral portion of the ophthalmic lens disposed radially outward of the inner portion; and

an anterior surface of the ophthalmic lens extending along the inner portion opposite the posterior surface so that viewing with the eye through the ophthalmic lens mitigates the refractive error.

2. The ophthalmic lens of claim 1, wherein the rigidity of the inner portion is greater than the rigidity of the peripheral portion.

3. The ophthalmic lens of claim 1, wherein the rigidity of the inner portion is from about 2.0E10 MPa-μm^3 to about 8.0E9 MPa-μm^3.

4. The ophthalmic lens of claim 1, wherein the inner portion is characterized by a thickness from about 100 μm to about 900 μm.

5. The ophthalmic lens of claim 4, wherein the force required to flex the inner portion by 1% is from about 0.5 gm to about 50 gm.

6. The ophthalmic lens of claim 1, wherein the inner portion comprises a material having a modulus from about 10 MPa to about 100 MPa and the peripheral portion comprises a material having a modulus from about 0.01 MPa to about 10 MPa.

7. The ophthalmic lens of claim 1 wherein the inner optic portion is characterized by a thickness from 100 μm to 900 μm , by a modulus from about 10 MPa to about 1,000 MPa, and a rigidity of at least about 4E8MPa-μm^3.

8. The ophthalmic lens of claim 1, wherein the inner portion and the outer portion comprise a material selected from silicone, silicone hydrogel, a hydrogel, or a combination of any of the foregoing.

9. The ophthalmic lens of claim 1, wherein the inner portion is characterized by a thickness from about 100 μm to about 900 μm and is formed from a material characterized by a modulus from about 20 MPa to about 100 MPa.

10. The ophthalmic lens of claim 1, wherein the anterior surface of the inner portion is characterized by a substantially spherical profile.

11. The ophthalmic lens of claim 1, wherein

the refractive error of the eye includes a cylindrical error; and

the anterior surface of the inner portion is characterized by a substantially spherical surface so that correction of the cylindrical error by the lens is primarily effected by the divergence of the shape of the posterior surface from the shape of the epithelium when viewing with the eye through the ophthalmic lens.

12. The ophthalmic lens of claim 1, wherein the inner portion is characterized by a spherical anterior surface.

13. The ophthalmic lens of claim 1, wherein the inner portion and the peripheral portion are configured to allow movement relative to the eye in response to blinking of the eye.

14. The ophthalmic lens of claim 1, wherein the inner portion and the peripheral portion are configured to provide a tear fluid flow between the peripheral portion of the ophthalmic lens and the epithelium.

15. The ophthalmic lens of claim 1, wherein the refractive error of the eye comprises astigmatism, wherein the anterior surface of the inner portion and the posterior surface of the inner portion are radially symmetric.

16. The ophthalmic lens of claim 1, further comprising a plurality of fenestrations, wherein the plurality of fenestrations is disposed in the peripheral region.

17. The ophthalmic lens of claim 16, wherein the plurality of fenestrations is disposed at a radius from a central optical axis of the ophthalmic lens.

18. The ophthalmic lens of claim 16, wherein the plurality of fenestrations is configured to pump tear liquid between the peripheral portion and the epithelium when the eye blinks.

19. The ophthalmic lens of claim 16, wherein the plurality of fenestrations are configured to facilitate removal of the lens from the eye, to facilitate air dissipation if airbubbles are trapped underneath the lens, or a combination thereof.

20. The ophthalmic lens of claim 16, wherein the plurality of fenestrations improves the reproducibility of visual outcome in a population of patients wearing the lens compared to the visual outcome in a population of patients wearing a comparable lens without fenestrations.

21. The ophthalmic lens of claim 1, wherein the inner portion is configured to correct vision and the peripheral portion is configured to enhance comfort.

22. The ophthalmic lens of claim 1, comprising a reinforcement ring disposed proximate an interface between the inner portion and the peripheral portion.

23. The ophthalmic lens of claim 22, wherein the reinforcement ring is embedded within the inner portion.

24. The ophthalmic lens of claim 22, wherein the reinforcement ring is disposed within the inner portion at a location that is not coincident with the optical region of the cornea.

25. The ophthalmic lens of claim 22, wherein the reinforcement ring is formed from a material having a higher modulus than a modulus of a material forming the inner portion.

26. The ophthalmic lens of claim 22, wherein the reinforcement ring is formed from polymethylmethacrylate.

27. The ophthalmic lens of claim 1, wherein the lens is configured to center on the optical region of the cornea following blinking of the eye.

28. The ophthalmic lens of claim 1, wherein the inner portion is characterized by a diameter from 5 mm to 10 mm and the peripheral portion is characterized by an outer diameter of 12 mm to 16 mm.

29. A method for selecting an ophthalmic lens for correcting a refractive error of an eye of a patient, the eye having a cornea with an epithelium providing a refractive shape, the method comprising:

determining a desired spherical power so as to mitigate any spherical component of the refractive error; and

identifying, from among a plurality of alternative ophthalmic lenses having differing spherical powers, a selected ophthalmic lens so as to provide:

an anterior surface corresponding to the desired spherical power, the anterior surface extending along an inner portion of the ophthalmic lens, wherein the inner portion of the ophthalmic lens is characterized by a thickness from about 100 μm to about 900 μm and a peripheral portion of the ophthalmic lens has a rigidity lower than a rigidity of the inner portion; wherein the ophthalmic lens is configured to allow movement relative to the eye upon blinking of the eye and to be substantially centered on the optical region of the cornea following the blinking of the eye.

30. A method for correcting a refractive error of an eye, the eye having a cornea with an epithelium providing a refractive shape extending across an optical region of the cornea, the method comprising:

positioning an ophthalmic lens on the eye so that an inner portion of the ophthalmic lens is disposed over the optical region of the cornea, wherein a posterior surface of the positioned ophthalmic lens extends adjacent the eye and is deformed by the epithelium of the eye; and

viewing with the eye through an anterior surface of the ophthalmic lens while a shape of the posterior surface diverges from the refractive shape of the epithelium so that the ophthalmic lens mitigates the refractive error.

31. The method of claim 30, wherein the ophthalmic lens comprises:

an inner optic portion configured to be disposed over the optical region of the cornea and characterized by a thickness from 100 μm to 900 μm;

the posterior surface extending along the inner portion adjacent the eye when the inner portion is disposed over the optical region, the posterior surface having a shape diverging from the refractive shape of the epithelium;

the peripheral portion of the ophthalmic lens is disposed radially outward of the inner portion; and

the anterior surface of the ophthalmic lens extends along the inner portion opposite the posterior surface so that viewing with the eye mitigates the refractive error.

32. The method of claim 30, wherein following wearing the lens for at least 30 minutes, an average comfort score in a population of patients is at least 6.5.

33. The method of claim 30, wherein following the positioning of the lens, an average corrected visual acuity in a population of patients having from 2.25DC to 3.00DC cylindrical error is 0.1 ± 0.15 LogMAR or better.

34. The method of claim 30, wherein following the positioning of the lens, an average corrected visual acuity in a population of patients having from 1.25DC to 2.00DC cylindrical error is 0.0 ± 0.15 LogMAR or better.

35. The method of claim 30, the refractive error of the eye comprising astigmatism, spherical aberration, or a combination thereof, wherein:

a plurality of fenestrations extends between the anterior surface and the posterior surface, the plurality of fenestrations disposed outside the optical region;

the inner portion of the ophthalmic lens is deformable and the peripheral portion is characterized by a rigidity lower than a rigidity of the inner portion;

mitigation of the refractive error when viewing with the eye through the anterior surface is substantially independent of the shape of the peripheral portion throughout a range of astigmatic errors of at least about 1.5D, and is independent of a rotational orientation of the ophthalmic lens about a viewing axis of the eye.

36. A set of alternatively selectable ophthalmic lenses for correcting refractive errors of eyes in a population of patients, each eye having a cornea with an epithelium providing a refractive shape, the set comprising:

a plurality of alternative ophthalmic lenses having differing spherical powers, each ophthalmic lens comprising:

an anterior surface corresponding to an associated desired spherical power, the anterior surface extending along an inner portion of the ophthalmic lens, wherein the inner portion of the ophthalmic lens is deformable; and

a peripheral portion of the ophthalmic lens extending radially outward from the inner portion, the peripheral portion characterized by a rigidity lower than a rigidity of the inner portion and configured for engaging tissue outside an optical region of the eye so as to support the inner portion in alignment with the optical region.

37. An ophthalmic lens for correcting a refractive error of an eye, the eye having a cornea with an epithelium providing a refractive shape extending across an optical region of the eye, the ophthalmic lens comprising:

an inner optic portion configured to be disposed over the optical region of the cornea;

a posterior surface extending along the inner portion adjacent the eye when the inner portion is disposed over the optical region, the inner portion configured so that engagement of the posterior surface against the eye deforms the posterior surface and so that the posterior surface has a shape diverging from the refractive shape of the epithelium when viewing with the eye through the ophthalmic lens;

a peripheral portion of the ophthalmic lens disposed radially outward of the inner portion; and

an anterior surface of the ophthalmic lens extending along the inner portion opposite the posterior surface so that viewing with the eye through the ophthalmic lens mitigates the refractive error;

wherein the inner optic portion is characterized by a thickness from 100 μm to 900 μm , and by a modulus from about 10 MPa to about 1,000 MPa, and a rigidity from about 4E8MPa-μm^3 to about 1.2E10MPa; and

wherein the anterior surface is characterized by a spherical profile without a cylindrical component.

38. The ophthalmic lens of claim 37, wherein the modulus is from about 10 MPa to about 100 MPa.

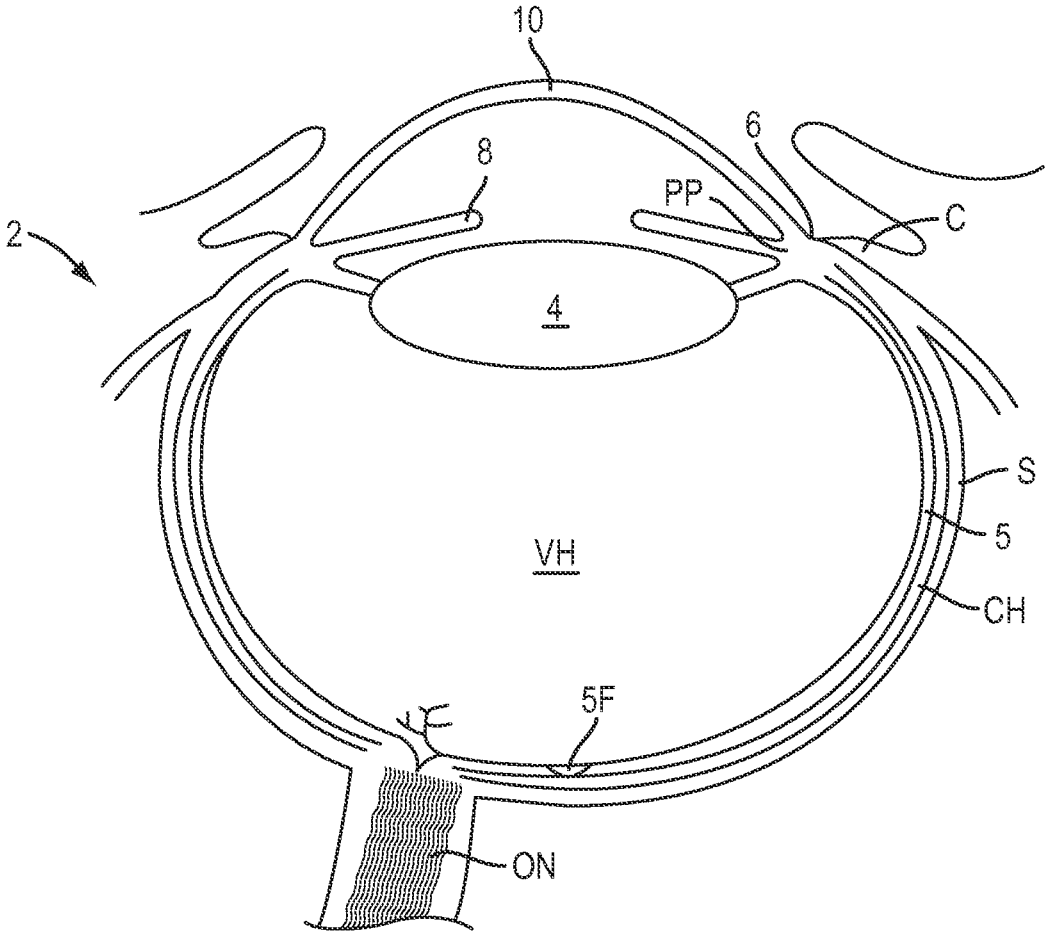


FIG. 1

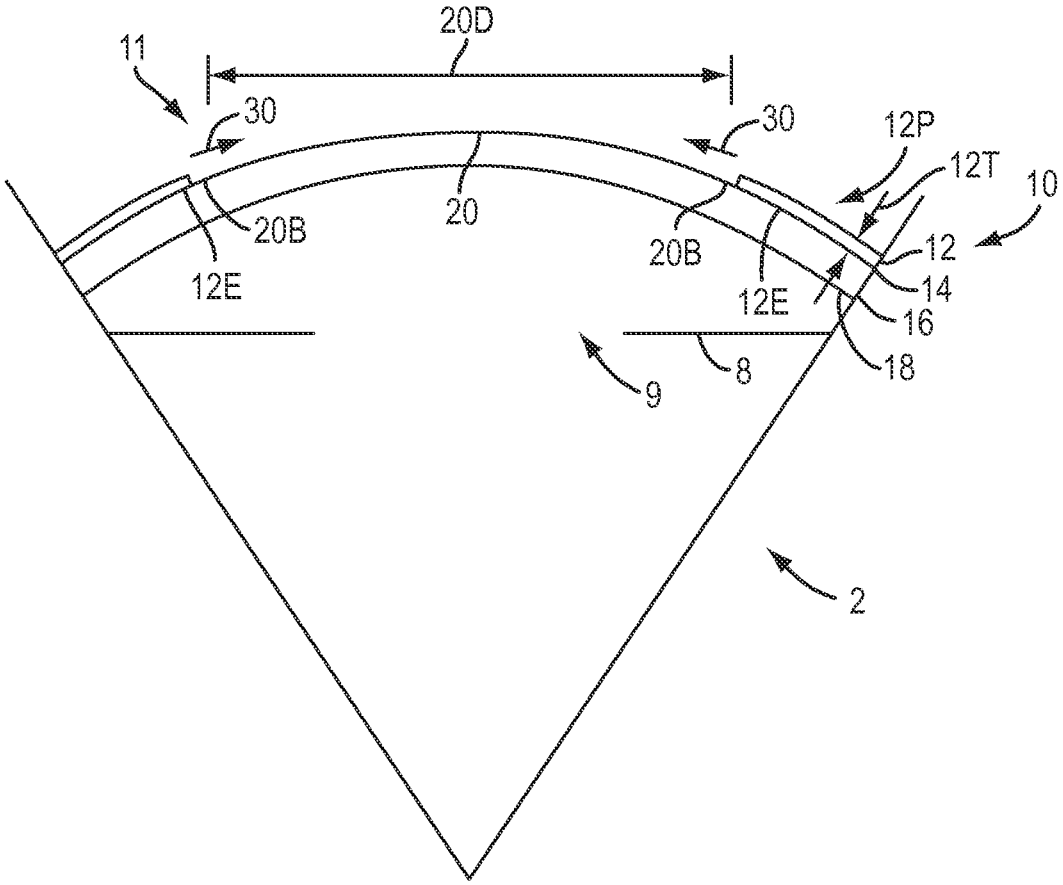
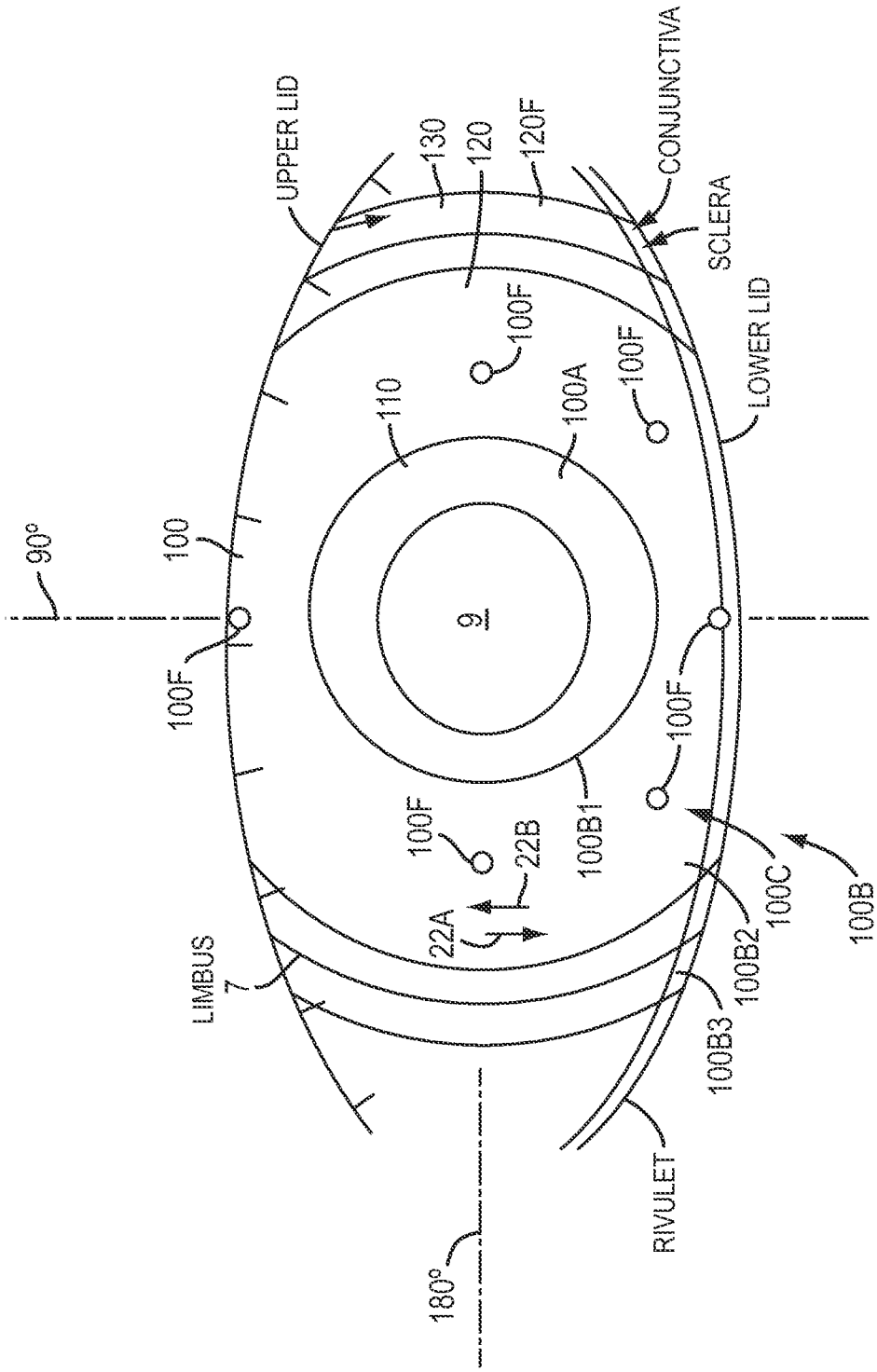


FIG. 1-1A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120F
CONJUNCTIVA
SCLERA
LOWER LID
100F
110
100A
100F
90°
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9
100F
100F
100F
100B1
22B
22A
LIMBUS
7
100C
100B
100B2
100B3
RIVULET
180°

FIG. 1A1

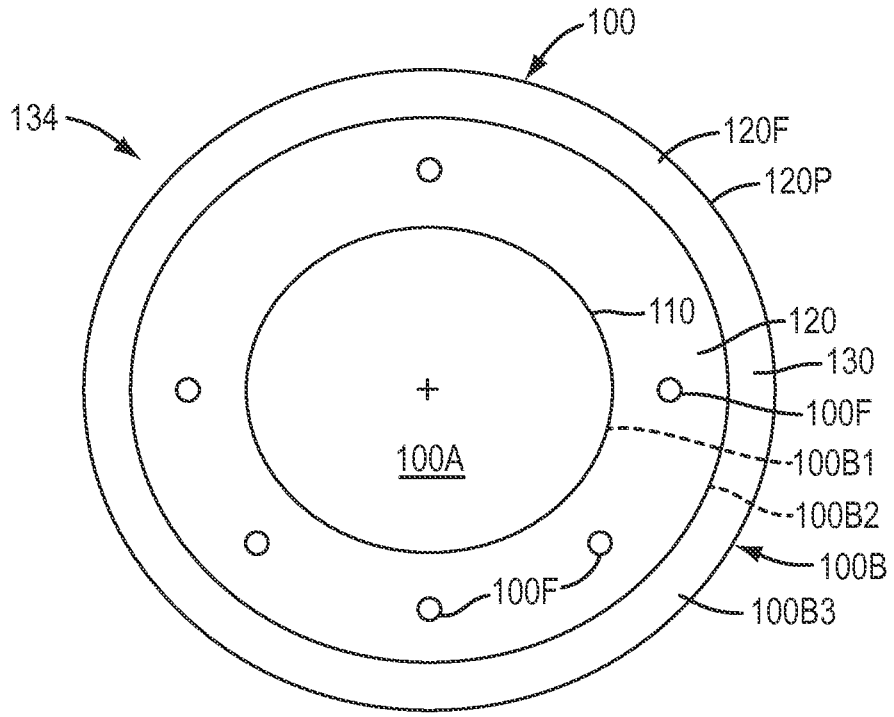
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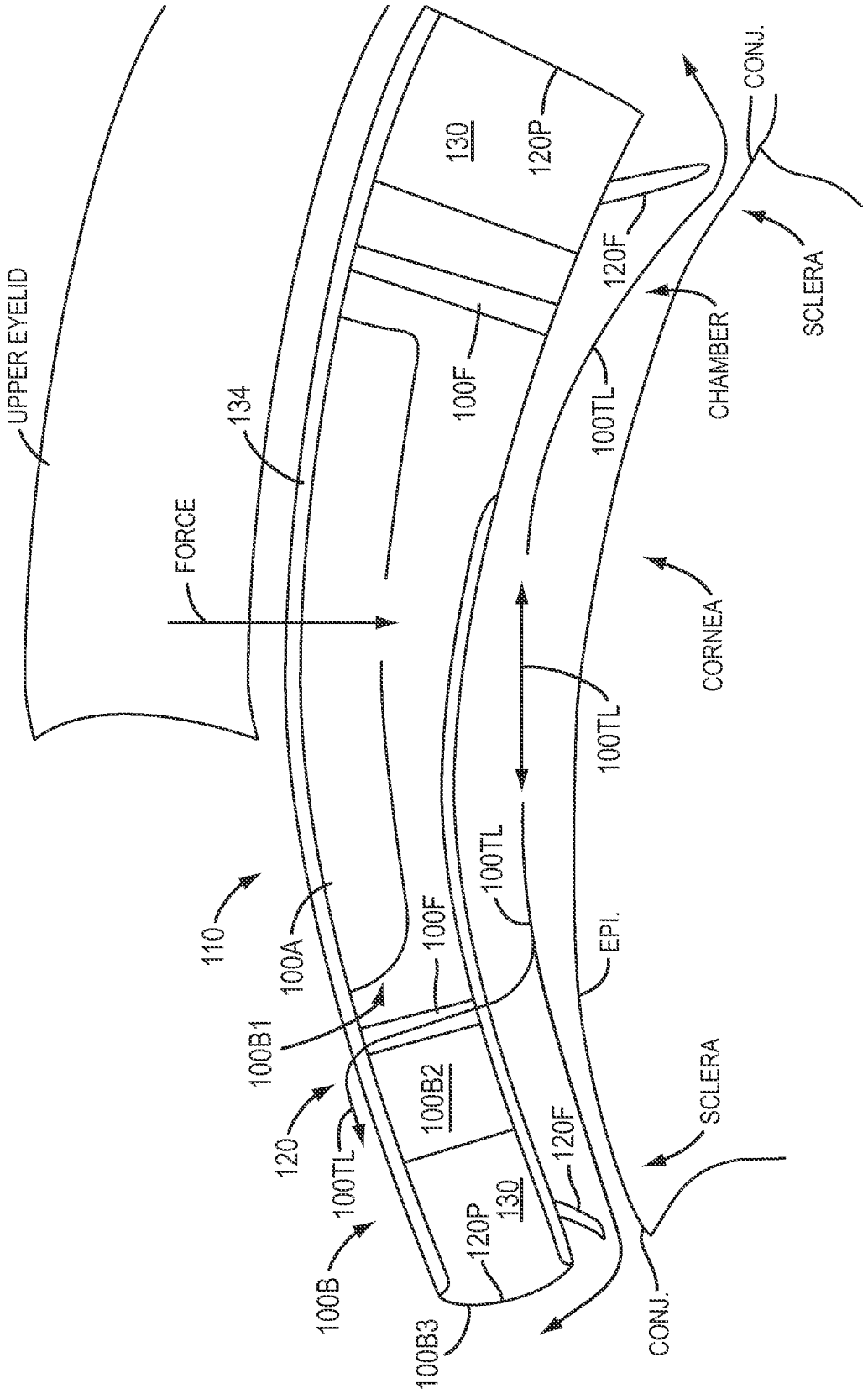
FIG. 1A2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FORCE
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CONJ.
CHAMBER
SCLERA
100TL
CORNEA
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100A
100F
100TL
EPI.
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100TL
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120P
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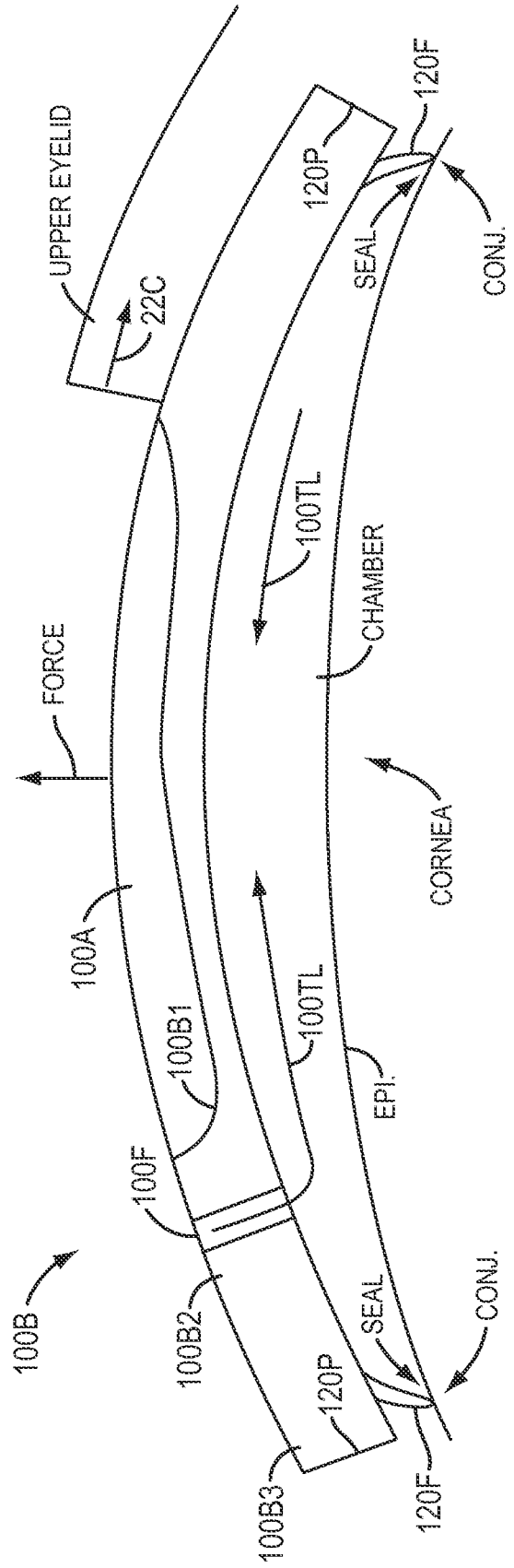
CONJ.
100B3

FIG. 1A3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SEAL
CONJ.
FORCE
100TL
CHAMBER
CORNEA
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100B1
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EPI.
100F
100B
100B2
SEAL
CONJ.
120P
100B3
120F

FIG. 1A4

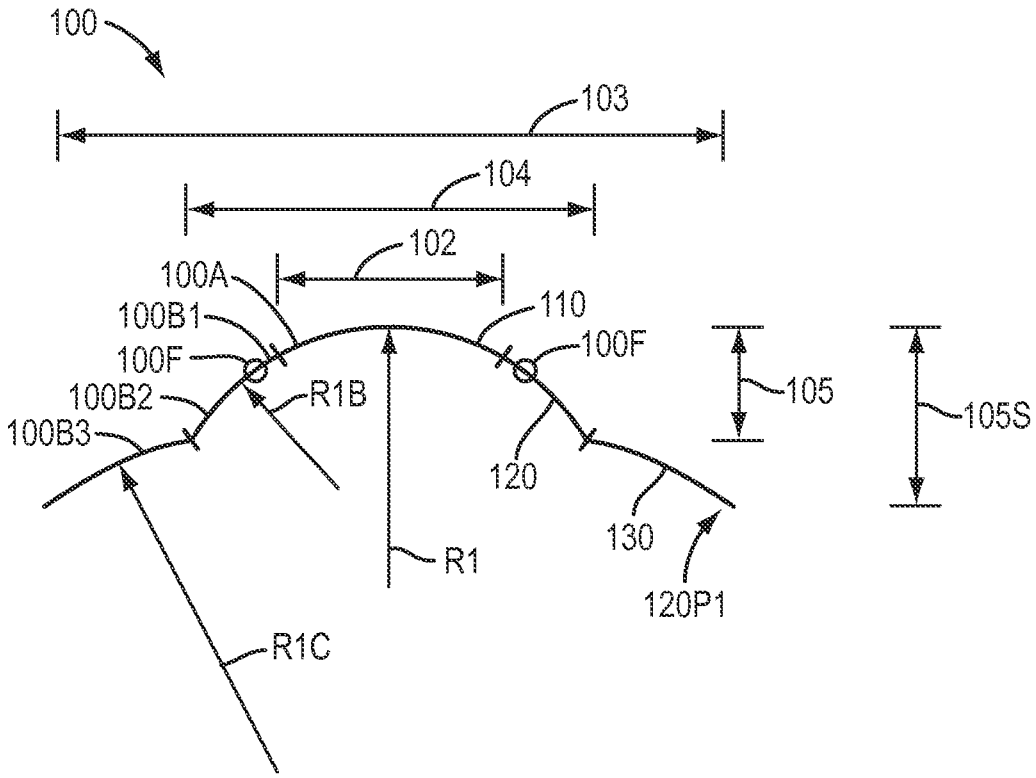


FIG. 1B1

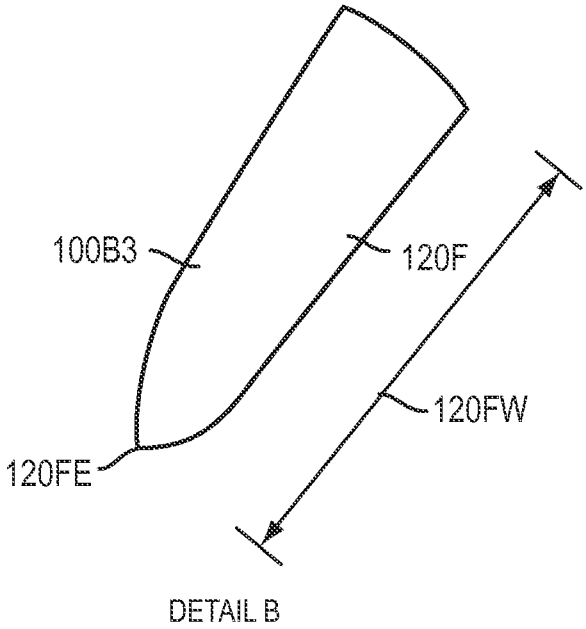


FIG. 1B3

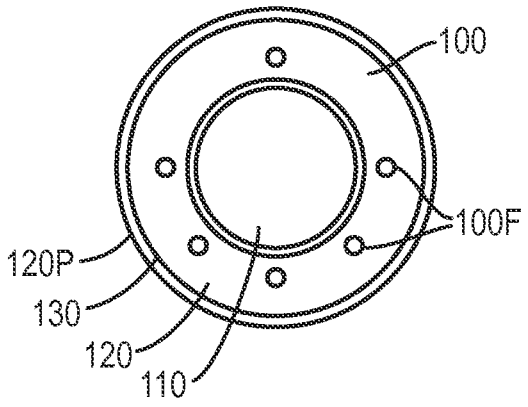


FIG. 1B4

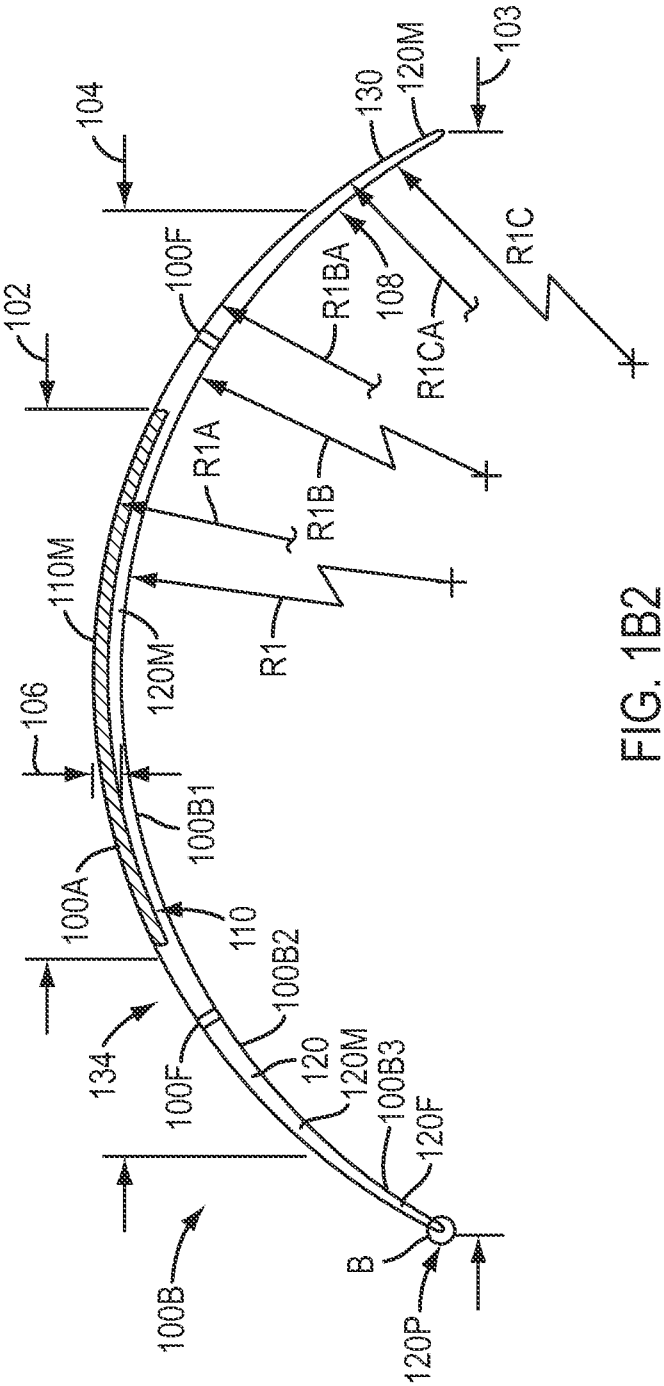


FIG. 1B2

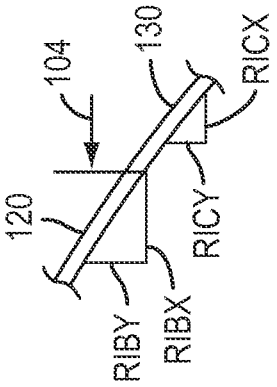
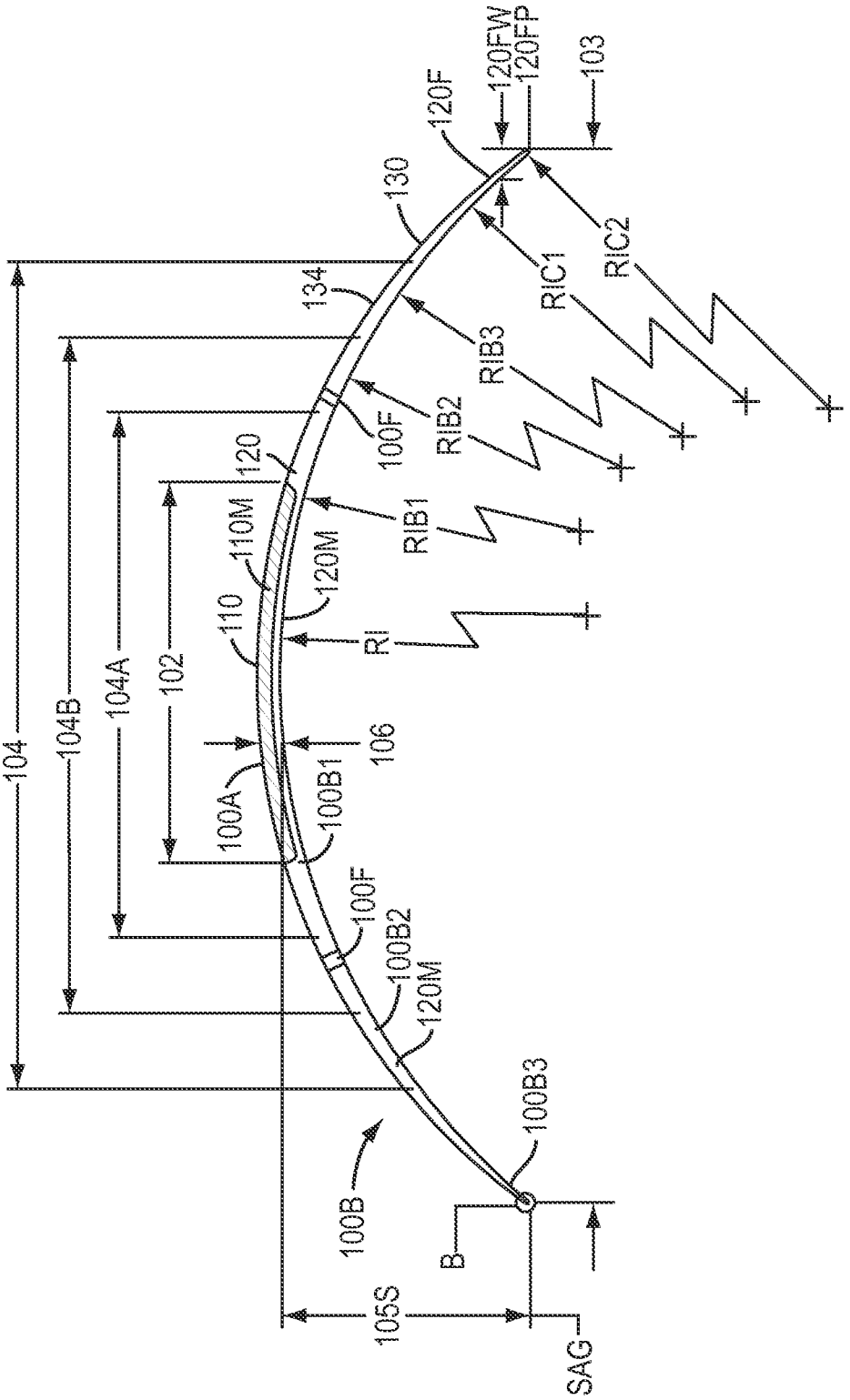


FIG. 1B2-1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134
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RIC2
RIB3
RIB2
RIB1
RI
100F
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110M
120M
110
102
104A
104B
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100A
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100F
100B2
120M
100B3
100B
B
105S
SAG

FIG. 1B5

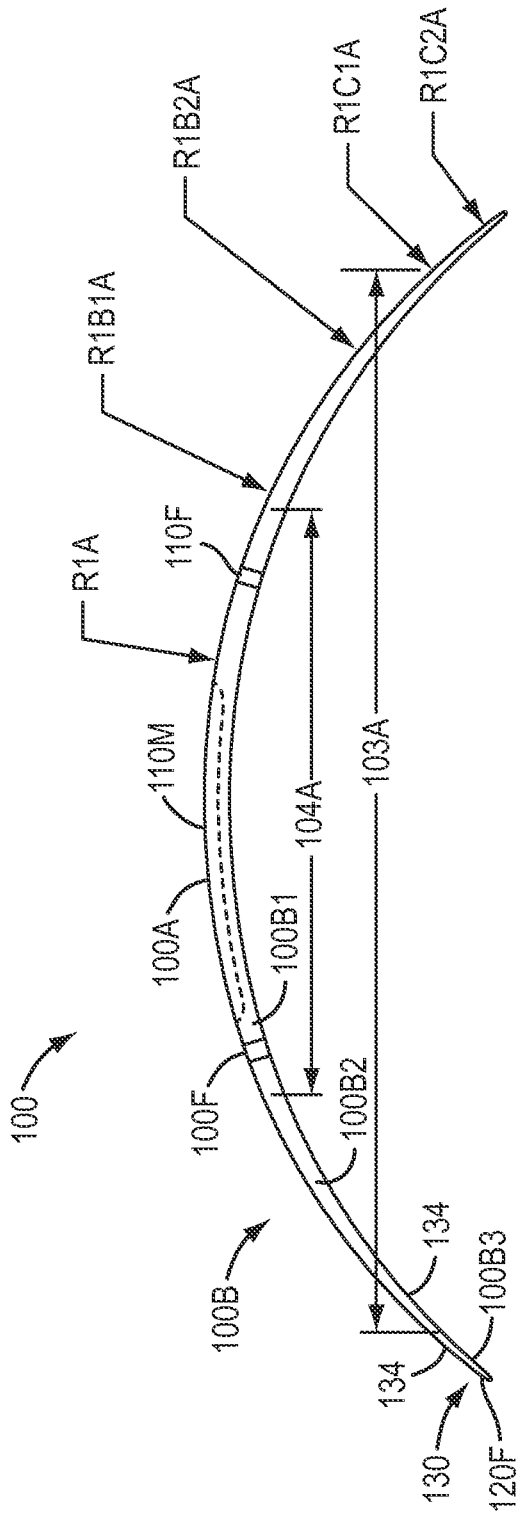

FIG. 1B6

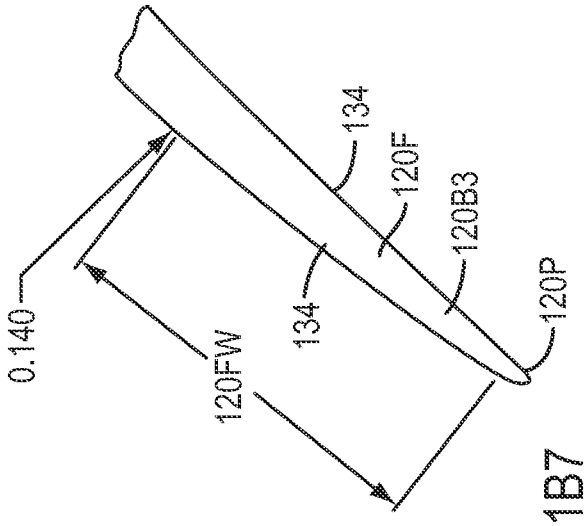

FIG. 1B7

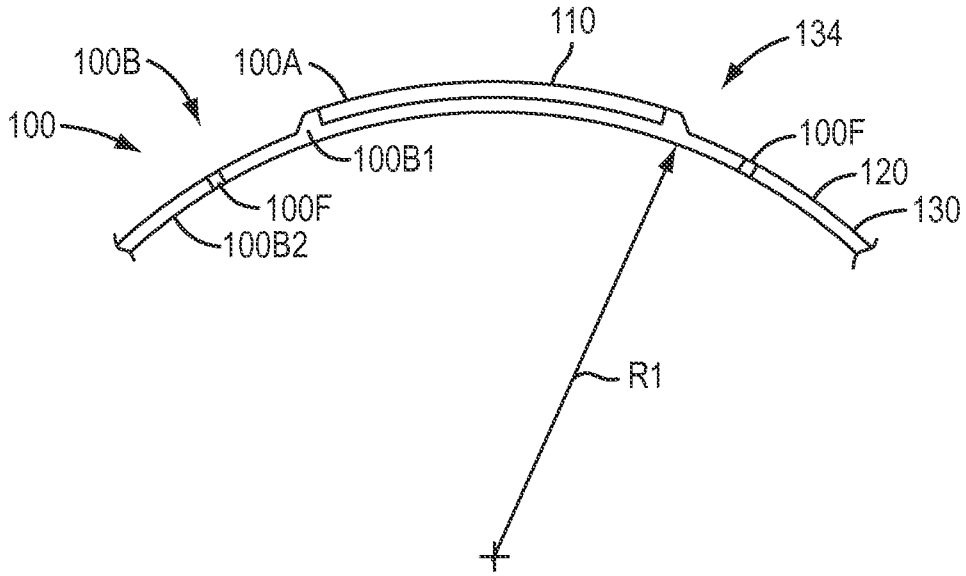

FIG. 1C

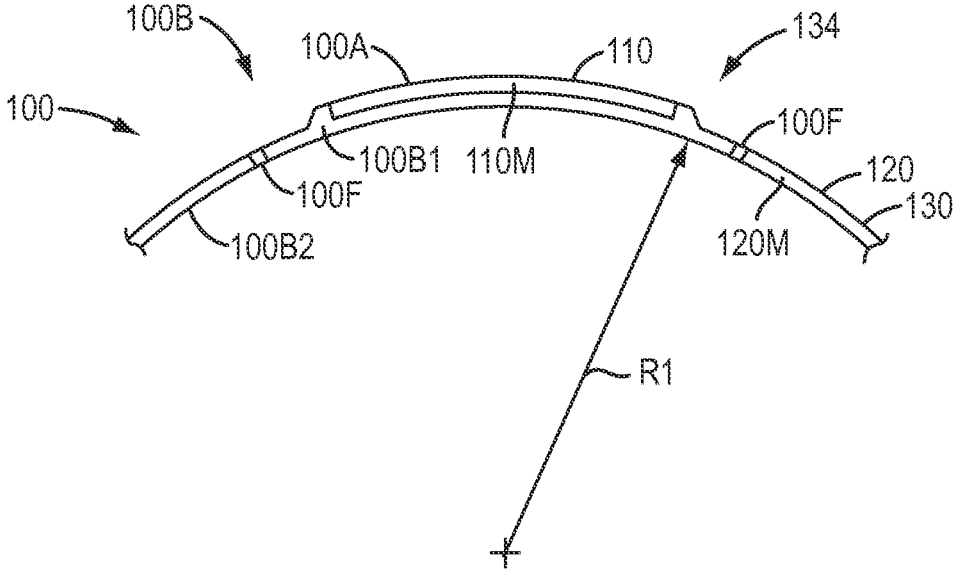

FIG. 1C1

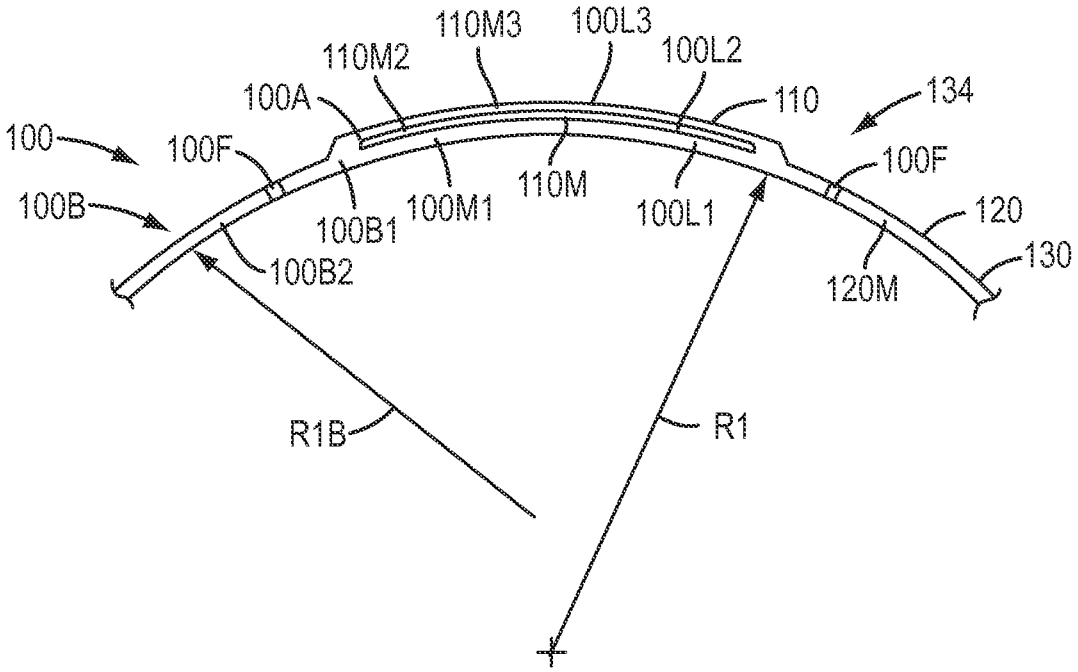

FIG. 1C2

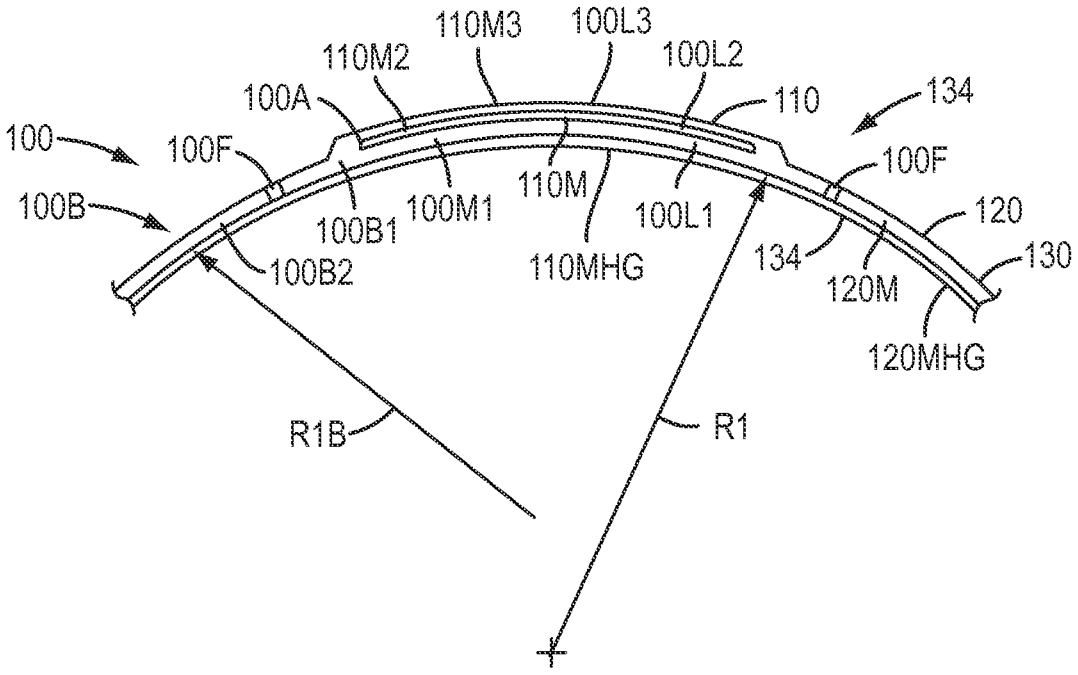

FIG. 1C2A

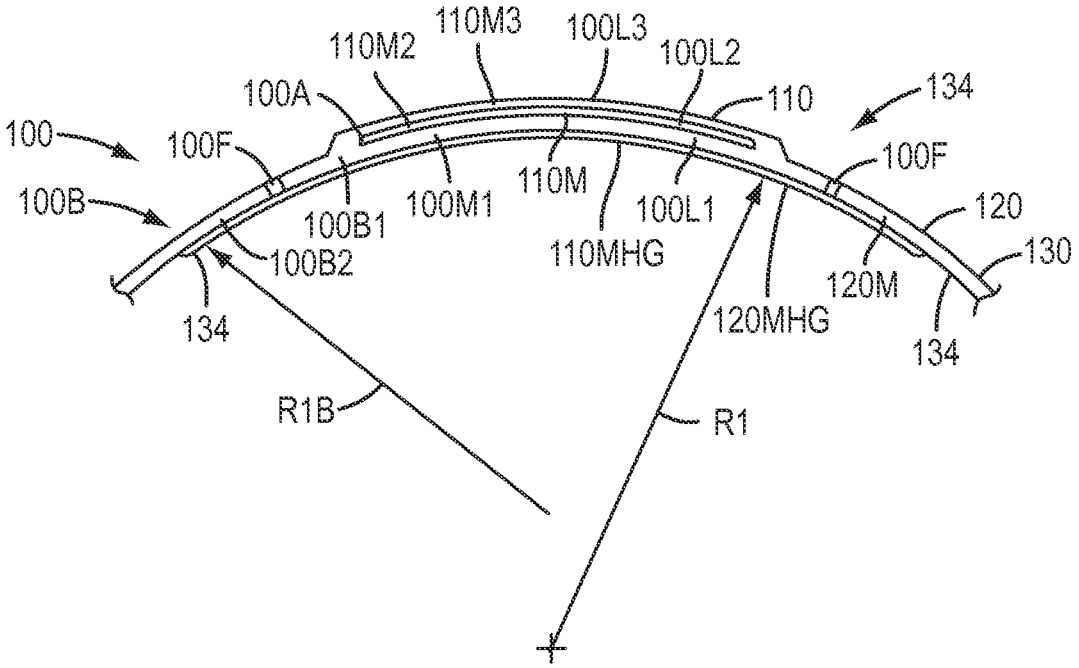

FIG. 1C2B

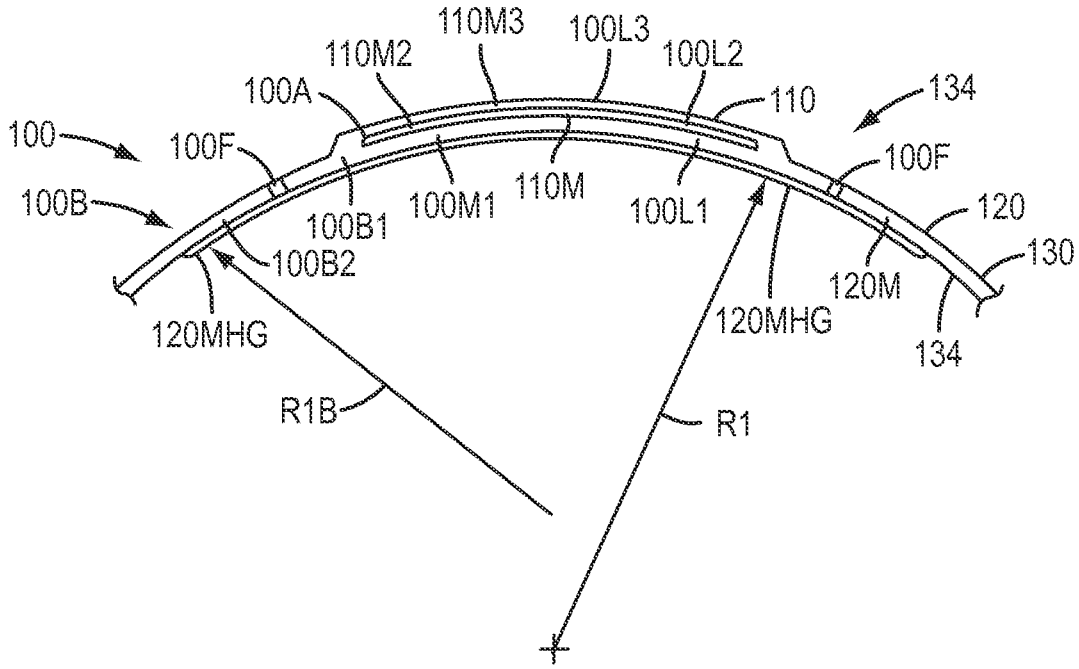

FIG. 1C2C

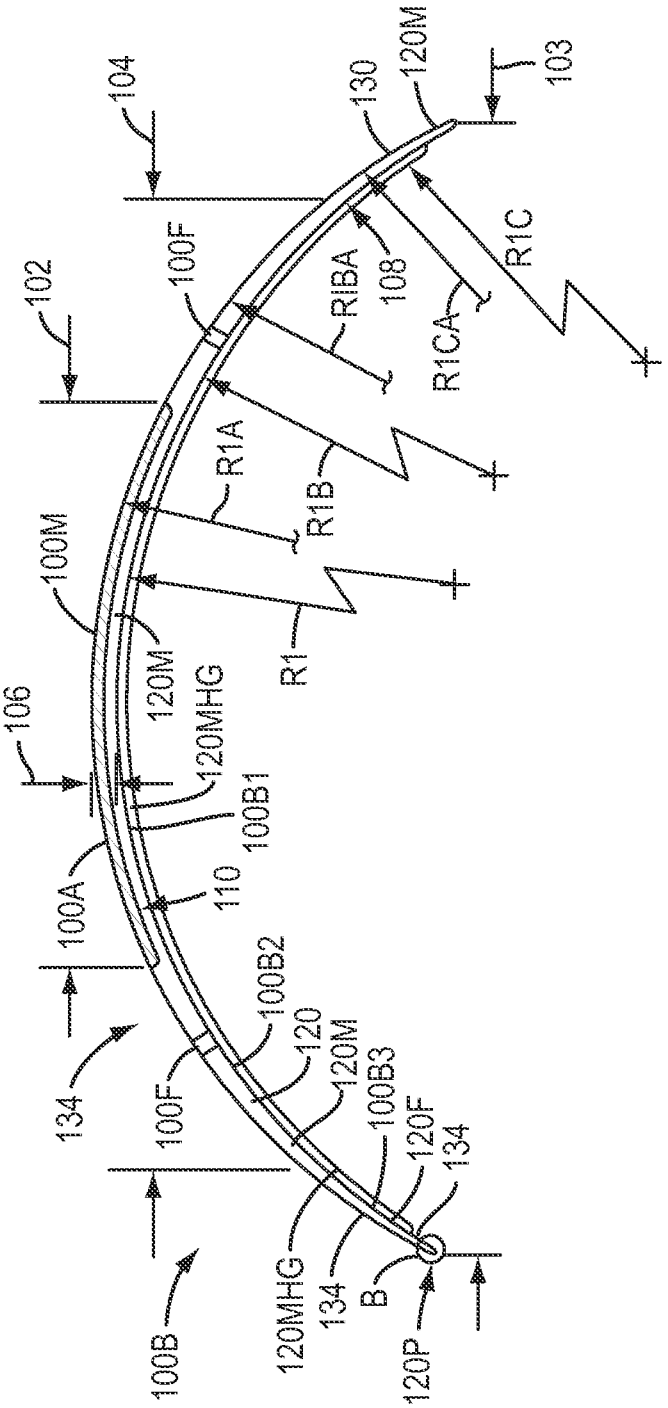
104
102
106
100M
100A
134
100B
100F
120M
120MHG
100B1
110
100B2
120
100B3
120MHG
134
B
120P
120F
134
130
120M
103
100F
RIBA
108
R1CA
R1C
R1A
R1B
R1

FIG. 1C3

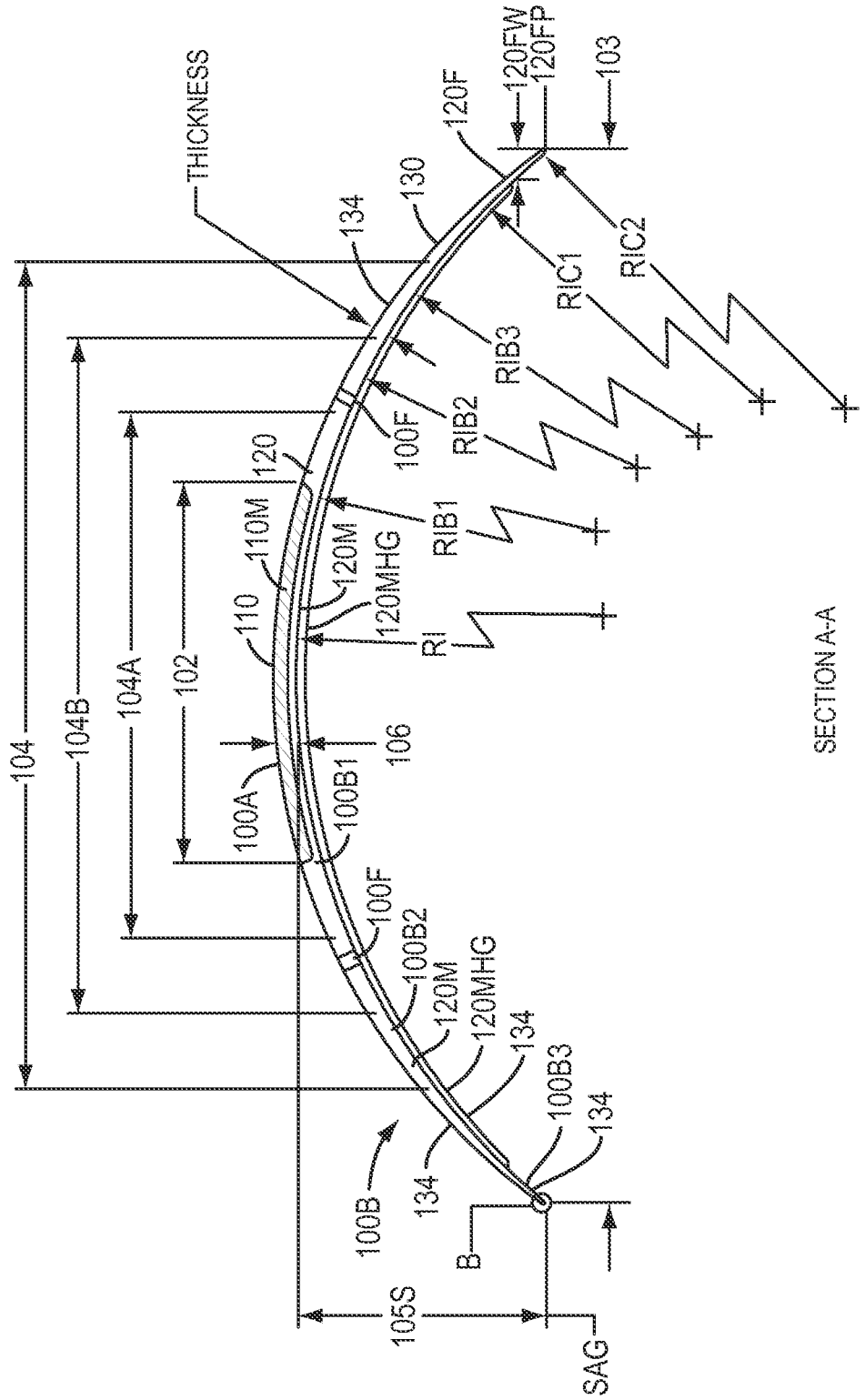
THICKNESS
134
130
120F
120FW
120FP
103
RIC1
RIC2
RIB3
RIB2
RIB1
RI
100F
120
110M
120M
120MHG
110
102
104A
104B
104
106
100A
100B1
100F
100B2
120M
120MHG
134
100B3
134
134
100B
B
105S
SAG
SECTION A-A

FIG. 1C4

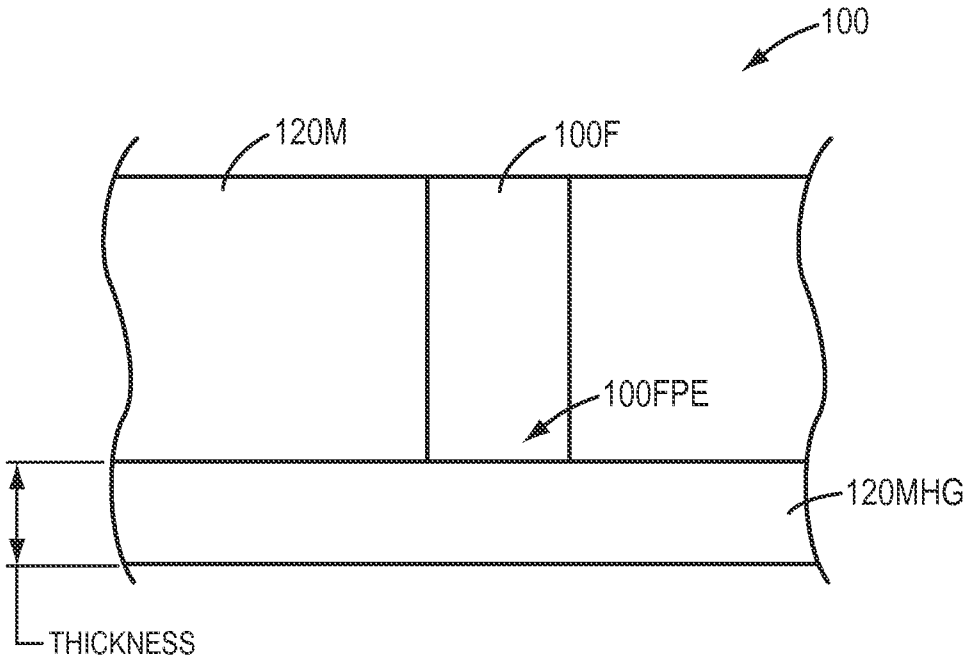

FIG. 1C5

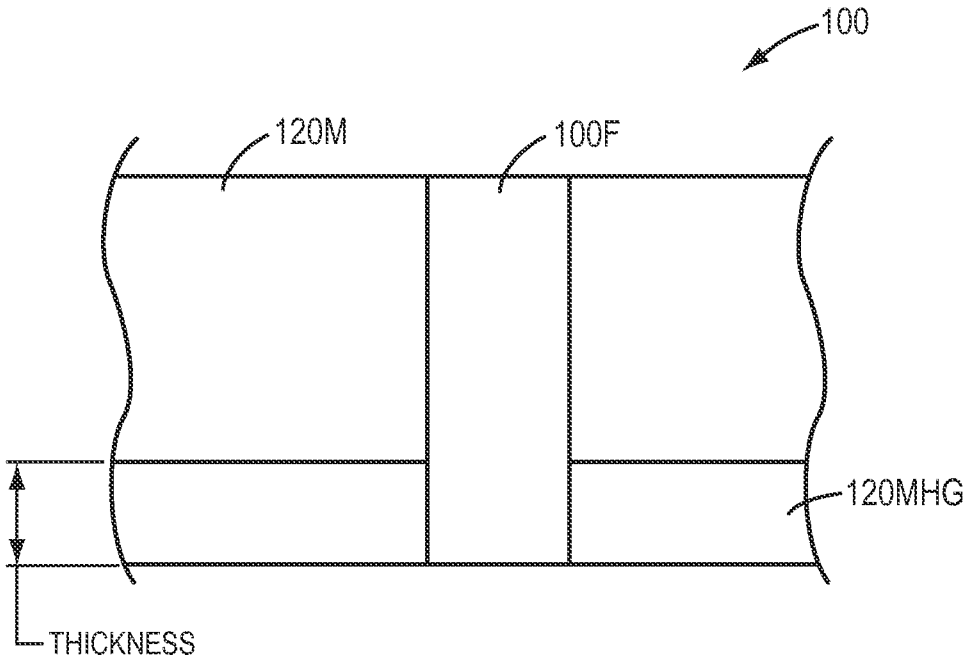

FIG. 1C6

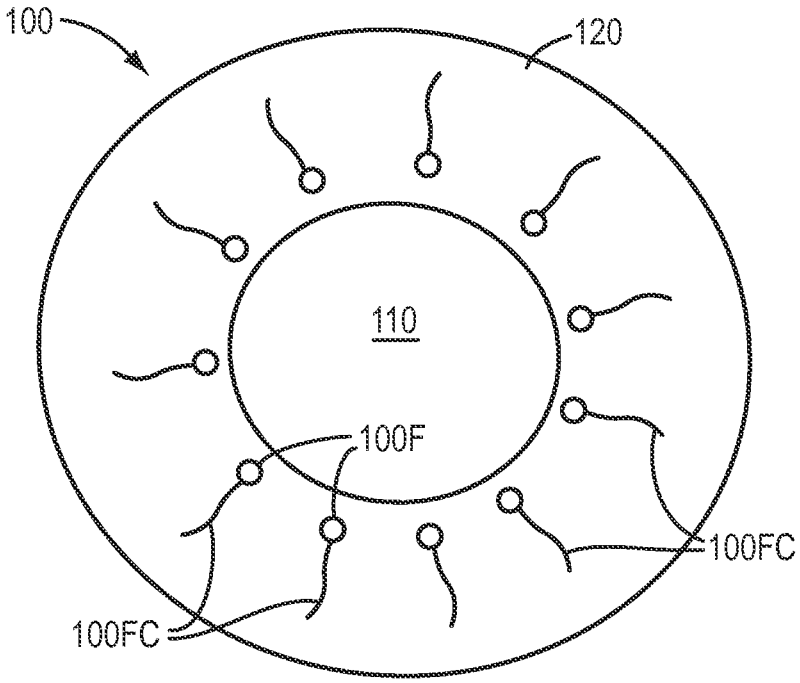

FIG. 1D

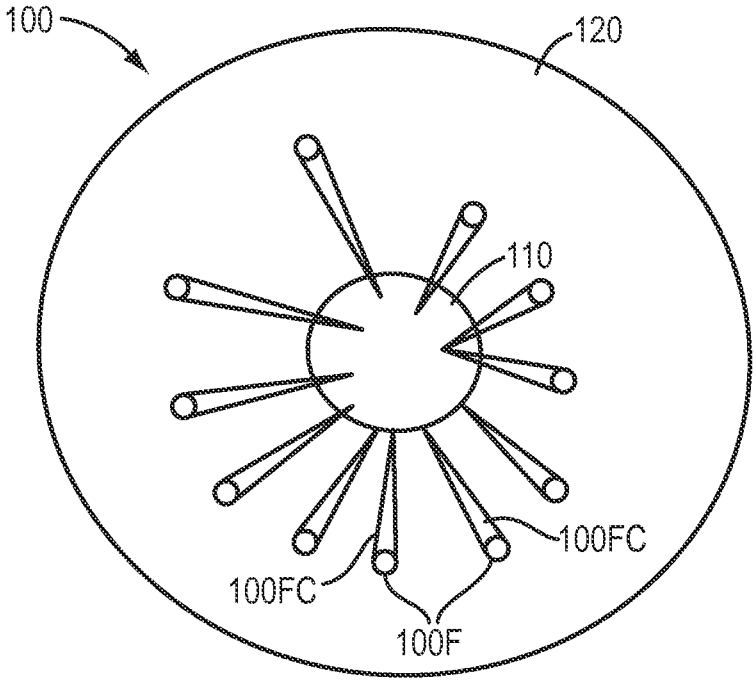

FIG. 1E

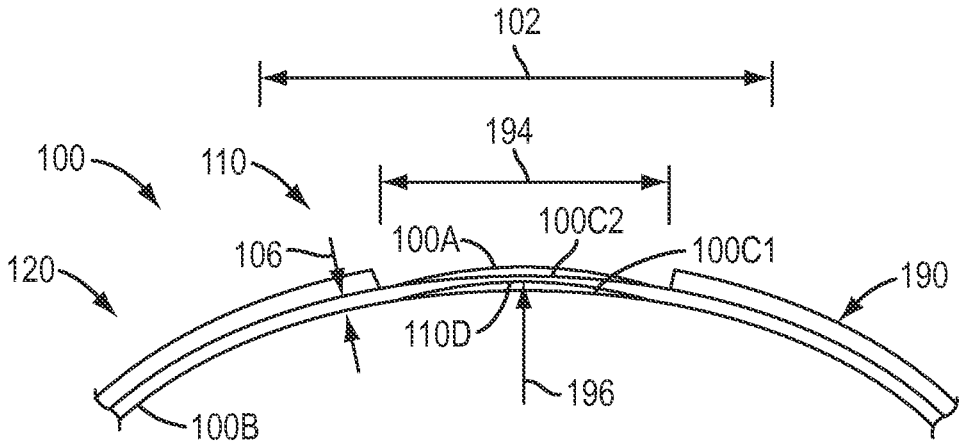

FIG. 1F

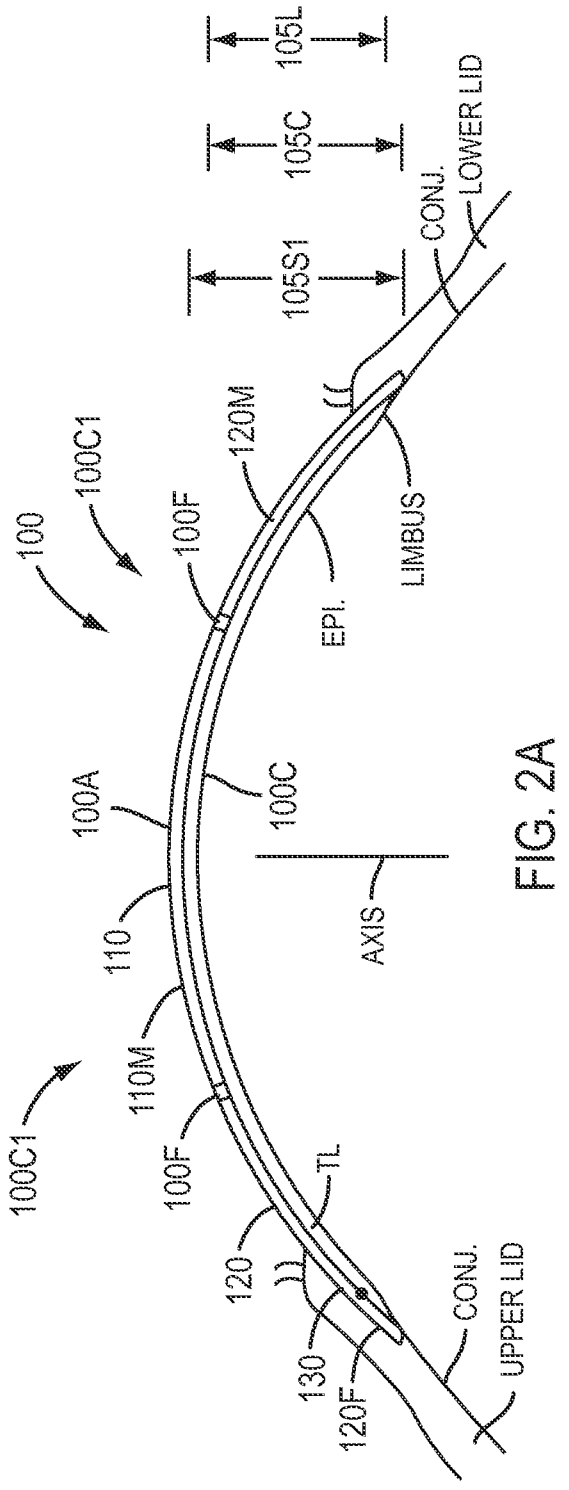
100
100C1
100F
120M
105L
105C
105S1
CONJ.
LOWER LID
EPI.
LIMBUS
100A
100C
110
AXIS
110M
100F
TL
120
130
120F
CONJ.
UPPER LID
100C1

FIG. 2A

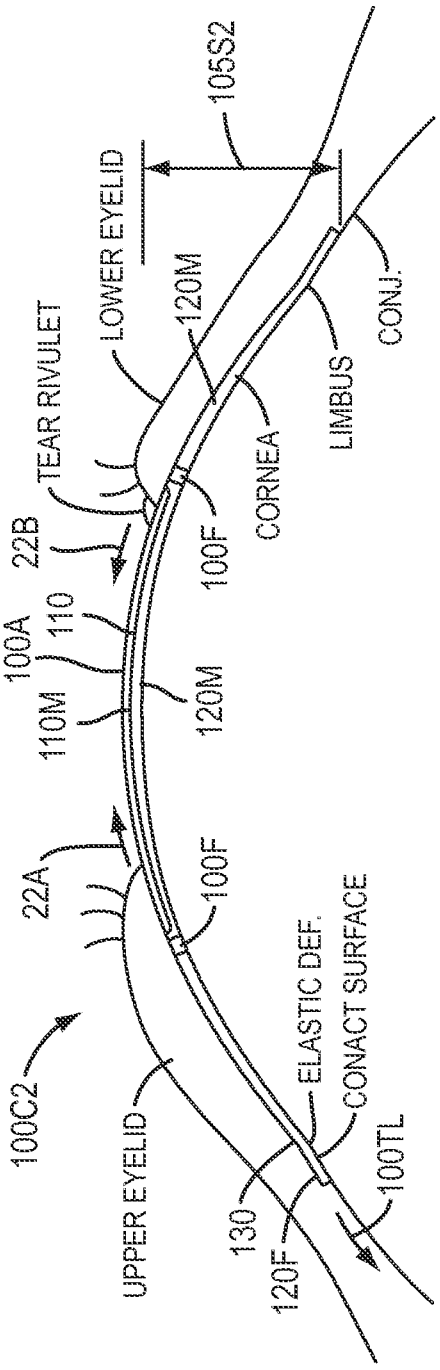
105S2
LOWER EYELID
TEAR RIVULET
22B
120M
CONJ.
CORNEA
LIMBUS
100A
110
110M
100F
120M
22A
100F
ELASTIC DEF.
CONACT SURFACE
100C2
UPPER EYELID
130
120F
100TL

FIG. 2B

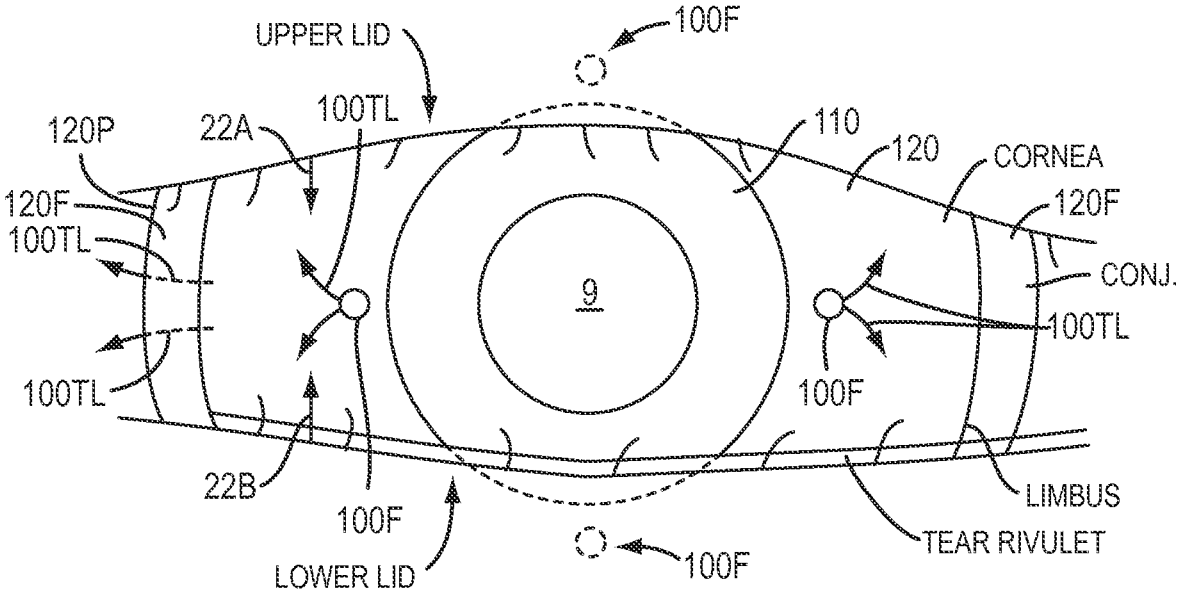
UPPER LID
100F
120P
22A
100TL
110
120
CORNEA
120F
120F
100TL
CONJ.
9
100TL
100TL
100F
22B
100F
LIMBUS
LOWER LID
100F
TEAR RIVULET

FIG. 2C

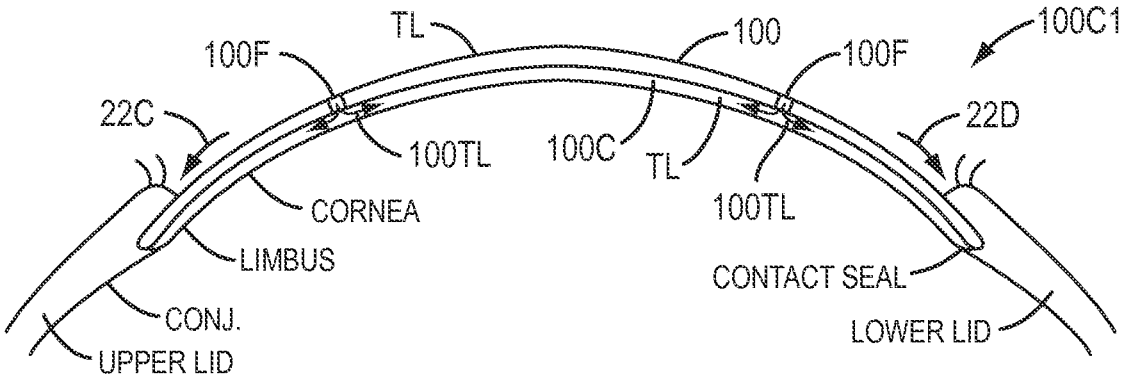
TL
100
100C1
100F
100F
22C
22D
100TL
100C
TL
CORNEA
100TL
LIMBUS
CONTACT SEAL
CONJ.
LOWER LID
UPPER LID

FIG. 2D

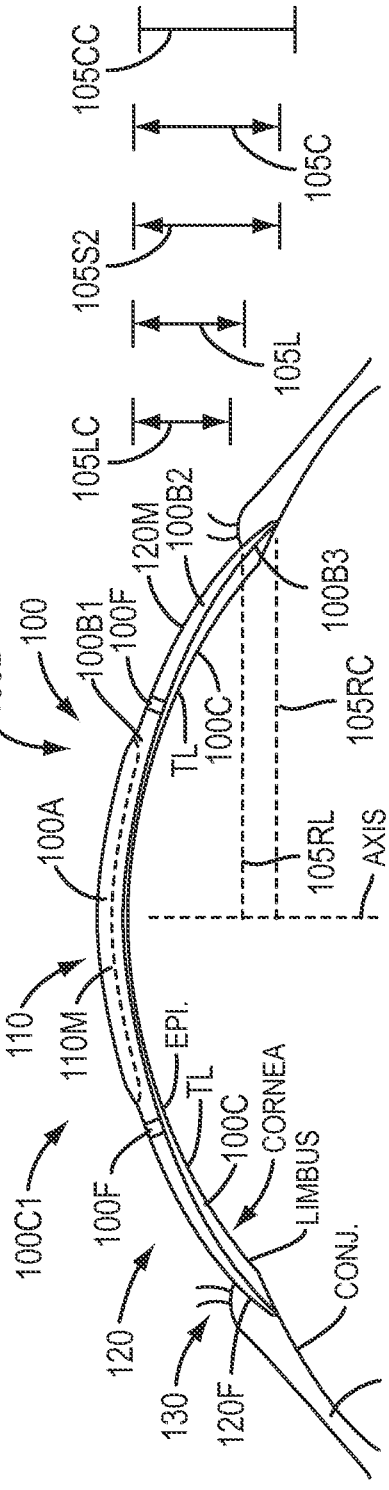
105CC
105C
105S2
105L
105LC
120M
100B2
100B3
100B
100
100B1
100F
100A
TL
100C
105RC
105RL
AXIS
110
110M
EPI.
TL
100C
CORNEA
LIMBUS
CONJ.
100C1
100F
120
130
120F
UPPER LID

FIG. 2E

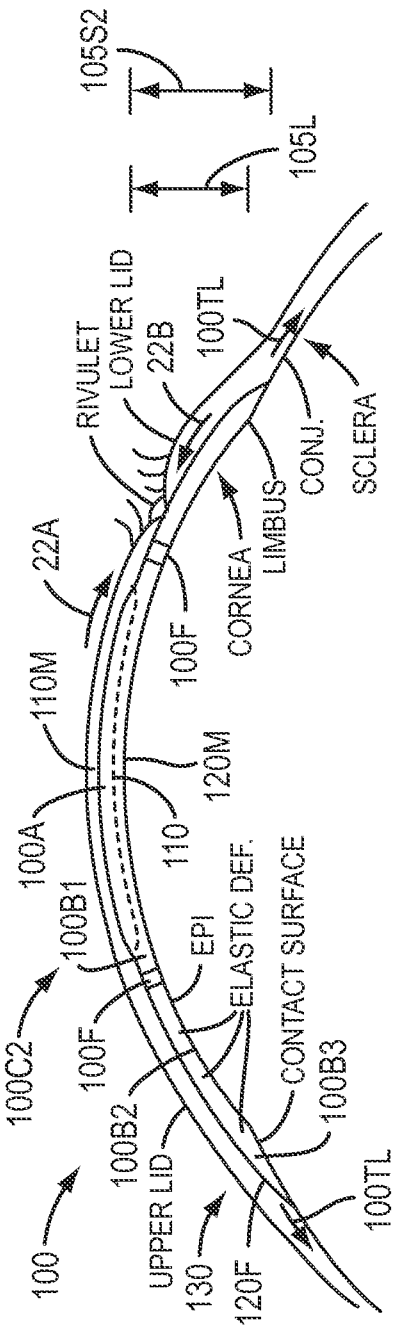
105S2
105L
RIVULET
LOWER LID
22B
100TL
22A
110M
100A
120M
110
100C2
100B1
100F
EPI
ELASTIC DEF.
CONTACT SURFACE
100B3
100B2
UPPER LID
100
130
120F
100TL
CORNEA
LIMBUS
CONJ.
SCLERA

FIG. 2F

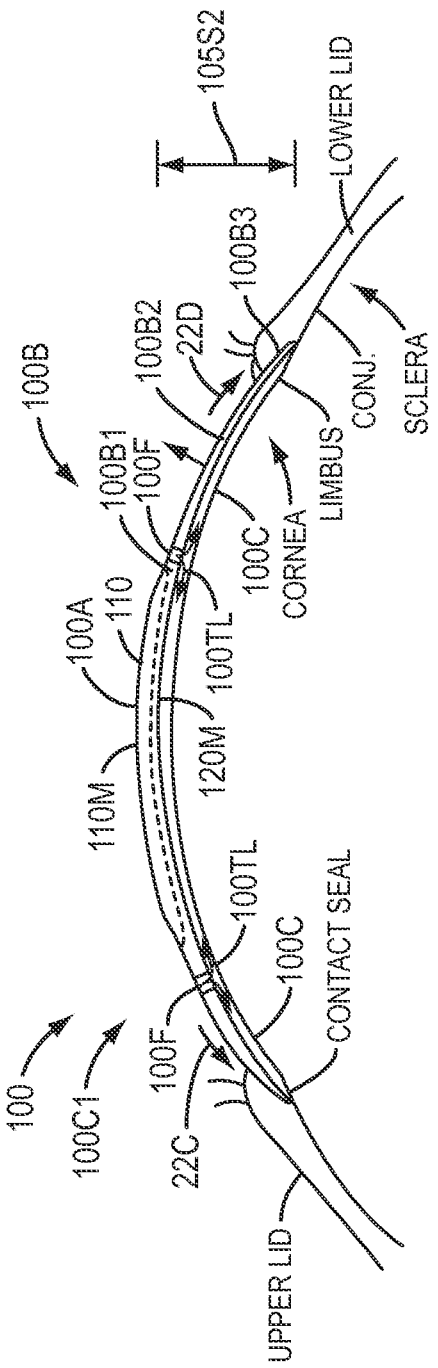
100
100C1
100F
22C
UPPER LID
100C
CONTACT SEAL
100TL
110M
120M
100A
110
100TL
100C
CORNEA
LIMBUS
CONJ.
SCLERA
100B
100B1
100F
100B2
22D
100B3
LOWER LID
105S2

FIG. 2G

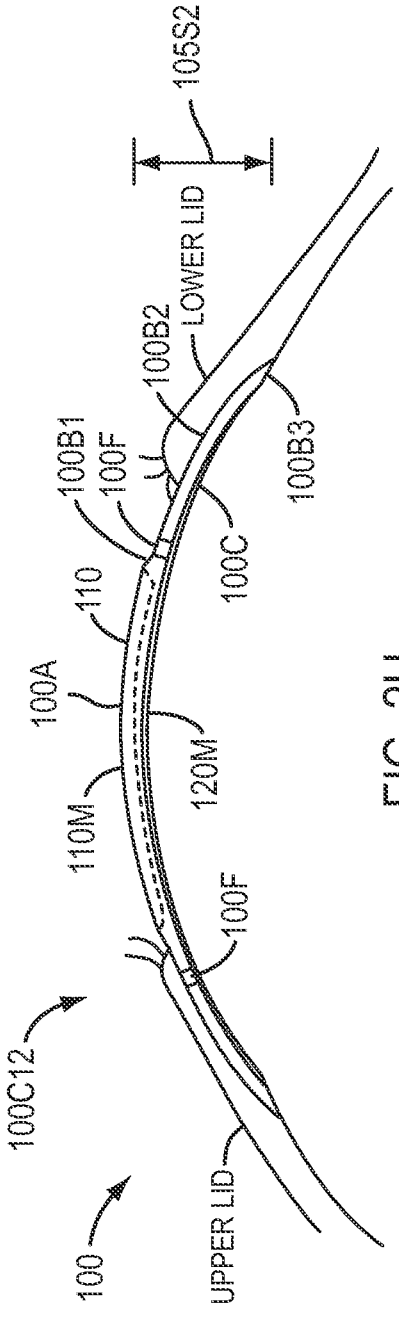
100
UPPER LID
100C12
100F
110M
120M
100A
110
100C
100B1
100F
100B2
LOWER LID
100B3
105S2

FIG. 2H

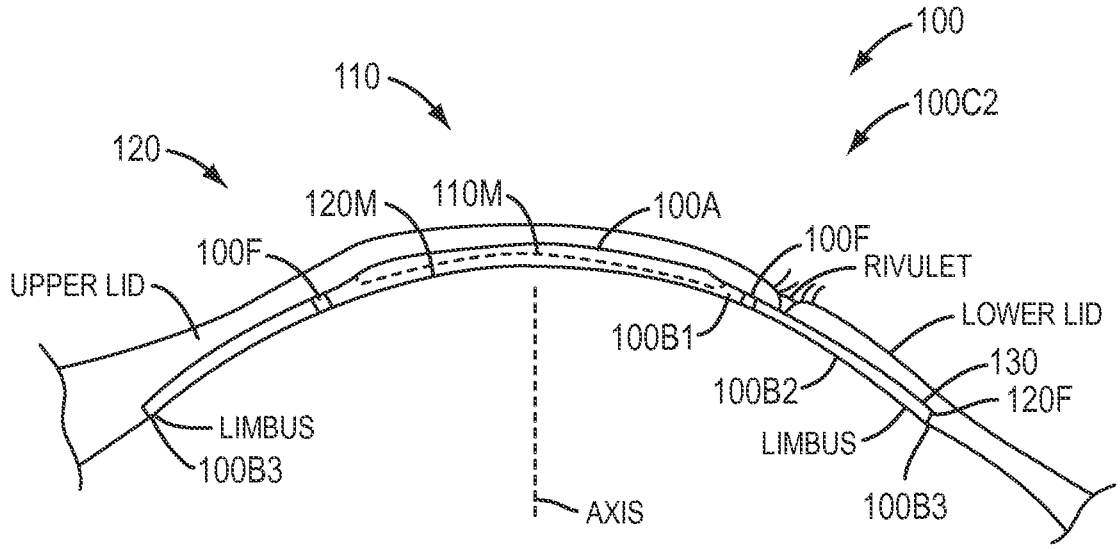
100
110
100C2
120
120M
110M
100A
100F
100F
RIVULET
UPPER LID
LOWER LID
100B1
130
100B2
120F
LIMBUS
LIMBUS
100B3
AXIS
100B3

FIG. 2F1

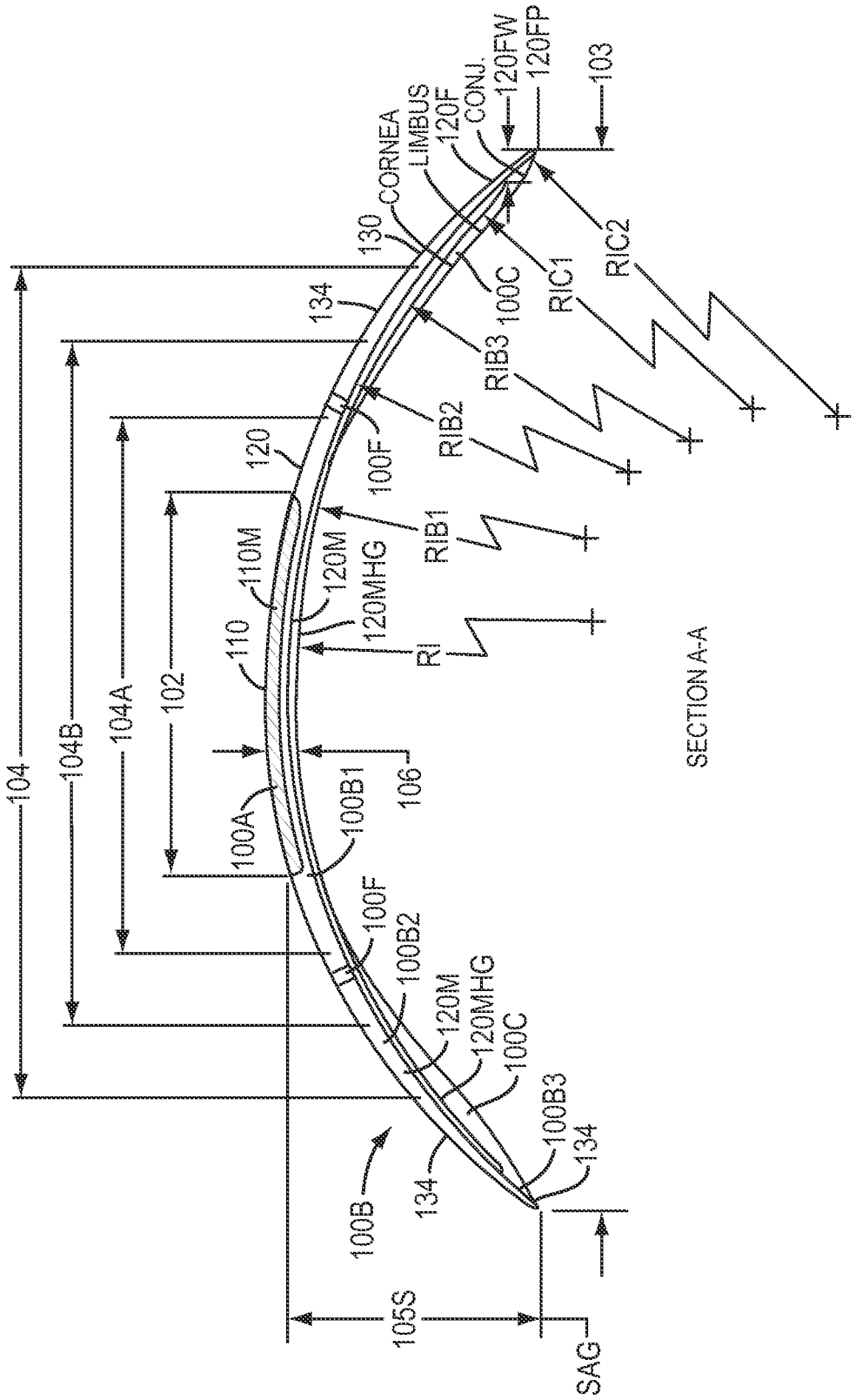
104
104B
104A
102
105S
SAG
100B
134
100B3
100C
120MHG
120M
100B2
100F
100A
100B1
106
110
110M
120
134
130
CORNEA
LIMBUS
120F
CONJ.
120FW
120FP
103
100C
RIB3
RIB2
100F
RIB1
RI
RIC1
RIC2
SECTION A-A

FIG. 2I

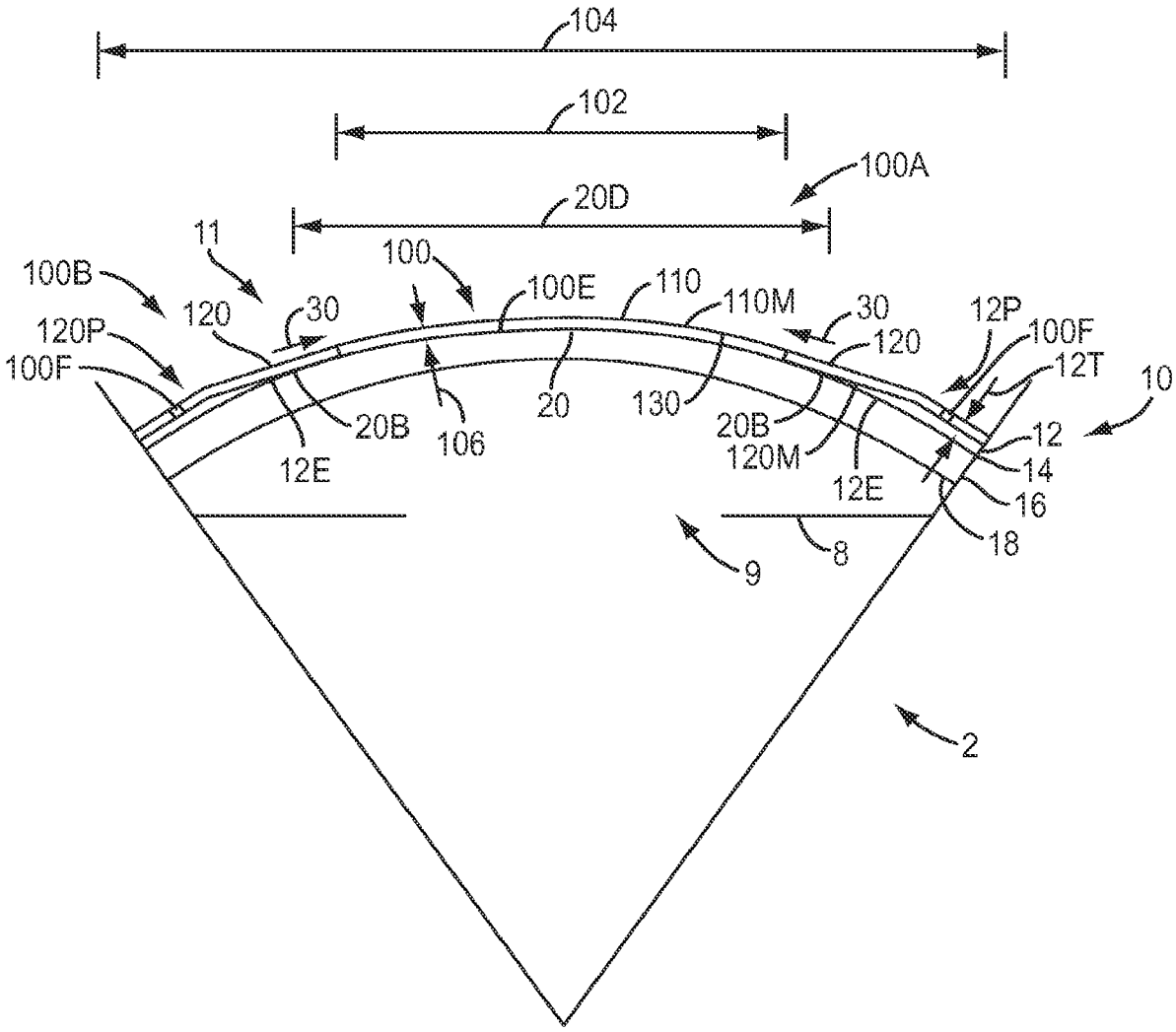
104
102
100A
20D
11
100B
100
100E
110
110M
30
12P
100F
120P
120
30
120
12T
100F
10
20B
106
20
130
20B
12
12E
120M
14
12E
16
18
9
8
2

FIG. 3A

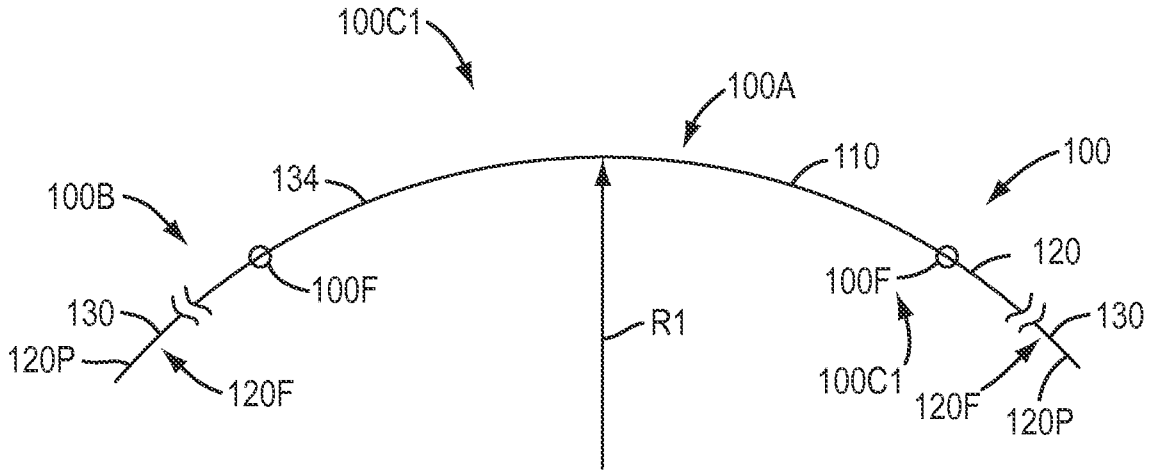
100C1
100A
110
100
134
100B
100F
120
100F
130
R1
130
120P
120F
100C1
120F
120P

FIG. 3B

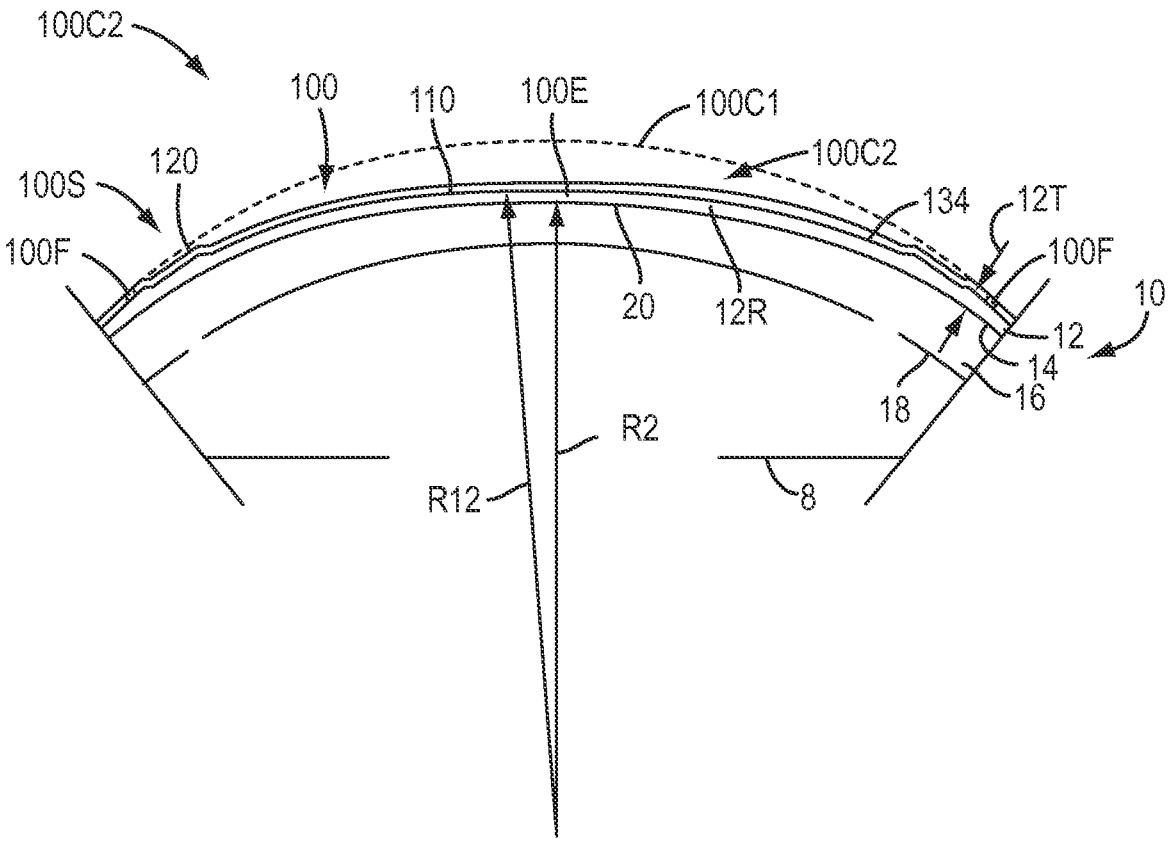
100C2
100
110
100E
100C1
100C2
120
100S
134
12T
100F
100F
20
12R
10
12
14
16
18
R2
R12
8

FIG. 3C

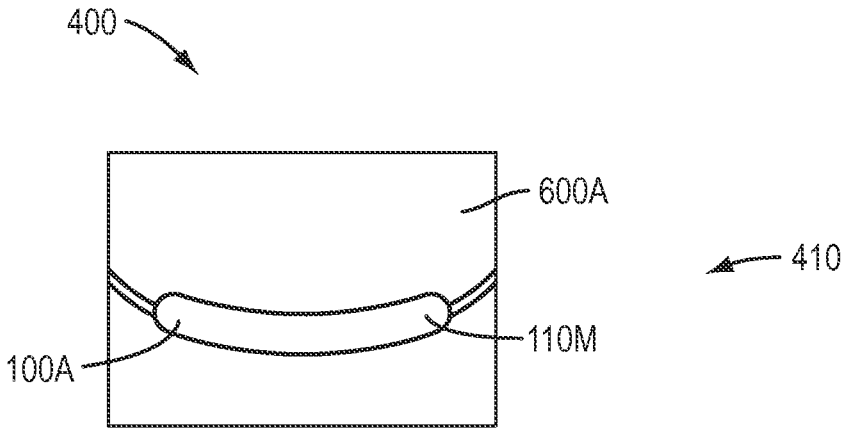
400
600A
410
110M
100A

FIG. 4A

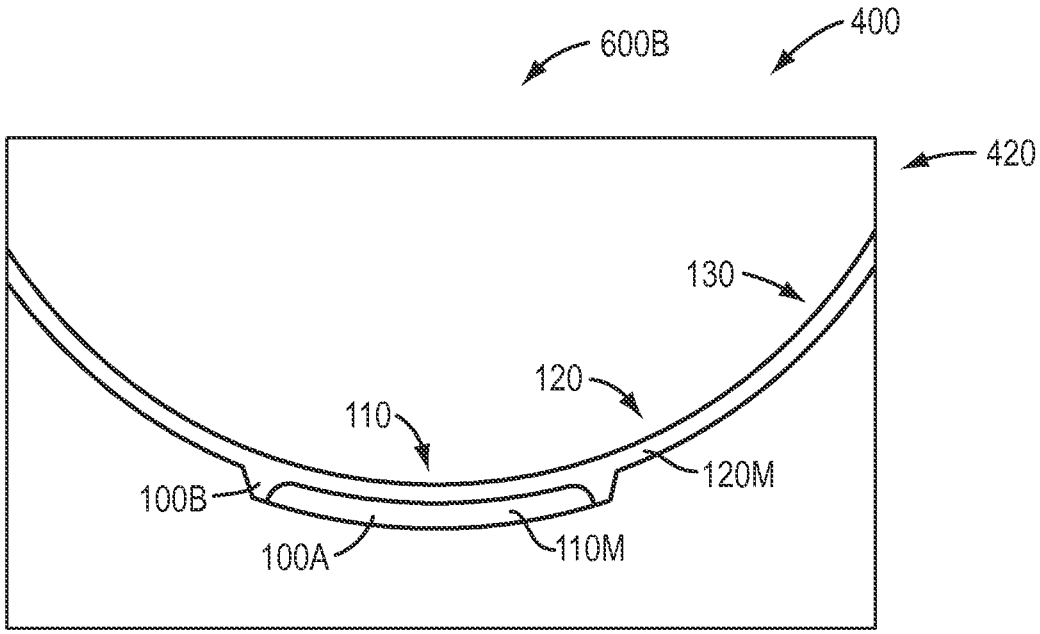
600B
400
420
130
120
110
120M
100B
100A
110M

FIG. 4B

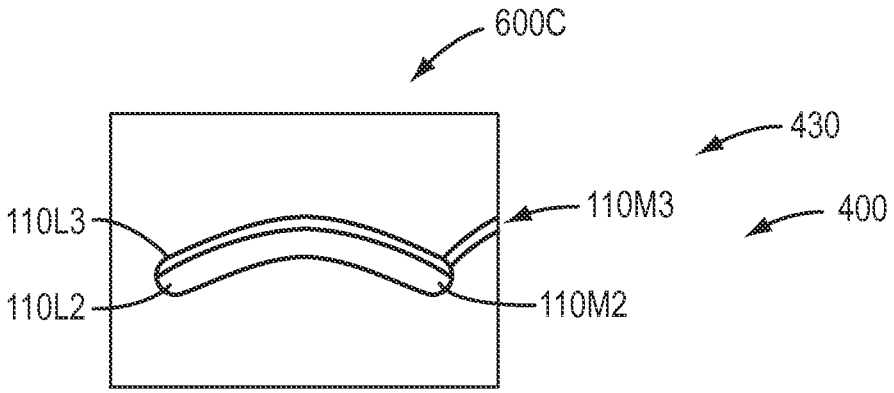
600C
430
400
110L3
110M3
110L2
110M2

FIG. 4C

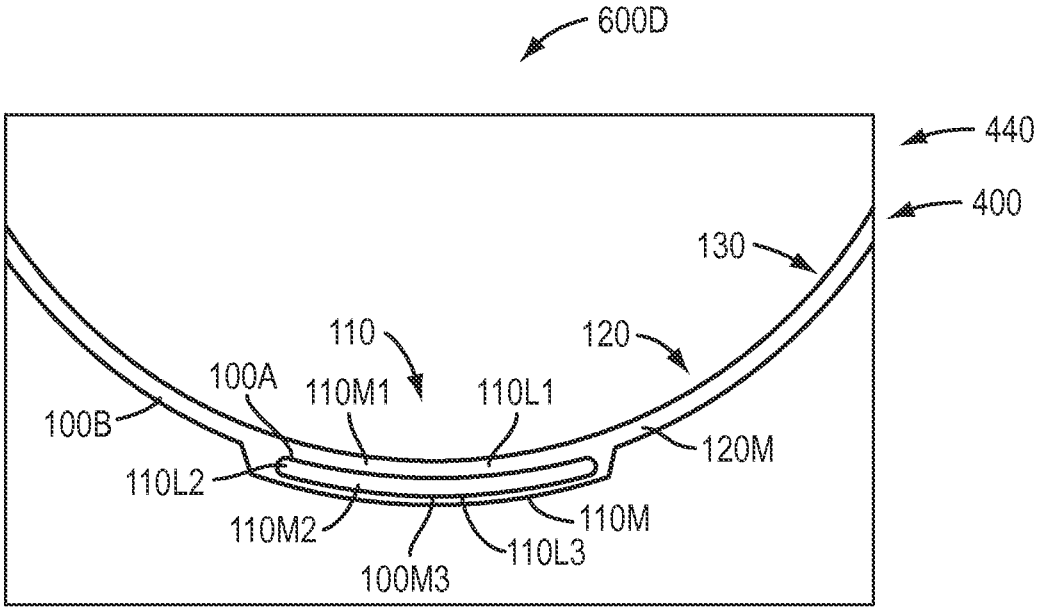
600D
440
400
130
110
120
100A
110M1
110L1
100B
120M
110L2
110M
110M2
110L3
100M3

FIG. 4D

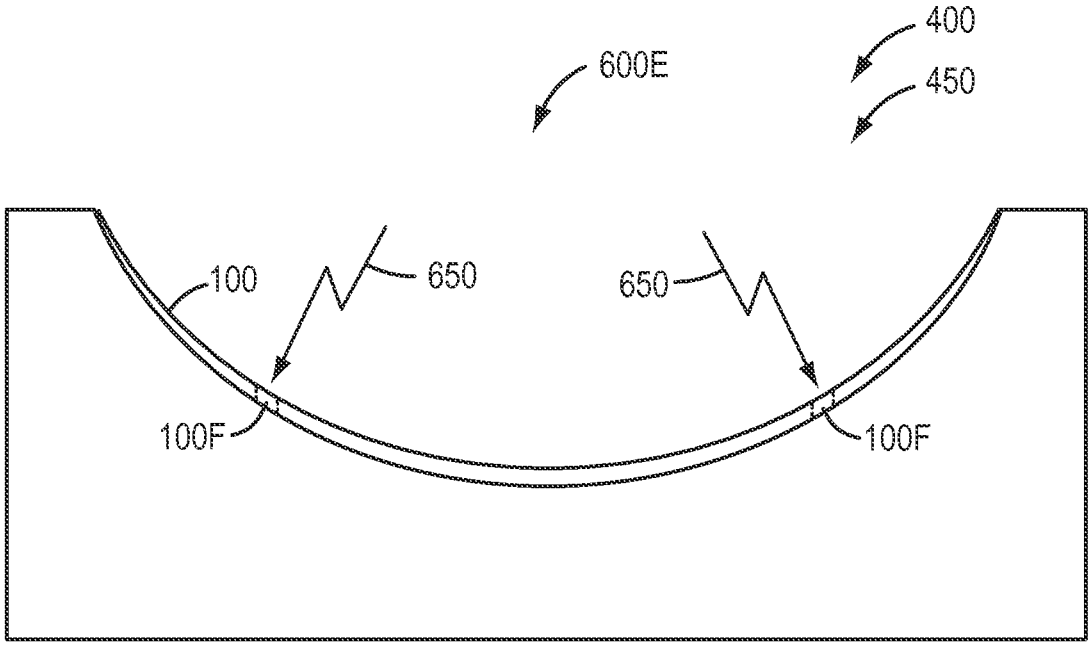

FIG. 4E

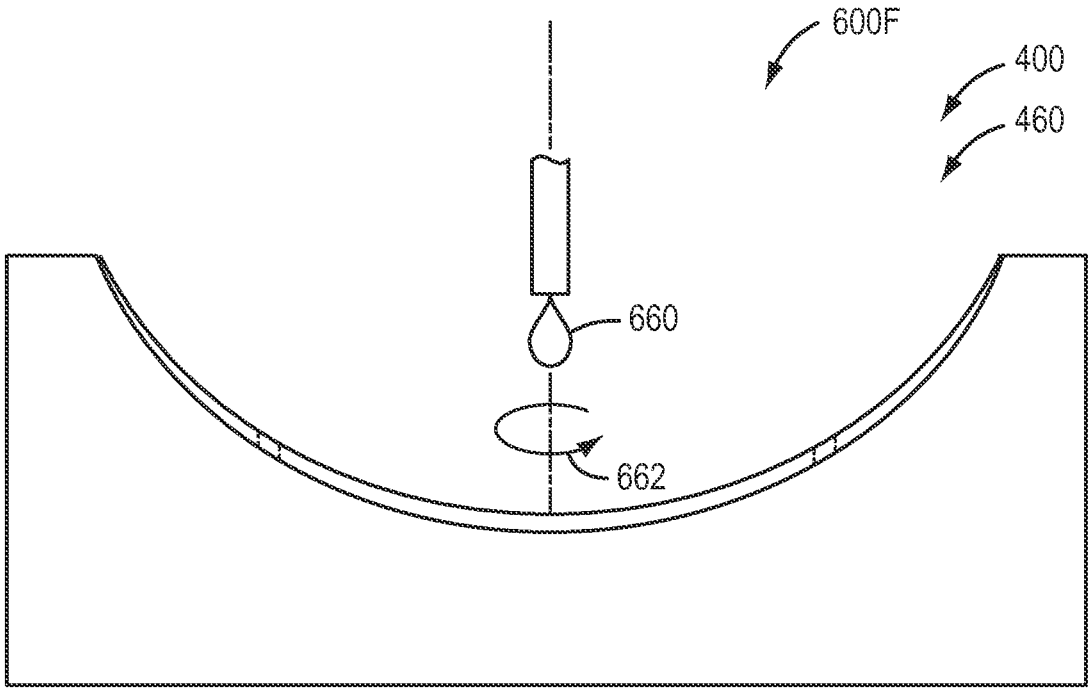

FIG. 4F

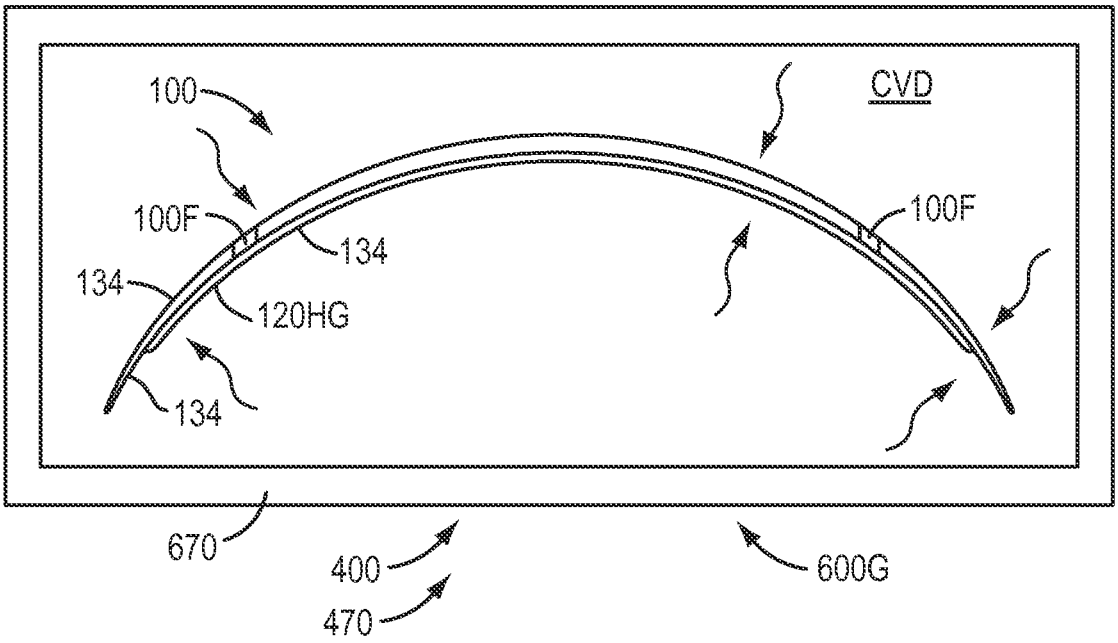
100
CVD
100F
134
134
120HG
100F
134
670
400
470
600G

FIG. 4G

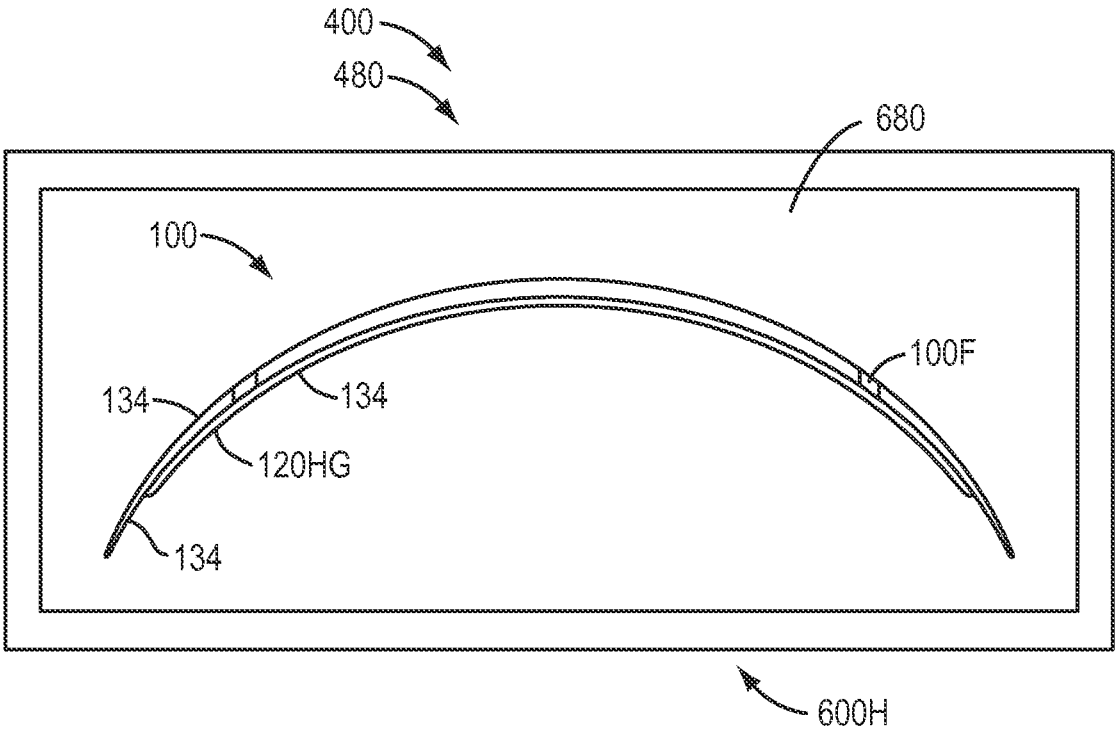
400
480
680
100
100F
134
134
120HG
134
600H

FIG. 4H

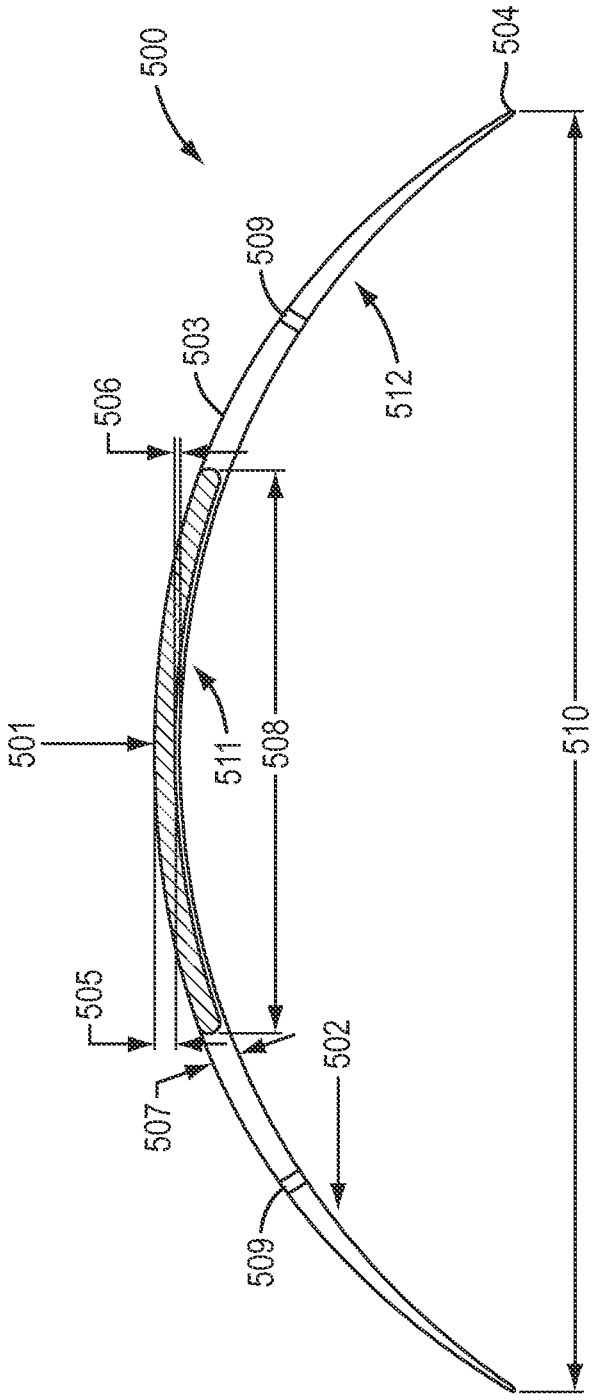

FIG. 5

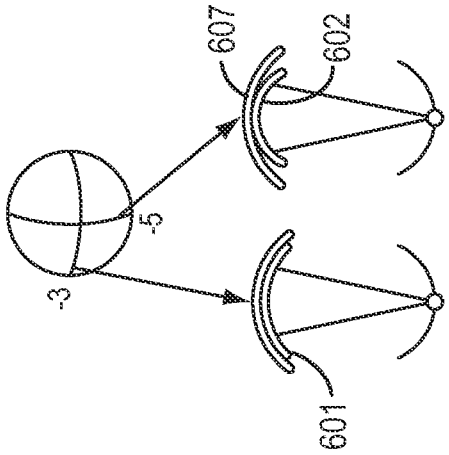

FIG. 6C

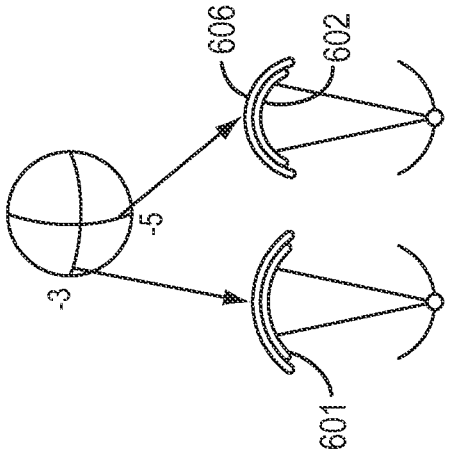

FIG. 6B

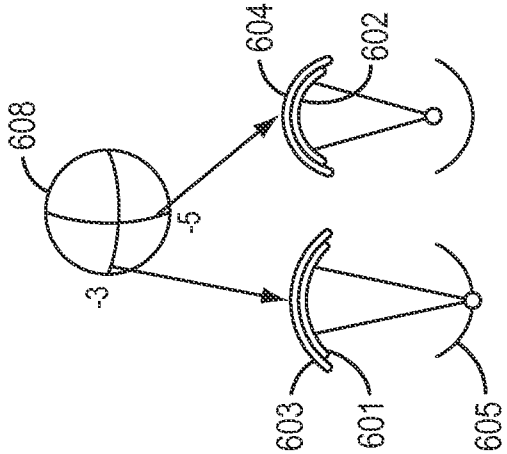

FIG. 6A

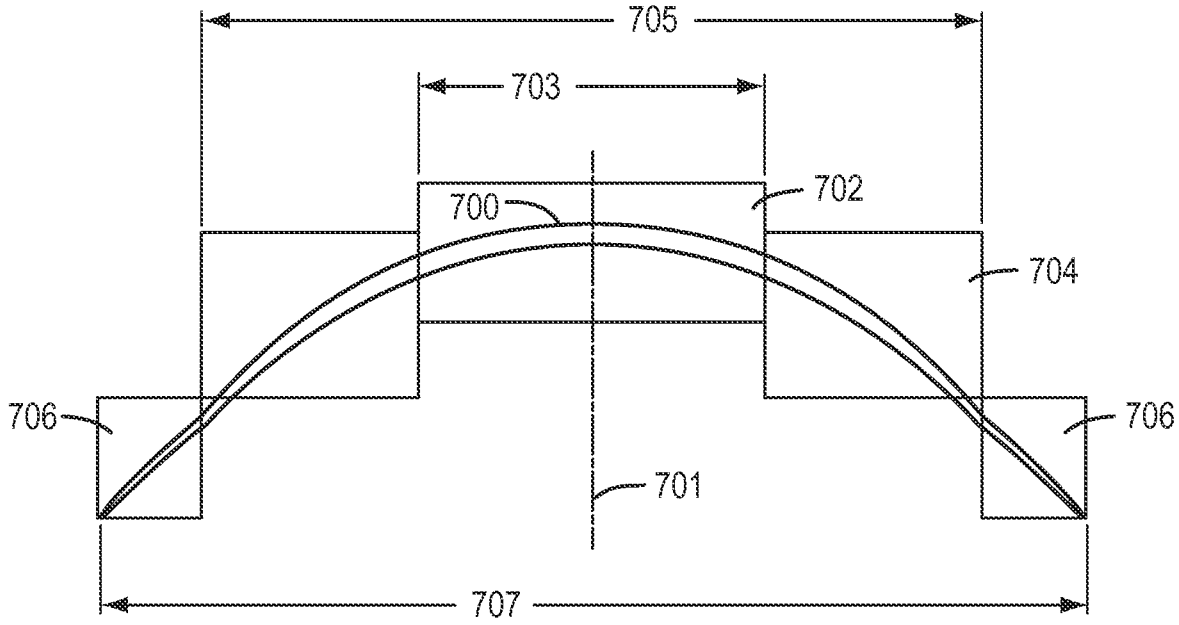

FIG. 7

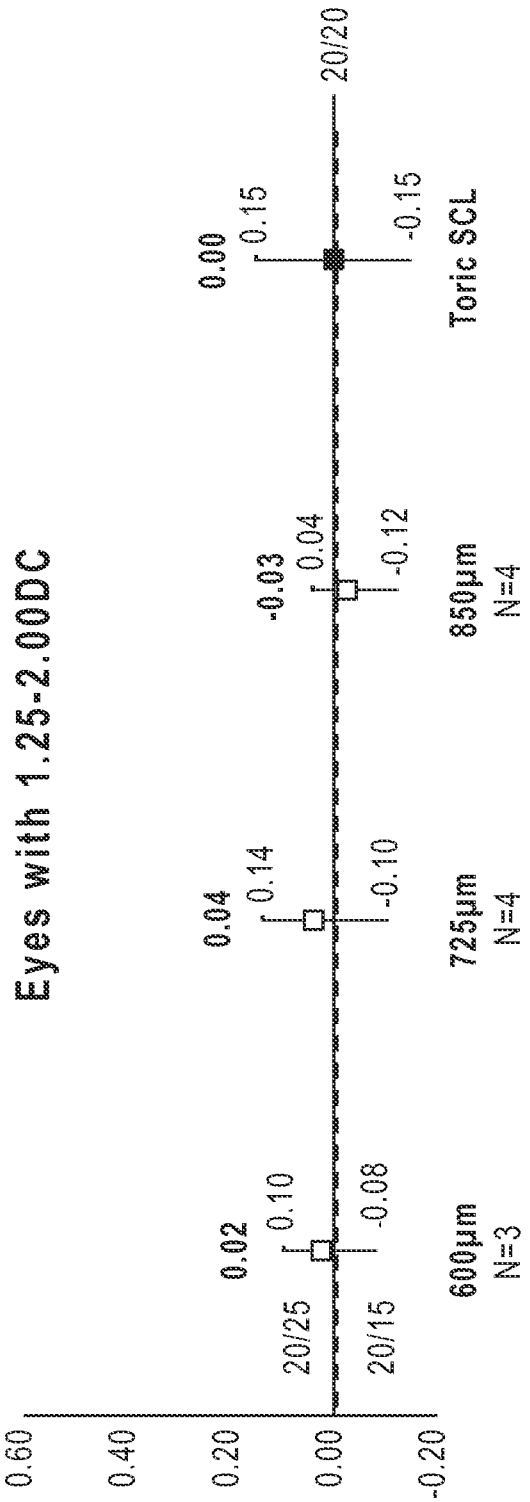
Eyes with 1.25-2.00DC
0.60
0.40
0.20
0.00
-0.20
20/25
20/15
0.02
0.10
-0.08
600µm
N=3
0.04
0.14
-0.10
725µm
N=4
-0.03
0.04
-0.12
850µm
N=4
0.00
0.15
-0.15
20/20
Toric SCL

FIG. 8A

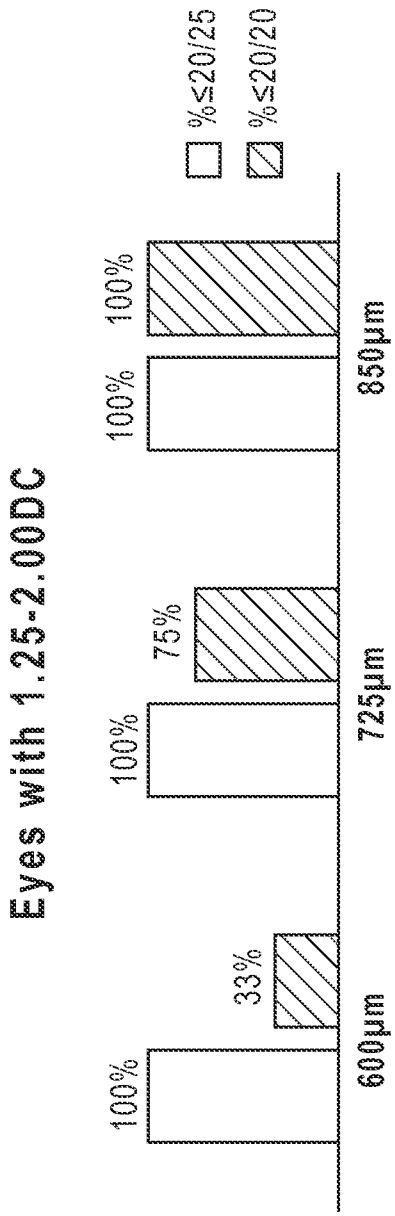
Eyes with 1.25-2.00DC
%≤20/25
%≤20/20
100%
33%
600µm
100%
75%
725µm
100%
100%
850µm

FIG. 8B

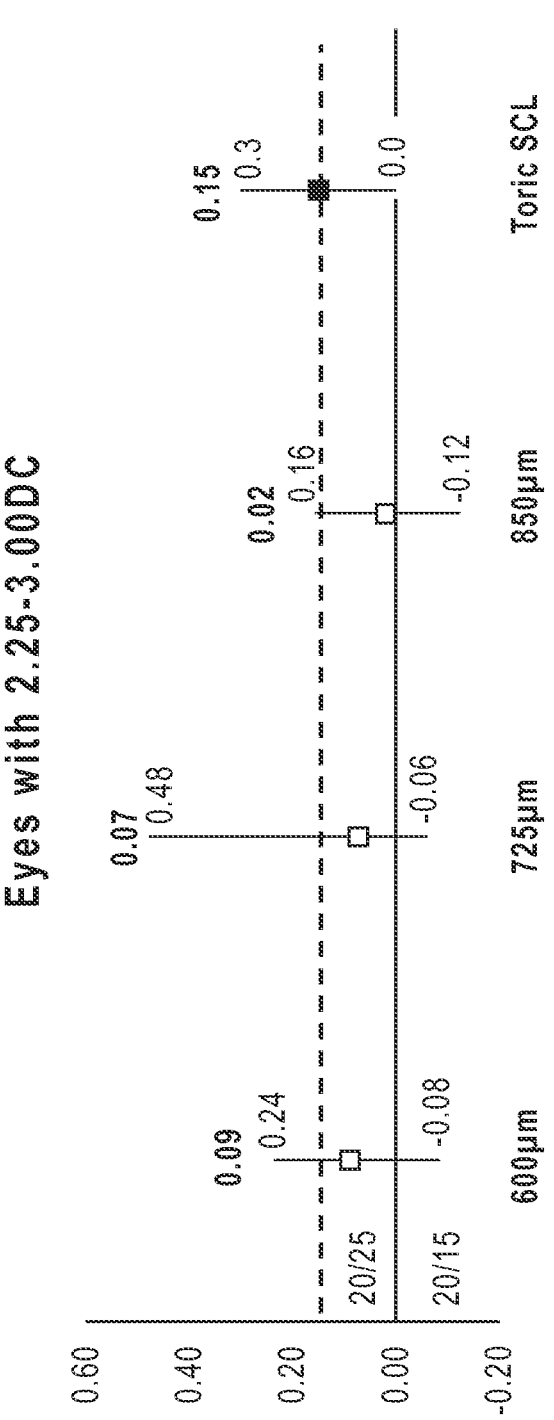
Eyes with 2.25-3.00DC
0.60
0.40
0.20
0.00
-0.20
20/25
20/15
0.09
0.24
-0.08
0.07
0.48
-0.06
0.02
0.16
-0.12
0.15
0.3
0.0
600µm
N=9
725µm
N=9
850µm
N=10
Toric SCL

FIG. 9A

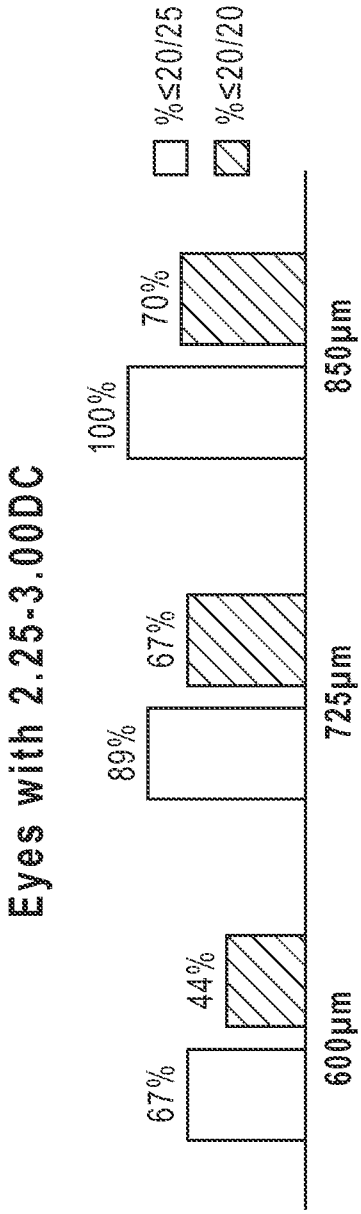
Eyes with 2.25-3.00DC
%≤20/25
%≤20/20
67%
44%
89%
67%
100%
70%
600µm
725µm
850µm

FIG. 9B

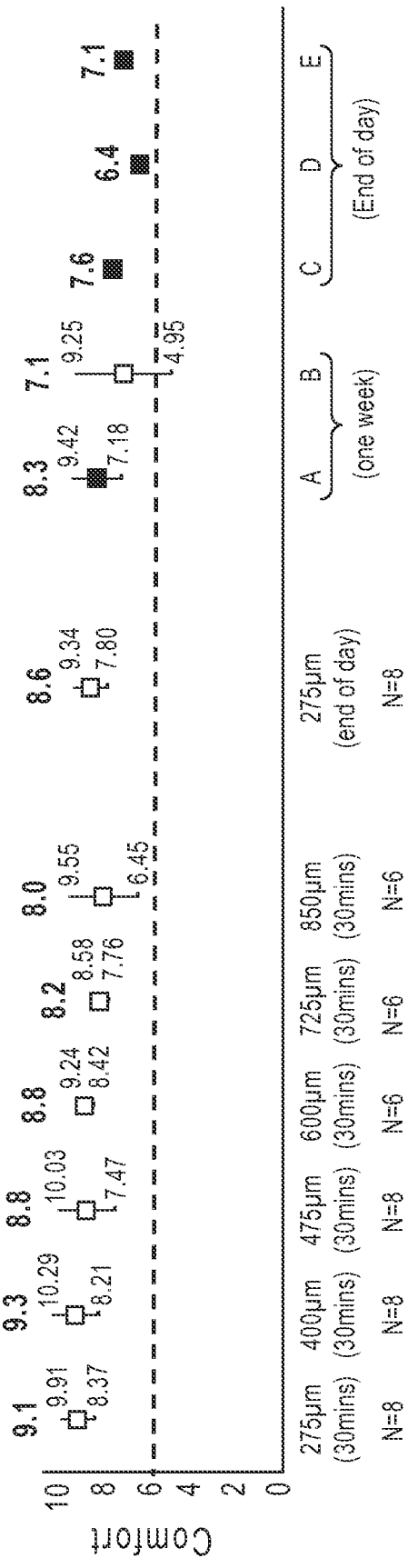

FIG. 10A

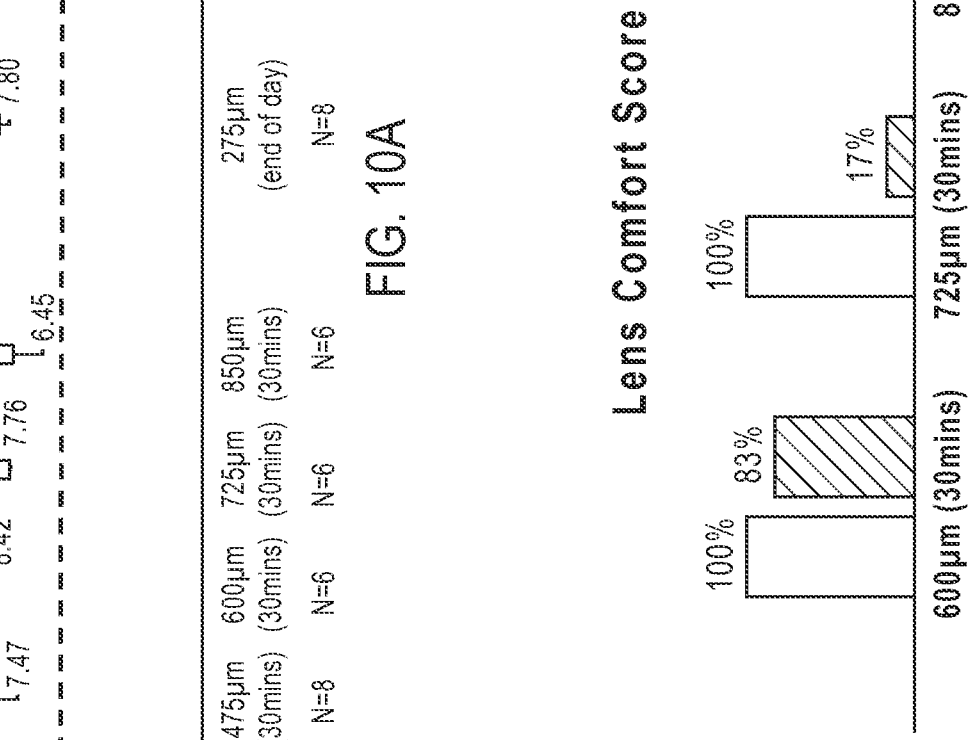

FIG. 10B

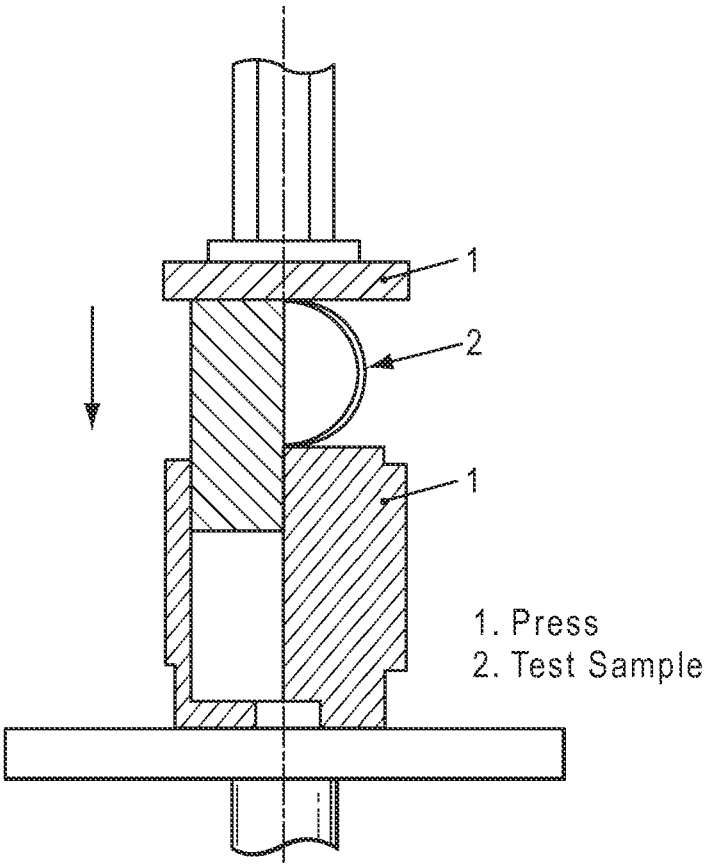

FIG. 11

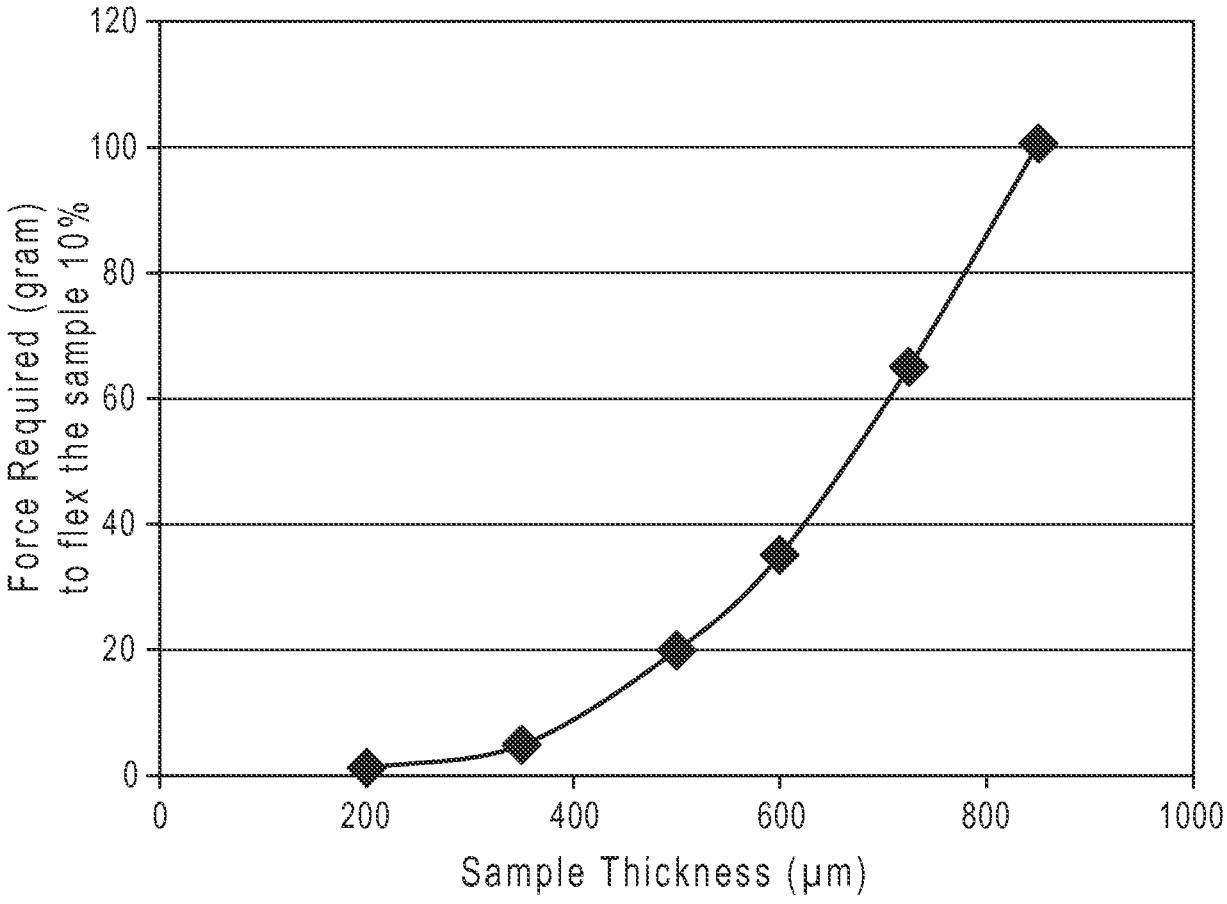
120
100
80
60
40
20
0
Force Required (gram) to flex the sample 10%
0
200
400
600
800
1000
Sample Thickness (µm)

FIG. 12

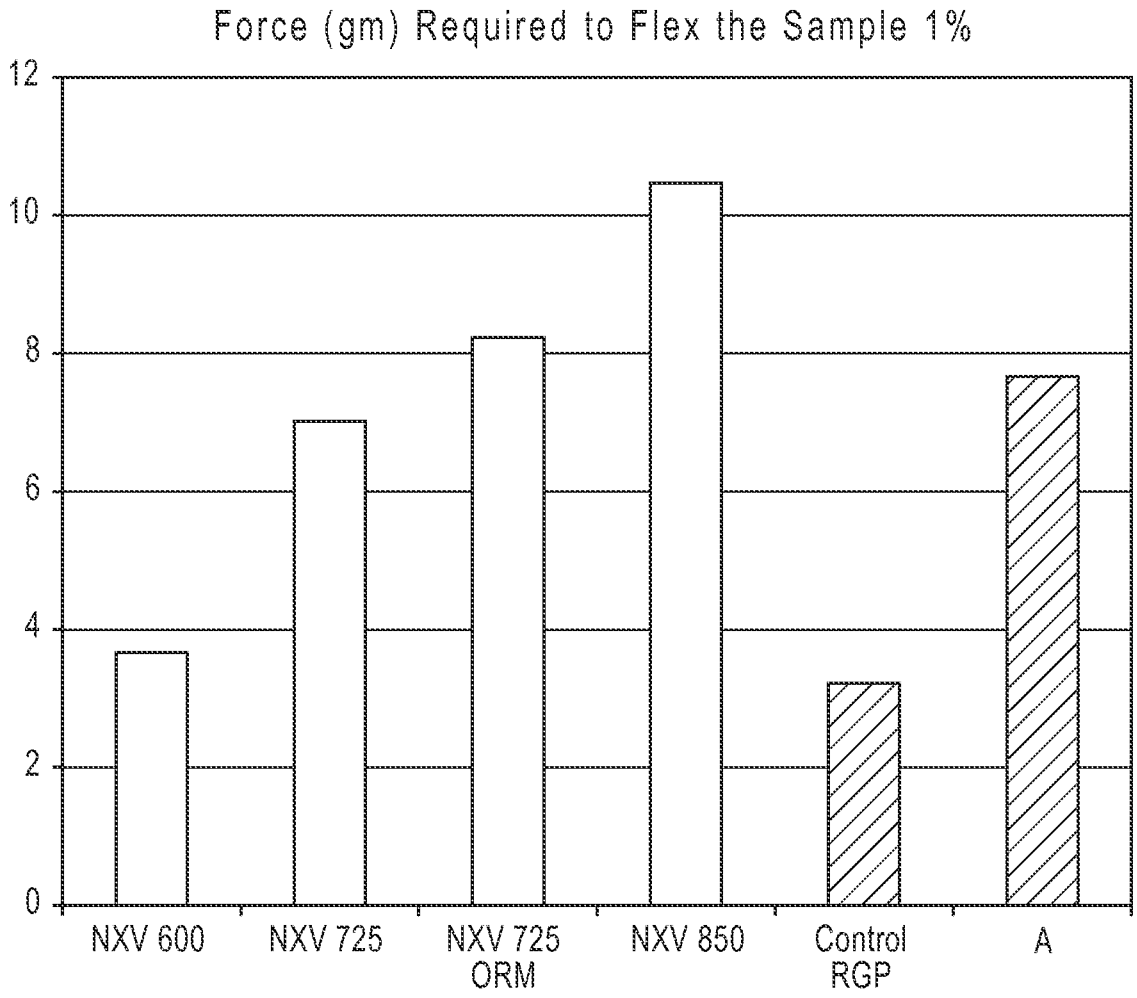
Force (gm) Required to Flex the Sample 1%
12
10
8
6
4
2
0
NXV 600
NXV 725
NXV 725 ORM
NXV 850
Control RGP
A

FIG. 13

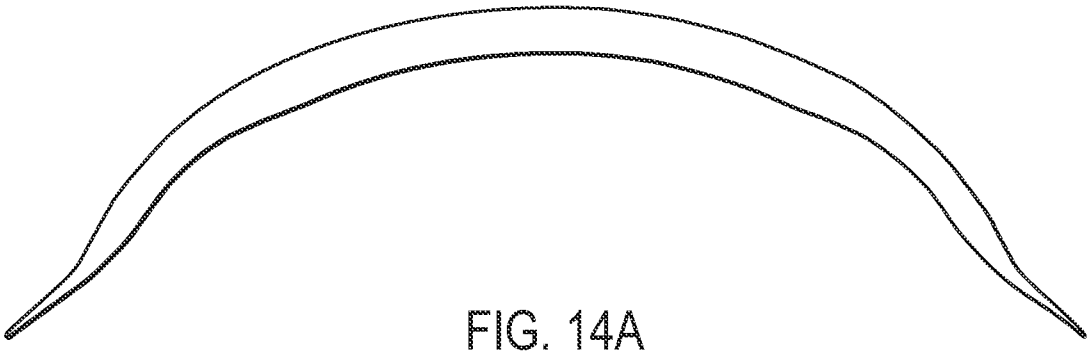

FIG. 14A

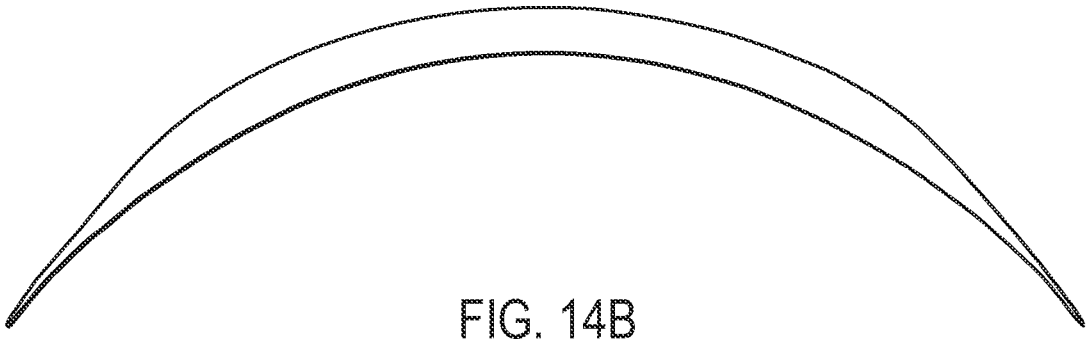

FIG. 14B

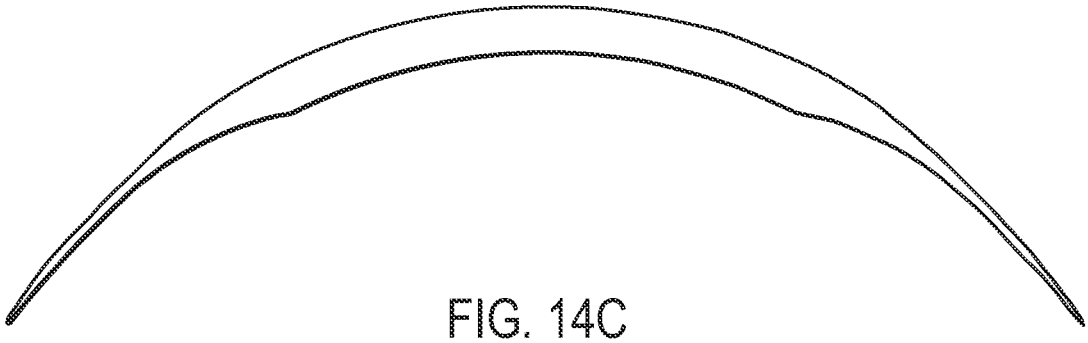

FIG. 14C

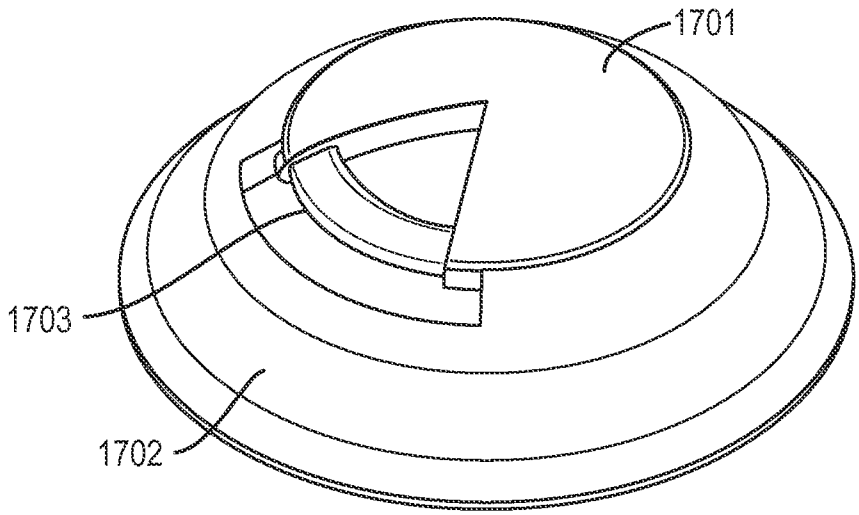

FIG. 15A

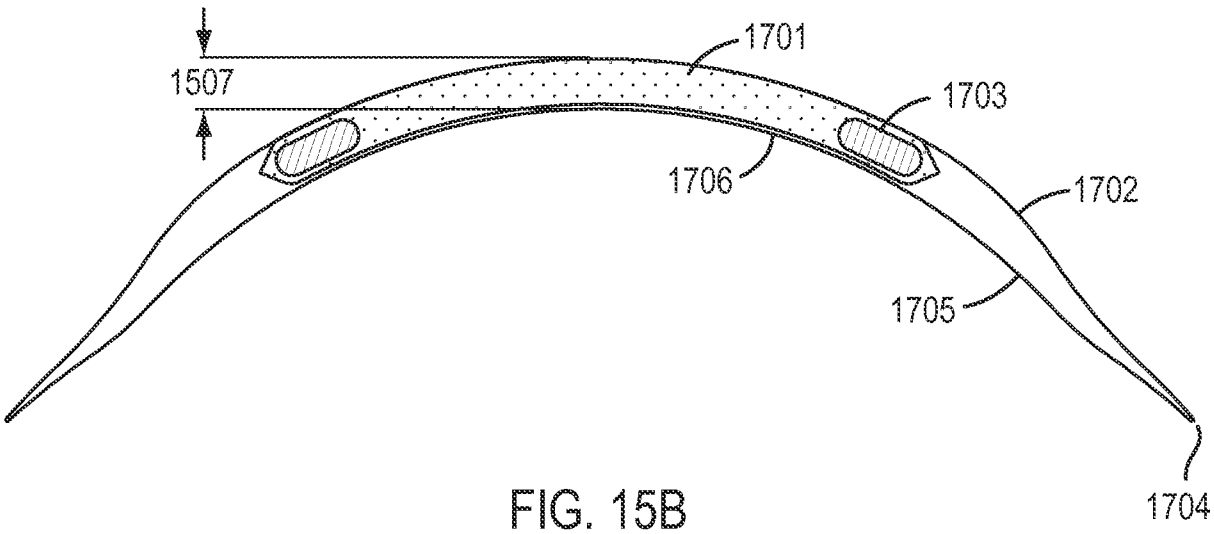

FIG. 15B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/037219

A. CLASSIFICATION OF SUBJECT MATTER
INV. G02C7/04
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G02C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2011/050365 A1 (FORSIGHT LABS LLC [US]; DE JUAN EUGENE JR [US]; REICH CARY J [US]; ALS) 28 April 2011 (2011-04-28) figure 1K; table A1 paragraphs [0014], [0028], [0048] - [0050], [0071], [0079], [0083], [0095] paragraphs [0192], [0193], [0203], [0206], [0319], [0320], [0323], [0324] paragraphs [0344], [0382], [0396], [0410], [0412], [0423] ----- -/--	1-21,27, 28,36-38

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 July 2013	30/09/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Vazquez Martinez, D

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/037219

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 29-35
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-21, 27-38

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JORGE L ALIÓ ET AL: "Contact lens fitting to correct irregular astigmatism after corneal refractive surgery", JOURNAL OF CATARACT & REFRACTIVE SURGERY, vol. 28, no. 10, 1 October 2002 (2002-10-01), pages 1750-1757, XP055071935, ISSN: 0886-3350, DOI: 10.1016/S0886-3350(02)01489-X page 1754, column 2	1,11,15, 37
X	US 4 640 594 A (BERGER RICHARD [US]) 3 February 1987 (1987-02-03) column 2, line 11 - line 28 column 2, line 46 - column 3, line 16 column 3, line 46 - column 5, line 11	1,2, 10-15,36
A	WO 2006/134649 A1 (MENICON CO LTD [JP]; GOTO YUJI [JP]; MATSUSHITA RYO [JP]; SAKAI YUKIHI) 21 December 2006 (2006-12-21) abstract figure 4	1,36,37

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2013/037219

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2011050365 A1	28-04-2011	EP 2490620 A1	29-08-2012
		US 2012310133 A1	06-12-2012
		US 2013025606 A1	31-01-2013
		US 2013070200 A1	21-03-2013
		WO 2011050365 A1	28-04-2011
US 4640594 A	03-02-1987	NONE	
WO 2006134649 A1	21-12-2006	JP 4608544 B2	12-01-2011
		WO 2006134649 A1	21-12-2006

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-21, 27-38

   Properties of an ophthalmic lens and method of correcting refractive error

1.1. claims: 1-9, 13, 14, 28, 29, 36-38

   Properties of the material /s of an ophthalmic lens

1.2. claims: 10-12, 15, 21, 27

   Optical properties of the inner portion of an ophthalmic lens

1.3. claims: 30-35

   Method of correcting a refractive error with an ophthalmic lens

1.4. claims: 16-20

   Ophthalmic lens with peripheral fenestrations

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2. claims: 22-26

   Ophthalmic lens with reinforcement ring around the optical region

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Continuation of Box II.1

Claims Nos.: 29-35

Independent claim 29 relates to a method of selecting an ophthalmic lens that could, at least in principle, be carried out without any technical assistance and would, therefore, have to be regarded as a mental act in the sense of Rule 39.1.(iii) PCT. Thus, according to Rule 39.1 (iii) PCT, the International Searching Authority is not required to search the subject-matter of claim 29. Regarding claims 30 to 35 , the applicant is informed that the subject-matter of such claims is to be interpreted as referred to a treatment of a patient's eye in order to lessen the symptoms of an error of the optical system of the human eye, i.e. a malfunction of the human body. Consequently, according to Rule 39.1 (iv) PCT, the International Searching Authority is not required to search the subject-matter of claims 30 to 35 since it refers to a therapeutic treatment of the human body.

(19)中华人民共和国国家知识产权局

(12)发明专利申请

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(22)申请日 2013.04.18
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PCT/US2013/037219 2013.04.18
(87)PCT国际申请的公布数据
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(71)申请人 内希斯视觉股份有限公司
地址 美国加利福尼亚
(72)发明人 小E·德胡安 C·J·赖克
Y·阿尔斯特 M·克拉克 K·A·团
B·利维 R·鲁姆
J·D·爱丽詹德罗
(74)专利代理机构 中国国际贸易促进委员会专利商标事务所 11038
代理人 金晓
(51)Int.Cl.
G02C 7/04(2006.01)

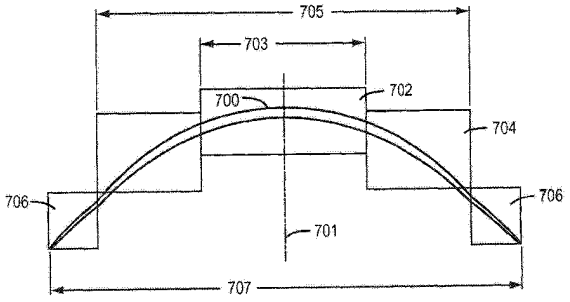
权利要求书4页 说明书49页 附图40页

(54)发明名称

用于屈光矫正的接触透镜

(57)摘要

本发明公开了用于矫正眼睛屈光误差的眼用透镜。眼用透镜包括可变形内部部分和可变形外围部分。当设置在眼睛的光学区域上时，内部部分被配置使得后表面对眼睛的接合使后表面变形，以便在用眼睛通过眼用透镜进行观察时后表面具有从上皮的屈光形状分离的形状。内部部分的刚性大于外围部分的刚性并且眼用透镜被配置为允许当眨眼睛时相对于眼睛的运动并且继眨眼睛之后基本上以角膜的光学区域为中心。还公开了使用眼用透镜矫正眼睛屈光误差（例如，散光或者球面像差）的方法。



CN 104335104 A

1. 一种用于矫正眼睛的屈光误差的眼用透镜，所述眼睛具有角膜，所述角膜由上皮提供跨越所述眼睛的光学区域延伸的屈光形状，所述眼用透镜包括：

内部光学部分，配置为设置在所述角膜的所述光学区域上；

后表面，当所述内部部分设置在所述光学区域上时，所述后表面沿着所述内部部分邻近所述眼睛延伸，所述内部部分被配置为使得所述后表面对所述眼睛的接合使所述后表面变形，并且使得在用所述眼睛通过所述眼用透镜进行观看时所述后表面具有从所述上皮的所述屈光形状偏离的形状；

所述眼用透镜的外围部分，从所述内部部分径向向外设置；以及

所述眼用透镜的前表面，沿着所述内部部分与所述后表面相对地延伸，以使得用所述眼睛通过所述眼用透镜的观看减轻所述屈光误差。

2. 根据权利要求 1 所述的眼用透镜，其中所述内部部分的刚度大于所述外围部分的刚度。

3. 根据权利要求 1 所述的眼用透镜，其中所述内部部分的刚度从大约 2.0E10MPa-μm^{3}到大约 8.0E9MPa-μm^3。

4. 根据权利要求 1 所述的眼用透镜，其中所述内部部分的特征在于其厚度为从大约 100μm 到大约 900μm。

5. 根据权利要求 4 所述的眼用透镜，其中使所述内部部分弯曲 1％需要的力从大约 0.5gm 到大约 50gm。

6. 根据权利要求 1 所述的眼用透镜，其中所述内部部分包括具有从大约 10MPa 到大约 100MPa 的模量的材料以及所述外围部分包括具有从大约 0.01MPa 到大约 10MPa 的模量的材料。

7. 根据权利要求 1 所述的眼用透镜，其中所述内部光学部分的特征在于厚度从 100μm 到 900μm、模量从大约 10MPa 到大约 1,000MPa，以及刚度至少大约 4E8MPa-μm^3。

8. 根据权利要求 1 所述的眼用透镜，其中所述内部部分和所述外部部分包括从硅酮、硅酮水凝胶、水凝胶或者上述中任何的组合中选择的材料。

9. 根据权利要求 1 所述的眼用透镜，其中所述内部部分的特征在于厚度从大约 100μm 到大约 900μm 以及由以从大约 20MPa 到大约 100MPa 的模量为特征的材料形成。

10. 根据权利要求 1 所述的眼用透镜，其中所述内部部分的所述前表面的特征在于基本上球面的轮廓。

11. 根据权利要求 1 所述的眼用透镜，其中

所述眼睛的所述屈光误差包括圆柱形误差；以及

所述内部部分的所述前表面的特征在于基本上球面的表面，从而当用所述眼睛通过所述眼用透镜观看时由所述透镜矫正所述圆柱形误差主要受所述后表面的形状从所述上皮的形状的偏离影响。

12. 根据权利要求 1 所述的眼用透镜，其中所述内部部分的特征在于球面前表面。

13. 根据权利要求 1 所述的眼用透镜，其中所述内部部分和所述外围部分被配置为允许响应于眨动所述眼睛而相对于所述眼睛的移动。

14. 根据权利要求 1 所述的眼用透镜，其中所述内部部分和所述外围部分被配置为在所述眼用透镜的所述外围部分与所述上皮之间提供泪液流动。

15. 根据权利要求 1 所述的眼用透镜，其中所述眼睛的所述屈光误差包括散光，其中所述内部部分的所述前表面与所述内部部分的所述后表面径向地对称。

16. 根据权利要求 1 所述的眼用透镜，还包括多个开窗，其中所述多个开窗被设置在外围区域中。

17. 根据权利要求 16 所述的眼用透镜，其中所述多个开窗被设置在从所述眼用透镜的中央光轴开始的半径处。

18. 根据权利要求 16 所述的眼用透镜，其中所述多个开窗被配置为当所述眼睛眨动时在所述外围部分与所述上皮之间泵送泪液。

19. 根据权利要求 16 所述的眼用透镜，其中所述多个开窗被配置为便于从所述眼睛移除所述透镜，如果气泡被截留在所述透镜下面便于空气消散，或者它们的组合。

20. 根据权利要求 16 所述的眼用透镜，其中与在佩戴没有开窗的可比较透镜的患者群体中的视觉结果相比，所述多个开窗改善在佩戴所述透镜的患者群体中的视觉结果的再现性。

21. 根据权利要求 1 所述的眼用透镜，其中所述内部部分被配置为矫正视力并且所述外围部分被配置为增强舒适度。

22. 根据权利要求 1 所述的眼用透镜，包括靠近所述内部部分与所述外围部分之间的对接设置的加强环。

23. 根据权利要求 22 所述的眼用透镜，其中所述加强环被嵌入在所述内部部分内。

24. 根据权利要求 22 所述的眼用透镜，其中所述加强环被设置在所述内部部分内与所述角膜的所述光学区域不重合的位置处。

25. 根据权利要求 22 所述的眼用透镜，其中所述加强环由具有比形成所述内部部分的材料的模量高的模量的材料形成。

26. 根据权利要求 22 所述的眼用透镜，其中所述加强环由聚甲基丙烯酸甲酯组成。

27. 根据权利要求 1 所述的眼用透镜，其中所述透镜被配置为在眨动眼睛之后以所述角膜的所述光学区域为中心。

28. 根据权利要求 1 所述的眼用透镜，其中所述内部部分的特征在于直径从 5mm 到 10mm 以及所述外围部分的特征在于外直径 12mm 到 16mm。

29. 一种用于选择用于矫正患者眼睛的屈光误差的眼用透镜的方法，所述眼睛具有角膜，所述角膜由上皮提供屈光形状，所述方法包括：

确定期望球光焦度以便减轻所述屈光误差的任何球面成分；以及

从具有不同球光焦度的多个可选眼用透镜中标识选择的眼用透镜以便提供：

与所述期望球光焦度相对应的前表面，所述前表面沿着所述眼用透镜的内部部分延伸，其中所述眼用透镜的所述内部部分的特征在于厚度从大约 100μm 到大约 900μm 以及所述眼用透镜的外围部分具有比所述内部部分的刚度低的刚度；其中所述眼用透镜被配置为当眨动所述眼睛时允许相对于所述眼睛的移动并且在所述眼睛的所述眨动之后基本上以所述角膜的所述光学区域为中心。

30. 一种用于矫正眼睛的屈光误差的方法，所述眼睛具有角膜，所述角膜由上皮提供跨越所述角膜的光学区域延伸的屈光形状，所述方法包括：

在所述眼睛上安置眼用透镜以使得所述眼用透镜的内部部分被设置在所述角膜的所

述光学区域上，其中所述安置的眼用透镜的后表面邻近所述眼睛延伸并且由所述眼睛的所述上皮变形；以及

当所述后表面的形状从所述上皮的所述屈光形状偏离时，用所述眼睛通过所述眼用透镜的前表面观看以使得所述眼用透镜减轻所述屈光误差。

31. 根据权利要求 30 所述的方法，其中所述眼用透镜包括：

内部光学部分，配置为设置在所述角膜的所述光学区域上并且特征在于厚度从 100μm 到 900μm；

所述后表面，在所述内部部分被设置在所述光学区域上时沿着所述内部部分邻近所述眼睛延伸，所述后表面具有从所述上皮的所述屈光形状偏离的形状；

所述眼用透镜的外围部分，从所述内部部分径向向外设置；以及

所述眼用透镜的所述前表面，沿着所述内部部分与所述后表面相对地延伸，以使得用所述眼睛的观看减轻所述屈光误差。

32. 根据权利要求 30 所述的方法，其中在佩戴所述透镜至少 30 分钟之后，患者群体中的平均舒适度分数为至少 6.5。

33. 根据权利要求 30 所述的方法，其中在安置所述透镜之后，在具有从 2.25DC 到 3.00DC 圆柱形误差的患者群体中的平均矫正视敏度是 0.1±0.15LogMAR 或者更好。

34. 根据权利要求 30 所述的方法，其中在安置所述透镜之后，在具有从 1.25DC 到 2.00DC 圆柱形误差的患者群体中的平均矫正视敏度是 0.0±0.15LogMAR 或者更好。

35. 根据权利要求 30 所述的方法，所述眼睛的所述屈光误差包括散光、球面像差或者它们的组合，其中：

多个开窗在所述前表面与所述后表面之间延伸，所述多个开窗设置在所述光学区域外；

所述眼用透镜的内部部分是可变形的，以及所述外围部分的特征在于比所述内部部分的刚度低的刚度；

当用所述眼睛通过所述前表面观看时，减轻所述屈光误差在至少大约 1.5D 的散光误差的整个范围内基本上独立于所述外围部分的所述形状，并且独立于所述眼用透镜围绕所述眼睛的观看轴的旋转定向。

36. 一种用于在患者群体中矫正眼睛的屈光误差的替换地可选择眼用透镜的集合，每个眼睛具有角膜，所述角膜由上皮提供屈光形状，所述集合包括：

具有不同球光焦度的多个替换眼用透镜，每个眼用透镜包括：

与关联的期望球光焦度相对应的前表面，所述前表面沿着所述眼用透镜的内部部分延伸，其中所述眼用透镜的所述内部部分是可变形的；以及

所述眼用透镜的外围部分，从所述内部部分径向向外延伸，所述外围部分的特征在于比所述内部部分的刚度低的刚度，并且所述外围部分被配置用于接合所述眼睛的光学区域外的组织以便支持所述内部部分与所述光学区域对齐。

37. 一种用于矫正眼睛的屈光误差的眼用透镜，所述眼睛具有角膜，所述角膜由上皮提供跨越所述眼睛的光学区域延伸的屈光形状，所述眼用透镜包括：

内部光学部分，配置为设置在所述角膜的所述光学区域上；

后表面，当所述内部部分设置在所述光学区域上时所述后表面沿着所述内部部分邻近

所述眼睛延伸，所述内部部分被配置为使得所述后表面对所述眼睛的接合使所述后表面变形，并且使得在用所述眼睛通过所述眼用透镜进行观看时所述后表面具有从所述上皮的所述屈光形状偏离的形状；

所述眼用透镜的外围部分，从所述内部部分径向向外设置；以及

所述眼用透镜的前表面，沿着所述内部部分与所述后表面相对地延伸，以使得用所述眼睛通过所述眼用透镜的观看减轻所述屈光误差；

其中所述内部光学部分的特征在于厚度从100μm到900μm，以及模量从大约10MPa到大约1,000MPa，以及刚度从大约4E8MPa-μm^3到大约1.2E10MPa；以及

其中所述前表面的特征在于没有圆柱形成分的球面轮廓。

38. 根据权利要求37所述的眼用透镜，其中所述模量从大约10MPa到大约100MPa。

用于屈光矫正的接触透镜

[0001] 本申请根据35U.S.C.§119(e)要求2012年4月20日提交的美国临时申请No.61/636,404的权益，该申请的全部内容通过引用合并于此。

[0002] 领域

[0003] 公开了涉及用于矫正眼睛的屈光误差的眼用透镜的公开。眼用透镜包括可变形内部部分和可变形外围部分。当设置在眼睛的光学区域上时，内部部分被配置使得后表面对眼睛的接合使后表面变形，以便在用眼睛通过眼用透镜进行观看时后表面具有从上皮的屈光形状偏离的形状。内部部分的刚度大于外围部分的刚度并且眼用透镜被配置为允许当眨眼睛时相对于眼睛的运动并且继眨眼睛之后基本上以角膜的光学区域为中心。本公开还涉及使用眼用透镜矫正眼睛屈光误差（例如，散光或者球面像差）的方法。

背景技术

[0004] 眼睛包括若干组织，该若干组织允许患者观看。眼睛的角膜是眼睛的前部组织，其在健康的眼睛中是透明的并且折射光以便在视网膜上形成图像。视网膜是眼睛的后部组织，其感测来自在其上形成的图像的光并且将来自图像的信号发送到大脑。角膜包括组织的外层，上皮，其保护角膜的底层组织，例如，Bowman膜、基质和延伸到基质和Bowman膜中的神经纤维。健康的眼睛包括处于上皮上的泪膜。泪膜可以使上皮的小的不规则平滑以便提供光学上光滑的表面并且维持眼睛健康。泪膜基本上由底层上皮、基质和Bowman膜（如果存在）的形状成形。泪膜包括主要是水并且包括另外的成分（例如类粘蛋白和脂类）的液体。角膜的许多神经纤维提供感觉以促进眨眼，眨眼可以用泪膜覆盖角膜。神经纤维还感测疼痛以使得一个人通常会避免对角膜的损伤并且还避免物体对角膜的直接接触以便保护该重要组织。

[0005] 本发明实施例的相关工作表明先前的接触透镜和治疗覆盖物中的至少一些在至少一些实例中可能不够理想。许多接触透镜和治疗覆盖物可能留在眼睛中少于理想时间，由于患者移除或者更换接触透镜或者治疗覆盖物可能稍微繁琐，在至少一些实例中，患者可能将接触透镜或者治疗覆盖物留在眼睛中比理想更长的时间。尽管长期佩戴的透镜可以留在眼睛中稍微更长的时间，但是这种透镜可能留在眼睛中的时间可能比理想的少。本发明实施例相关的工作还表明先前的接触透镜的泪流可能少于理想的，并且少于理想的泪流可能与潜在的并发症相关并且可能限制这种透镜可以留在眼睛中的时间量。

[0006] 在健康的角膜中，维持角膜适当量的水合作用（有时称为角膜脱水）以使得角膜保持透明。角膜包括后部内皮层，其将来自角膜的水泵送到相邻前房中。上皮抑制水从泪液流到角膜中，以使得通过内皮泵送能够维持角膜基质适当量的水合作用。将水从角膜内皮泵送以维持眼睛的适当水合作用和厚度称为减轻肿胀(deturgescence)。当角膜上皮愈合时，在至少一些实例中缺损上形成的细胞层可能是至少稍微不规则的，以至于患者的视力可能不够理想。

[0007] 在角膜手术（例如屈光角膜切除术）之后，消融后角膜可以具有复杂形状，并且许多先前市场上可买到的透镜可能不像理想的那样适合消融的角膜，并且在至少一些实例中

适配透镜可能是费时并且尴尬的。市场上可买到的接触透镜具有硬性透气性(RGP)中央部分和软性外围裙边，该接触透镜适配到消融的角膜可能很难和/或费时并且在至少一些实例中可能适配得不是很好。消融的角膜可以包括消融边缘附近的曲率上的突变，并且在至少一些实例中，可能很难将这种透镜适配在消融边缘附近。同样地，市场上可买到的接触透镜中的至少一些可能不适用于长期佩戴并且可能每天移除，这对于患者来说可能稍微尴尬并且可能导致不适合，以及在至少一些实例中透镜比理想时间更长地保留在眼睛中。

[0008] 混合接触透镜，具有硬性中央质子和软性裙边的透镜也用于矫正眼睛的屈光误差(例如散光)。除了必须为每个患者确定并且相对于角膜的光学区域取向以维持最优视力矫正的任何球面矫正组件以外，用于矫正屈光误差当前产品(例如RGP和软性复曲面透镜)还包括圆柱形组件。将特征部件结合到透镜中以维持佩戴期间眼睛的透镜对中和径向定向。由于需要适配和定向圆柱形矫正组件，必须在库存中维持大量透镜并且为每个患者单独地适配和选择。

[0009] 鉴于上述，期望提供用于视力矫正的改良接触透镜和用于与角膜上皮缺损(例如PRK之后的上皮缺损)相关治疗的覆盖物。理想地，在提供改善的患者舒适度和/或视力时，这些接触透镜和覆盖物将提供治疗以改善泪流并且避免已知技术的缺陷中的至少一些。还希望提供用于矫正屈光误差的改良接触透镜，其仅需要球面适配，并且提供和当前复曲面透镜产品一样或者比当前复曲面透镜产品更好的舒适度和视力矫正。

发明内容

[0010] 本发明实施例提供改良的眼用器件，该眼用器件在延长的时间量内提供改善的视力并且可以用于治疗正常眼睛或者具有上皮缺损(例如在诸如PRK的屈光手术之后的上皮缺损)的眼睛。器件可以包括接触透镜并且可以提供改善的泪流以使得器件可以在延长的时间内留在眼睛上以矫正视力。器件可以包括水抑制层和泵送器件水抑制层下方的泪液的一个或者多个结构，以使得器件可以在延长时间量内保持在眼睛中并且矫正视力。可选地或者组合地，器件可以包括硅酮(silicone)或者水凝胶(hydrogel)层，所述硅酮或者水凝胶层沿着器件的后表面延伸，耦合至开窗以提供水合作用和患者舒适度。硅酮或者水凝胶层可以流动地将角膜耦合至开窗以便将泪液和治疗剂从器件前表面通过开窗和硅酮或者水凝胶传送到角膜。在某些实施例中，器件包括具有开窗的材料以及被成形为与结膜接触的外部部分，以在眼睛眨动时泵送泪液。器件可以包括可偏移外部部分，所述可偏移外部部分具有对偏移的抵抗以使得当器件放置在眼睛上并且眼睛睁开眼睑分开时形成腔室。耦合至开窗的硅酮或者水凝胶层可以沿着器件下表面延伸腔室的至少部分。可偏移外部部分对偏移的抵抗可以被配置为使得当眼睑闭合时外部部分朝向角膜向内偏移以泵送泪液。当眼睛睁开时开窗可以将泪液吸取到位于器件下方的腔室中并且腔室可以扩展。开窗可以延伸穿过硅酮或者水凝胶层以提供泵送。可选地或者组合地，硅酮或者水凝胶层可以覆盖开窗的后端并且外部部分的偏移可以促进液体和药剂沿着硅酮或者水凝胶移动。器件外部部分包括成形为接触结膜以在器件放置在眼睛上时限定腔室的巩膜耦合部分。器件的开窗和巩膜耦合部分可以在眼睛闭合并且一个或者多个眼睑的压力朝角膜推动器件时将泪液传送离开腔室以使得腔室体积减小。在某些实施例中，睁开眼睛从而分开眼睑减小器件外部部分上的压力，以使得角膜外部部分上的器件的外部部分可以与角膜外部部分分开以便通过

开窗吸取液体并且将液体吸取到位于器件下方的腔室中。在眼睛睁开并且通过开窗吸取泪液时，器件的巩膜耦合部分可以接触结膜以抑制巩膜耦合部分下方的泪液流动，例如在器件接触结膜处形成密封。当随后眨动眼睛时，一个或者多个眼睑的压力可以将器件朝向角膜推动以使得泪液可以通过开窗，并且巩膜耦合部分可以与结膜稍微分开以在巩膜耦合部分下方传送泪液，以便用泵送的泪液清洗角膜、角膜缘、结膜和器件下侧。器件可以包括具有高透氧性的材料（例如硅酮）以使得器件可以提供改善的泪流和高透氧性。这种改善的泪液流动可以允许器件（例如接触透镜）被佩戴至少大约一个星期的延长时间，例如三十天或者六十天或者更久。改善的泪流可以改善具有上皮缺损（例如在 PRK 之后的上皮缺损）的眼睛的愈合和视力。改善的泪流还可以维持眼睛健康并且促进更久佩戴。

[0011] 在某些实施例中，器件包括用于视力的内部光学组件（例如透镜），以及用以相对于瞳孔保持内部组件以改善视力的外部耦合组件。耦合组件可以包括可偏移材料，所述可偏移材料抑制泪液通过所述材料以使得泪液在眼睛眨动并且眼睑在光学组件上施加压力时通过开窗。外部耦合组件可以包括传送泪液的开窗以及接触结膜的外部巩膜耦合部分。光学组件可以包括与第一刚度相对应的第一厚度以及第一材料。耦合组件可以包括与第二刚度相对应的第二厚度以及第二材料。第二材料可以比第一材料软并且第二厚度可以小于第一厚度，在眼睑闭合以覆盖第一组件和第二组件时，使得耦合组件可以由眼睑偏移，并且使得耦合组件可以比光学组件偏移更大的量。光学组件可以比耦合组件更刚性，使得光学组件可以在外部部分由一个或者多个眼睑偏移时提供视力。

[0012] 用耦合至结膜和底层巩膜提供的光学组件与瞳孔的对齐可以对视力有益。在某些实施例中，光学组件可以相对于瞳孔保持在基本上固定的位置处以便提供改善视力，例如远视矫正和像差视力矫正，其可以依赖瞳孔位置，例如测量的波前像差、球面像差、彗形像差和三叶草像差。

[0013] 光学组件和耦合组件可以有助于改善具有上皮缺损的眼睛中的上皮再生和视力。光学组件能够平滑角膜并且可以平滑消融基质和上皮的不规则。耦合组件能够支持光学组件以便抵抗光学组件的滑动并且提供促进上皮再生的环境。泪液的泵送可以改善上皮缺损附近到再生上皮的泪流以便促进缺损上的上皮再生。泪液的泵送还能够促进药剂（例如类固醇）向消融区域传送，以便抑制角膜浸润和模糊。

[0014] 在第一方面中，提供了用于矫正眼睛屈光误差的眼用透镜，该眼睛具有角膜，所述角膜由上皮提供跨越眼睛的光学区域延伸的屈光形状，该眼用透镜包括：内部光学部分，配置为设置在角膜的光学区域上；后表面，当内部部分设置在光学区域上时沿着内部部分邻近眼睛延伸，该内部部分被配置为使得后表面对眼睛的接合使后表面变形，并且使得在用眼睛通过眼用透镜进行观看时后表面具有从上皮的屈光形状偏离的形状；眼用透镜的外围部分，从内部部分径向向外设置；以及眼用透镜的前表面，沿着内部部分与后表面相对地延伸，以使得用眼睛通过眼用透镜的观看减轻屈光误差。

[0015] 在第二方面中，提供了用于选择用于矫正患者眼睛的屈光误差的眼用透镜的方法，该眼睛具有由上皮提供屈光形状的角膜，该方法包括：确定期望球光焦度以便减轻屈光误差的任何球面成分；以及从具有不同球光焦度的多个替换眼用透镜中标识选择的眼用透镜以便提供：与期望球光焦度相对应的前表面，该前表面沿着眼用透镜的内部部分延伸，其中眼用透镜内部部分的特征在于厚度从大约 100 μm 到大约 900 μm 并且眼用透镜外围部分

具有比内部部分的刚度低的刚度；其中眼用透镜被配置为允许当眨动眼睛时相对于眼睛的移动并且在眨动眼睛之后基本上以角膜的光学区域为中心。

[0016] 在第三方面中，提供了用于矫正眼睛屈光误差的方法，该眼睛具有角膜，所述角膜由上皮提供跨越角膜的光学区域延伸的屈光形状，该方法包括：在眼睛上安置眼用透镜以使得眼用透镜的内部部分被设置在角膜的光学区域上，其中安置的眼用透镜的后表面邻近眼睛延伸并且由眼睛的上皮变形；以及当后表面的形状从上皮的屈光形状偏离时，用眼睛通过眼用透镜的前表面观看以使得眼用透镜减轻屈光误差。

[0017] 在第四方面中，提供了用于在患者群体中矫正眼睛屈光误差的替换地可选择眼用透镜的集合，每个眼睛具有由上皮提供屈光形状的角膜，该集合包括：具有不同球光焦度的多个替换眼用透镜，每个眼用透镜包括：与关联的期望球光焦度相对应的前表面，该前表面沿着眼用透镜的内部部分延伸，其中眼用透镜的内部部分是可变形的；以及眼用透镜的外围部分，从内部部分径向向外延伸，该外围部分的特征在于比内部部分的刚度低的刚度并且被配置用于接合眼睛光学区域外的组织以便支持内部部分与光学区域对齐。

[0018] 在第五方面中，提供了用于矫正眼睛屈光误差的眼用透镜，该眼睛具有角膜，所述角膜由上皮提供跨越眼睛光学区域延伸的屈光形状，该眼用透镜包括：内部光学部分，配置为设置在角膜的光学区域上；后表面，当内部部分设置在光学区域上时所述后表面沿着内部部分邻近眼睛延伸，该内部部分被配置为使得后表面对眼睛的接合使后表面变形，并且使得在用眼睛通过眼用透镜进行观看时后表面具有从上皮的屈光形状偏离的形状；眼用透镜的外围部分，从内部部分径向向外设置；以及眼用透镜的前表面，沿着内部部分与后表面相对地延伸，以使得用眼睛通过眼用透镜的观看减轻屈光误差；其中内部光学部分的特征在于厚度从 100μm 到 900μm，并且模量从大约 10MPa 到大约 1,000MPa，并且刚度从大约 4E8MPa-μm^3 到大约 1.2E10MPa-μm^3；以及其中前表面的特征在于没有圆柱形成分的球面轮廓。

[0019] 在第六方面中，本发明实施例提供治疗患者眼睛的器件。该眼睛具有泪液、瞳孔、角膜和结膜。器件包括矫正眼睛视力的光学组件和耦合组件。光学组件包括当放置在眼睛上时足够抵抗变形的第一刚度。耦合组件接触角膜和结膜并且相对于瞳孔支持光学组件。耦合组件包括大小设定成接触结膜的外部部分、耦合至光学组件的内部部分以及在内部部分与外部部分之间延伸的中间部分。光学组件或者耦合组件中的一个或者多个包括当眼睛眨动时用以泵送泪液的多个开窗。

[0020] 在某些实施例中，器件包括内部部分和外部部分，该内部部分包括光学组件以及该外部部分包括耦合组件。器件的外部部分可以包括耦合组件的中间部分和耦合组件的外部部分。

附图说明

[0021] 图 1 示出了根据本发明实施例适于使用如此处描述的眼用器件的眼睛。

[0022] 图 1-1A 示出了在紧接着导致上皮缺损的屈光手术之后的消融的眼睛，适用于根据本发明实施例补救。

[0023] 图 1A1 示出了根据本发明实施例安置在眼睛上的器件和眼睛的眨动。

[0024] 图 1A2 示出了根据本发明实施例能够泵送器件下方泪液的图 1A1 的器件。

[0025] 图 1A3 示出了根据本发明实施例，当闭上眼睛时泵送泪液的图 1A1 和图 1A2 的器件的示意图。

[0026] 图 1A4 示出了根据本发明实施例，当睁开眼睛时泵送泪液的图 1A1 和图 1A2 的器件的示意图。

[0027] 图 1B1 示出了根据本发明实施例具有适配眼睛巩膜的三弯曲轮廓的器件，该器件可以用于适配消融的角膜。

[0028] 图 1B2 示出了根据本发明实施例具有适配眼睛巩膜的三弯曲轮廓的器件，弯曲轮廓的斜率对齐以便抑制弯曲部分边界处隆起。

[0029] 图 1B2-1 示出了根据本发明实施例角膜接触部分下表面的斜率与巩膜耦合部分下表面的斜率的对齐，以使得对角膜缘的压力大体地减小。

[0030] 图 1B3 示出了根据本发明实施例图 1B1 的器件的渐尖边缘。

[0031] 图 1B4 示出了根据本发明实施例具有适配角膜、角膜缘和巩膜的三弯曲轮廓的器件的平面图，弯曲轮廓的斜率对齐以便抑制弯曲部分边界处隆起。

[0032] 图 1B5 示出了根据本发明实施例图 1B4 的器件及耦合至角膜、角膜缘和巩膜的相应弯曲部分的侧面剖视图。

[0033] 图 1B6 示出了根据本发明实施例图 1B4 的器件和上表面的相应弯曲部分的侧面剖视图。

[0034] 图 1B7 示出了根据本发明实施例图 1B4 的器件的渐尖边缘。

[0035] 图 1C 示出了根据本发明实施例包括具有比外部厚度大的内部厚度的单片材料的器件。

[0036] 图 1C1 示出了根据本发明实施例如图 1-2A 至 1B2 中具有内部部分和外部部分的器件，内部部分包括内部厚度和内部材料，外部部分包括外部厚度和外部材料，其中内部厚度大于外部厚度。

[0037] 图 1C2 示出了根据本发明实施例如图 1-2A 至 1B2 中具有内部部分和外部部分的器件，内部部分包括内部厚度和内部材料，外部部分包括外部厚度和外部材料，其中内部厚度大于外部厚度并且外部材料围绕内部材料延伸。

[0038] 图 1C2A 示出了根据本发明实施例如图 1-2A 至 1B7 中的一个或者多个中在器件后表面上具有硅酮或者水凝胶材料层的器件。

[0039] 图 1C2B 示出了根据本发明实施例如图 1-2A 至 1B7 中的一个或者多个中在器件后表面上具有硅酮或者水凝胶材料层的器件，该硅酮或者水凝胶材料层延伸小于跨越器件最大距离以使得器件的末端部分被配置为接合远离硅酮或者水凝胶层的眼睛上皮并且抑制器件放置在眼睛上时的移动。

[0040] 图 1C2C 示出了根据本发明实施例如图 1-2A 至 1B7 中的一个或者多个中的器件，该器件在器件后表面上具有硅酮或者水凝胶材料的环形层，以便在放置在眼睛上时器件内部部分接触远离硅酮或者水凝胶层的角膜并且器件外部部分接触远离器件的角膜。

[0041] 图 1C3 示出了根据本发明实施例如图 1B2 中具有三弯曲轮廓适配巩膜的器件，弯曲轮廓的斜率对齐以便抑制弯曲部分的边界处的隆起，并且在下表面上具有硅酮或者水凝胶材料层。

[0042] 图 1C4 示出了根据本发明实施例如图 1B4 中具有三弯曲轮廓以适配角膜、角膜缘

和巩膜的器件，弯曲轮廓的斜率对齐以便抑制弯曲部分的边界处的隆起，并且在下表面上具有硅酮或者水凝胶材料，该硅酮或者水凝胶材料延伸小于跨越器件最大距离以将结膜远离硅酮或者水凝胶材料与器件接合。

[0043] 图 1C5 示出了根据本发明实施例具有覆盖有硅酮或者水凝胶层的后端部的开窗，该硅酮或者水凝胶层沿着器件后表面延伸。

[0044] 图 1C6 示出了根据本发明实施例延伸穿过硅酮或者水凝胶层的开窗，该硅酮或者水凝胶层沿着器件后表面延伸。

[0045] 图 1D 示出了根据实施例包括沿着器件下表面径向向外延伸的通道的器件。

[0046] 图 1E 示出了根据实施例包括沿着器件下表面或者后表面径向向内延伸的通道的器件。

[0047] 图 1F 示出了根据实施例用以测量响应于负载透镜的一部分的偏移的测试装置。

[0048] 图 2A 示出了根据实施例包括放置在眼睑分开的眼睛上的接触透镜的器件。

[0049] 图 2B 示出了根据实施例图 2A 的器件在眼睑闭合时的侧视图。

[0050] 图 2C 示出了根据实施例图 2A 的器件在眼睑闭合时的正视图。

[0051] 图 2D 示出了根据实施例图 2A 的器件在眼睑睁开时的侧面轮廓。

[0052] 图 2E 示出了根据实施例包括放置在眼睛上的接触透镜的器件，以使得器件在眼睑分开时由角膜的内部部分和结膜支持并且与角膜外部部分分开以限定腔室。

[0053] 图 2F 示出了根据实施例图 2E 的器件在眼睑闭合时的侧视图。

[0054] 图 2F1 示出了根据实施例当眼睑闭合时眼睛转动，从而当泵送泪液时抑制器件沿着上皮滑动的图 2F 的器件的侧视图。

[0055] 图 2G 示出了根据实施例图 2E 的器件在眼睑睁开时的侧视图。

[0056] 图 2H 示出了根据实施例图 2E 的器件在眼睑位于中间位置时使得腔室包括中间体积的侧视图。

[0057] 图 2I 示出了根据实施例图 1C4 的器件放置在眼睛上用硅酮或者水凝胶接触眼睛时的侧视图。

[0058] 图 3A 示出了根据本发明实施例安置在具有上皮缺损的眼睛的角膜上的器件。

[0059] 图 3B 示出了根据本发明实施例在放置在具有上皮缺损的眼睛的角膜上之前的第一配置中的器件。

[0060] 图 3C 示出了根据实施例放置在眼睛上具有第二配置的图 3B 的器件。

[0061] 图 4A 示出了适于形成器件的光学组件的模具。

[0062] 图 4B 示出了适于形成包括图 4A 的光学组件的器件的模具。

[0063] 图 4C 示出了适于形成包括图 4A 的光学组件的器件和器件的软性材料层的模具。

[0064] 图 4D 示出了根据本发明实施例在注入可流动材料之前用以形成器件并且具有包括放置在其中的硬性材料的固体内部组件的模具。

[0065] 图 4E 示出了根据本发明实施例用能量在器件中形成开窗。

[0066] 图 4F 示出了根据本发明实施例在器件后表面上旋转涂覆硅酮或者水凝胶材料。

[0067] 图 4G 示出了根据本发明实施例在其上形成有硅酮或者水凝胶材料的器件上进行化学气相淀积。

[0068] 图 4H 示出了根据本发明实施例包括封装在容器中的硅酮或者水凝胶材料的器

件。

[0069] 图 5 示出了根据某些实施例的器件。

[0070] 图 6A 示出了安置在散光眼上的硬性透镜的例子的径向线的视图。

[0071] 图 6B 示出了安置在散光眼上的软性透镜的例子的径向线的视图。

[0072] 图 6C 示出了根据本发明某些实施例安置在散光眼上的器件的例子的径向线的视图。

[0073] 图 7 示出了根据本公开某些实施例的眼用器件的截面视图。

[0074] 图 8A 示出了对于具有有 1.25DC 至 2.00DC 未矫正圆柱形误差并且佩戴由本公开提供的眼用透镜（其特征在于内部光学区域的不同厚度）的患者群体的平均球面透镜矫正视敏度 (LogMAR)。

[0075] 图 8B 示出了在患者群体中当佩戴由本公开提供的具有不同厚度的眼用透镜时具有小于 20/25 或者小于 20/20 的视敏度的患者的百分比，其中患者具有有 1.25DC 至 2.00DC 的未矫正圆柱形误差的眼睛。

[0076] 图 9A 示出了对于具有有 2.25DC 至 3.00DC 未矫正圆柱形误差的眼睛并且佩戴由本公开提供的眼用透镜（其特征在于内部光学区域的不同厚度）的患者群体的平均球面透镜矫正视敏度 (LogMAR)。

[0077] 图 9B 示出了在患者群体中当佩戴由本公开提供的具有不同厚度的眼用透镜时具有小于 20/25 或者小于 20/20 的视敏度的患者的百分比，其中患者具有有 2.25DC 至 3.00DC 未矫正圆柱形误差的眼睛。

[0078] 图 10A 示出了对于佩戴由本公开提供的具有不同厚度内部光学部分的眼用透镜的患者的舒适度分数与对于佩戴市场上可买到的用于散光矫正的复曲面接触透镜的患者的舒适度分数相比的比较。

[0079] 图 10B 示出了在佩戴由本公开提供的具有不同内部光学区域厚度的眼用透镜 30 分钟之后舒适度分数等于或者大于 8 以及舒适度分数等于或者大于 9 的患者百分比的直方图。

[0080] 图 11 示出了用于根据 ISO 18369-4 测试眼用透镜内部部分的挠曲度的实验构造。

[0081] 图 12 是示出了弯曲由本公开提供的具有不同截面厚度的眼用透镜内部部分的某些实施例需要的力 (gm) 的图表。

[0082] 图 13 是弯曲由本公开提供的眼用透镜内部部分 1％需要的力 (gm) 与用于矫正屈光误差的两个市场上可买到的透镜比较的直方图。

[0083] 图 14A-14C 示出了针对由本公开提供的眼用透镜的三个示例的截面轮廓。

[0084] 图 15A 和 15B 分别示出了根据某些实施例用于矫正屈光误差的眼用透镜的透视图和截面视图。

[0085] 现在详细地参照由本公开提供的实施例。本公开实施例并不旨在限制权利要求。

具体实施方式

[0086] 如此处描述的本发明实施例可以与如在 2009 年 4 月 6 日提交的美国申请 No. 12/384,659 中描述的用于疼痛处理和视力的治疗器件结合，该申请的全部公开内容通过引用合并于此并且适合于根据如此处描述的本发明的一些实施例进行组合。

[0087] 眼用器件或者器件包括眼用覆盖物和眼用透镜两者。如此处使用的，覆盖物用于指覆盖患者眼睛并且本身不提供屈光视力矫正的眼用器件。提供屈光矫正的眼用器件在此称为接触透镜或者眼用透镜。透镜可以包括如此处公开的用于覆盖物的某些特征部件并且覆盖物可以包括如此处公开的用于透镜的某些特征部件。

[0088] 此处描述的实施例可以用于用器件（例如接触透镜）以许多方式治疗眼睛。此处描述的器件可以用于用长期佩戴接触透镜的长期视力矫正，该接触透镜在器件长时间安置在眼睛上时抑制角膜肿胀，并且还可以与许多形式的眼睛手术（例如屈光性角膜切除术）结合。

[0089] 如此处使用的，数学公式和科学记数法可以用于以本领域普通技术人员理解的许多方式标识值，例如以便根据在许多市场上可买到的电子表格（例如市场上可从 Microsoft 买到的 Excel™）中使用的记数法表示数据。如此处使用的，符号 "E" 可以用于表示底数为 10 的指数，从而 1E1 等于大约 10，2E1 等于大约 20 以及 4E2 等于大约 400。如此处使用的，符号“^”可以用于表示指数，以使得 A^B 等于 A^B。可以以许多方式表示单位并且如本领域普通技术人员将理解的，例如“m”表示米，“Pa”表示压力的帕斯卡单元，“Mpa”表示兆帕斯卡。

[0090] 如此处使用的，硅氧烷键包括例如硅酮弹性体的 -Si-O-Si- 共价键。

[0091] 如此处使用的，器件（例如接触透镜）基于 K 适配包括将接触透镜适配至角膜最平坦的子午线并且基于 K 适配可以比大约 1.5D 内的最平坦的子午线更平坦。例如，对于具有大约 44D 轴 90 和 43D 轴 180 的角膜曲率计 (keratometer) 值（在下文中，“K's”）的角膜而言，基于 K 适配将提供对于测量的眼睛区域具有与从大约 43D 至大约 41.5D 范围内的光焦度相对应的曲率的器件。如此处描述的基于 K 适配可以允许泪液在器件下方形成以使得可以根据如此处描述的实施例对泪液进行泵送。

[0092] 以屈光度（“D”）表示的角膜光焦度可以与角膜曲率的半径 R 相关，公式 D = (1.3375-1)/R 其中 1.3375 与房水的折射率相对应。角膜曲率与曲率半径 R 负相关，从而随着曲率半径增大角膜曲率减小而随着曲率半径减小，角膜曲率增大。

[0093] 如此处使用的，可交换地使用术语透镜外部部分和透镜外围部分。围绕覆盖物或者透镜的内部部分径向地设置外部部分或者外围部分并且外部部分或者外围部分连接到覆盖物或者透镜的内部部分。通常，外部部分或者外围部分从与内部部分的接口处的厚度朝覆盖物或者透镜的外部边缘或者外围边缘逐渐变细。外部部分或者外围部分可以进一步地用子部分表征，该子部分用例如不同曲率半径、厚度、刚度和材料表征。此外，覆盖物或者透镜以眼睛角膜为中心，外部部分或者外围部分通常设置在角膜的光学区域外。内部部分在此还称为内部或者光学组件或者扣状物 (button)。外部部分在此还称为外部组件或者耦合组件。

[0094] 图 1 示出了适于使用如此处描述的器件 100（未示出）的眼睛 2。在某些实施例中，器件 100 包括接触透镜。眼睛具有角膜 10 和晶状体 4，配置为在视网膜 5 上形成图像，并且图像可以在与高视敏度相对应的凹 5F 上形成。角膜可以延伸到眼睛的角膜缘 6，并且角膜缘可以连接到眼睛的巩膜 S。眼睛 2 具有位于角膜缘 6 附近的睫状体扁平部 PP。眼睛的结膜 C 可以位于巩膜上。晶状体可以调节以对患者所看到物体进行聚焦。眼睛具有限定瞳孔 9 的虹膜 8，该瞳孔可以响应于光线扩张和收缩。眼睛还包括位于巩膜 7 与视网膜 5 之

间的脉络膜 CH。眼睛具有在晶状体与视网膜之间延伸的玻璃体液 VH。视网膜 5 感测图像的光并且将光图像转换为沿着视觉神经 ON 处理并且发送到患者大脑的神经脉冲。

[0095] 图 1-1A 示出了在紧接着导致上皮缺损的屈光手术（例如，PRK 手术）之后的消融的眼睛。如此处描述的包括接触透镜的器件可以放置在消融的角膜上并且耦合至结膜以提供提高的视力。眼睛 2 包括限定瞳孔 9 的虹膜 8，光线穿过该瞳孔使得患者可以看见。角膜 10 包括位于基质 16 上的上皮 12。上皮 12 包括可以是大约 50μm 的厚度 12T。泪液覆盖上皮 12 的前表面。在至少人类、灵长类动物和一些鸟中，Bowman 膜 14 位于上皮 12 与基质 16 之间。Bowman 膜 14 包括具有大约 5 至 10 微米厚度的基本上非细胞的胶原组织。基质 16 包括具有角膜细胞位于其中的基本上胶原的组织。在一些动物中，可以缺少 Bowman 膜并且上皮可以位于邻近基质层处。内皮 18 位于基质 16 下方。内皮 18 包括将水从角膜 10 向虹膜 8 泵送的细胞层。泪液还覆盖由上皮缺损暴露的角膜表面，例如 Bowman 膜的暴露表面和暴露的基质表面。

[0096] 用屈光手术（例如 PRK）可以移除上皮以将屈光矫正消融到 Bowman 膜 14 和 / 或基质 16 中。将基质和 / 或 Bowman 膜的前表面的初始轮廓消融为消融轮廓 20 以矫正患者视力。在标题为 "Photorefractive keratectomy" 的美国专利 No. 5,163,934 中描述了移除组织轮廓以矫正视力，其公开可以适用于根据此处描述的本发明的一些实施例进行组合。消融的轮廓 20 通常包括跨越角膜延伸以矫正眼睛屈光误差并且可以矫正眼睛像差（例如波前像差）的光学区。消融的轮廓 20 以可以围绕消融轮廓的边界 20B 为边界。消融轮廓 20 包括跨越例如直径 20D 的最大尺寸。

[0097] 上皮可以包括内边界，其如箭头 30 所指示的向心地向内移动。

[0098] 在此处描述的某些实施例中，当上皮再生时，角膜的不规则性减小以便提供提高的视力或者舒适度中的一个或者多个。可以对如此处描述的器件进行配置以便减小角膜不规则性对视力的影响。

[0099] 图 1A1 示出了安置在眨动眼睛上的器件 100。上眼睑和下眼睑可以在眼睛上眨动。与实施例相关的工作表明上眼睑可以在眼睛上施加向下运动 22A 并且下眼睑可以在眼睛上施加上部移动 22B。向下运动 22A 可以大于上部移动 22B。如此处描述的可湿润涂层材料可以减小从眼睑传递到器件的力和移动以便抑制器件的移动。

[0100] 图 1A2 示出了能够泵送器件下方泪液的图 1A1 的器件。器件 100 具有内部部分 110 和外部部分 120，以及开窗 100F，该开窗 100F 在外部部分上延伸穿过器件厚度以便允许泪液 TL（其可以包括药剂）穿过器件。药剂可以包括例如，麻醉剂、止痛剂或者其它药物。

[0101] 器件 100 包括光学组件 100A 和耦合组件 100B。光学组件 100A 可以包括器件 100 的内部部分 110 并且耦合组件 100B 可以包括器件 100 的外部部分 120。光学组件 100A 包括足够抵抗变形的刚度以使得光学组件 100 可以矫正眼睛的视力。光学组件 100A 可以包括单个材料层或者多个材料层。耦合组件 100B 可以包括比光学组件 100A 小的刚度，以使得耦合组件可以进行偏移或者弹性地变形中的一个或者多个以便在用眼睑覆盖时顺应角膜。耦合组件 100B 可以包括耦合至光学组件的内部组件 100B1，耦合至巩膜的外部部分 100B3 以及中间部分 100B2。中间部分 100B2 可以在内部组件 100B1 与外部组件 100B3 之间延伸以便当放置在眼睛上时限定腔室。

[0102] 当眼睛闭合和睁开时（例如当眼睛眨动时），光学组件 100A 和耦合组件 100B 可以

将泪液泵送至角膜。包括外部部分 120 的外部组件 100B 可以包括开窗 100F。例如，中间部分 100B2 可以包括开窗 100F。外部部分 120 可以包括外部部分 100B3，该外部部分 100B3 包括巩膜耦合部分 130，用以接触外围部分 120P 和巩膜上的结膜。巩膜耦合部分 130 可以包括延伸到外围部分 120P 的薄凸缘部分。巩膜耦合部分可以包括能够在眼睛眨动时弹性变形以允许光学组件向下移动的薄的弹性部分。可选地或者组合地，外部部分 120 可以包括足够的刚度以当眼睛眨动时偏移。

[0103] 图 1A3 示出了根据本发明某些实施例，当眼睛闭合时泵送泪液的图 1A1 和图 1A2 的器件的示意图。

[0104] 当放置在眼睛上时，器件 100 可以用沿着角膜、角膜缘和巩膜上的结膜延伸的器件下表面限定腔室。当眼睑分开时，用来自在器件外部部分下方延伸的眼睑的轻微压力将器件 100 松弛地固定在眼睛上。当眼睛眨动时，眼睑在器件的外部部分 120 和内部部分 110 上延伸以便在器件上施加压力以使得器件被朝着角膜向下推动并且器件下面的腔室体积减小。器件 100 内部部分 110 的光学组件 100A 的向下运动可以将器件向下移动以便通过开窗传递泵送的泪液 100TL，并且在某些实施例中，泵送的泪液 100TL 可以在外围部分 120P 下方通过。

[0105] 图 1A4 示出了根据本发明实施例，当睁开眼睛时泵送泪液的图 1A1 和图 1A2 的器件的示意图。

[0106] 当眼睑睁开时，器件上的压力减小，以使得器件可以远离角膜移动并且增大腔室体积。光学部分 100A 远离角膜移动可以将泵送的泪液 100TL 通过开窗吸取到器件中，并且外围部分 120P 和巩膜耦合部分 130 与结膜接触可以抑制泪液在外围部分 120P 下方流动。在某些实施例中，外围部分 120P 和巩膜耦合部分 130 可以接触结膜以便在眼睑睁开并且光学部分 100A 远离角膜移动时形成密封。

[0107] 开窗 100F 可以位于远离光学组件处（例如距光学组件中心大约 3.5mm 至大约 4.5mm）以减小开窗 100F 的光学伪像。然而，当开窗直径足够小并且开窗足够少而不会产生可察觉的视觉伪像时，开窗可以位于光学组件内。开窗可以包括指示器件 100 在角膜上的定向的图案。例如，上开窗和下开窗可以指示患者上的 90 度轴以及可以提供水平开窗以指示患者眼睛上的 180 度轴的位置。开窗可以包括位于下面的附加开窗，用以指示器件没有在患者上 180 度翻转，例如上下颠倒。附加的下开窗还可以耦合至包括在下眼睑附近形成的泪液的细流（rivulet）以便促进泪液的泵送。例如，当眼睛眨动时下眼睑可以在下开窗上延伸并且上眼睑可以向下延伸以耦合至下细流。当眼睛睁开并且眼睑分开时，上眼睑可以吸取上开窗上细流的泪液并且下眼睑可以在下面移动以使细流在下细流上通过。

[0108] 器件可以包括许多光学透明材料中的一个或者多个，例如合成材料或者天然材料（例如基于胶原的材料）以及它们的组合（例如，在美国公开 No. U. S. 2010/0036488 中描述的）。例如，器件可以包括天然存在的材料，例如基于胶原的材料。可选地或者组合地，器件材料可以包括已知合成材料，例如甲基丙烯酸羟乙酯（HEMA）水凝胶、水凝胶、硅酮水凝胶、硅酮（例如水合硅酮）及其衍生物。例如，光学透明材料可以包括硅酮、硅酮水凝胶、包括树脂的硅酮、包括硅酸盐的硅酮、丙烯酸盐、胶原或者上述中任何的组合中的一个或者多个。固化硅酮可以包括双组分、热固化和 RTV（室温硫化）的硅酮。例如，聚二甲基硅氧烷（例如 NuSil）或者聚（二甲基）（二苯基）硅氧烷可以用于模制器件，例如用小于 10％的

含水量以便增大通过器件的氧扩散。器件可以包括全氟聚醚或者 fluorofocal。材料可以包括，例如具有设置在其中的光学透明硅酸盐和不超过大约 10％的含水量（例如不超过大约 5％或者不超过大约 1％）的硅酮弹性体，以使得器件具有超过 150 的超高 Dk 并且在某些实施例中超过300，并且可以对包括硅酸盐的硅酮透镜进行处理以提供可湿润表面。器件可以包括水凝胶（例如硅酮水凝胶）或者硅酮并且可以用从大约 5％至大约 35％范围内的含水量和从大约 0.1Pa 至大约 40Pa 的范围或者范围组合内的模量形成该器件，以使得器件至少部分地顺应角膜的前表面。在某些实施例中，由本公开提供的器件不包括水并且为穿过器件的流体流动提供屏障。例如，当施加至角膜时，器件最小化或者阻止从角膜的流体流动以及诸如从器件外表面到角膜的泪液的流体流动。器件提供流体密封并且选择形成器件的一个或者多个材料以最小化或者阻止跨越器件厚度的水分输送。

[0109] 在某些实施例中，形成由本公开提供的器件的材料特征在于高透氧性 (Dk，cm^2 •mL O_2/sec •mL •mm Hg)，例如从 100 至 500、从 200 至 500、从 250 至 450、从 300 至 400 以及在某些实施例中大约 350。在某些实施例中，由本公开提供的器件特征在于高透氧性 (Dk)，例如至少大约 250、至少大约 300、至少大约 350 以及在某些实施例中至少大约 400。

[0110] 器件可以包括具有低离子多孔性 (ionoporosity) 的硅酮水凝胶或者硅酮。例如，器件可以包括包括低离子渗透性的硅酮或者硅酮水凝胶，并且水的范围可以是从大约 5％到大约 35％，以使得 Dk 为 100 或者更大。在某些实施例中，低离子渗透性可以包括不超过大约 $0.25\times10^{-3}cm^2/sec$ 的 Ionoton 离子渗透性系数，例如不超过大约 $0.08\times10^{-3}cm^2/sec$。在某些实施例中，低离子渗透性包括不超过大约 $2.6\times10^{-6}mm^2/min$ 的 Ionoton 离子渗透性，例如不超过大约 $1.5\times10^{-6}mm^2/min$。

[0111] 器件 100 可以包括设置在器件的至少上侧（前表面）上的可湿润表面涂层 134，以使得患者的泪膜在器件上平滑并且患者能够看见。可湿润表面涂层可以包括用于患者舒适度的润滑涂层，例如用以在患者眨眼时润滑眼睛。可湿润涂层可以包括不超过大约 80 度的接触角度。例如涂层可以包括不超过大约 70 度的接触角度，并且接触角度可以在从大约 55 至 65 度的范围内用以为视力提供具有平滑泪层的表面。例如，可湿润涂层可以设置在器件上表面和下表面两者上。上表面可以包括在至少内部部分 110 上延伸的可湿润涂层。

[0112] 可湿润涂层 134 可以包括许多材料中的一个或者多个。例如，可湿润涂层 134 可以包括聚乙二醇 (PEG)，并且 PEG 涂层可以设置在 Parylene™ 上。可选地，可湿润涂层 134 可以包括等离子涂层，并且等离子涂层可以包括发光化学气相淀积 (LCVD) 膜。例如，等离子涂层包括碳氢化合物（例如 CH_4O_2）或者含氟碳氢化合物（例如 CF_4 涂层）中的至少一个。可选地或者组合地，可湿润涂层可以包括聚乙二醇 (PEG) 涂层或者 2- 甲基丙烯酸羟乙酯 (HEMA)。例如，可湿润涂层可以包括设置在 Parylene™ 涂层上的 HEMA，或者可湿润涂层可以包括设置在 Parylene™ 涂层上的 N- 乙烯基吡咯烷酮 (NVP)。

[0113] 器件 100 可以包括与角膜中央部分的曲率相对应的曲率基圆半径 R1。器件 100 包括当放置在角膜上并且眼睑分开时的第一配置 100C1 和当放置在角膜上并且眨动眼睑时的第二配置 100C2。第一配置 100C1 和第二配置 100C2 泵送器件 100 下方的泪液。

[0114] 器件 100 可以包括与将器件适配至角膜（例如天然的未消融角膜或者屈光手术（例如 PRK）之后的消融角膜）的许多合适形状中的一个或者多个相对应的下表面。器件 100 内部部分 110 的下表面可以与曲率基圆半径相对应。对于消融后角膜，器件可以抵抗变

形并且将上皮平滑超过大约 3mm 并且可以偏移以在较大尺寸（例如 6mm）上基本上顺应消融的角膜。器件可以包括与第一弯曲组合的第二弯曲，以使得下表面包括双弯曲表面。可选地，下表面可以与非球面表面相对应。例如，非球面表面可以包括扁圆形状和二次曲面系数以适配 PRK 后的眼睛。如此处描述的弯曲和非球面表面可以适配未消融的眼睛并且可以基于角膜未消融中央区域的曲率来选择器件。同样地，标识适配角膜的器件可以是有帮助的，例如通过从多个尺寸中选择一个器件。

[0115] 器件 100 可以包括具有光学组件 1100A 的内部部分 110。光学组件 100A 可以包括器件 100 的内部部分 110。光学组件可以具有从大约 5MPa 到大约 40MPa 范围内的模量，以及从大约 100μm 到大约 300μm 范围内的厚度以使得中央部分可以具有足够抵抗变形和平滑不规则以及矫正视力的刚度。例如，器件可以包括弹性体可拉伸材料，以使得器件可以拉伸以适配角膜。可以如此处描述的以很多方式形成具有从大约 4MPa 到大约 40MPa 范围内的模量的器件。例如，器件可以包括具有跨越角膜延伸的不均匀厚度的单片材料。器件可以以很多方式成形并且可以包括一种材料的单片，或者可以包括由两种类似材料组成的单片或者可以包括结合在一起的多种材料。

[0116] 图 1B1 示出了具有三弯曲轮廓以适配巩膜和角膜的器件 100。三弯曲轮廓可以用于适配未消融的天然眼睛，其中基圆曲率 R1 与角膜的光学使用的中央部分相对应。对于消融的角膜，基圆曲率 R1 可以与消融的角膜相对应。三弯曲器件可以包括具有有曲率半径 R1 的内部下表面的内部部分以及包括具有曲率半径 R1B 的外部下表面的外部部分。外部部分 130 可以包括具有第三曲率半径 R1C 的巩膜耦合部分 130，其尺寸适配位于巩膜上的结膜并且接触结膜以便抑制内部部分 110 的滑动。与实施例相关的工作表明耦合至巩膜可以改善角膜上的透镜对齐。

[0117] 具有三弯曲轮廓的器件 100 可以包括大小适配眼睛 2 的角膜和巩膜的尺寸。具有至少三弯曲轮廓的器件 100 可以包括如此处描述的内部部分 110 和外部部分 120。外部部分 120 可以包括具有曲率 R1C 的第三巩膜耦合部分 130，其成形为适配眼睛的巩膜，例如成形以接触眼睛的结膜以使得结膜位于巩膜与巩膜耦合部分 130 之间。如此处描述的，内部部分 110 可以包括尺寸 102 以及外部部分 120 可以包括尺寸 104。器件 100 可以包括成形以适配角膜的、在内部部分 110 的上部位置与外部部分 120 的外边界之间延伸的下垂高度 105。巩膜耦合部分 130 可以包括跨越 103 的尺寸。

[0118] 可以基于眼睛测量值调整尺寸 102、尺寸 104、尺寸 103、尺寸 105 和尺寸 105S 对眼睛的大小。尺寸 103 可以与巩膜的环形区域相对应，其跨越从大约 1 至 4mm 范围内（例如从大约 1.5 到 2mm 范围内）的距离从角膜缘延伸到巩膜耦合部分外边界。例如，可以测量眼睛的角膜缘尺寸以便与尺寸 104 相对应，并且测量的眼睛的角膜缘尺寸可以在从大约 11 到 13mm 范围内。尺寸 105 可以与从角膜顶点到角膜缘的眼睛高度相对应，并且尺寸 105S 可以与下垂高度相对应，其中器件外部位置耦合至覆盖巩膜的结膜。

[0119] 尺寸 102 可以与天然角膜的内部区域或者跨越消融的尺寸相对应。尺寸 102 可以与更刚性内部部分 110 相对应，尺寸可以小于跨越消融区的尺寸大约 0.5 到大约 2mm，以使得柔软并且不那么刚性的外部部分 120 在消融的边缘和上皮清创附近接触眼睛。

[0120] 可以确定部分 130 的曲率半径 R1C 以便适配眼睛，并且曲率半径 R1C 可以在大约 12mm±3mm 范围内。外部部分的半径 R1B 可以被适配至大约 ±0.5mm 内，例如大约 ±0.25mm

内。

[0121] 可以以很多方式确定器件 100 的尺寸，例如用角膜和巩膜的形貌测量值。可以用许多仪器测量角膜和巩膜形貌，例如用市场上可从 Bausch and Lomb 购得的 OrbscanTM 形貌系统，和市场上可从 Oculus 购得的 PentacamTM Scheimpflug 照相机系统以及市场上可购得的光学相干层析成像 (OCT)。消融轮廓可以与形貌结合以确定眼睛形状。

[0122] 可以基于可以临床确定的容差将器件 100 的尺寸的大小定为角膜和巩膜中的一个或者多个。

[0123] 外部部分 120 和巩膜耦合部分 130 可以包括硅酮或者水凝胶材料，例如硅酮或者硅酮水凝胶材料，以及内部部分 110 可以包括刚性材料 110M，例如如此处描述的第一材料 110M1 的第一层 110L1 与第三材料 110M3 的第三层 110L3 之间的第二层 110L2 和第二材料 110M2。

[0124] 如此处描述的器件的部分（例如内部部分和外部部分）可以包括第一部分与第二部分连接的接合，并且接合可以具有如此处描述的模量。器件可以包括具有耦合至外部透镜接合部分的中央透镜部分的接触透镜，该中央透镜部分具有至少大约 2psi-mm^2 的中央硬度，该外部透镜接合部分具有至少大约 5psi-mm^2 的透镜接合硬度。

[0125] 图 1B2 示出了根据本发明实施例具有三弯曲轮廓以适配巩膜的器件 100，弯曲轮廓的斜率对齐以便抑制弯曲部分边界处隆起。内部部分 110 包括光学组件 100A，以及外部部分 120 包括耦合组件 100B。耦合组件 100B 可以包括在光学组件 100A 下方延伸用于改善舒适度和支持光学组件的薄材料层 120M。包括耦合组件 100B 的外部部分 120 可以包括如此处描述的开窗 100F。内部部分 120 包括沿着下表面的第一半径 R1 和沿着上表面的第一前半径 R1A。外部部分 120 在与尺寸 102 相对应的边界处以与第一半径 R1A 对齐的第二半径 R1B 耦合至内部部分。外部部分 120 具有沿着前表面延伸的第二前半径 R1BA。包括沿着下表面的第二半径 R1B 以接触角膜的外部部分 120 可以在与眼睛角膜缘相对应的位置处（例如沿着与尺寸 104 相对应的边界）耦合至巩膜耦合部分 130。与实施例相关的工作表明在角膜接触部分与巩膜耦合部分的边界附近形成隆起可以比理想状态稍微多地减小上皮细胞迁移，并且抑制形成隆起的弯曲轮廓的对齐可以在角膜缘上提供平滑过渡并且可以减小对角膜缘的机械压力。巩膜接触部分 130 包括具有前曲率半径 R1CA 的上表面。

[0126] 内部部分 110 可以弯曲以适配消融的眼睛或者未消融的眼睛。可以以很多方式对巩膜耦合部分的模量和厚度进行配置以舒适地适配许多眼睛并且以便抵抗内部部分 120 的移动。巩膜耦合部分 130 的模量可以不超过大约 5MPa 并且厚度不超过大约 200μm（例如不超过 100μm），以便当放置在巩膜上时为了舒适度基本上拉伸并且抵抗内部部分的移动。

[0127] 巩膜耦合部分 130 的尺寸 103 可以与跨越从 1 至 4mm 范围内的距离从角膜缘延伸到巩膜耦合部分外边界的巩膜的环形区域相对应，以使得尺寸 103 可以从大约 12mm 至大约 16mm，例如从大约 14mm 到大约 16mm。

[0128] 部分 130 的曲率半径 R1C、厚度和模量可以被配置为适配眼睛以抵抗内部部分 110 的移动并且具有舒适度。曲率半径 R1C 的尺寸可以比巩膜和结膜的曲率半径小。例如，曲率半径 R1C 可以不超过大约 10mm，例如，当眼睛巩膜部分的曲率为例如至少大约 12mm 时，曲率半径 R1C 不超过大约 9mm。第三相对刚度可以包括不超过大约 4E-5Pa-m^3 以便当外部部

分放置在巩膜上时为了舒适度基本上拉伸并且抵抗内部部分的移动。

[0129] 具有曲率半径R1C的巩膜耦合部分的厚度可以改变，例如从大约100μm的厚度到渐尖边缘。

[0130] 图1B2-1示出了包括第二半径R1B的角膜接触部分下表面的斜率与包括半径R1C的巩膜耦合部分下表面的斜率对齐以使得对角膜缘的压力大体地减小。由高度R1BY和长度R1BX给出与第二半径R1B相对应的第二斜率，并且由高度R1CY和宽度R1CX给出与第三半径R1C相对应的第三斜率。第二斜率与第三斜率对齐以使得不会在与角膜缘相对应的位置处形成大量隆起。例如，第一斜率可以基本上等于第二斜率。内部部分110的斜率可以以类似方式在与尺寸102相对应的位置处与第二部分120的斜率对齐。

[0131] 图1B3示出了具有适配巩膜和角膜的三弯曲轮廓的图1B1的器件的渐尖边缘。巩膜耦合部分130可以包括凸缘120F，凸缘120F具有延伸距离120FW至倒角120FE的变窄锥形。可以沿着第一凸弯曲的下表面接合第二凸弯曲的上表面的外缘限定倒角120FE。沿着外缘的凸表面允许器件沿着结膜滑动并且变窄锥形允许器件的巩膜耦合部分基本上拉伸并且为了舒适度以减小的阻力耦合至巩膜和结膜。

[0132] 可以以很多方式确定器件100的尺寸，例如用角膜和巩膜的一个或者多个形貌测量值或者层析成像测量值。可以用许多仪器测量角膜和巩膜形貌，例如用市场上可从Bausch and Lomb购得的OrbscanTM形貌系统，和市场上可从Oculus购得的PentacamTM Scheimpflug照相机系统。可以用光学相干层析成像（在下文中，“OCT”）测量层析成像以便确定角膜缘和结膜的下垂高度，例如用市场上可从Zeiss/Humphrey购得的OCT测量系统。消融的轮廓可以与形貌结合以确定眼睛形状。

[0133] 图1B4示出了根据本发明实施例具有多弯曲轮廓以适配角膜、角膜缘和巩膜的器件100的平面图，弯曲轮廓的斜率对齐以便抑制弯曲部分边界处隆起。如此处描述的，器件100包括开窗100F和用于视力矫正的光学组件100A以及可以泵送泪液的外部耦合组件100B。

[0134] 图1B5示出了根据本发明实施例图1B4的器件和耦合至角膜、角膜缘和巩膜的相应弯曲部分的侧面剖视图。

[0135] 内部部分110包括可以包括材料110M的光学组件100A。外部部分120包括可以包括外部材料120M的耦合组件100B。内部部分110沿着与尺寸102相对应的边界耦合至外部部分。内部部分110的下表面具有与第一半径R1相对应的形状轮廓。外部部分120以第一外曲率半径R1B1耦合至内部部分，以使得斜率如此处描述的在与尺寸102相对应的位置处对齐。外部部分120包括耦合至第一外曲率半径R1B1的第二外曲率半径R1B2。第一外曲率半径R1B1耦合至第二外曲率半径R1B2，以如此处描述的，在与尺寸104A相对应的位置处对齐斜率。外部部分120包括耦合至第二外曲率半径R1B2的第三外曲率半径R1B3。第二外曲率半径R1B2耦合至第三外曲率半径R1B3，如此处描述的，在与尺寸104B相对应的位置处对齐斜率。

[0136] 第一外曲率半径R1B1、第二外曲率半径R1B2以及第三外曲率半径R1B3可以包括从患者群体确定的值。第一曲率半径R1可以包括基于患者群体确定的值。可选地或者组合地，第一曲率半径R1可以与消融后轮廓对应。

[0137] 第一外曲率半径R1B1、第二外曲率半径R1B2以及第三外曲率半径R1B3可以组合

或者用诸如二次曲面的非球面表面代替。可以根据第一外曲率半径 R1B1、第二外曲率半径 R1B2 以及第三外曲率半径 R1B3 确定二次曲面，以使得该二次曲面与从患者群体确定的值相对应。

[0138] 巩膜耦合部分 130 可以具有包括第一巩膜耦合曲率半径 R1C1 的下表面和具有第二巩膜耦合曲率半径 R1C2 的第二巩膜耦合部分。包括半径 R1C1 的第一巩膜耦合部分可以在与尺寸 104 相对应的位置处与第三半径 R1B3 对齐。包括半径 R1C2 的第二巩膜耦合部分可以在与尺寸 120FW 相对应的位置处与具有半径 R1C1 的第一巩膜耦合部分对齐，尺寸 120FW 与渐尖凸缘 120F 的内边界相对应。

[0139] 图 1B6 示出了根据本发明实施例图 1B4 的器件和上表面的相应弯曲部分的侧视图。上表面可以包括内部前曲率半径 R1A、第一外部前曲率半径 R1B1A、第二外部前曲率半径 R1B2A。巩膜耦合部分 130 可以包括第一前曲率半径 R1C1A 和第二前耦合曲率半径 R1C2A。

[0140] 图 1B7 示出了根据本发明实施例图 1B4 的器件的渐尖边缘。

[0141] 图 1C 示出了包括用均质材料模制的器件的器件 100，其中外部部分包括被配置为顺应角膜表面的厚度并且其中内部部分 110 包括被配置为平滑上皮和角膜的厚度。内部部分 110 包括光学组件 100A，以及外部部分 120 包括耦合组件 100B。内部部分 110 可以包括不超过大约 300 微米的厚度，例如不超过大约 200 微米。如此处描述的可以使用许多材料，并且器件可以包括一个或者多个材料。例如，器件可以包括单片材料，诸如具有从大约 0.1％到大约 10％范围内（例如不超过大约 1％）含水量的硅酮，以及从大约 5 到大约 90 范围内（例如从大约 40 到大约 85 范围内）的硬度 Shore A 硬度计参数。

[0142] 图 1C1 示出了具有包括内部厚度和内部材料 110M 的内部部分 110 和包括外部厚度和外部材料 120M 的外部部分 120 的器件 100，其中内部厚度大于外部厚度。内部材料 110M 可以包括许多材料并且可以包括光学透明的硅酮，例如具有树脂的硅酮。内部材料可以包括安置在模具中的硅酮，其中外部部分 120 围绕内部部分形成。内部部分可以包括类似于外部部分的硬度。外部部分 120 的外部材料 120M 可以包括类似于内部部分的材料。例如，外部材料 120M 可以包括硅酮以及内部材料 110M 可以包括硅酮。在内部部分和外部部分上这种类似材料的使用可以改善内部部分与外部部分的粘着。外部材料 120M 可以沿着内部部分 110（例如沿着内部部分 110 的下侧）延伸，以使得内部材料 110M 保持在外部材料 120M 的袋中。可选地，内部材料 110M 可以基本上跨越内部部分 110 的厚度延伸，以使得外部材料 120M 包括基本上环形形状，其中内部材料 110M 包括设置在环形内的圆盘形部分并且基本上从上表面涂层延伸到下表面涂层（当存在时）。

[0143] 图 1C2 示出了具有包括内部厚度和内部材料 110M 的内部部分 110 和包括外部厚度和外部材料 120M 的外部部分 120 的器件 100，其中内部厚度可以大于外部厚度并且外部材料 120M 围绕内部材料 110M 延伸。内部部分 110 包括光学组件 100A 并且外部部分 120 包括耦合组件 100B。器件 100 可以至少包括具有至少第二半径 R1B 的双弯曲器件。内部部分 110M 可以包括三个材料层，第一材料 110M1 的第一层 110L1、第二材料 110M2 的第二层 110L2 和第三材料 110M3 的第三层 110L3。第二材料 110M2 可以包括刚性材料，例如刚性透气材料、刚性硅酮或者刚性硅酮丙烯酸脂中的一个或者多个。第一材料 110M1 和第三材料 110M3 可以包括软性材料，例如软性弹性体、软性水凝胶或者软性硅酮，诸如软性光学透明

硅酮或者软性硅酮水凝胶中的一个或者多个。第一材料、第三材料和外部材料 120M 可以包括类似材料，以使得刚性材料 110M2 的第二层用第一软性材料 110M1、第三软性材料 110M3 以及在外围上用软性外部材料 120M 进行封装。在某些实施例中，第二刚性材料 110M2 包括类似于第一材料 110M1、第三材料 110M3 和外部材料 120M 中的每一个（例如各自可以包括硅酮）的材料，以使得器件 100 的相应部分可以用例如类硅酮的硅酮弹性体材料结合在一起。在某些实施例中，可以通过将刚性第二材料 110M2 放置在模具中并且在单片材料（包括第一材料 110M1、第三材料 110M3 和外部材料 120M）内进行封装在模具中形成器件 100，以使得第一材料 110M1、第三材料 110M3 和外部材料 120M 包括基本上相同的材料，例如硅酮弹性体。刚性第二材料 110M2 可以包括例如通过固化结合至第一材料 110M1、第三材料 110M3 和外部材料 120M 中的每一个的硅酮，以使得第一材料 110M1、第三材料 110M3 和外部材料 120M 包括结合至包括刚性硅酮的第二材料 110M2 的相同软性硅酮材料。

[0144] 包括由软性材料 120M 组成的软性外部部分 120、由软性材料 110M1 组成的第一层 110L1 和由软性材料 120M3 组成的第三层 110L3 的软性材料可以为患者提供改善的舒适度和愈合，并且在与如此处描述的开窗 100F 和巩膜耦合组件 130 以及外围部分 120P 和凸缘 120F 相结合时可以延长器件能够佩戴的时间量。软性材料可以偏移、弯曲或者凹进以便在包括刚性材料 110M2 的刚性部分矫正患者视力时至少部分地顺应眼睛的组织。跨越内部部分 110 的尺寸 102 的大小可以为基本上覆盖眼睛的入射瞳孔或者消融区中的一个或者多个。对于消融的眼睛，尺寸 102 的大小可以稍微小于消融尺寸（例如消融直径 20D），以便在内部部分 110M 用刚性材料 110M2 层矫正视力时，上皮可以向内生长并且接触软性第一材料 110M1 的层 110L1 而不会对刚性材料 120M2 实质性破坏。眼睑还可以在第三层 110M3 上移动用于改善舒适度。软性第一材料 110M1 和软性第三材料 110M3 可以包括例如软性弹性体、软性水凝胶或者软性硅酮，并且可以各自包括相同材料以便封装刚性第二材料 110M2 的第二层 110L2。

[0145] 包括由软性材料 120M 组成的软性外部部分 120、由软性材料 110M1 组成的第一层 110L1 和由软性材料 120M3 组成的第三层 110L3 的软性材料可以具有从大约 1MPa 到 20MPa 范围内的模量，例如在从大约 1MPa 到 5MPa 范围内。

[0146] 第二层 120L2 的材料内部材料 120M 和 120M2 可以具有从大约 5MPa 到大约 35MPa 或者更多范围内的模量，例如在下面的表格 A 中阐述的。例如，当材料 120M 包括硅酮弹性体或者材料 120M2 的层 110L2 包括硅酮弹性体时，模量可以在从大约 5MPa 至大约 35MPa 范围内，例如在从大约 20MPa 到 35MPa 范围内。

[0147] 器件 100 的层可以包括用以在放置在眼睛 2 上时提供治疗益处的尺寸。层 101L1 的厚度可以从大约 5μm 至大约 50μm（例如，在从大约 10μm 至大约 30μm 范围内），以便层 101L1 可以提供至少部分软性的舒适材料以容纳透镜。中间层 110L2 可以为例如从大约 20μm至大约 150μm，并且材料 M2 可以具有大于第一层 110L1 的第一材料 110M1 的模量，以便在偏移中间层时偏移眼睛上皮。第三层 110L3 可以在从大约 5μm 至 50μm 范围内（例如在从大约 10μm至大约 30μm 范围内），并且可以覆盖第二层 110L2 以便将第二层保持在器件 100 的内部部分 110 中。

[0148] 治疗器件 100 可以包括第一内部材料 110M 和第二外部材料 120M，其中外部部分 120 包括被配置为弹性地拉伸并且顺应角膜上皮或者结膜中的一个或者多个的硬度，并且

其中内部部分 110 包括被配置为平滑角膜以提供光学益处的第二硬度。外部材料 120M 可以包括如此处的许多材料。内部部分和外部部分中的每一个的 Shore A 硬度可以在从大约 5 到 90 范围内。例如，外部材料 120M 可以包括具有从大约 20 到大约 50 的 Shore A 硬度计硬度（例如从大约 20 至大约 40）的硅酮，并且内部材料 110M 可以包括具有从大约 40 到大约 90（例如从大约 50 到大约 90）的 Shore A 硬度的硅酮。外部部分包括外周 120P，外周可以包括例如当器件基圆半径小于角膜时邻近上皮以形成与上皮的密封的外围和圆周边缘结构。可以以很多方式成形外围和圆周边缘结构以限定围绕外周延伸的边缘以邻近上皮，例如用延伸至外周的边缘部分的锥形、延伸至外周的边缘部分的斜角或者延伸至外周的边缘部分的倒角中的一个或者多个。内部部分 110 可以包括内部厚度和内部材料 110M，并且外部部分 120 可以包括外部厚度和外部材料 120M，其中内部厚度基本上类似于外部厚度。

[0149] 可以用如此处描述的内部部分的许多配置使用邻近上皮的外围边缘结构。例如，内部部分可以包括 RGP 透镜材料，其具有接触和平滑角膜的低刚性表面和高刚性光学表面。可选地，内部部分可以如此处描述的顺应角膜。外部部分可以包括裙边，并且裙边可以包括邻近和密封角膜的外围边缘结构（例如倒角）。如此处描述的，可以用硬度和厚度中的一个或者多个确定包括边缘结构的外部部分的刚度以密封角膜。

[0150] 图 1C2A 示出了如图 1-2A 至 1B7 中的一个或者多个中在器件后表面上具有硅酮或者水凝胶材料层的器件。器件 100 可以包括如此处描述的设置在至少器件上侧上的可湿润表面涂层 134。硅酮或者水凝胶材料层可以包括硅酮或者水凝胶材料层的内部部分 110MHG 和硅酮或者水凝胶材料层的外部部分 120MHG。硅酮或者水凝胶材料层延伸到开窗以便将硅酮或者水凝胶材料耦合至开窗。硅酮或者水凝胶材料可以以很多方式耦合至开窗。例如，硅酮或者水凝胶材料层可以覆盖开窗，或者开窗 100F 可以延伸穿过硅酮或者水凝胶材料。延伸穿过硅酮或者水凝胶材料层的开窗 100F 可以促进如此处描述的泪液泵送。可选地或者组合地，覆盖开窗 100F 的后表面以将开窗 100F 耦合至硅酮或者水凝胶层可以促进治疗剂沿着硅酮或者水凝胶层（例如朝角膜中央部分）移动。例如，硅酮或者水凝胶可以沿着器件可偏移部分延伸以便在硅酮或者水凝胶层上施加至少一些压力以促进泪液或者治疗剂中的一个或者多个在患者眨眼时沿着硅酮或者水凝胶层移动。

[0151] 如此处描述的硅酮或者水凝胶层可以促进上皮再生并且可以提供与在消融上再生的上皮接触的软性表面以便促进如此处描述的光学组件下方的上皮再生，并且光学组件可以抵抗变形以便保护上皮并且提供促进上皮再生的环境。

[0152] 硅酮或者水凝胶材料可以包括如此处描述的硅酮或者水凝胶材料中的一个或者多个。沿着下表面延伸的硅酮或者水凝胶材料可以在器件放置在眼睛上时提高舒适度。硅酮或者水凝胶材料可以包括从大约 1μm 到大约 100μm 范围内的均匀厚度，例如从大约 2μm 到大约 50μm 并且在某些实施例中在从大约 5μm 到大约 20μm 的范围内。沿着后表面延伸的硅酮或者水凝胶材料可以包括与如此处描述的材料 100M、100M1、100M2、100M3 或者 120M 中的一个或者多个相结合的如此处描述的硅酮或者水凝胶材料中的一个或者多个。例如，材料 110M、110M1、110M2、110M3 中的一个或者多个可以包括诸如包括硅氧烷的硅酮弹性体的硅酮，并且硅酮或者水凝胶可以包括例如如此处描述的硅酮或者水凝胶材料的硅酮或者水凝胶。

[0153] 图 1C2B 示出了如图 1-2A 至 1B7 中的一个或者多个中的器件，该器件在器件后

表面上具有延伸小于跨越器件的最大距离的水凝胶材料层，以使得当放置在眼睛上时，器件的端部被配置为远离水凝胶层接合眼睛上皮并且抑制器件移动。在某些实施例中，材料120M可以耦合至眼睛表面（例如上皮）以便抑制器件移动。材料120M可以包括接合上皮以抑制移动的粘性发粘疏水材料（例如硅酮），并且可以用如此处描述的一个或者多个涂层对材料120M进行涂覆，例如用气相沉积。硅酮或者水凝胶材料可以以很多方式耦合至开窗。例如，硅酮或者水凝胶材料层可以覆盖开窗，或者开窗100F可以延伸穿过硅酮或者水凝胶材料。

[0154] 图1C2C示出了如图1-2A至1B7中的一个或者多个中的器件100，该器件在器件后表面上具有硅酮或者水凝胶材料的环形层120MHG以使得当放置在眼睛上时器件内部部分与远离硅酮或者水凝胶层的角膜接触并且器件外部部分与远离器件的角膜接触。与实施例相关的工作表明环形硅酮或者水凝胶层可以提供促进上皮沿着如此处描述的内部材料110M1后表面生长的环境，并且可以用具有例如比硅酮或者水凝胶小的厚度的材料对材料110M1的下表面进行涂覆。

[0155] 图1C3示出了具有三弯曲轮廓以适配巩膜并且在下表面上具有硅酮或者水凝胶材料层120MHG的器件，弯曲轮廓的斜率对齐以便抑制如图1B2中的弯曲部分的边界处隆起。硅酮或者水凝胶材料120M可以基本上跨越器件后表面延伸。硅酮或者水凝胶材料可以沿着下表面延伸小于跨越器件距离的距离以便提供没有硅酮或者水凝胶的器件部分以接合眼睛（例如可以包括角膜上皮或者结膜上皮中的一个或者多个的眼睛上皮）。可选地，硅酮或者水凝胶材料可以基本上沿着器件的后表面延伸，与跨越器件的距离相对应，以便在接合眼睛的器件外部部分上提供具有硅酮或者水凝胶材料的器件部分。

[0156] 图1C4示出了具有三弯曲轮廓以适配角膜、角膜缘和巩膜的器件的平面图，弯曲轮廓的斜率对齐以便阻止如图1B4中弯曲部分的边界处隆起，并且所述器件在下表面上具有硅酮或者水凝胶材料的，该硅酮或者水凝胶材料延伸小于跨越器件最大距离以将结膜远离硅酮或者水凝胶材料与器件接合。可选地，硅酮或者水凝胶材料可以基本上沿着器件的后表面延伸，与跨越器件的距离相对应，以便在接合眼睛的器件外部部分上提供硅酮或者水凝胶材料。硅酮或者水凝胶器件可以包括如此处描述的沿着下表面延伸的环形形状。

[0157] 图1C5示出了根据本发明实施例具有后端100FPE的开窗100F，所述后端100FPE覆盖有沿着器件100后表面延伸的硅酮或者水凝胶材料层29MHG。

[0158] 图1C6示出了根据本发明实施例延伸穿过硅酮或者水凝胶材料120HG层的开窗，该硅酮或者水凝胶材料层沿着器件100后表面延伸。

[0159] 图1D示出了根据实施例包括从开窗100F沿着器件下表面径向向外延伸的通道100FC的器件。

[0160] 图1E示出了根据实施例包括从开窗100F沿着器件下表面径向向内延伸的通道100FC的器件。

[0161] 图1F示出了测量响应于负载透镜的一部分的偏移的测试装置190。如此处描述的器件和合成物层的负载偏移可以用于确定器件的偏移和相应泵送。与实施例相关的工作表明接触上皮的外部器件或者内部器件中的一个或多个可以包括这样的刚度以便如此处描述的使得眨动眼睛用弹性变形充分地偏移器件以便推动来自器件下面的泪液。例如，如此处描述的，适合于覆盖消融的角膜并且提供泵送的器件内部部分120也非常适合于覆盖天

然未消融角膜以提供具有泪液泵送的视力矫正。外部部分 120 可以包括如此处描述的在眼睛眨动时充分偏移并且提供可以泵送器件（例如接触透镜）下方泪液的弹性变形的刚度。

[0162] 测试装置 190 可以包括具有孔径 192 的刚性支撑，以使得通过孔径 192 的器件 100 偏移可以被测量。孔径 192 具有跨越 194 的尺寸，其大小可以小于跨越内部部分 110 的尺寸，以便测量内部部分 110 响应于负载 196 的偏移 110D。偏移 110D 可以包括尖峰偏移，例如距离。负载 196 可以包括点负载或者在与直径 104 相对应的区域上分布的负载，例如来自器件下侧上的气体或者液体压力。器件可以包括与在眼睛上放置之前的器件形状相对应的第一配置 C1，并且器件可以包括当放置在眼睛上时的第二配置 C2，并且可以确定偏移器件 100 的力和 / 或压力的量以使得器件 100 在基本上不降低视力的情况下偏移并且以便平滑上皮。例如，器件可以稍微偏移使得视力下降不超过视敏度的大约 1 或者 2 线并且使得器件可以如此处描述的平滑上皮并且提供环境 100E。

[0163] 器件的模量和厚度可以用于确定如此处描述的用偏移器件平滑上皮的相应压力的量、器件 100 的相对刚度量以及跨越距离偏移器件 100 的相应力的量。

[0164] 可以基于与厚度的立方相乘的模量确定相对刚度的量。偏移量与跨越器件的偏移跨度的六次方、模量以及厚度的立方相对应。跨度与偏移的近似四阶关系可以允许器件如此处描述的在从大约 4mm 到 6mm 范围内至少部分地顺应消融轮廓，并且基本上抑制例如具有大约 3mm 或者更小直径的不规则。

[0165] 偏移可以用下列公式近似：

[0166] 偏移≈（常数）×（负载 × 跨度 ^{4}）/（模量 × 厚度 ^{3}）

[0167] 上述近似值对理解器件 100 的特性（例如具有基本上均匀厚度的内部部分）有用。基本上均匀的厚度可以包括在大约 ±25％内（例如在大约 ±10％内）均匀的厚度，以使得器件可以基本上顺应消融区表面面积的至少大多数并且抑制在与不超过消融表面面积的少数相对应的消融区的较小部分上的不规则。在某些实施例中，器件在具有至少大约 4mm 直径的区域上顺应并且抑制具有不超过大约 4mm 直径的区域上的不规则，例如抑制不超过大约 3mm 的区域上的不规则。例如，基于上述公式，偏移与跨度的四次方相关，以使得对于可比较负载，2mm 跨度将具有大约 4mm 跨度的 $1/16^h$ 偏移的偏移。类似地，3mm 跨度将具有大约 6mm 跨度的 $1/16^h$ 偏移的偏移。由于偏移与厚度的立方相关，因此双倍厚度可以使偏移降低大约 1/8。上述近似值可以与临床试验结合以确定根据如此处描述的的实施例适用于并入的厚度和模量。

[0168] 用于具有基本上均匀厚度的材料的未支持圆形跨度的偏移的公式是：

[0169] $$E_c = E_1\left(\frac{t_1}{t_1+t_2}\right) + E_2\left(\frac{t_2}{t_1+t_2}\right)$$

[0170] ″相对″刚度

[0171] $= E_c(t_1+t_2)^3$

[0172] $$y = \frac{3wR^4}{16Et^3}(5+v)(1-v)$$

[0173] $$w = \frac{y16Et^3}{(5+v)(1-v)3R^4}$$

[0174] 其中：

[0175] W＝在表面上均匀分布的负载，压力（Pa）；

[0176] R＝未支持材料的跨度（m）；

[0177] E＝杨氏模量（Pa）；

[0178] t＝厚度（m）；

[0179] v＝泊松比（无单位，假定为材料间的常量）；以及

[0180] y＝偏移（m）。

[0181] 用于偏移的公式在Theory and analysis of elastic plates，Junuthula Narasimha Reddy，201页公式5.3.43(1999)中进行了描述。

[0182] 尽管上述公式描述了用于基本平坦表面的相对刚度，但是公式能够近似弯曲表面并且本领域普通技术人员能够凭经验基于此处描述的教导（例如用有限元建模）确定偏移负载和相对刚度。

[0183] 表格A1.如此处描述的器件内部部分的材料、模量、厚度、相对刚度Dk/以及偏移负载。

[0184]

扣状物材料	均匀扣状物厚度 (um)	扣状物厚度 (m)	挠曲模量 (MPa)	挠曲模量 (Pa)	相对刚度 (Pa*m^3)	材料 Dk	Dk/t
刚性硅酮	250	2.50.E-04	35	35000000	5.47E-04	600	240
刚性硅酮	200	2.00.E-04	35	35000000	2.80E-04	600	300
刚性硅酮	150	1.50.E-04	35	35000000	1.18E-04	600	400
刚性硅酮	100	1.00.E-04	35	35000000	3.50E-05	600	600
刚性硅酮	50	5.00.E-05	35	35000000	4.38E-06	600	1200
示例性硅酮	293	2.93.E-04	20	20000000	5.03E-04	600	205
示例性硅酮	272	2.72.E-04	20	20000000	4.02E-04	600	221
示例性硅酮	250	2.50.E-04	20	20000000	3.13E-04	600	240
示例性硅酮	215	2.15.E-04	20	20000000	1.99E-04	600	279
示例性硅酮	200	2.00.E-04	20	20000000	1.60E-04	600	300
示例性硅酮	175	1.75.E-04	20	20000000	1.07E-04	600	343
示例性硅酮	150	1.50.E-04	20	20000000	6.75E-05	600	400
示例性硅酮	100	1.00.E-04	20	20000000	2.00E-05	600	600
示例性硅酮	50	5.00.E-05	20	20000000	2.50E-06	600	1200
enflufocon	25	2.50.E-05	1900	1900000000	2.97E-05	18	72

扣状物材料	均匀扣状物厚度 (um)	扣状物厚度 (m)	挠曲模量 (MPa)	挠曲模量 (Pa)	相对刚度 (Pa*m^3)	材料 Dk	Dk/t
A (Boston ES)							
enflufocon A	50	5.00.E-05	1900	1900000000	2.38E-04	18	36
enflufocon A	150	1.50.E-04	1900	1900000000	6.41E-03	18	12
hexafocon B (Boston XO2)	25	2.50.E-05	1160	1160000000	1.81E-05	141	564
hexafocon B	50	5.00.E-05	1160	1160000000	1.45E-04	141	282
hexafocon B	150	1.50.E-04	1160	1160000000	3.92E-03	141	94

[0185] 如表格A1所示，具有大约50μm厚度的RGP材料（例如enflufocon或者hexafocon）可以具有适合于上皮平滑并且由此至少部分地顺应消融基质的相对刚度。具有大约20MPa模量和大约250μm厚度的刚性硅酮将提供相对刚度3E-4，以及与具有大约50μm厚度和大约1900MPa模量以便提供大约2.4E-4的相对刚度的RGP材料类似的负载下的偏移。可以根据如此处描述的实施例组合如表格A1所示的市场上可购得的RGP透镜材料以便提供器件100。基于此处描述的教导，本领域普通技术人员可以基于模量和预期相对

刚度确定器件厚度。

[0186] 与如此处描述的根据临床研究的实施例相关的工作已经示出了具有大约3E-4(3×10^{-4}Pa-m^3)相对刚度的器件100的内部部分110可以是有效的，用以改善视力并且至少部分地顺应眼睛以便提供至少一些舒适度并且改善适配。已经用许多器件测量了许多眼睛并且与实施例相关的工作指示具有从大约1E-4到大约5E-4(Pa-m^3)范围内的相对刚度的内部部分110可以如此处描述的允许器件顺应消融并且平滑上皮。例如，内部部分110可以具有从大约2E-4到大约4E-4范围内的相对刚度，并且可以基于器件100的偏移相应地适配眼睛。

[0187] 相对刚度可以与器件100在眼睛上的偏移量相关。与实施例相关的工作指示大约3E-4相对刚度的内部部分110在放置在眼睛上时可以偏移大约±2D，以使得在平滑大约2mm或者3mm内直径时在跨越大约5mm或者6mm消融直径的大约±2D内顺应消融。具有大约1.5E-4相对刚度的器件100在放置在眼睛上时可以偏移大约±4D，以使得在平滑大约2mm或者3mm内直径时在跨越大约5mm或者6mm直径的大约±4D内顺应消融。

[0188] o-n，例如用于具有有多个材料的多个层的覆盖物。

[0189] 表格A3. 分层器件的相对刚度

[0190]

总厚度	分层材料	材料1（刚性）		材料2（软性）		合成		相对刚度 (Pa-m^3)
		厚度 (m)	模量 (Pa)	厚度 (m)	挠曲模量 (Pa)	厚度 (m)	合成模量 (Pa)	
270 μm厚	示例性硅酮覆盖	2.40E-04	2.00E+07	3.00E-05	2.00E+06	2.70E-04	1.80E+07	3.54E-04
	软性和硬性相等	1.35E-04	2.00E+07	1.25E-04	2.00E+06	2.70E-04	1.13E+07	1.99E-04
150 μm厚	示例性硅酮覆盖	1.20E-04	2.00E+07	3.00E-05	2.00E+06	1.50E-04	1.64E+07	5.54E-05
	软性和硬性相等厚度	7.50E-05	2.00E+07	7.50E-05	2.00E+06	1.50E-04	1.10E+07	3.71E-05

[0191] 当组合两个或更多个材料以提供两个或更多个层时，可以组合每个层的相对刚度以确定总合成刚度。例如，可以为具有第一材料的第一层110L1、第二材料M2的第二层110L2和第三材料110L3的第三层110L3的器件确定组合刚度，其中第一材料和第三材料可以是相同材料。

[0192] 加权平均系统可以用于将两层作为一个材料处理。可以组合每个材料的相对量和两个材料的模量以基于每个层厚度的加权平均确定合成模量。例如，可以组合90μm的20MPa材料层与10μm的5MPa材料层以将合成模量确定为

[0193] 20MPa×0.9+5MPa×0.1 = 18.5MPa

[0194] 此处描述的公式适合不同材料和厚度的许多层。

[0195] 基于合成模量，可以将合成模量乘以总厚度的立方，在本示例中为18.5MPa×100^3。尽管这些计算可以基于近似值，但是本领域普通技术人员可以进行模拟（例如有限元建模模拟）以确定如此处描述的相对刚度、压力以及偏移力和压力的量。

[0196] 器件 100 的一个或者多个层的折射率可以基本上与角膜折射率相对应。

[0197] 材料 110M1、110M2 或者 110M3 中的一个或者多个可以包括从大约 1.38 到大约 1.43 范围内的折射率以使得匹配角膜的折射率至大约 ±0.05 内。例如，材料 110M1 和 110M3 可以包括具有大约 1.41 折射率的光学透明软性硅酮弹性体，以及材料 M2 可以包括具有大约 1.43 折射率的光学透明刚性硅酮弹性体，例如可从 NuSil 获得。可选地，例如，材料 110M1 和材料 110M3 可以包括硅酮硅酮或者水凝胶以及材料 110M2 可以包括硅酮。

[0198] 尽管器件可以包括诸如与软性硅酮相结合的更刚性硅酮的类似材料，但是器件可以包括不相似材料。例如，RGP 材料可以与硅酮或者水凝胶结合，例如如此处描述的双弯曲或者三弯曲实施例。为了稳定性，器件可以至少延伸至角膜缘。RGP 材料可以例如根据表格 A1 包括第二材料 110M2 的第二层 110L2，并且水凝胶可以包括第一材料 110M1 的第一层 110L1 和第三材料 110M3 的第三层 110L3。水凝胶可以具有从大约 1.38 至大约 1.42 的折射率以使得匹配大约 1.377 的角膜折射率到大约 0.05 内，并且水凝胶可以包括例如市场上可从英国的 Vista Optics 购得的 HEMA，NVP、GMA、MMA、SiH、TRS、HEMA/NVP、MMA/NVP、HEMA/GMA 或者 SiH/TRS 中的一个或者多个。包括 HEMA/NVP、MMA/NVP 或者 HEMA/GMA 的水凝胶可以具有从大约 40％到大约 70％范围内的含水量以提供从大约 1.38 到大约 1.43 范围内的折射率。大约 40％的含水量与大约 1.43 的折射率相对应并且大约 70％的含水量与大约 1.38 的折射率相对应。包括 SiH/TRS 的水凝胶可以包括从大约 20％到大约 70％范围内的含水量以提供从大约 1.38 到大约 1.43 范围内的折射率。对于这些 SiH 水凝胶，大约 20％的含水量与大约 1.43 的折射率相对应并且大约 70％的含水量与大约 1.38 的折射率相对应。

[0199] 图 2A 示出了根据某些实施例包括放置在眼睑分开的眼睛上的接触透镜的器件 100。器件 100 放置在眼睛上以使得泪液 TL 在器件与角膜之间的器件的至少一部分下方延伸以提供腔室 100C。器件 100 可以适配在 K 上或者比角膜稍微平坦以提供腔室 100C。可选地或者组合地，外部部分 120 的凸缘 120F 和巩膜耦合部分 120S 可以包括比结膜更陡的角度，从而推动器件在内部部分 110 附近远离角膜以提供腔室 100C。器件 100 包括与从器件中央到巩膜耦合部分 130 的外周 120P 的提升距离相对应的下垂高度 105S1。为了患者看见物体，眼睑可以分开。

[0200] 图 2B 示出了眼睑闭合时图 2A 的器件的侧视图。

[0201] 图 2C 示出了根据实施例眼睑闭合的图 2A 的器件的正视图。眼睑可以随着上眼睑的向下运动 22A 和下眼睑的向上运动 22B 而闭合。眼睑的闭合在器件 100 上施加压力以使得器件 100 包括第二配置 100C2。第二配置 100C2 包括下垂高度 105 减小到第二下垂高度 105S2 以使得腔室 100C 体积减小并且推动从器件下方泵送的泪液 100TL。泵送的泪液 100TL 在外部部分 120P 下方径向向外流动并且通过开窗 100F（例如没有被眼睑覆盖的开窗）。眼睑的压力可以将器件 100 朝角膜 100 推动以使得降低腔室 100C 的体积。当包括凸缘 120F 的外部部分 120 随着弹性变形而偏移时，腔室 100C 的体积大体地减小。可选地或者组合地，与角膜相对应的外部部分 120 能够偏移以减小腔室 100C 的体积。在某些实施例中，包括光学组件 100A 的内部部分 110 可以随着眼睑的压力偏移以减小腔室 100 的体积。

[0202] 图 2D 示出了根据实施例眼睑睁开的图 2A 的器件的侧面轮廓。当眼睑随着上眼睑的向上运动 22C 和下眼睑的向下运动 22D 而缩回时，器件 100 能够回到具有第一下垂高度

105S1 的第一配置 100C1，以使得腔室体积增大。包括凸缘 120F 和巩膜耦合部分 130 的外围部分 120F 的外部部分 120 可以接触结膜以使得与结膜形成接触密封。与结膜的接触密封促进泪液 TL 流动通过开窗 100F 并且进入腔室 100C 中，以使得泵送的泪液 100TL 能够位于角膜与器件 100 之间。

[0203] 下眼睑的泪细流可以在眼睛闭合时向上移动以使得在眼睛表面上提供泪液，并且细流的至少一部分在眼睑彼此接触时能够耦合至上眼睑。在上眼睑随着移动 22C 向上移动并且下眼睑随着移动 22D 向下移动时，上眼睑在上开窗附近提供泪液 TL 以通过上开窗并且下眼睑能够在下开窗附近提供泪液 TL 以移动通过下开窗。

[0204] 重复眨动眼睛可以自然地发生，由此泵送覆盖物下方的泪液并且清洗器件下方的角膜和结膜。由器件提供的这种泵送和清洗能够延长器件能够被患者（例如具有正常未消融眼睛的患者）佩戴的时间量，并且可以促进例如 PRK 后眼睛中的上皮再生。

[0205] 图 2E 示出了根据实施例包括放置在眼睛上的接触透镜的器件，以使得器件在眼睑分开时由结膜和角膜的内部部分支持，器件与角膜外部部分分开以限定腔室。器件 100 可以在角膜内部部分处（例如在中央位置处）接触角膜。内部部分 110 的大小可以设定为如此处描述的例如以基于 K 适配来居中地适配角膜。包括凸缘 120F 和巩膜耦合部分 130 的器件外部部分 120 的大小可以设定为在内部部分 110 居中地接触巩膜时接触结膜，以使得通过在角膜外部部分与器件之间延伸的空隙在角膜外部部分上形成腔室 100C。在角膜外部部分上延伸的器件外部部分 120 可以具有比角膜小的曲率，以使得在内部部分 110 由角膜支持并且包括凸缘 120F 的外部部分 120 耦合至结膜时，角膜外部部分上的外部部分 120 可以形成腔室 100C。开窗 100F 可以位于器件上以与眼睑打开时空隙和腔室 100C 的位置相对应。外部部分 120 包括在眼睑打开时对足以形成腔室 100C 的偏移的抵抗，而在眼睑在外部部分上移动时对偏移不足的抵抗以使得外部部分在眼睑闭合时朝角膜移动并且减小空隙距离。

[0206] 器件 100 可以适配角膜以促进腔室 100C 的形成并且使得器件 100 包括在下面形成有腔室 100C 的初始配置 100C1。角膜可以包括与从角膜顶点延伸到角膜缘的提升距离相对应的角膜缘下垂高度 105L。角膜缘可以位于距眼睛测量轴径向距离 105RL 处。眼睛可以在距眼轴径向距离 105RC 处包括结膜下垂高度 105C。器件可以在与到角膜缘的径向距离 RL 相对应的位置处包括角膜缘下垂高度 105LC。器件可以在与结膜的径向距离 105RC 相对应的结膜接触位置处（例如沿着凸缘 120F）包括结膜下垂高度 105CC。在某些实施例中，器件在与角膜缘相对应的位置处的下垂高度 105LC 不超过角膜缘下垂高度 105L，并且器件在与结膜相对应的位置处的下垂高度 105CC 不超过结膜下垂高度 105C，以使得对角膜缘的压力减小。在器件放置在眼睛上时，包括凸缘部分 120F 的结膜耦合部分 130 可以偏移以使得结膜接触部分的下垂高度从结膜下垂高度 105CC 降低到结膜下垂高度 105C，使得器件下垂高度包括下垂偏移的下垂高度 105S2。

[0207] 图 2F 示出了图 2E 的器件在眼睑闭合时使得器件 100 包括具有减小体积的腔室 100C 的配置 100C2 的侧截面图。当眼睑闭合时，上眼睑和下眼睑在器件上施加压力以将器件朝结膜和角膜外部部分推动。角膜外部部分上的器件外部部分可以不具有对偏移的足够抵抗以使得器件外部部分朝角膜外部部分向下偏移。在器件外部部分与角膜外部部分之间延伸的空隙距离减小，以使得腔室 100C 的体积减小并且泵送的泪液 100TL 从腔室 100C 通

过开窗 100F 流动并且在包括凸缘部分 120F 的结膜接触部分 130 下方流动。上眼睑可以跨越瞳孔延伸以覆盖下级开窗和上级开窗 100F。上眼睑可以接触下眼睑以在眼睛睁开时在上面吸取细流的泪液，以使得细流的泪液可以通过下级和上级开窗吸取到腔室中。

[0208] 角膜外部部分上的器件外部部分的偏移可以由具有从大约 1.0E-6Pa-m^3 到大约 6E-4Pa-m^3 范围内（例如从大约 2.5E-6Pa-m^3 到大约 5E-4Pa-m^3）的相对刚度的器件提供。表格 A2 示出了可以基于此处描述的教导确定的与角膜外部部分相对应的外部部分 120 的对应范围和相对刚度的适当值，从而确定器件外部部分的相对刚度以在眼睑离开器件部分时提供对偏移的抵抗并且形成具有空隙的腔室，并且使得在眼睑覆盖器件部分时朝角膜偏移并且减小空隙和对应腔室体积。

[0209] 巩膜接触部分 130 耦合至结膜的偏移可以由包括不超过大约 2E-4Pa-m^3（例如不超过大约 1E-4Pa-m^3，并且在某些实施例中不超过大约 2E-5Pa-m^3）的相对刚度的巩膜接触部分 130 提供。表格 A2 示出了可以基于此处描述的教导确定的巩膜耦合部分 130 的对应范围和相对刚度的适当值，以便确定器件巩膜耦合部分的相对刚度，以在眼睑离开器件部分时提供对偏移的抵抗并且形成具有空隙的腔室并且使得在眼睑覆盖角膜外部部分上的器件外部部分时朝角膜偏移并且减小空隙和对应腔室体积。

[0210] 凸缘部分 120F 耦合至结膜的偏移可以由包括不超过大约 1E-4Pa-m^3（例如不超过大约 2E-5Pa-m^3，并且在某些实施例中不超过大约 2.5E-6Pa-m^3）的相对刚度的凸缘部分 130 提供。表格 A2 示出了可以基于此处描述的教导确定的外部凸缘部分 120F 的对应范围和相对刚度的适当的值，以便确定器件凸缘部分 120F 的相对刚度，以在眼睑离开器件部分时提供对偏移的抵抗并且形成具有空隙的腔室并且使得在眼睑覆盖角膜外部部分上的器件外部部分时朝角膜偏移并且减小空隙和对应腔室体积。

[0211] 图 2F1 示出了根据某些实施例图 2F 的器件在眼睑闭合时眼睛转动使得在泵送泪液时抑制器件沿着上皮滑动的侧视图。眼轴可以在上面转动以使得器件沿着上眼睑和下眼睑滑动。眼轴可以包括一个或者多个已知眼轴并且可以由本领域普通技术人员以很多方式确定。

[0212] 图 2G 示出了根据实施例图 2E 的器件在眼睑睁开时的侧视图。眼睑的睁开减小了压力并且允许角膜外部部分上的器件外部部分远离角膜移动。泪液 TL 可以通过开窗 100F 并且进入腔室 100C 中。包括部分 130 和凸缘 120F 的器件外部部分可以接触结膜以抑制泪流并且可以密封器件。

[0213] 图 2H 示出了根据实施例图 2E 的器件在眼睑位于中间位置时使得腔室包括中间配置 100C12 体积的侧视图。包括内部部分 110 的光学组件 100A 可以包括足够刚度和对偏移的抵抗以使得在器件包括外部部分 120 偏移以减小腔室 100C 体积的中间部分 100C12 时为患者提供视力。例如，患者可以将眼睑闭合至瞳孔边缘以偏移外部部分并且光学组件 100B 和内部部分 110 可以保持基本上不偏移以使得患者可以通过一个或者多个眼睛眼睑的部分接触内部部分 110 具有 20/20 或者更好（度量 6/6 或者更好）的视力。眼睑的打开可以增大腔室体积并且泵送泪液并且眼睑的闭合可以减小腔室体积并且泵送泪液。

[0214] 图 2I 示出了图 1C4 的器件放置在眼睛上，用硅酮或者水凝胶接触眼睛时的侧视截面图。器件 100 包括沿着器件后表面延伸的硅酮或者水凝胶材料层 120MHG，使得眼睛与硅酮或者水凝胶的至少一部分接触。器件 100 的尺寸可以设为形成至少部分地用硅酮或者水

凝胶材料层限定的腔室100C。开窗可以延伸穿过硅酮或者水凝胶层以提供如此处描述的泵送。可选地或者组合地，可以用硅酮或者水凝胶材料覆盖开窗后端以用硅酮或者水凝胶材料层将角膜耦合至开窗。用硅酮或者水凝胶材料层120MHG覆盖的开窗可以沿着器件可偏移部分定位以在例如眼睛眨动时促进水和治疗剂沿着硅酮或者水凝胶材料移动。硅酮或者水凝胶层可以包括将液体和治疗剂从开窗传送至角膜期望位置的介质，例如通过毛细作用将液体和治疗剂带到角膜中央位置。如此处描述的包括沿着下表面的延伸硅酮或者水凝胶层的器件可以适配未消融眼睛以提供屈光矫正或者如此处描述的适配消融的眼睛。

[0215] 根据实施例的临床试验已经示出了器件的弯曲部分可以根据患者群体的角膜曲率和下垂高度以及角膜缘下垂高度和结膜下垂高度与K值适配。

[0216] 下面在此示出的附录I根据如此处描述的教导和实施例提供了用于器件100的尺寸和适配参数。器件可以包括例如在此示出的系列A表格中的材料中的一个或者多个。根据此处描述的实施例，当器件放置在角膜上时，器件的尺寸和适配参数可以时提供泪液泵送。附录I的表格标识供例如陡峭K角膜、中度K角膜和平坦K角膜使用的器件。列出的K值能够基于群体标准，以使得器件在放置在眼睛上时提供如此处描述的泵送。器件可以用于未消融的眼睛或者消融的眼睛，并且器件能够至少部分地基于第一内部曲率R1进行标识。

[0217] 表格B1示出了具有跨越大约14mm直径的器件100并且能够例如如此处描述的基于K适配或者更平坦。表格列出了与角膜的中央消融部分相对应的R1。包括光学组件100A和内部耦合组件100B1的内部部分110具有跨越大约5mm延伸的尺寸R1，并且消融区可以更大，例如大约6mm。与半径R1B1相对应的部分具有跨越大约5-7mm的尺寸，并且曲率可以用与以屈光度(D)为单位的眼睛光焦度相对应的角膜曲率计值(K值)表示。与半径R1B2相对应的部分具有跨越大约7-9mm的尺寸。与半径R1B3相对应的部分具有跨越大约9-11mm的尺寸。与R1C1相对应的部分可以跨越大约11到13.5mm延伸，并且可以包括具有部分R1B3与部分R1C2之间的一个或者多个值的曲率，例如大约8mm与大约12mm之间(例如大约10mm)的曲率半径。与R1C2相对应的部分可以跨越大约13.5到14mm延伸。部分R1C2的下垂高度可以例如大约3.1到大约3.4mm。与R1C1相对应的部分可以如此处描述的以很多方式适配至角膜，例如用在内边界上与R1B3对齐并且沿着外边界与R1C2对齐的部分R1C1的正切，以使得如此处描述的抑制隆起形成。

[0218] 表格B2示出了具有跨越大约14mm直径的器件100并且能够例如如此处描述的基于K适配或者更平坦。表格列出了与角膜的中央消融部分相对应的R1。包括光学组件100A和内部耦合组件100B1的内部部分110具有跨越大约5mm延伸的尺寸R1，并且消融区可以更大，例如大约6mm。与半径R1B1相对应的部分具有跨越大约5-7mm的尺寸，并且曲率可以用与以屈光度(D)为单位的眼睛光焦度相对应的角膜曲率计值(K值)表示。与半径R1B2相对应的部分具有跨越大约7-9mm的尺寸。与半径R1B3相对应的部分具有跨越大约9-11mm的尺寸，并且这些值的范围从大约35.75到大约40，使得在外围部分处的每个值比表格B1的对应值稍微平坦。例如，表格B1列出了针对R1B3的如具有从大约36.75到大约41D范围的值。与R1C1相对应的部分可以跨越大约11到13.5mm延伸。与R1C2相对应的部分可以跨越大约13.5到14mm延伸。部分R1C2的下垂高度可以例如大约3.1到大约3.4mm。与R1C1相对应的部分可以如此处描述的以很多方式适配至角膜，例如用在内边界

上与 R1B3 对齐并且沿着外边界与 R1C2 对齐的部分 R1C1 的正切，以使得如此处描述的抑制隆起形成。

[0219] 表格 B3 示出了具有跨越大约 16mm 直径的器件 100 并且能够例如如此处描述的基于 K 适配或者更平坦。表格列出了与角膜的中央消融部分相对应的 R1。包括光学组件 100A 和内部耦合组件 100B1 的内部部分 110 具有跨越大约 5mm 延伸的尺寸 R1，并且消融区可以更大，例如大约 6mm。与半径 R1B1 相对应的部分具有跨越大约 5-7mm 的尺寸，并且曲率可以用与以屈光度 (D) 为单位的眼睛光焦度相对应的角膜曲率计值 (K 值）表示。与半径 R1B2 相对应的部分具有跨越大约 7-9mm 的尺寸。与半径 R1B3 相对应的部分具有跨越大约 9-10.5mm 的尺寸，并且这些值的范围从大约 36.75 到大约 41。与 R1C 相对应的部分可以跨越大约 13 到大约 16mm 延伸。部分 R1C2 的下垂高度可以例如小于大约 3.6mm，以使得放置在眼睛上时部分 R1C2 能够偏移。与 R1C1 相对应的部分能够如此处描述的以很多方式适配到角膜。

[0220] 表格 B4 示出了具有供未消融眼睛使用的曲率以如此处描述的泵送泪液的器件 100，例如用长期佩戴的接触透镜。器件 100 具有跨越大约 14mm 的直径并且能够例如如此处描述的基于 K 适配或者更平坦。表格列出了与角膜的中央消融部分相对应的 R1。包括光学组件 100A 和内部耦合组件 100B1 的内部部分 110 具有跨越大约 5mm 延伸的尺寸 R1。与 R1 相对应的内部部分的曲率具有与从大约 39D 到大约 48D 的光焦度相对应的曲率值，其可以基于未消融眼睛的群体数据并且与例如用于部分 R1B1 到 R1B3 以及 R1C1 和 R1C2 的曲率结合。与半径 R1B1 相对应的部分具有跨越大约 5-7mm 的尺寸，并且曲率可以用与以屈光度 (D) 为单位的眼睛光焦度相对应的角膜曲率计值 (K 值）表示。与半径 R1B2 相对应的部分具有跨越大约 7-9mm 的尺寸。与半径 R1B3 相对应的部分具有跨越大约 9mm 到 11mm 的尺寸。与 R1C1 相对应的部分可以跨越大约 11mm 到 13.5mm 延伸。与 R1C2 相对应的部分可以跨越大约 13.5 到 14mm 延伸。部分 R1C2 的下垂高度可以例如大约 3.1 到大约 3.4mm。与 R1C1 相对应的部分可以如此处描述的以很多方式适配至角膜，例如用在内边界上与 R1B3 对齐并且沿着外边界与 R1C2 对齐的部分 R1C1 的正切，以使得如此处描述的抑制隆起形成。

[0221] 尽管表格 B1-B4 举例列出了特定曲率值，但是本领域普通技术人员能够基于此处描述的教导和实施例确定许多曲率值并且曲率中的一个或者多个能够与非球面表面（例如具有二次曲面系数）的非球面表面结合。

[0222] 图 3A 示出了安置在具有上皮缺损 11 的眼睛 2 的角膜 10 上的器件 100。器件可以包括弯曲主体，例如成形为适配角膜的弯曲接触透镜主体。

[0223] 器件 100 的大小可以设定为覆盖消融轮廓和上皮缺损。内部部分 110 包括大小可以设定为跨越消融的大部分延伸的跨越尺寸 102，并且外部部分 120 包括大小设定为至少跨越上皮缺损延伸并且在缺损的相对侧接触上皮的跨越尺寸 104。

[0224] 跨越消融的大部分延伸的尺寸 102 可以延伸例如大约 6 到 8mm，并且大小可以设定为大于消融。尺寸 104 可以包括跨越例如大约 12mm 到 14mm，以延伸到角膜缘并且大小可以设定至例如患者的角膜缘。与实施例相关的工作表明大小设定为延伸到角膜缘并且圆周地围绕角膜缘的器件可以在角膜上居中。器件可以延伸以使得器件的外缘例如与设置在角膜缘外围的巩膜上的结膜接触，并且这种配置可以例如使透镜在角膜上居中。

[0225] 可以以很多方式对器件厚度进行大小设定和成形。器件的内部部分 110 包括厚度

106 并且器件的外部部分 120 包括厚度 108。内部部分的厚度 106 可以包括基本上均匀的厚度，以使得内部部分在放置在眼睛上之前（例如在保持在眼睛前面并且与角膜分开距离时）包括不超过大约 ±1D 的光焦度。可选地，内部部分的厚度可以改变，使得包括光焦度（例如用以矫正患者视力的光焦度）。

[0226] 再生上皮 12R 的平滑层 12S 可以基本上覆盖消融的轮廓。环境 100E 被配置为引导上皮再生并且平滑再生上皮。再生上皮包括厚度轮廓 12RP。

[0227] 上皮从限定边界 12E 朝消融轮廓 20 的中央向心生长以覆盖暴露的基质，如箭头 30 指示的。

[0228] 器件 100 可以包括内部部分 110 和外部部分 120。外部部分 110 可以被配置为在上皮缺损和消融的边缘附近形成与角膜的密封 100S，例如用软性顺应的材料（例如硅酮弹性体或者硅酮水凝胶）。内部部分 120 被安置在瞳孔上并且配置用于患者观看，并且可以包括大于外部部分的刚度，以使得在角膜愈合时平滑上皮的不规则。可选地，内部部分也可以包括等于或者小于外部部分刚度的刚度。例如，内部部分可以包括硅酮并且外部部分可以包括硅酮，并且内部部分可以包括更刚性硅酮或者更大厚度中的一个或者多个以使得内部部分可以比外部部分更刚性以平滑上皮。尽管内部部分可以比外部部分更刚性，但是内部部分可以足够地软性、柔性和顺应以至少部分地顺应基质中的消融轮廓 20，以使得当患者通过内部部分观察并且内部部分平滑上皮时，患者得到用消融轮廓 20 进行视力矫正的益处。与本发明实施例相关的工作表明再生上皮比消融轮廓 20 的底层基质更软，以使得内部部分可以被配置为，当内部部分例如如此处描述的用偏移压力平滑设置在内部部分下方的上皮时顺应消融轮廓 20 的形状。

[0229] 图 3B 示出了在放置具有上皮缺损的眼睛（例如具有 PRK 消融的眼睛）的角膜上之前的第一配置中的器件。器件 100 包括开窗 100F。开窗 100F 可以位于器件上以使得开窗远离上皮缺损布置以如此处描述的泵送器件下方的泪液。器件 100 可以包括具有曲率的基圆半径 R1 的内部部分 110，并且曲率的基圆半径可以比消融角膜稍微更长以使得器件在放置在角膜上之前可以比角膜更平坦。包括巩膜耦合部分 130 的外部部分 120 可以包括比角膜更陡的部分以减小对角膜缘的压力。例如，凸缘部分 120F 可以比结膜和巩膜的对应部分更陡以减小器件在角膜缘上的压力。

[0230] 可以以很多方式将基圆半径 R1 的大小设定到角膜。例如，基圆半径 R1 可以具有与消融后眼睛相对应的半径。

[0231] 器件 100 可以包括从大约 4MPa 到大约 35MPa 范围内的模量，以使得中央部分可以至少部分地顺应消融基质并且使得器件可以平滑消融角膜的角膜不规则和基质不规则。器件可以包括弹性体可拉伸材料，以使得器件例如能够拉伸以适配角膜。可以如此处描述的以很多方式形成具有从大约 4MPa 到大约 35MPa 范围内的模量的器件。例如，器件可以包括具有跨越消融角膜和未消融角膜的至少一部分延伸的基本均匀厚度的单片材料，并且单片材料可以包括诸如硅酮弹性体或者水凝胶的弹性材料。可选地，器件可以包括具有跨越消融角膜和未消融角膜的至少一部分延伸的不均匀厚度的单片材料。器件可以以很多方式成形并且可以包括一种材料的单片，或者可以包括由两种类似材料组成的单片或者可以包括结合在一起的多种材料。

[0232] 器件 100 可以包括如此处描述的在内部部分外部延伸的一个或者多个外部部分。

[0233] 图 3C 示出了放置在眼睛上的图 3B 的器件，该器件具有顺应消融基质组织并且平滑消融基质上的上皮的第二配置 100C2，以使得器件能够此处描述的泵送泪液。角膜包括可以具有对应曲率半径（例如半径 R2）以矫正视力的消融表面 20。消融轮廓 20 可以包括附加、替换或者组合的形状，与半径 R2 相对应，例如用以矫正眼睛像差的角膜中像差消融和角膜中散光消融，并且器件 100 的内部部分 110 能够顺应角膜的这些消融轮廓以使得当器件安置在角膜上时患者能够得到消融视力矫正的益处。例如，角膜消融轮廓 20 可以与曲率半径 R2 相对应，并且内部部分 110 可以从在放置前与曲率半径 R1 相对应的配置 100C1 平坦至基本上与消融轮廓 20 相对应的第二配置 100C2，以使得患者通过消融轮廓 20 的帮助进行观看。例如，第二配置 100C2 可以包括基本上与曲率半径 R2 相对应的曲率顺应半径 R12。与器件 100 的第一配置 100C1 相对应的轮廓显示为安置在角膜 10 上以图示器件轮廓从放置之前的配置 100C1 到安置在角膜上时的器件 100 的顺应配置 100C2 的变化。

[0234] 顺应器件 100 包括足够的刚度以在器件 100 安置在消融轮廓 20 上的角膜上时平滑上皮。上皮包括可以基本上与在清创上皮以消融角膜之前的上皮厚度相对应的外围厚度 12T。上皮还包括设置在消融轮廓 20 上的再生上皮 12R。器件 100 能够在第二配置 12C2 中顺应角膜时平滑上皮 12R。例如，能够在上皮沿着器件 100 内部部分再生时对设置在消融上的再生上皮 12R 的不规则 12I 进行平滑，以使得再生上皮 12R 的不规则 12I 比外围上皮的厚度 12T 更薄。

[0235] 如此处描述的与实施例相关的工作指示具有从大约 4MPa 到大约 35MPa 范围内的模量的至少部分顺应的器件能够至少部分地顺应消融基质并且平滑上皮和基质的不规则以如此处描述的改善视力。可以如此处描述的以很多方式形成具有从大约 4MPa 到大约 35MPa 范围内的模量的器件。

[0236] 图 4A 至 4H 示出了如此处描述的制造器件 100 的方法 400 和用于制造器件的装置。

[0237] 图 4A 示出了如此处描述的用以形成包括材料 110M 的器件 100 的光学组件 100A 的模具 600A。光学组件 100A 可以包括诸如硅酮的光学透明材料。光学组件可以包括如此处描述的模量和厚度以及对应刚度，以便提供视力和角膜的平滑。模具 600A 可以包括例如一个表面上的光学矫正和相对表面上的基圆曲率。利用步骤 410，可以在模具 600A 中形成光学组件 100A。

[0238] 图 4B 示出了模具 600B 用以形成包括图 4A 的光学组件和耦合组件 100B 的器件。光学组件 100A 可以放置在模具中并且耦合组件的可流动材料 120M 被注入到模具中以形成器件。包括放置在其中 D 刚性材料的固体内部组件在注入可流动材料之前。模具 600B 可以包括作为固体材料片安置在模具内的内部材料 110M，以及外部材料 120M，外部材料 120M 包括被注入到模具 600B 中并且围绕包括内部材料 120M 的预成型件固化的可流动材料。可以以很多方式围绕内部材料 100M 注入可流动材料。例如，内部材料 110M 可以包括如此处描述的内部部分 110 的刚性材料 110M2 的第二层 110L2，并且可以围绕第二材料 110M2 的上表面和下表面注入可流动材料以利用可流动材料形成第一材料 110M1 的第一层 110L1 和第三材料 110M3 的第三层 110L3，使得当固化时第一材料 110M1、第三材料 110M3 和外部材料 120M 各自包括基本上相同的软性材料。利用步骤 420，可以形成包括光学组件 100A 和耦合组件 100B 的器件。

[0239] 图 4C 示出了用以形成包括图 4A 的光学组件和器件的软性材料层的模具，以使得

光学组件可以位于两层耦合组件之间。光学组件 100M 可以从如图 4A 所示的模具移除并且放置在模具 600C 中。与层 110L3 相对应的可流动材料 M3 可以被注入到模具中并且固化。可以从模具 600C 移除包括层 110L2 和层 110L3 的部分形成的内部组件。利用步骤 430，可以形成包括两层的器件部分。

[0240] 图 4D 示出了根据本发明实施例用以形成器件并且具有包括为可流动材料注入而放置的刚性材料的固体内部组件的模具 600D。模具 600 可以包括作为固体材料片安置在模具内的内部材料 110M 和外部材料 120M，外部材料 120M 包括被注入到模具 600 中并且围绕包括内部材料 600 的预成型件而固化的可流动材料。模具可以上部和下部。在某些实施例中，可以通过将刚性第二材料 110M2 放置在模具中并且在单片材料（包括第一材料 110M1、第三材料 110M3 和外部材料 120M）内进行封装以在模具中形成器件 100，以使得第一材料 110M1、第三材料 110M3 和外部材料 120M 包括相同的材料，例如硅酮。刚性第二材料 110M2 可以包括例如通过固化结合至第一材料 110M1、第三材料 110M3 和外部材料 120M 中的每一个的硅酮，以使得第一材料 110M1、第三材料 110M3 和外部材料 120M 包括结合至包括刚性硅酮的第二材料 110M2 的相同软性硅酮材料。利用步骤 440，可以形成在第一材料 110M1 与第三材料 110M3 之间包括固体内部组件的器件。

[0241] 图 4E 示出了用能量在器件中形成开窗。利用步骤 450，可以用诸如机械能量或者电磁能量（例如光能）的能量 650 处理如在图 4B 或者图 4D 中描述的器件以形成延伸穿过器件的开窗。例如，开窗可以从模具移除并且机械地穿孔或者用激光能量消融以形成开窗。

[0242] 图 4F 示出了在器件后表面上旋转涂覆硅酮或者水凝胶材料。可以在器件后表面上沉积一定量的如此处描述的可固化硅酮或者水凝胶形成材料 660 并且以一定速率的转动 662 旋转，以使得涂层远离器件中央并且朝硅酮或者水凝胶材料的外边界移动。可以基于可固化材料 660 材料量和旋转速率确定硅酮或者水凝胶材料的外边界，并且可固化硅酮或者水凝胶材料可以被配制为提供如此处描述的期望厚度，例如当完全水合时从大约 1μm 到大约 100μm 范围内的基本均匀厚度。利用步骤 460，可固化硅酮或者水凝胶形成材料 660 可以被固化以在器件 100 下表面上提供硅酮或者水凝胶材料层。

[0243] 图 4G 示出了在其上形成有硅酮或者水凝胶材料的器件上的化学气相淀积。器件 100 可以放置在化学气相淀积腔室 670 中，并且用如此处描述的化学气相淀积的一个或者多个形式进行处理。利用步骤 460，可以用 CVD 涂覆器件 100 以在器件表面上提供可湿润材料。

[0244] 图 4H 示出了包括封装在容器 680 中的硅酮或者水凝胶材料 120HG 的器件 100。器件可以被消毒并且可以在容器 680 中湿封装或者干封装或者它们的组合。例如，器件可以在容器中放置于包括盐水的流体中。可选地，器件 100 可以例如干封装在容器 680 中。利用步骤 480，器件 100 可以放置在容器 680 上并且容器密封。

[0245] 应该理解在方法 400 中图示的特定步骤提供了制造根据本发明实施例的器件的具体方法。还可以根据可选实施例执行其它步骤序列。例如，本发明的可选实施例可以以不同顺序执行上面概述的步骤。另外，图示的单独步骤可以包括可以以适合于单独步骤的各种序列执行的多个子步骤。此外，可以根据具体应用添加或者删除额外步骤。本领域普通技术人员将认识到许多变化、修改和替换方案。

[0246] 制造包括接触透镜以泵送泪液的器件 100 的方法 500 可以包括下列步骤中的一个

或者多个：

[0247] 505- 提供用于光学组件第一模具

[0248] 510- 将第一可流动材料注入到第一模具中

[0249] 515- 固化第一可流动材料以形成第一光学组件

[0250] 520- 从第一模具中移除第一光学组件

[0251] 525- 在第二模具中放置第一光学组件

[0252] 530- 将第二可固化材料注入到第二模具中

[0253] 535- 固化第二可流动材料以形成第二组件

[0254] 540- 从第二模具中移除第二组件

[0255] 545- 在第三模具中放置第二组件

[0256] 550- 将第三可流动材料注入到第三模具中

[0257] 555- 固化第三可流动材料以形成器件

[0258] 560- 移除器件

[0259] 565- 对开窗进行钻孔

[0260] 570- 用可湿润材料覆盖

[0261] 可以由材料硬度、模量或者厚度中的一个或者多个确定模制器件的刚度和硬度。模制器件可以包括例如内部中央比外部外围更刚性的器件，并且中央可以比边缘更厚。例如，器件可以包括内部部分比外部部分更厚以使得内部部分比外部部分更刚性的单片器件。可选地或者组合地，可以模制光学透明的内部部分；将内部部分放置在模具中，并且对器件进行模制以围绕内部部分形成外部部分。例如，模制的内部部分包括如此处描述的材料 110M2 的层 110L2，并且围绕层 110L2 模制层 110L1 或者 110L3 中的一个或者多个。

[0262] 应该理解在方法 500 中图示的特定步骤提供了制造根据本发明实施例的器件的具体方法。还可以根据可选实施例执行其它步骤序列。例如，本发明的可选实施例可以以不同顺序执行上面概述的步骤。另外，图示的单独步骤可以包括可以以适合于单独步骤的各种序列执行的多个子步骤。此外，可以根据具体应用添加或者删除额外步骤。本领域普通技术人员将认识到许多变化、修改和替换方案。

[0263] 已经进行了并且构想了临床研究来示出根据此处描述的实施例随着眼睛的眨动泵送透镜下方的泪液。本领域普通技术人员可以凭经验确定如此处描述的器件 100 的特性以使得提供器件下方的泪液泵送以提供长期佩戴接触透镜或者用于在 PRK 之后的角膜上放置以改善视力并且促进上皮再生的器件中的一个或者多个。

[0264] 如此处使用的，相似的参考字符指示可以根据此处描述的教导和实施例进行组合的相似结构。

[0265] 在某些实施例中，提供了用于选择眼用透镜的方法。方法可以用于矫正患者眼睛的屈光误差，该眼睛具有由上皮提供屈光形状的角膜。在某些实施例中，用于选择眼用透镜的方法包括确定期望球光焦度以减轻患者眼睛的屈光误差的任何球面成分；以及从具有不同球光焦度的多个替换眼用透镜中标识与期望球光焦度相对应的眼用透镜。随后可以选择标识的眼用透镜并且应用于患者眼睛以矫正球面屈光误差。标识的眼用透镜具有与期望光焦度相对应的前表面，并且该前表面沿着眼用透镜内部部分延伸。

[0266] 眼用透镜具有用于矫正球面屈光误差的内部部分和用于接触光学组织的外围部

分。眼用透镜的内部部分是可变形的并且眼用透镜的外围部分是可变形的。眼用透镜的内部部分具有比外围部分的模量和刚度更高的模量和刚度。眼用透镜的外围部分具有适合于在光学区域外接合眼睛的形状以支持内部部分与眼睛光学区域对齐。在某些实施例中，外围部分被配置为接合眼睛的组织（例如上皮）并且防止或者最小化眼用器件相对于眼睛光学区域的移动。在某些实施例中，当眨动眼睛时，内部部分、外围部分或者内部部分和外围部分两者可以变形或者偏移。

[0267] 在某些实施例中，上皮的屈光形状跨越眼睛的光学区域延伸从而屈光误差包括散光和/或高阶光学像差。在这种实施例中，跨越光学区域邻近眼睛延伸的后表面可以包括或者可以不包括屈光形状以减轻散光和/或高阶像差。执行对期望的眼用透镜的选择以使得眼用透镜的外围部分具有维持眼用器件后表面与眼睛表面（例如上皮）之间的透镜体积的合适形状。在眼睛上安置眼用器件之前、期间和/或之后，透镜体积用泪液填充以使得眼用透镜的前部形状矫正屈光误差。因此，在某些方法中，执行对眼用透镜的选择以使得外围部分具有合适的形状使得泪液将填充后表面与眼睛屈光形状之间的透镜体积以减轻散光和/或高阶像差。在泪液设置在接触透镜与眼睛之间，并且透镜具有足够接近泪液的折射率的折射率的情况下，眼睛的屈光可以大大地独立于后表面形状和/或透镜体积，至少在后表面初始地接触透镜和/或接触透镜保持设置在眼睛上时如此。在某些方法中，标识眼用透镜独立于下组中的至少一个成员：散光度；以及散光关于眼睛光轴的定向，和/或高阶像差的强度和/或高阶像差的类型。由于如由眼睛后表面和屈光形状限定的透镜体积用泪液填充的结果，没有必要相对于眼睛定向眼用器件的轴或者位置。

[0268] 由本公开提供的眼用透镜还可以用于治疗远视。用于治疗远视的方法包括，例如在眼睛上安置眼用透镜以使得眼用透镜的内部部分设置在眼睛角膜的光学区域上，以及通过在眼用透镜外围部分与光学区域外的眼睛组织之间的接合以支持眼用透镜的内部部分。眼用透镜的内部部分和眼用透镜的外围部分可以是可变形的，从而内部部分具有比外围部分的模量和刚度更大的模量和刚度。为了矫正远视，内部部分包括远视减轻屈光形状。在某些实施例中，从添加区域、多焦形状、非球面形状以及上述任何组合中选择远视减轻形状。在某些实施例中，外围部分包括配置为接合眼睛组织（例如上皮）的一个或者多个曲率半径以防止或者最小化内部部分相对于角膜光学区域的移动。眼用透镜的前部部分和眼睛的后表面限定了配置为用泪液填充的透镜体积。为了促进泪液的填充和/或流动，可以在外围区域中设置延伸穿过外围区域厚度的多个开窗。设置开窗以结合眼用透镜的移动促进泪液传送通过透镜体积。使用由本公开提供的眼用透镜治疗远视的这种方法可以不需要眼用透镜相对于眼睛的精确对齐。

[0269] 类似地，还提供了用于矫正眼睛屈光误差（例如散光和/或球面像差）的方法，其中眼睛具有角膜，所述角膜由上皮提供跨越眼睛光学区域延伸的屈光形状。用于矫正屈光误差的方法包括在眼睛上安置眼用透镜以使得眼用透镜的内部部分设置在角膜光学区域上，其中安置的眼用透镜后表面邻近眼睛延伸，并且具有从上皮的屈光形状偏离的形状以使得在后表面与上皮之间设置透镜体积。眼用透镜的外围部分可以包括延伸穿过外围部分厚度并且允许泪液在透镜体积与眼用透镜（外部）表面之间通过的多个开窗。在这种实施例中，安置的眼用透镜的内部部分由眼用透镜外围部分与眼睛组织（例如光学区域外的上皮）的接合支持。外围部分被配置为支持眼用透镜内部部分以防止或者最小化内部部分相

对于眼睛光学区域的移动并且促进用泪液填充透镜体积。

[0270] 开窗可以设置在眼用透镜光学区域外并且朝向眼用透镜外围部分与眼睛组织之间的接合区域。眼用透镜的内部部分和外围部分是可变形的，例如，当眼睑移动时可变形和/或在局部突出上皮区域上可变形以抑制疼痛，从而内部部分具有比外围部分的模量和刚度高的模量和刚度。在某些实施例中，眼用透镜内部部分和外部部分的可变形性被配置以使得眨动眼睛引起泪液通过开窗流到透镜体积中并且从透镜体积中流出，并且在眼睛不眨动时内部部分保持矫正眼睛屈光误差的形状。

[0271] 在某些实施例中，外围部分包括配置为接合眼睛表面并且从而抵抗内部部分相对于眼睛光学区域的移动的一个或者多个曲率半径。例如，在某些实施例中，外围部分包括多个曲率半径，其中曲率半径从眼用透镜中央朝外围变得更小。在某些实施例中，外围部分与眼睛组织表面之间沿着接合区域的接合抑制眨眼期间内部部分相对于角膜的侧向移动。

[0272] 在某些实施例中，由本公开提供的矫正屈光误差的方法可以例如在用眼睛通过前表面观看时以在至少约0.5D、至少约1.0D并且在某些实施例中至少约1.5D的散光误差范围内基本上独立于透镜体积形状并且独立于眼用透镜围绕眼睛观看轴旋转定向的方式减轻屈光误差。

[0273] 由本公开提供的方法还包括重塑眼睛上皮形状的方法。在某些实施例中，用于光学地重塑上皮相对形状的方法包括在眼睛上安置眼用透镜以使得眼用透镜的内部部分设置在角膜光学区域上，其中安置的眼用透镜后表面邻近眼睛延伸并且具有从上皮的屈光形状偏离的形状以使得透镜体积设置在其间；以及由眼用透镜外围部分与光学区域外的眼睛之间的接合支持眼用透镜的内部部分以使得流体填充透镜体积，并且用眼睛通过眼用透镜前表面观看减轻了屈光误差。在重塑上皮形状以矫正眼睛屈光误差的方法中，眼用透镜可以（尽管未必总是）不包括开窗。眼用透镜后表面限定用于矫正球光焦度的屈光形状并且当安置在眼睛上时与眼睛表面限定透镜体积。随着时间的过去，眼睛的上皮和/或底层组织可以填充或者以其它方式占据设置在光学区域上的透镜体积中的一些、大部分或者全部。如同某些其它实施例一样，用于重塑上皮形状的眼用透镜包括可变形内部部分和可变形外围部分，从而内部部分具有比外围部分更高的模量和刚度并且外围部分被配置为接合眼睛组织表面并且抑制内部部分相对于角膜光学区域的侧向移动。

[0274] 在某些实施例中，重塑上皮屈光形状的方法在用眼睛通过前表面观看时以在至少约0.5D、至少约1.0D并且在某些实施例中至少约1.5D的散光误差范围内基本上独立于透镜体积形状并且独立于眼用透镜围绕眼睛观看轴旋转定向的方式减轻屈光误差。

[0275] 此外，当眼用透镜从眼睛移除时，光学重塑上皮在从眼睛移除眼用透镜之后至少约8小时、至少约24小时并且在某些实施例中至少约48小时减轻眼睛屈光误差至少约1D。

[0276] 由本公开提供的某些实施例包括用于矫正患者群体眼睛屈光误差的可选地可选择眼用透镜的集合。这种眼用透镜集合可以在此公开的方法中使用。多个替换眼用透镜具有表示不同屈光矫正的不同球光焦度。多个替换眼用透镜中的每一个包括与关联的期望球光焦度相对应的前表面，该前表面沿着眼用透镜的内部部分延伸，其中眼用透镜的内部部分是可变形的；以及眼用透镜的外围部分，从内部部分径向向外延伸，外围部分具有比内部部分的刚度低的刚度并且配置用于接合光学区域外的组织以支持内部部分与光学区域对齐。

[0277] 在某些实施例中，适用于由本公开提供的方法的眼用透镜包括内部部分和外围部分，内部部分配置为设置在眼睛角膜光学区域上的，外围部分配置为通过眼睛组织（例如设置在光学区域外的上皮）外围部分之间的接合支持眼用透镜内部部分。内部部分和外围部分是可变形的使得内部部分的模量和刚度比外围部分的模量和刚度高。在某些实施例中，外围部分包括一个或者多个曲率半径，借此外围部分接合眼睛表面组织以在眨眼期间防止或者减轻内部部分相对于角膜光学区域的移动。

[0278] 为了治疗远视，眼用透镜的内部部分包括沿着包括远视减轻屈光形状的内部部分延伸的表面。

[0279] 为了治疗球面屈光误差，沿着眼用透镜内部部分延伸的表面包括配置为矫正球面屈光误差的形状。

[0280] 在某些实施例中，内部部分可以配置为矫正诸如散光误差、多焦误差、高阶像差的非球面屈光误差，并且光学地定制诸如针孔 (pin holes) 的矫正功能。

[0281] 由本公开提供的某些实施例包括包括光学组件和耦合组件的器件，光学组件包括具有第一模量的第一材料，并且耦合组件包括具有第二模量的第二材料，其中第一模量大于第二模量。图 5 示出了包括光学组件 501 和耦合组件 502 的器件 500。

[0282] 在某些实施例中，器件 500 具有从约 9mm 至约 16mm 的直径 510，在某些实施例中，从约 10mm 至约 15mm，并且在某些实施例中，从约 12mm 至约 14mm。

[0283] 在某些实施例中，光学组件 501 包括从约 150μm 至约 500μm、从约 200μm 至约 400μm 并且在某些实施例中从约 250μm 至约 350μm 的中央厚度。

[0284] 在某些实施例中，光学组件 501 包括具有第一厚度 505 的第一材料和具有第二厚度 503 的第二材料。在这种实施例中，第二材料可以设置在光学组件 501 的内表面（例如，面向角膜的表面）上，并且可以是与形成耦合组件 502 的材料相同的材料。第二材料可以具有从约 5μm 至约 60μm、从约 10μm 至约 50μm 以及在某些实施例中从约 20μm 到约 40μm 的厚度 503。在这种实施例中，其中光学组件 501 包括两种材料，光学组件的总厚度可以从大约 100μm 至大约 550μm、从大约 200μm 至大约 450μm 以及在某些实施例中从大约 250μm 至大约 350μm。

[0285] 在某些实施例中，光学组件 501 包括具有从约 10MPa 到约 70MPa、从约 20MPa 至约 60MPa、从约 20MPa 至约 50MPa 以及在某些实施例中从约 30MPa 至约 40MPa 的模量的光学透明材料。

[0286] 光学组件 501 可以被配置为矫正视力或者可以不被配置为矫正视力。

[0287] 在某些实施例中，光学组件 501 包括从硅酮、硅酮水凝胶以及它们的组合中选择的材料。在某些实施例中，光学组件 501 包括硅酮，在某些实施例中，包括硅酮水凝胶并且在某些实施例中包括硅酮和硅酮水凝胶的组合。

[0288] 在某些实施例中，光学组件 501 包括从约 150μm 至约 500μm 的中央厚度、从约 3mm 至约 9mm 的直径、从约 7mm 至约 12mm 的曲率半径以及从约 20MPa 到约 50MPa 的模量。

[0289] 在某些实施例中，耦合组件 502 从光学组件 501 延伸至外部外围 504，其中与光学组件 501 接合处的厚度与跟光学组件 502 的接合处厚度相同或者相似，并且朝外部外围 504 逐渐地变尖，其中耦合组件在外围处的厚度从约 5μm 至约 60μm、从约 10μm 至约 50μm 以及在某些实施例中从约 20μm 至约 40μm。

[0290] 在某些实施例中，耦合组件 502 包括至少一个曲率半径 512。例如，在某些实施例中，耦合组件 502 包括单个曲率半径，并且在某些实施例中，耦合组件 502 包括超过一个曲率半径，诸如两个、三个、四个、五个、六个或者超过六个曲率半径。至少一个曲率半径可以例如从约 5mm 至约 15mm、从约 6mm 至约 13mm、从约 7mm 至约 12mm 以及在某些实施例中从约 6mm 至约 10mm。表征耦合组件 502 的一个或者多个曲率半径 512 小于光学组件 501 的曲率半径。

[0291] 在某些实施例中，耦合组件 502 包括具有从约 0.05MPa 到约 4MPa、从约 0.1MPa 至约 3MPa、从约 0.1MPa 至约 2MPa 以及在某些实施例中从约 0.2MPa 至约 1.5MPa 的模量的材料。

[0292] 在某些实施例中，耦合组件 502 包括从硅酮、硅酮水凝胶以及它们的组合中选择的材料。在某些实施例中，耦合组件包括硅酮，在某些实施例中，包括硅酮水凝胶，并且在某些实施例中包括硅酮和硅酮水凝胶的组合。

[0293] 在某些实施例中，耦合组件 502 包括延伸穿过耦合组件厚度的多个开窗 509。耦合组件 502 可以包括，例如从 1 个至约 30 个开窗、从 1 个至约 20 个开窗以及在某些实施例中从约 1 个到约 10 个开窗。开窗 509 可以具有提供泪液出口的任何合适形状。合适形状包括，例如圆形、椭圆形、卵形、矩形、正方形、长条形或者上述任何组合。多个开窗 509 中的每一个可以具有相同形状或者开窗中的至少一些可以具有不同形状。在某些实施例中，开窗具有从约 50μm 至约 700μm、从约 100μm 至约 500μm 以及在某些实施例中从约 200μm 至约 400μm 的最大尺寸（孔大小）。开窗中的每一个可以具有相同最大尺寸或者开窗中的至少一个可以具有不同尺寸。

[0294] 在某些实施例中，耦合组件 502 不包括开窗。

[0295] 在某些实施例中，耦合组件 502 包括从光学组件 501 的厚度到耦合组件外围 504 处约 30μm 厚度渐尖的厚度；从约 7mm 到约 12mm 的多个曲率半径；并且包括具有从约 0.1MPa 到约 2MPa 的模量的材料。在耦合组件 502 包括多个曲率半径 512 的实施例中，曲率半径从光学组件朝外围减小。

[0296] 包括光学组件 501 和耦合组件 502 的器件被配置为提供对眼睛组织（例如上皮）的密封从而抵抗光学组件在眼睛上的移动。

[0297] 图 6A-6C 示出了安置在散光眼上的各种透镜。对于图 6A-6C 中的每一个，左边图像示出了第一径向的配置并且右边图像示出了与非球面投射 608 相对应的第二径向的配置。在图 6A 中，与第一径向相对应的配置包括眼睛 601 的光学表面和软性屈光透镜 603，其提供在视网膜 605 上的聚焦。在图 6A 的右边图像中，第二径向与不在视网膜上的聚焦的不同屈光形状 602 相对应。软性的顺应眼用透镜 604 顺应形状 602 并且从而无法矫正非球面像差。图 6B 示出了使用硬性的非顺应眼用透镜 606 的非球面矫正。再次，第一径向和第二径向分别与不同光学形状 601 和 602 相对应。尽管硬性眼用透镜 606 矫正视力，但是透镜必须被定向以矫正眼睛的不对称轮廓。图 6C 示意性地示出了使用由本公开提供的眼用透镜和方法的非球面像差矫正（为简单起见，省略了光学区域外的眼睛和透镜的外围部分）。由本公开提供的眼用透镜具有配置为在眼睛 602 光学表面与眼用透镜 607 之间提供透镜体积的模量和刚度。为了矫正远视，眼用透镜被配置使得透镜体积用泪液填充。如可以理解的，无需定向眼用透镜 607 以矫正非球面光学像差。

[0298] 由本公开提供的器件可以在包括例如上皮愈合、散光的球面校正、远视解决方案、上皮再成形和干眼的若干眼科应用中用作平台。

[0299] 在某些实施例中，器件可以用于促进上皮愈合。上皮缺损会例如由于 PRK、丝状角膜炎、蒸发式干眼或者眼睛物理损伤而出现。在这些应用以及其它应用中，包括矫正视力的应用。

[0300] 当安置在患者眼睛上时，器件内表面和眼睛外表面（可以包括例如，角膜、Bowman 膜和 / 或上皮）能够限定腔室以促进愈合和 / 或上皮生长。在这种应用中，期望器件控制含湿量并且呈现高 Dk 以促进长期佩戴。使用由本公开提供的器件和方法，PRK 手术后的完全上皮再生能够在 PRK 之后约 48 小时、约 72 小时、96 小时并且对于某些患者在 1 周内出现。

[0301] 当用于角膜散光的球面校正时，由本公开提供的器件和方法呈现与透气性透镜相比改善的舒适度、与软性接触透镜相比增强的视力以及与复曲面和 GP 透镜相比减少的适配时间的优点。器件和方法在某些实施例中能够矫正大于 95％的散光误差、诸如由损伤或者 RK 引起的不规则散光以及早期圆锥形角膜。

[0302] 在某些实施例中，器件包括矫正视力的光学组件。因此，除球面校正以外，光学组件能够被配置为支持多焦、高阶像差或者定制诸如针孔的光学设计。

[0303] 在上皮再成形应用中，由本公开提供的器件和方法可以用于在佩戴期间对上皮再成形以及在器件从眼睛移除之后的一段时间内矫正视力。例如，为了矫正近视，器件可以用于引导上皮朝向眼睛外围并且创建更平坦的中央弯曲。为了矫正远视，器件可以用于引导上皮朝向眼睛中央并且创建更陡的中央弯曲。在某些实施例中，通过用非球面光学仪器进行模制，器件可以用于通过引导上皮朝向角膜上的一个或者多个期望位置引起多焦视力矫正。通过上皮再成形引起多焦能够对在远视和近视中矫正视力有用。

[0304] 在某些实施例中，由本公开提供的眼用透镜被配置为矫正诸如散光的屈光误差。透镜通过减小内部光学部分的挠曲以及通过佩戴期间维持透镜居中提供平滑的球面前表面并且最小化透镜引起的失真。减小内部光学部分的挠曲可以部分地通过增大内部部分的刚度以及创建眼泪透镜来完成。内部光学部分居中最小化了由倾斜光学器件引起的散光和棱镜效果并且还最小化边缘失真。

[0305] 由本公开提供的眼用透镜能够实现至少相当于软性复曲面接触透镜的视觉矫正并且实现与软性复曲面接触透镜相比优秀的舒适度水平。此外，由于由本公开提供的眼用透镜是径向对称的，适配至患者眼睛仅仅涉及适应球面校正，而不需要用于矫正圆柱形误差的透镜库存。

[0306] 由本公开提供的眼用透镜包括配置为设置在角膜光学区域上的内部光学部分以及从内部部分径向向外设置的外围或者外部部分。眼用透镜包括沿着透镜内部部分延伸并且在应用于患者眼睛时邻近眼睛的后表面。眼用透镜还包括沿着透镜外表面延伸并且与后表面相对的前表面。通常，透镜内部部分被配置为改善视力并且外围部分被配置为改善舒适度。然而，内部部分的配置能够在确定患者舒适度中起作用，并且外围部分至少部分地通过在佩戴期间维持内部光学部分在角膜光学部分上的居中增强视觉结果。

[0307] 透镜的内部光学部分被配置以使得后表面对眼睛的接合使后表面变形使得内部部分的后表面具有从上皮和角膜光学部分的屈光形状偏离的形状。眼用透镜内部部分的前

表面提供矫正患者视力的球面表面。

[0308] 在某些实施例中，透镜内部光学部分的特征在于从约 5mm 至约 10mm、从约 7mm 至约 9mm、从约 7.5mm 至约 8.5mm、从约 7.8mm 至约 8.2mm 以及在某些实施例中约 8mm 的直径。透镜的前内部部分特征在于没有圆柱形成分的基本球面轮廓。在某些实施例中，内部部分的特征在于从约 100μm 至约 900μm、从约 200μm 至约 900μm、从约 300μm 至约 700μm、500μm至900μm、从550μm至850μm、从600μm至750μm、从600μm至800μm、从600μm至 725μm 以及在某些实施例中从 600 至 700μm 的厚度。比较地，市场上可购得的用于矫正屈光误差的复曲面接触透镜的特征在于从约 150μm 至约 250μm 的厚度。

[0309] 在某些实施例中，内部部分包括形成透镜后表面的第一材料层以及形成透镜前表面的第二材料层。第一层很薄并且可以由与外围部分相同的材料组成。在某些实施例中，第一层为从 10μm 至 60μm、从 20μm 至 50μm 以及在某些实施例中从约 25 至约 35μm 的厚度。第一层保持内部部分。在某些实施例中，内部部分包括覆盖第二层前表面的第三层。再次，如同第一层一样，第三层很薄（具有例如与第一层类似的厚度），可以由与形成外围区域的材料相同的材料组成，并且保持第二层（也称为扣状物）。第二层或者扣状物提供透镜内部部分的大部分厚度。

[0310] 透镜内部光学部分的特征在于刚度，其中内部部分的刚度大于透镜外围部分的刚度。在某些实施例中，内部部分的特征在于从约 8E8MPa-μm^3 到约 2E10MPa-μm^3 的刚度。如此处公开的，刚度是材料的厚度和模量的函数。由本公开提供的眼用透镜采用软性、低模量的材料用于内部部分并且通过增大截面厚度获得增大的刚度。例如，在某些实施例中，形成内部光学部分的材料的模量从约 10MPa 到约 100MPa。人们相信软性的低模量材料改善患者舒适度。

[0311] 在某些实施例中，器件内部部分的刚度大于外部部分的刚度。例如，在某些实施例中，器件可以具有从约 1.2E-6Pa-m^3 至约 3.1E-3Pa-m^3、从约 1E-5Pa-m^3 至约 1E-3Pa-m^3 以及在某些实施例中从约 1E-4Pa-m^3 至约 1E-3Pa-m^3 的内部刚度。

[0312] 在某些实施例中，器件可以具有从约 5.4E-9Pa-m^3 至约 1.5E-4Pa-m^3、从约 1E-8Pa-m^3 至约 1E-4Pa-m^3、从约 1E-7Pa-m^3 至约 1E-5Pa-m^3，以及在某些实施例中从约 1E-6Pa-m^3 至约 1E-5Pa-m^3 的外部刚度。

[0313] 可以通过增大单个材料的厚度，使用对于相同厚度具有更高模量的材料或者通过具有不同模量和厚度的组合材料增大器件的部分的刚度。

[0314] 可以由包括该部分的材料的模量乘以厚度的立方近似器件的部分的刚度。当部分包括超过一个材料时，可以基于部分的平均模量乘以部分的厚度立方近似刚度。例如，包括具有 20MPa 模量和 90μm 厚度的第一材料以及具有 5MPa 模量和 10μm 厚度的第二材料的部分将具有 18.5MPa 的平均模量。然后，可以通过将平均模量乘以厚度的立方近似部分的刚度，对于本示例该刚度确定为 18.5E-6Pa-m3。尽管这些计算可以基于近似值，但是本领域普通技术人员可以进行模拟（例如有限元建模模拟）以更精确地估算相对刚度和/或可以测量压力和偏移力以确定器件各种部分的刚度。

[0315] 在某些实施例中，器件内部部分进一步地以可以基本上与角膜折射率相对应的折射率为特征，例如折射率可以在从约 1.38 到约 1.43 范围内以匹配角膜折射率到约 ±0.05 内。在某些实施例中，内部部分和外部部分特征在于从约 1.38 至约 1.43 的折射率以使得

匹配角膜折射率到约 ±0.05 内。

[0316] 在某些例如器件提供视力矫正的实施例中，内部部分可以以不同于角膜折射率的折射率为特征。

[0317] 在某些实施例中，内部部分包括具有从约 10MPa 到约 100MPa、从约 10MPa 至约 70MPa、从约 20MPa 至约 60MPa、从约 20MPa 至约 50MPa 以及在某些实施例中从约 30MPa 至约 40MPa 的模量的光学透明材料。在某些实施例中，内部部分包括以从约 20MPa 至约 30MPa、从约 22MPa 至约 28MPa 以及在某些实施例中约 25MPa 的模量为特征的材料。

[0318] 在某些实施例中，器件内部部分包括具有从约 1.2MPa 至约 25MPa 的模量、从约 100μm 至约 500μm 的厚度和从约 $1.2E^{-6}Pa-m^3$ 至约 $3.1E^{-3}Pa-m^3$ 的刚度的单个材料。在某些实施例中，器件外部部分包括具有从约 0.2MPa 至约 1.4MPa 的模量、从约 30μm 至约 500μm 的厚度（例如，从内部部分的厚度渐尖）和从约 $5.4E^{-9}Pa-m^3$ 至约 $1.5E^{-4}Pa-m^3$ 的刚度的单个材料。在某些实施例中，器件内部部分包括具有从约 1.2MPa 至约 25MPa 的模量、从约 100μm 至约 500μm 的厚度和从约 $1.2E^{-6}Pa-m^3$ 至约 $3.1E^{-3}Pa-m^3$ 的刚度的单个材料；以及器件外部部分包括具有从约 0.2MPa 至约 1.4MPa 的模量、从约 30μm 至约 500μm 的厚度（例如，从内部部分的厚度渐尖）和从约 $5.4E^{-9}Pa-m^3$ 至约 $1.5E^{-4}Pa-m^3$ 的刚度的单个材料。

[0319] 在某些实施例中，内部部分包括从硅酮、硅酮水凝胶、水凝胶以及上述任何组合中选择的材料，在某些实施例中，内部部分包括硅酮，在某些实施例中包括硅酮水凝胶，在某些实施例中，包括水凝胶，以及在某些实施例中包括硅酮和硅酮水凝胶的组合。

[0320] 图 7 示出了根据本发明某些实施例的器件的截面视图。图 7 所示器件具有包括中央曲率、中外围曲率和外围曲率的至少三弯曲轮廓。中央曲率指的是跨越器件中心大约 3mm 直径区域的器件内部部分的曲率。中外围曲率指的是距器件中央约 5mm 径向区域中的曲率。外围曲率指的是朝向器件边缘的曲率。在某些实施例中，如例如图 7 所示，从外围曲率区域到器件其它部分的过渡可以不是平滑的并且可以以角度为特征。图 7 示出了由本公开提供的器件 700 的中心线 701，具有中央区域 702 和中央区域 702 两侧上的中外围区域 704。在某些实施例中，中央区域 702 的直径 703 从约 5mm 至约 7mm、从约 5.5mm 至约 6.5mm 以及在某些实施例中为约 6mm。在某些实施例中，中外围区域 704 从中央区域 702 的边缘直径延伸到距中心线 701 的 5mm 处。因此，中外围区域的直径可以从约 7mm 至约 11mm、从约 7mm 至约 10mm、从约 6.5mm 至约 11mm、从约 6.5mm 至约 10mm 以及在某些实施例中从约 6mm 至约 10mm。在某些实施例中，器件的外围直径 707 可以从约 11mm 至约 16mm、从约 12mm 至约 15mm 以及在某些实施例中为约 14mm。如在此提到的，外部部分包括中外围区域（也称为中间部分）和外围部分。

[0321] 在某些实施例中，外部部分包括具有从约 0.05MPa 到约 4MPa、从约 0.1MPa 至约 3MPa、从约 0.1MPa 至约 2MPa 以及在某些实施例中从约 0.2MPa 至约 1.5MPa 的模量的材料。在某些实施例中，外部部分包括以从约 0.9MPa 至约 1.5MPa、从约 1MPa 至约 1.4MPa 以及在某些实施例中约 1.2MPa 的模量为特征的材料。在某些实施例中，形成外围部分的材料特征在于从约 0.01MPa 到约 10MPa、从约 0.01MPa 至约 8MPa、从约 0.01MPa 至约 5MPa 以及在某些实施例中从约 0.01MPa 至约 2MPa 的模量。在某些实施例中，器件包括由诸如以约 25MPa 的模量为特征的硅酮聚合物、硅酮水凝胶或者水凝胶的材料形成的内部部分，以及由诸如以约 1.2MPa 的模量为特征的硅酮聚合物或者硅酮水凝胶的材料形成的外部部分。

[0322] 在某些实施例中，外部部分包括从硅酮、硅酮水凝胶、水凝胶以及上述的任何组合中选择的材料。在某些实施例中，耦合组件包括硅酮，在某些实施例中，包括硅酮水凝胶、水凝胶，并且在某些实施例中包括硅酮、硅酮水凝胶和 / 或水凝胶的组合。

[0323] 在某些实施例中，形成包括内部和外部部分两者的器件的材料具有低含水量并且特征在于低透水性或者离子渗透性。在某些实施例中，含水量小于约 5％、小于约 4％并且在某些实施例中小于约 3％。在某些实施例中，形成器件的材料具有小于约 1％、小于约 0.6％并且在某些实施例中小于约 0.3％的含水量。在某些实施例中，材料小于约 $0.4\times10^{-6}cm^2/sec$、小于约 $0.2\times10^{-6}cm^2/sec$ 并且在某些实施例中小于约 $0.1\times10^{-6}cm^2/sec$。

[0324] 在某些实施例中，内部部分包括与外部部分不同的材料。在某些实施例中，内部部分和外部部分包括相同材料。在内部部分和外部部分包括相同材料的实施例中，可以由所使用聚合物的详细化学性质（诸如以不同交联密度为特征）实现不同模量。

[0325] 在某些实施例中，器件内部部分和器件外部部分包括以第一模量为特征并且沿着器件下表面延伸的第一材料；以及内部部分包括以第二模量为特征设置在第一材料前面的第二材料，第二模量大于第一模量。在这种实施例中，第一材料是薄层，配置为在应用于角膜时通过在角膜前表面与第一材料层之间缓冲提升器件舒适度。第二材料被配置为促进应用在眼睛上的器件前表面的有利的光学形状。

[0326] 作为反映内部部分刚度的度量，可以使用 ISO 18369-4 挠曲试验方法确定内部部分的挠曲。针对具有约 25MPa 的模量的硅酮材料的各种厚度确定内部部分或者扣状物的挠曲。

[0327] 外围部分从眼用透镜内部部分径向向外设置。通常，外围部分保持内部部分并且特征在于与内部与外围部分之间的对接处的内部部分大约相同的厚度，并且外围部分的厚度朝向外围边缘渐尖。在某些实施例中，外围边缘的直径从约 12mm 至约 16mm、从约 13mm 至约 16mm、从约 13.5mm 至约 15.5mm、从约 14mm 至约 15mm 以及在某些实施例中从约 14.2mm 至约 14.8mm。

[0328] 外围部分特征在于比内部部分低的刚度并且可以由具有比内部部分的模量低的模量的材料组成。在某些实施例中，形成外围部分的材料特征在于从约 0.5MPa 到约 2.0MPa、从约 0.8MPa 至约 1.7MPa、从约 1.0MPa 至约 1.4MPa 以及在某些实施例中为约 1.2MPa 的模量。

[0329] 外围部分被配置为在器件前表面与上皮之间提供泪流。在某些实施例中，外围部分包括从外围部分前表面延伸至后表面的多个开窗。在某些实施例中，多个开窗设置在距眼用透镜中央光轴半径处，例如在邻近内部部分与外围部分之间的对接的半径处。多个开窗可以对称地或者不对称地设置。开窗可以被配置为在眼睛眨动时在外围部分与上皮之间泵送泪液以使得维持在透镜后表面与上皮之间和 / 或跨越透镜前表面的泪层。在某些实施例中，多个开窗可以被配置为促进透镜从眼睛移除。在某些实施例中，多个开窗可以被配置为如果气泡截留在透镜下面时促进空气消散。在某些实施例中，多个开窗促进透镜应用于患者眼睛之后截留在任何透镜体积内的气泡的去除。多个开窗可以促进透镜从眼睛移除和气泡消散两者。在某些实施例中，与在佩戴没有开窗的可比较透镜的患者群体中的视觉结果相比，多个开窗改善在佩戴透镜的患者群体中的视觉结果的再现性。

[0330] 在某些实施例中，由本公开提供的眼用透镜的内部部分、外围部分或者内部和外

围部分两者径向对称。在某些实施例中，内部部分前表面和内部部分后表面径向对称。

[0331] 在由本公开提供的眼用透镜的某些实施例中，内部部分和外围部分被配置为响应于眼睛的眨动，允许透镜相对于眼睛移动。在这种实施例中，眼用透镜被配置使得内部光学部分在眨眼之后以角膜的光学部分为中心。在眨眼期间，内部部分、外围部分或者内部部分和外围部分两者可以变形和/或相对于角膜的中央光轴移动。当眼用透镜由患者佩戴时，至少部分地根据患者眼睛的形状和透镜配置，眼用透镜可以在眨眼期间移动或者仅呈现微移动。然而，在某些实施例中，透镜没有被配置为抵抗移动使得例如，透镜外围边缘没有被配置为固定地接合上皮或者巩膜以使内部部分抵抗相对角膜的移动。

[0332] 在由本公开提供的眼用透镜的某些实施例中，内部部分和外围部分被配置为在眼用透镜外围部分与上皮之间提供泪液流动。

[0333] 在某些实施例中，由本公开提供的眼用透镜包括朝向内部部分与外围部分之间的对接设置的加强环。图 15A 和 15B 示出了由本公开提供的并入加强环的眼用器件的透视图和截面视图。图 15A 和 15B 示出了具有中央光学部分 1501、外围部分或者裙边 1502 的眼用透镜，该外围部分或者裙边部分地通过沿着内部部分后表面设置的薄层 1706 机械地耦合至内部部分 1501。内部部分 1501 特征在于基本上均匀的厚度 1507 和大于外围部分 1702 的刚度的刚度。外围部分 1502 包括愈合 1505 和外围边缘 1504。朝向中央光学部分 1501 与外围部分 1502 之间的对接设置加强环 1503 并且在图 15A 和 15B 所示实施例中，加强环 1503 被嵌入在中央光学部分 1701 内。在图 15A 中，中央光学部分和外围部分的不同高度意在显示这些部分可以具有一个或者多个曲率半径。加强环可以设置或者嵌入在内部部分内，设置或者嵌入在外围部分内或者设置在内部与外围部分之间的对接处。加强环被配置为防止或者最小化诸如在眨眼期间内部光学部分由于眼睛上的力和/或眼睑的力的挠曲。加强环被设置在径向位置处以使得该环不妨碍视力。加强环可以是径向对称环并且可以被配置为在佩戴期间促进眼用透镜在角膜光学区域上居中。在某些实施例中，加强环可以由具有比形成透镜内部部分和外围部分的材料的模量更高的模量的材料制成。在某些实施例中，加强环可以由刚性、光学不透明或者半透明材料制成，例如聚酰亚胺、聚醚酮醚、聚醚酰亚胺、聚砜或者上述任何的组合。在某些实施例中，加强环可以由透明的刚性透气性聚合物制成，例如聚甲基丙烯酸甲酯、氟硅酮丙烯酸脂、硅酮丙烯酸脂或者上述任何的组合。在某些实施例中，加强环可以由金属制成，例如钛、不锈钢、钴钢或者上述任何的组合。在某些实施例中，形成加强环的材料具有与形成内部部分的材料相同的折射率。在某些实施例中，加强环可以具有例如从约 4mm 至约 12mm、从约 6mm 至约 12mm、从约 8mm 至约 12 以及在某些实施例中从约 8mm 至约 10mm 的内直径。在某些实施例中，加强环可以具有例如从约 0.1mm 至约 5mm、从约 1mm 至约 4mm、从约 2mm 至约 3mm 以及在某些实施例中从约 0.5mm 至约 2mm 的宽度。在某些实施例中，加强环可以具有例如从约 0.05mm 至约 0.5mm、从约 0.1mm 至约 0.4mm、从约 0.2mm 至约 0.3mm 以及在某些实施例中从约 0.2mm 至约 0.4mm 的厚度。加强环可以包括或者可以不包括用以增强环对形成中央光学部分的材料和/或形成透镜外围部分的材料的粘着的特征部件。例如，加强环可以包括凹面表面和/或凸圆表面、凹口、部分通孔、完全通孔、穿孔、锯齿形或者不规则边缘或者上述任何的组合。

[0334] 透镜外围部分可以朝向外围边缘渐尖。渐尖可以是连续或者不连续的。外围部分可以朝向外围边缘向外展开并且称为改变的倾斜的配置 (modified heeled

configuration)。由以基本上恒定厚度为特征的内部部分和外围部分的渐尖形状确定透镜的截面轮廓。在图 14A-14C 中示出了截面透镜轮廓的示例。通常,眼用透镜的截面形状被配置为矫正任何眼睛的屈光误差、将透镜在角膜光学部分上居中、促进透镜相对于眼睛的移动、在透镜后表面与上皮之间提供泪液流动以及为佩戴透镜的患者提供舒适度。透镜移动、提供流体层并且交换泪液的能力促进眼睛健康并且改善长期佩戴的舒适度。

[0335] 在表格 1 中呈现了由本公开提供的透镜内部部分的挠曲。表格 1 提供弯曲具有从 200μm 到 850μm 厚度的内部部分一定百分比的未弯曲直径需要的力 (gm)。对于 200μm、325μm 和 550μm 的厚度,位移内部部分 1%需要的力对于仪器来说太小以致于不能精确地测量。在表格 1 中还呈现了用于矫正屈光误差的标准 RGP 复曲面透镜的 150μm 厚的内部部分和 250μm 厚的混合复曲面透镜的结果。如表格 1 中呈现的结果所示,弯曲复曲面透镜比弯曲由本公开提供的具有类似厚度的眼用透镜明显需要更多力。这是至少部分由于制成复曲面透镜的材料的模量比制成当前设计的材料的模量更高。

[0336] 表格 1

[0337]

透镜设计	厚度 (μm)	弯曲力(gm)		
		1%	10%	20%
NXV 刚性硅酮	200	N/A	1.2	1.6
	325	N/A	4.9	6.7
	550	N/A	20	25
	600	8	35	36
	725	15	65	69
	850	20	101	96
RGP	150	6.4	29	39
软性复曲面	250	16	116	167

[0338] 在某些实施例中,使用 ISO 18369-4 挠曲试验方法弯曲内部部分 1%需要的力从约 0.5gm 至约 50gm、从约 1gm 至约 40gm 以及在某些实施例中从约 5gm 至约 25gm。

[0339] 在某些实施例中,内部部分特征在于从约 5.0E10Pa-μm^3 至约 5.0E8Pa-μm^3、2.0E10MPa-μm^3 至约 8E9MPa-μm^3、从约 1.8E10MPa-μm^3 至约 8.5E9MPa-μm^3、从约 1.6E10MPa-μm^3 至约 8.8E9MPa-μm^3 以及在某些实施例中从约 1.5E10MPa-μm^3 至约 9E9MPa-μm^3 的刚度。在这种实施例的某些中,内部部分的厚度从约 650μm 至约 850μm,在某些实施例中,从 200μm 至 800μm,以及在某些实施例中从 400μm 至 800μm。并且,在这种实施例的某些中,形成内部部分的材料的模量从约 20MPa 至约 30MPa、从约 23MPa 至约 27MPa 以及在某些实施例中约 25MPa。这可以与具有约 70μm 厚度、1.7MPa 模量和约 5.8E5MPa-μm^3 刚度的中央光学部件的软性复曲面透镜相比较。这也可以与具有 150μm 厚度、1,200MPa 模量和 4E9MPa-μm^3 刚度的中央光学部件的 RGP 透镜相比较。与软性复曲面透镜相比,在某些实施例中,由本公开提供的眼用透镜具有大于软性复曲面透镜中央部分刚度的从约 10,000 倍到 30,000 倍的中央光学部分的相对刚度。

[0340] 在某些实施例中,内部部分特征在于从 4E8MPa-μm^3 至 1E10MPa-μm^3、从 6E8MPa-μm^3 至 1E10MPa-μm^3、从 8E8MPa-μm^3 至 1E10MPa-μm^3、从 1E9MPa-μm^3 至 1E10MPa-μm^3、从 2E9MPa-μm^3 至 1E10MPa-μm^3、从 4E9MPa-μm^3 至 1E10MPa-μm^3 以及在某些实施例中从 6E9MPa-μm^3 至 1E10MPa-μm^3 的刚度。在这种实施例的某些中,内部部分的

厚度从约 100μm 至 900μm，在某些实施例中，从 200μm 至 800μm 以及在某些实施例中从 400μm 至 800μm。并且，在这种实施例的某些中，形成内部部分的材料的模量从约 20MPa 至约 30MPa、从约 23MPa 至约 27MPa 以及在某些实施例中约 25MPa。

[0341] 在某些实施例中，由本公开提供的眼用透镜特征在于至少约 6E9MPa-μm^3、至少约 8E9MPa-μm^3、至少约 1E10MPa-μm^3、至少约 1.2E10MPa-μm^3 以及在某些实施例中至少约 1.4E10MPa-μm^3 的中央刚度。可以基于所使用的一个或者多个材料的模量和厚度选择中央刚度以形成透镜的中央光学部分。通常，选择透镜中央部分的刚度以维持使用期间的球面前表面。在某些实施例中，光学部分中央的厚度为至少 200μm、至少 300μm、至少 400μm、至少 500μm、至少 600μm、至少 700μm 以及在某些实施例中至少 800μm。在某些实施例中，光学部分中央的厚度从 100μm 至 900μm、从 200μm 至 900μm、从 300μm 至 900μm、从 400μm 至 900μm、从 500μm 至 900μm、从 600μm 至 700μm、从 700μm 至 800μm 以及在某些实施例中至少 300μm 至 600μm。通常，具有更薄中央厚度的透镜佩戴更舒服。在某些实施例中，眼用透镜的内部部分由以小于 1,000MPa、小于 750MPa、小于 500MPa、小于 250MPa、小于 200MPa、小于 100MPa、小于 50MPa、小于 30MPa、小于 20MPa 以及在某些实施例中小于 10MPa 的模量为特征的材料形成。在某些实施例中，眼用透镜以至少约 6E9MPa-μm^3 的中央刚度、从 200μm 至 900μm 的厚度和从 10MPa 至 1,000MPa 的模量以及在某些实施例中从 10MPa 至 200MPa 的模量为特征。

[0342] 在某些实施例中，内部光学部分特征在于从 100μm 至 900μm 的厚度、从约 10MPa 至约 1,000MPa 和至少约 4E8MPa-μm^3 的刚度。在某些实施例中，内部光学部分特征在于从 100μm 至 900μm 的厚度、从约 10MPa 至约 600MPa 的模量和至少约 4E8MPa-μm3 的刚度。在某些实施例中，内部光学部分特征在于从 100μm 至 900μm 的厚度、从约 10MPa 至约 300MPa 的模量和至少约 4E8MPa-μm^3 的刚度。在某些实施例中，内部光学部分特征在于从 100μm 至 900μm 的厚度、从约 10MPa 至约 100MPa 的模量和至少约 4E8MPa-μm^3 的刚度。

[0343] 在某些实施例中，眼用透镜内部部分特征在于至少约 1E9MPa-μm^3 的中央刚度、从 100μm 至 800μm 的厚度和从 10MPa 至 800MPa 的模量以及在某些实施例中从 10MPa 至 200MPa 的模量。在某些实施例中，眼用透镜特征在于至少约 5E8MPa-μm^3 的中央刚度、从 100μm 至 800μm 的厚度和从 10MPa 至 800MPa 的模量以及在某些实施例中从 10MPa 至 200MPa 的模量。

[0344] 在某些实施例中并且至少部分地根据患者角膜的形状，眼用透镜后表面在佩戴期间可以不完全顺应上皮表面。因此，内部部分、外围部分或者内部部分和外围部分两者中的至少一部分通过在底层上皮的至少某些部分上形成拱顶以形成一个或者多个透镜体积。透镜体积可以用泪液填充。透镜在眨眼期间在眼睛上移动的能力和任何开窗（如果存在）可以循环透镜体积的泪液并且与眼睛其它部分交换泪液。

[0345] 在某些实施例中，内部部分和外围部分由硅酮、硅酮水凝胶、水凝胶或者上述任何的组合组成。

[0346] 图 8A 示出了当佩戴本公开的透镜时具有 1.25DC 至 2.00DC 未矫正圆柱形误差（低至中度散光）的患者群体中的平均球面透镜矫正视敏度 (LogMAR)。在最小值和最大值上方示出了对于透镜每个厚度的平均球面透镜视敏度 (LogMAR)。在图中还指示了测试的患者数量。适合于矫正低散光至中度散光的软性复曲面接触透镜以 ±0.15(±1SD) 的标准偏差

提供 20/20 视力（复曲面 SCL)0.00LogMAR。利用由本公开提供的内部部分厚度从 600μm 至 800μm 并且模量为 25MPa 的透镜获得类似的矫正视敏度。如通过针对由本公开提供的透镜的最小值和最大值反映的，矫正的视敏度中的偏差小于测试的复曲面软性接触透镜产品的偏差。

[0347] 图 8A 中呈现的结果在图 8B 中以不同格式表示以显示在佩戴具有由本公开提供的 600μm、725μm 或者 850μm 中央厚度的透镜时具有等于或者好于 20/25 视力或者具有等于或者好于 20/20 视力的患者百分比。在佩戴透镜之前，患者具有从 1.25DC 到 2.00DC 的未矫正圆柱形误差。如图 8B 所示，对于测试的每一个厚度，100％的患者具有 20/25 更好的视力。同样地，看到 20/20 或者更好的患者百分比随着透镜内部部分厚度而增大。

[0348] 在某些实施例中，用于矫正患者屈光误差的器件在由患者佩戴时提供至少 20/25 的视力或者 20/20 的视力，所述患者具有与从约 1.25DC 到约 2.00DC 的未矫正圆柱形误差相对应的低散光至中度散光。

[0349] 图 9A 和图 9B 示出了针对具有与中度散光至高度散光一致的 2.25DC 至 3.00DC 的未矫正圆柱形误差的患者的类似图 8A 和图 8B 中提供的那些的结果。在测量值的最小值和最大值上方示出了对于透镜每个厚度的平均球面透镜视敏度 (LogMAR)。测试的患者数量也在图中指出。对于具有中度至高度散光的患者，软性复曲面透镜提供 0.15±0.15(±1SD) 的平均球面透镜矫正视敏度 (LogMAR)。如图 9A 所示，由本公开提供的具有从 600μm 到 850μm 的中央厚度和 25MPa 的模量的眼用透镜提供相当于或者好于所测试复曲面软性接触透镜的平均球面透镜矫正视敏度。图 9B 中的直方图示出了对于具有中度散光至严重散光的患者，看到 20/25 或者更好的以及 20/20 的患者百分比随着透镜内部部分厚度的增大而增大。

[0350] 在某些实施例中，用于矫正患者屈光误差的器件在由患者佩戴时提供至少 20/25 的视力或者 20/20 的视力，所述患者具有与从约 2.25DC 到约 3.00DC 的未矫正圆柱形误差相对应的中度散光至高度散光。

[0351] 在某些实施例中，当佩戴由本公开提供的眼用透镜时，具有从 2.25DC 到 3.00DC 圆柱形误差的患者群体中的平均矫正视敏度是 0.1±0.15LogMAR 或者更好。

[0352] 在某些实施例中，当佩戴由本公开提供的眼用透镜时，具有从 1.25DC 到 2.00DC 圆柱形误差的患者群体中的平均矫正视敏度是 0.0±0.15LogMAR 或者更好。

[0353] 由本公开提供的眼用透镜被配置为提供相当于或者好于 RGP 和软性复曲面透镜的屈光矫正并且提供增强的舒适度。在图 10A 中，将由本公开提供的透镜的舒适度与市场上可购得的软性复曲面接触透镜的舒适度相比较。通过要求患者根据从 1 到 10 的度量 (10 分反映极限舒适度）对佩戴特定透镜时感受的舒适度水平进行评价来确定舒适度分数。在 ±1SD 的误差条上方示出了针对透镜每个厚度的平均舒适度分数。测试的患者数量也在图中指出。将佩戴本公开的具有从 275μm 到 850μm 内部厚度的透镜的患者的平均 (±1SD) 舒适度分数与五个 (5) 不同软性复曲面接触透镜设计 A-E 的舒适度分数相比较。在透镜应用于眼睛之后 30 分钟内获得当前透镜的结果。对于 275μm 厚度的透镜，还在一天的结束确定了舒适度。在应用到眼睛之后一个星期或者一天的结束时确定软性复曲面接触透镜的结果。最好的软性复曲面接触透镜在佩戴一周之后提供 8.3(±1.12) 的平均舒适度分数。由本公开提供的透镜利用呈现更好舒适度的更薄透镜提供增强的舒适度分数。

[0354] 在某些实施例中，在佩戴器件至少一天或者至少一周之后，用于矫正屈光误差的器件在患者群体中呈现至少 6.5、至少 7.5、至少 8 或者至少 9 的平均舒适度水平。在某些实施例中，在佩戴器件至少 30 分钟之后，用于矫正屈光误差的器件在患者群体中呈现至少 6.5、至少 7.5、至少 8 或者至少 9 的平均舒适度水平。

[0355] 在图 10B 中呈现了针对 600μm、725μm 和 μm 的内部区域厚度，感受等于或者大于 8 的舒适度水平或者等于或者大于 9 的舒适度水平的患者百分比。结果大体上表明对于具有大约 725μm 和更小厚度的透镜感受高舒适度的患者百分比增大。

[0356] 在某些实施例中，由本公开提供的眼用透镜不增大接触透镜相关的不良事件（诸如角膜溃疡、细菌性角膜炎和虹膜炎）的风险。

[0357] 图 11 是用于按照 ISO 18369-4 测试接触透镜内部部分或者扣状物的挠曲的测试设备的示意图。

[0358] 图 12 是针对由本公开提供的某些眼用透镜示出了厚度与挠曲之间的关系图表。在图 12 中示出了弯曲具有从 200μm 到 800μm 厚度的透镜的中央部分或者扣状物 10％需要的力 (gm)。

[0359] 图 13 是示出了弯曲透镜的内部部分或者扣状物 1％需要的力 (gm) 的直方图。将由本公开 (NXV) 提供的具有从 600μm 到 850μm 中央厚度的透镜的挠曲与用于治疗散光误差的刚性透气性 (RGP) 透镜和软性复曲面接触透镜 (A) 的挠曲相比较。

[0360] 由本公开提供的器件和方法还可以用于解决干眼。在这种应用中，器件材料包括具有低含水量和低吸水性的材料（例如硅酮），可以控制从眼睛蒸发的水并且维持眼泪或者润滑液蓄积。

[0361] 示例

[0362] 进一步地参考下列示例说明由本公开提供的实施例，其描述了由本公开提供的某些眼用器件的使用。可以在不背离本公开范围的情况下实施对材料和方法两者的许多修改，是对本领域技术人员是明显的。

[0363] 示例 1

[0364] 针对具有近视的受试需要光学矫正 -2.63 屈光度 (OD) 和 -2.13 屈光度 (OS) 特征的受试在两只眼睛上佩戴眼用透镜约 40 小时（非常粗略地）。在表格 1 中提供了眼用器件的内部曲率半径和外围曲率半径。在约 40 小时之后，眼用透镜被移除并且在各种时间确定需要矫正视力的光学矫正量（屈光度）。在表格 2 中呈现了在从受试移除眼用透镜之后需要光学矫正（屈光度）的量。

[0365] 表格 2. 佩戴眼用透镜之后需要的光学矫正的量（屈光度）。

[0366]

		眼用透镜的曲率半径		眼用透镜移除之后的时间						
	（在覆盖佩戴之前）需要矫正的量	内部弯曲（度数）	外部弯曲（度数）	5分钟	2小时	4小时	8小时	24小时	30小时	48小时
受试 #1 OD	-2.63	39.5	43.0	-0.63	+0.13	+0.13	NM	-0.50	-0.75	-1.25
受试 #1 OS	-2.13	39.5	41.5	-0.63	-0.13	NM	NM	0.00	0.00	-2.38

[0367] *NM =没有测试结果

[0368] 示例 2

[0369] 针对具有远视的受试需要光学矫正 +0.13 屈光度 (OD) 和 +0.25 屈光度 (OS) 特征的受试在右眼上佩戴眼用透镜约 35 小时（非常粗略地），并且在左眼上佩戴约 17 小时（非常粗略地）。在表格 2 中提供了眼用器件的内部曲率半径和外围曲率半径。在大约指定数量的小时之后，眼用透镜被移除并且在各种时间确定需要矫正视力的光学矫正的量（屈光度）。在表格 3 中呈现了在从受试移除眼用透镜之后需要光学矫正的量（屈光度）。

[0370] 表格 3 佩戴眼用透镜之后需要的光学矫正的量（屈光度）。

[0371]

		眼用透镜的曲率半径		眼用透镜移除之后的时间						
	（在覆盖佩戴之前）需要矫正的量	内部弯曲（度数）	外部弯曲（度数）	5分钟	2小时	4小时	8小时	24小时	30小时	48小时
受试 #2 OD	+0.13	39.5	43.0	-2.38	-3.13	-3.37	-2.00	NM	NM	NM
受试 #2OS	+0.25	39.5	41.5	-1.00	-1.25	NM	NM	0.00	NM	NM

[0372] *NM =没有测试结果

[0373] 虽然为了理解清楚，通过示例的方式描述了一些示例性实施例，但是本领域的技术人员将意识到，可以采用各种修改、适应和变化。从而，本发明的范围应当仅由所附权利要求限定。

[0374]

附录 1
表格 B1

14mm 多弯曲设计	R1 中夹 BC (D)	R1B1 5-7mm K (D)	R1B2 7-9mm K (D)	R1B3 9-11mm K (D)	R1 C2 13.5-14mm K (D)	下垂 mm	直径
陡坡 K	36.5	43.50	42.25	39.50	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
中度	36.5	42.00	40.75	38.25	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
平坦 K	36.5	40.50	39.25	36.75	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
陡坡 K	38.5	44.25	43.00	40.25	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
中度	38.5	42.75	41.50	39.00	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
平坦 K	38.5	41.25	40.00	37.50	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
陡坡 K	40.5	45.00	43.75	41.00	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
中度	40.5	43.50	42.25	39.75	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
平坦 K	40.5	42.00	40.75	38.25	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm

[0375]

表格B2

更平坦的外围设计

14mm 多弯曲设计	R1 中央 BC (D)	R1B1 5-7mm K (D)	R1B2 7-9mm K (D)	R1B3 9-11mm K (D)	R1C2 13.5-14mm K (D)	下垂 (mm)	直径
陡增 K	36.5	43.50	42.25	38.50	<12mm BC (140 级未厚)	3.1-3.4	13.8-14.1mm
中度	36.5	42.00	40.75	37.25	<12mm BC (140 级未厚)	3.1-3.4	13.8-14.1mm
平坦 K	36.5	40.50	39.25	35.75	<12mm BC (140 级未厚)	3.1-3.4	13.8-14.1mm
陡增 K	38.5	44.25	43.00	39.25	<12mm BC (140 级未厚)	3.1-3.4	13.8-14.1mm
中度	38.5	42.75	41.50	38.00	<12mm BC (140 级未厚)	3.1-3.4	13.8-14.1mm
平坦 K	38.5	41.25	40.00	36.50	<12mm BC (140 级未厚)	3.1-3.4	13.8-14.1mm
陡增 K	40.5	45.00	43.75	40.00	<12mm BC (140 级未厚)	3.1-3.4	13.8-14.1mm
中度	40.5	43.50	42.25	38.75	<12mm BC (140 级未厚)	3.1-3.4	13.8-14.1mm
平坦 K	40.5	42.00	40.75	37.25	<12mm BC (140 级未厚)	3.1-3.4	13.8-14.1mm

[0376]

表格B3

大覆盖 (16mm) 多弯曲设计	R1 中央BC	R1B1 5-7mm K (D)	R1B2 7-9mm K (D)	R1B3 9-10.5mm K (D)	10.5-13mm K (D)	13-16mm*	下垂 (mm)	直径
陡峭K	36.5	43.50	42.25	39.50	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
中度	36.5	42.00	40.75	38.25	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
平坦K	36.5	40.50	39.25	36.75	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
陡峭K	38.5	44.25	43.00	40.25	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
中度	38.5	42.75	41.50	39.00	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
平坦K	38.5	41.25	40.00	37.50	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
陡峭K	40.5	45.00	43.75	41.00	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
中度	40.5	43.50	42.25	39.75	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm
平坦K	40.5	42.00	40.75	38.25	<10.0mm/33.75D	<14.5 mm/23D	≤3.6	15.6-16.1mm

*可以不与前弯曲汇切（可以将外弯曲插入以帮助其展开）

[0377]

表格 B4

	多弯曲CL设计	RJ 中央 BC (D)	R1B1 5.7mm K (D)	R1B2 7.9mm K (D)	R1B3 9-11mm K (D)	R1C 13.5-14mm K (D)	下垂 (mm)	直径
CL中央弯曲1	陡增K	40	41.75	39.00	39.00	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
	中度	40.00	39.75	37.25	37.25	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
	平坦K	40.00	37.75	35.25	35.25	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
CL中央弯曲2	陡增K	42.00	43.75	41.00	41.00	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
	中度	42.00	41.75	39.25	39.25	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
	平坦K	42.00	39.75	37.25	37.25	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
CL中央弯曲3	陡增K	44.000	44.75	42.00	42.00	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
	中度	44.00	43.25	40.75	40.75	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
	平坦K	44.00	41.75	39.25	39.25	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
CL中央弯曲4	陡增K	46.00	46.75	44.00	44.00	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
	中度	46.00	45.25	42.75	42.75	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm
	平坦K	46.00	43.75	41.25	41.25	<12mm BC (140 微米厚)	3.1-3.4	13.8-14.1mm

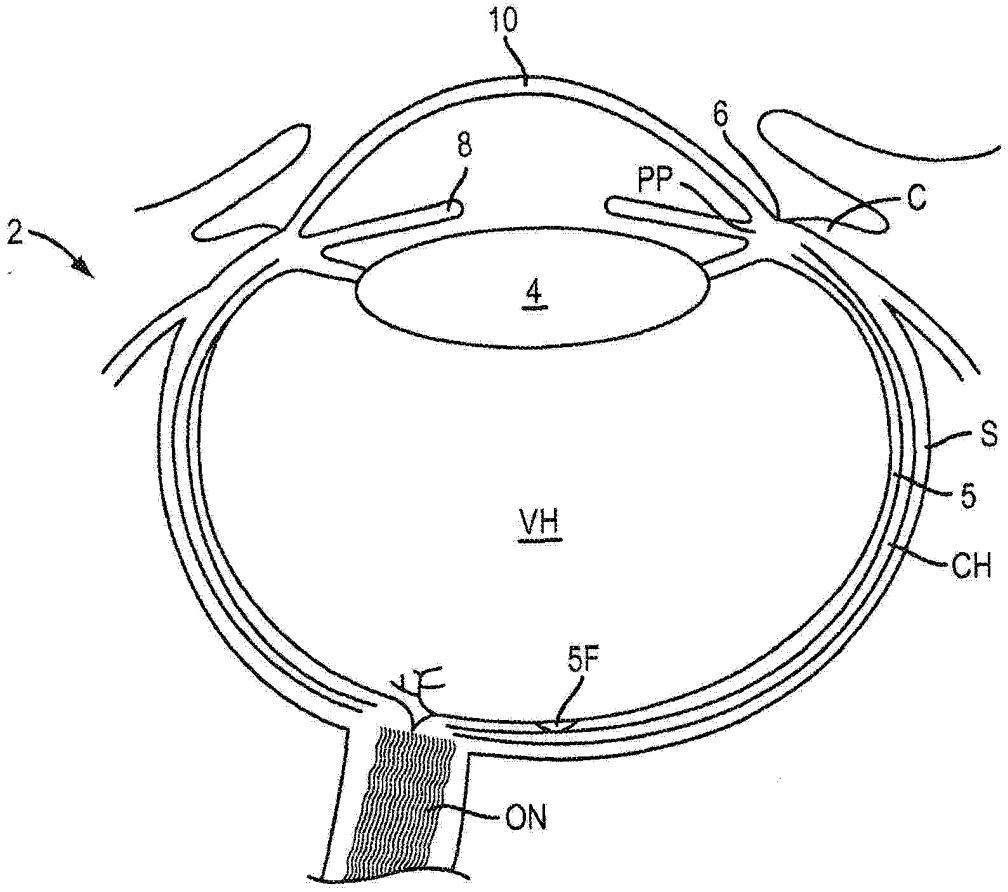


图 1

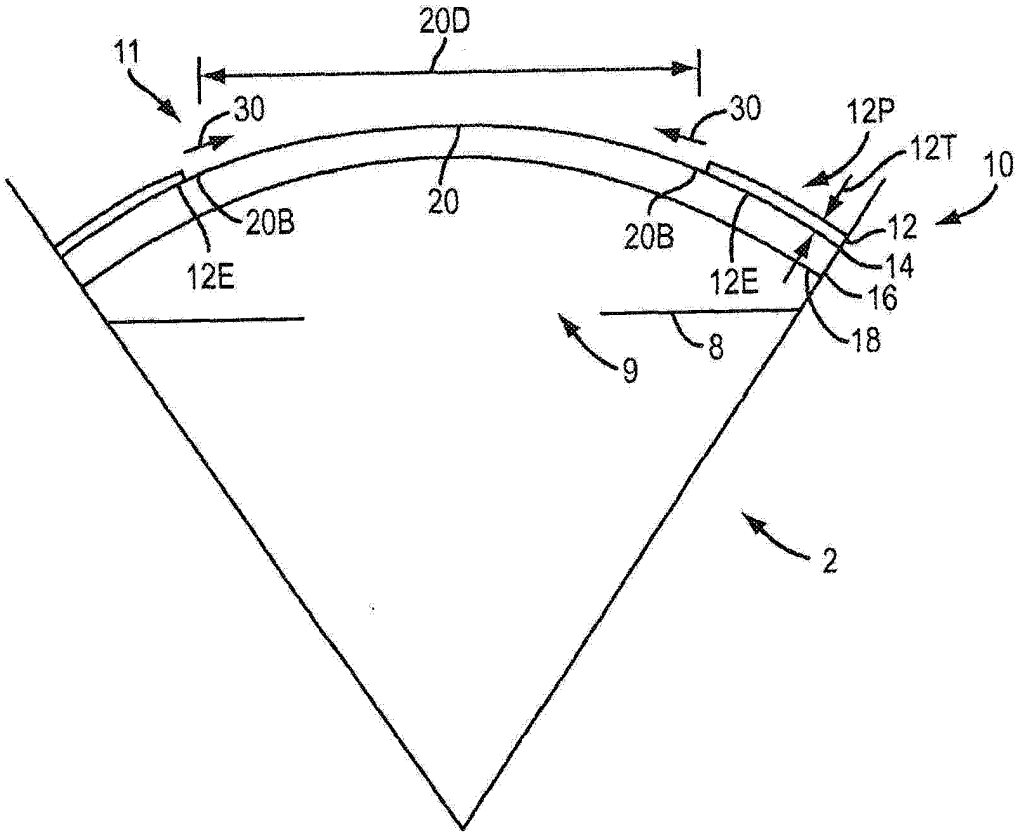


图 1-1A

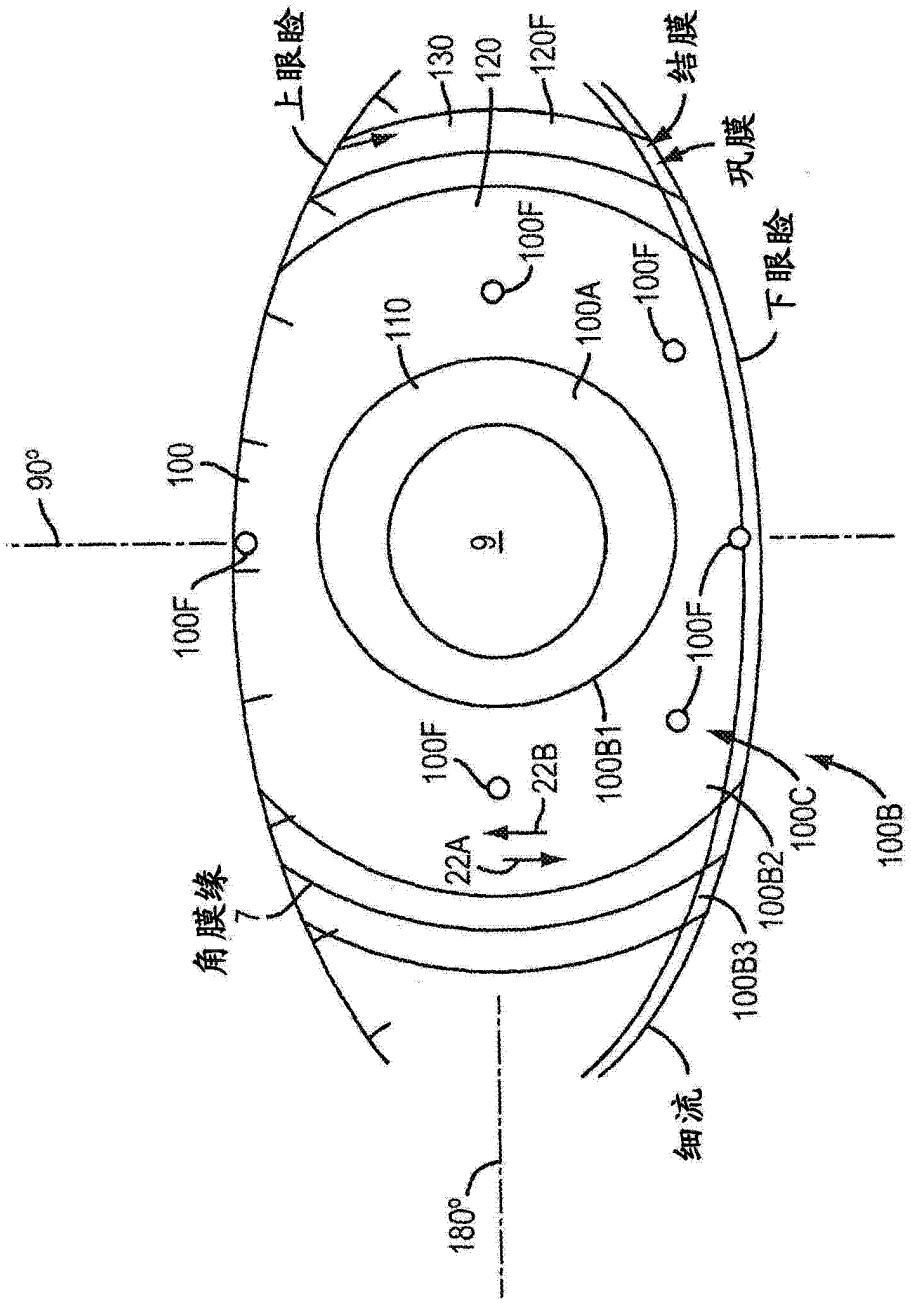


图 1A1

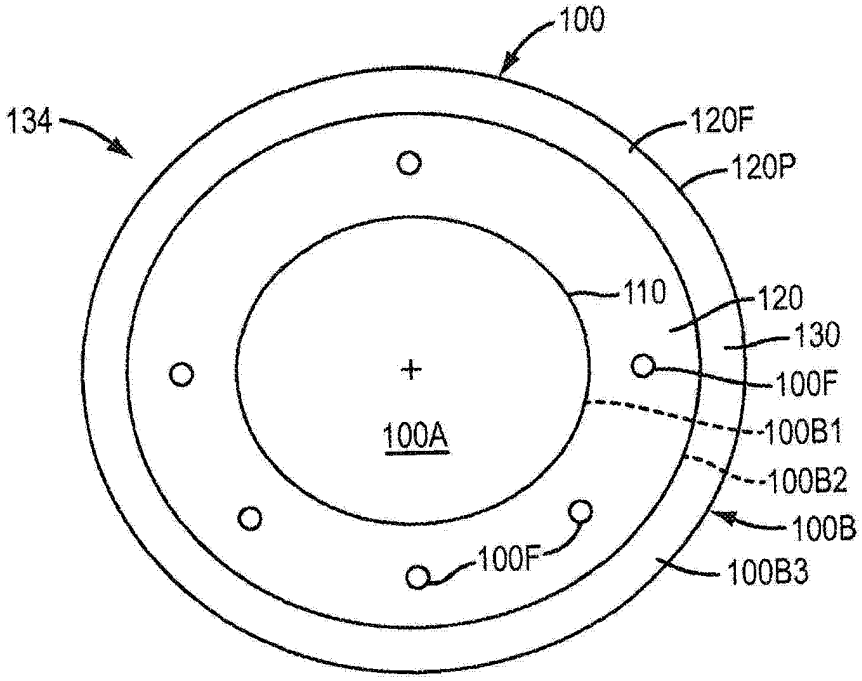


图 1A2

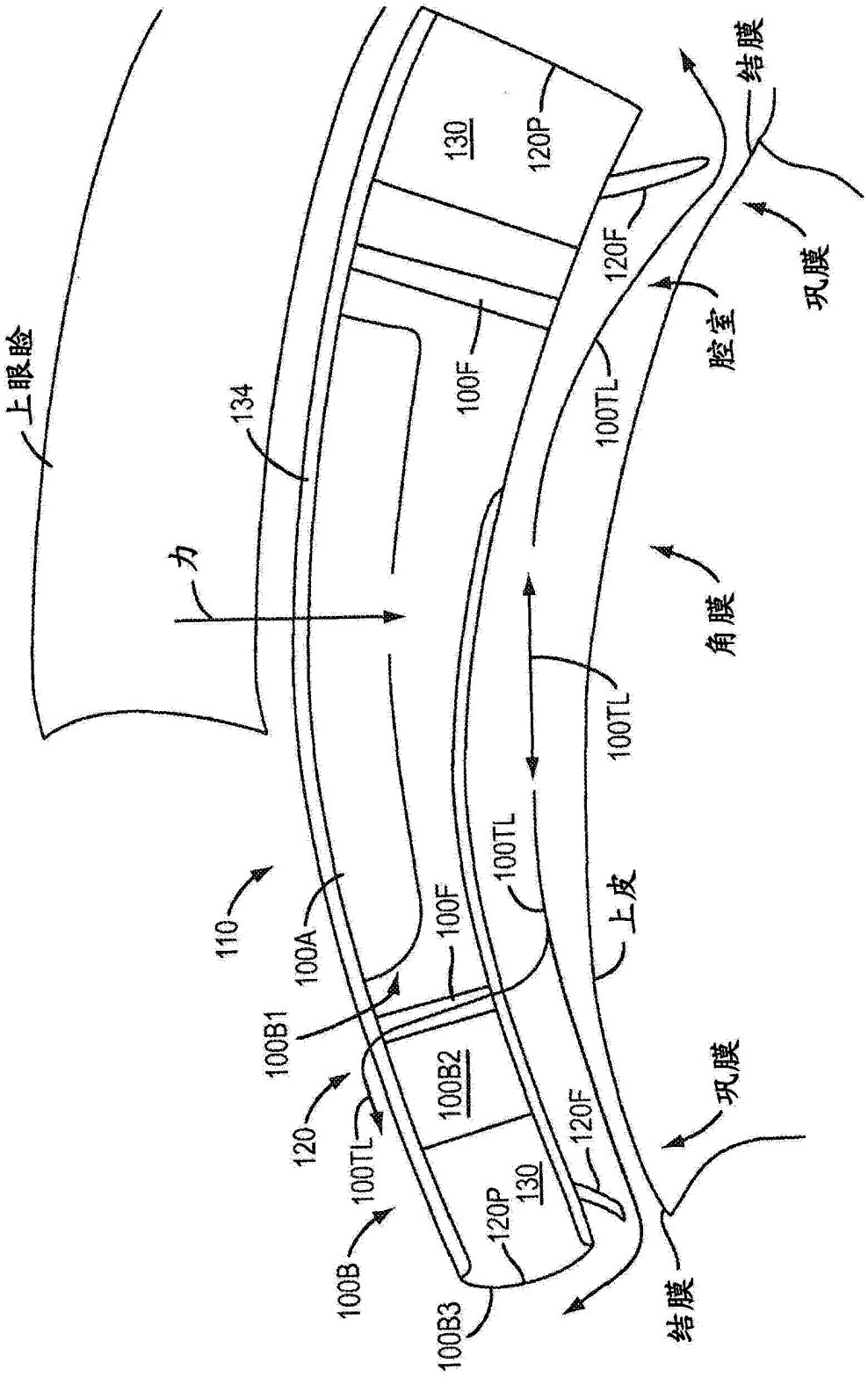


图 1A3

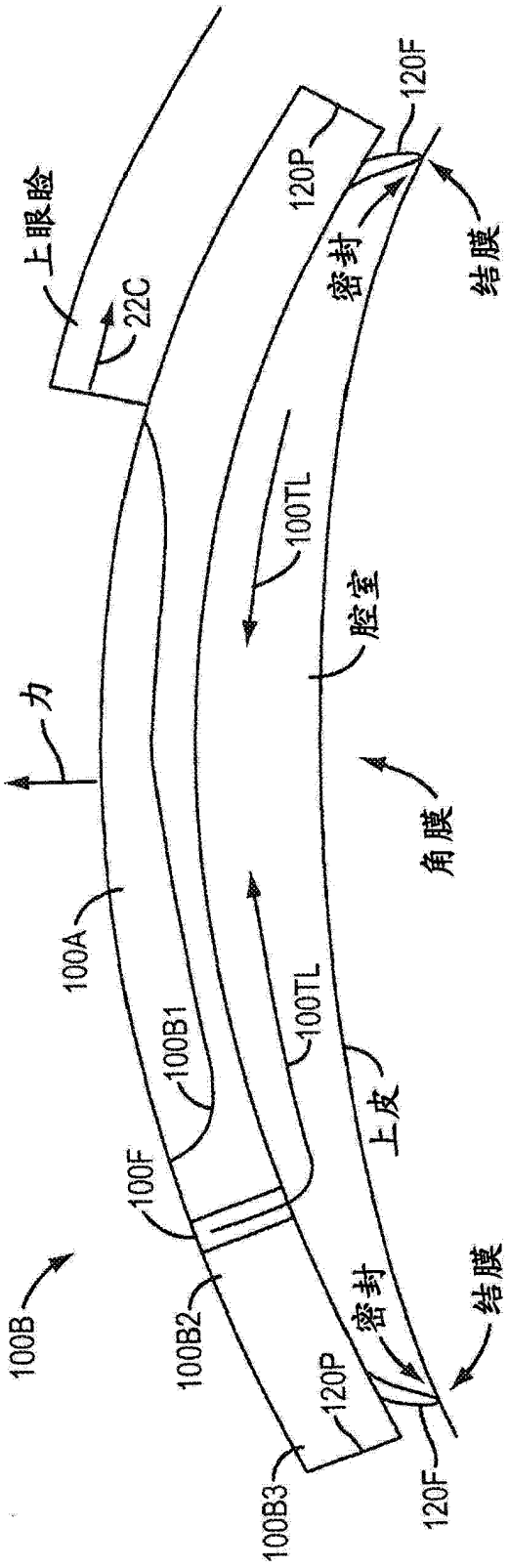


图 1A4

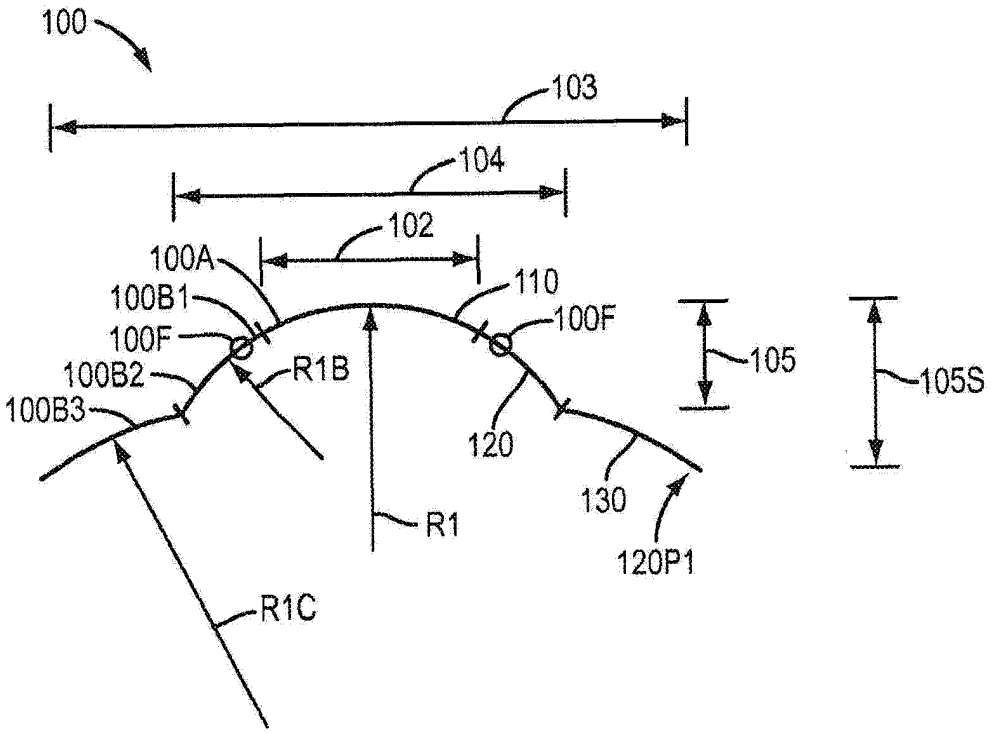


图 1B1

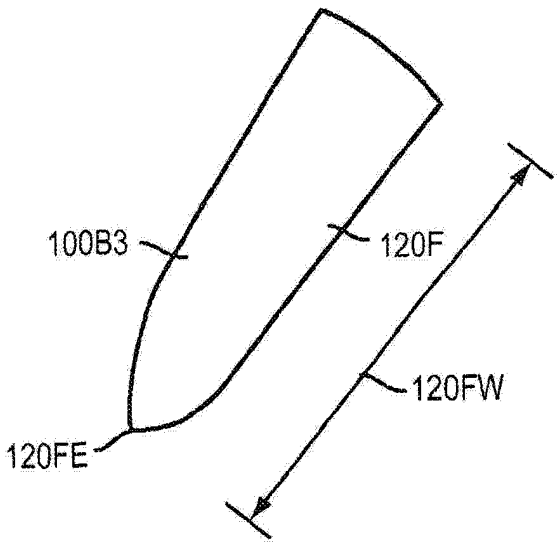


图 1B3

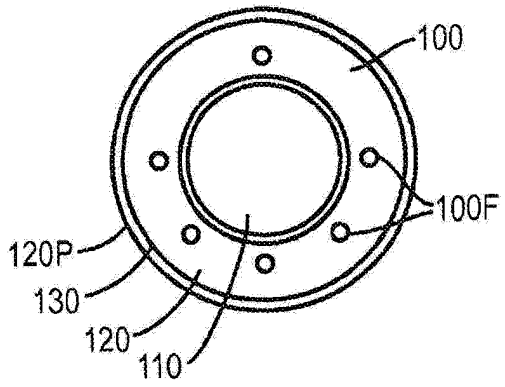


图 1B4

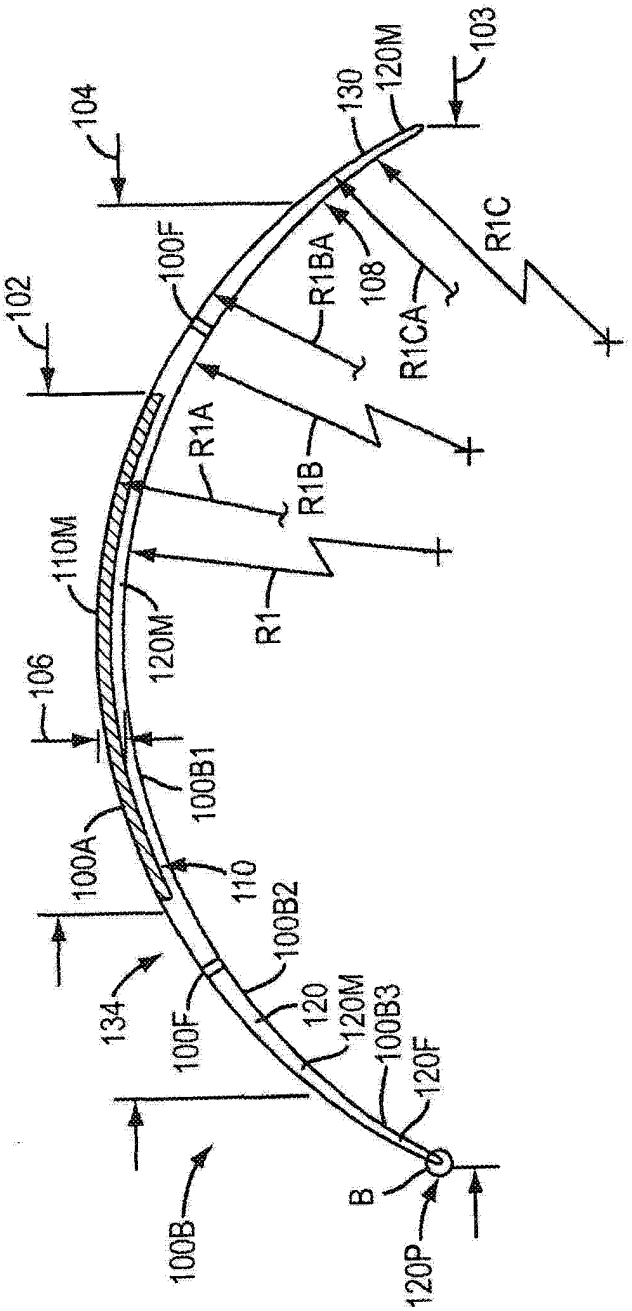


图 1B2

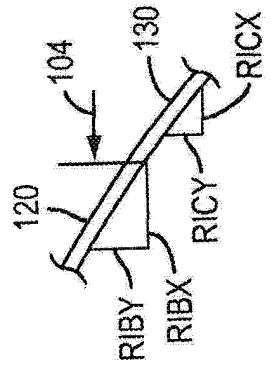


图 1B2-1

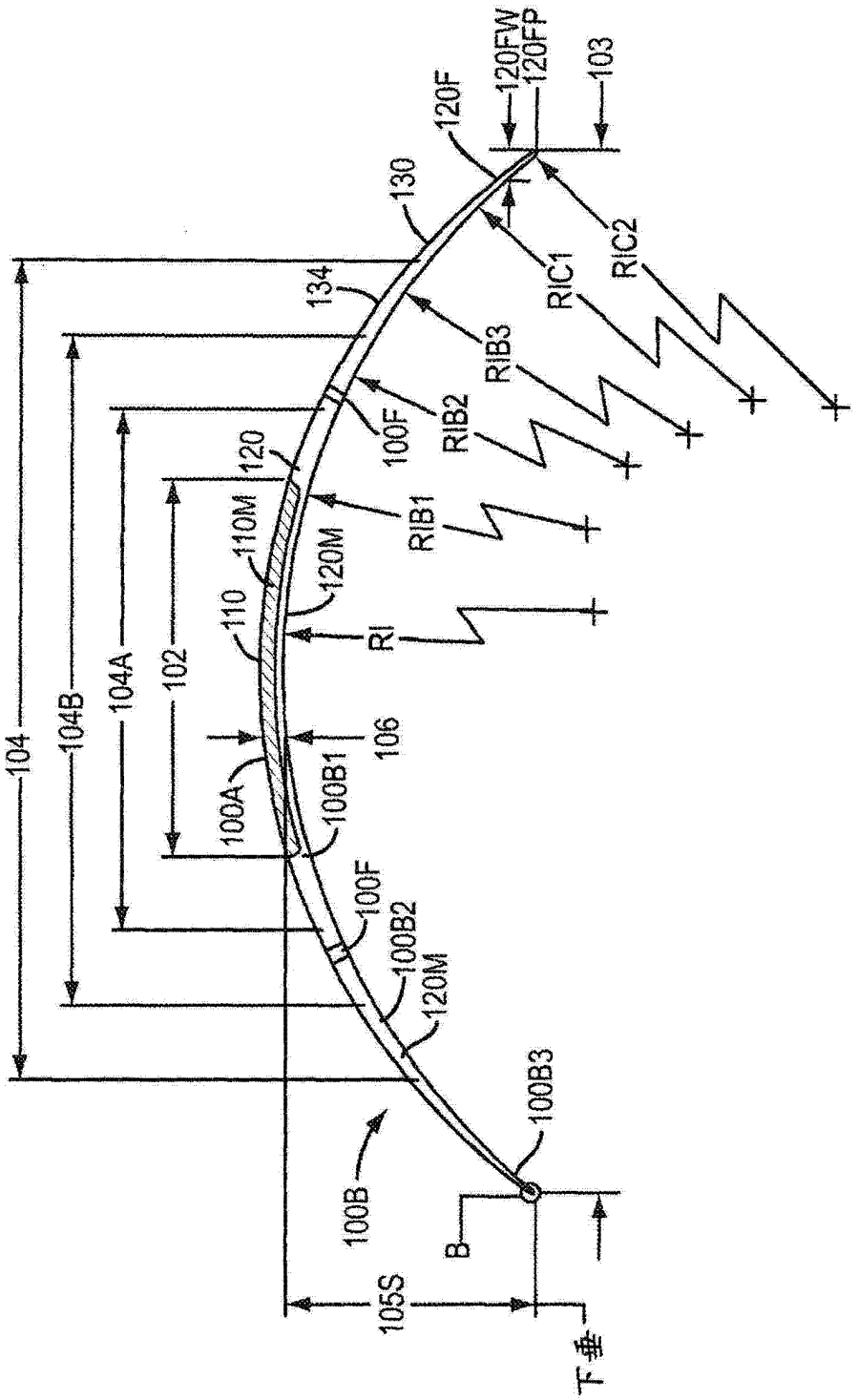


图 1B5

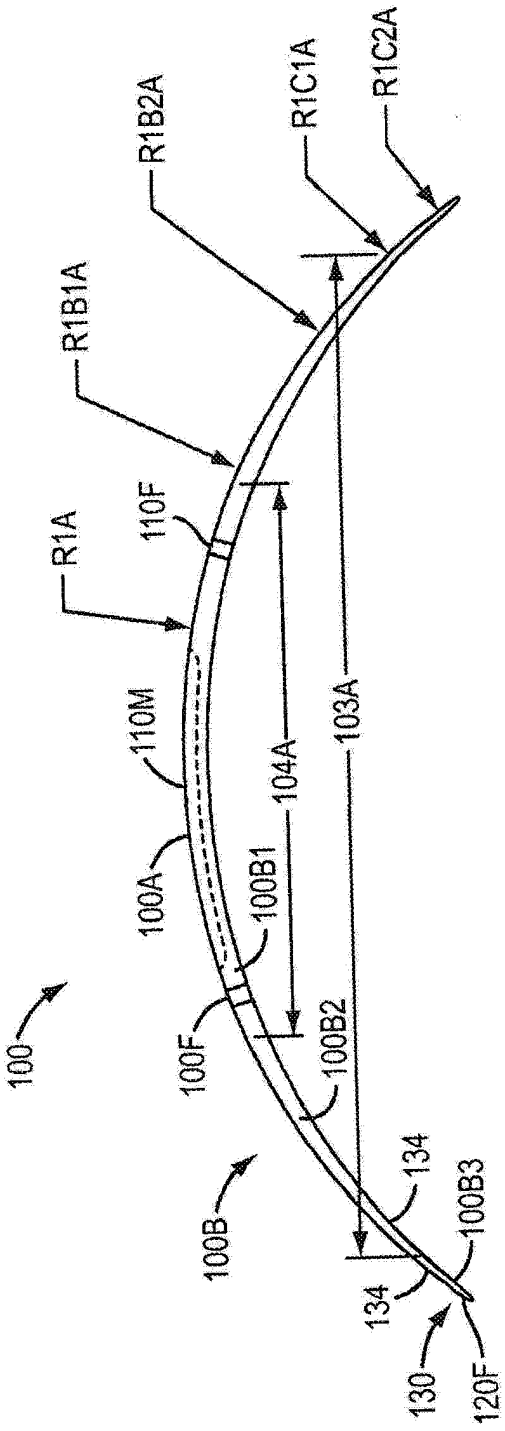


图 1B6

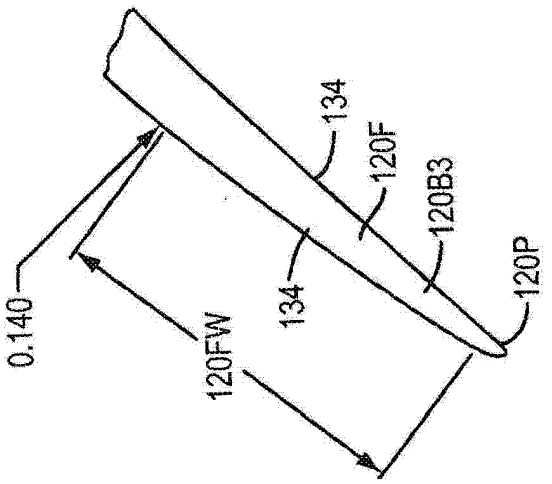


图 1B7

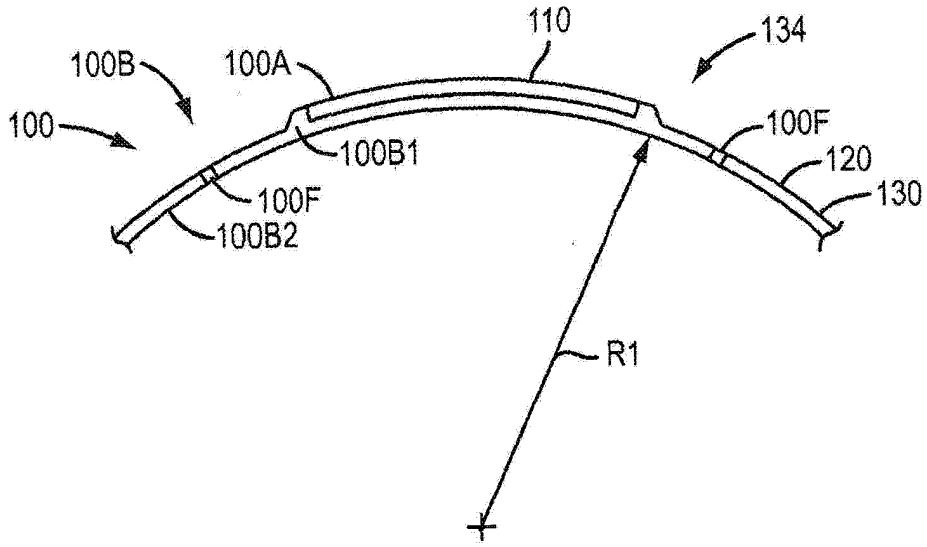


图 1C

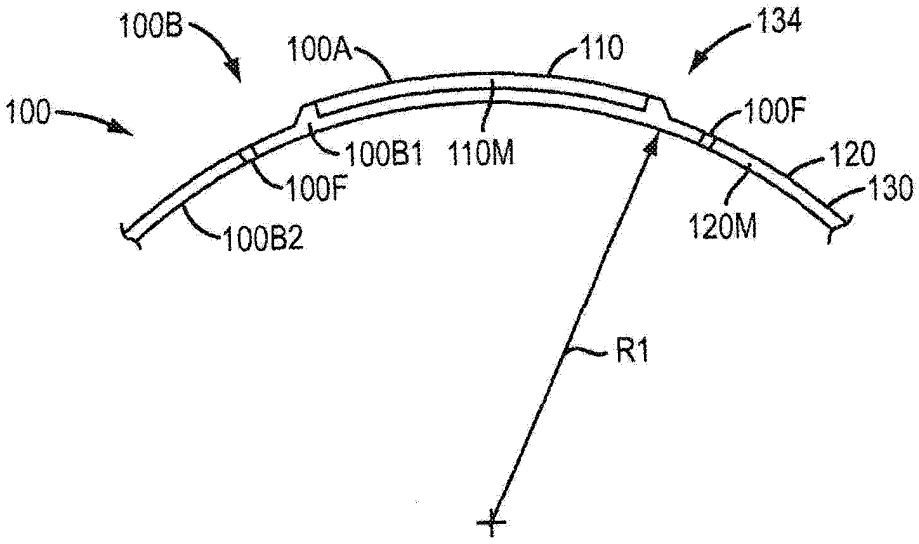


图 1C1

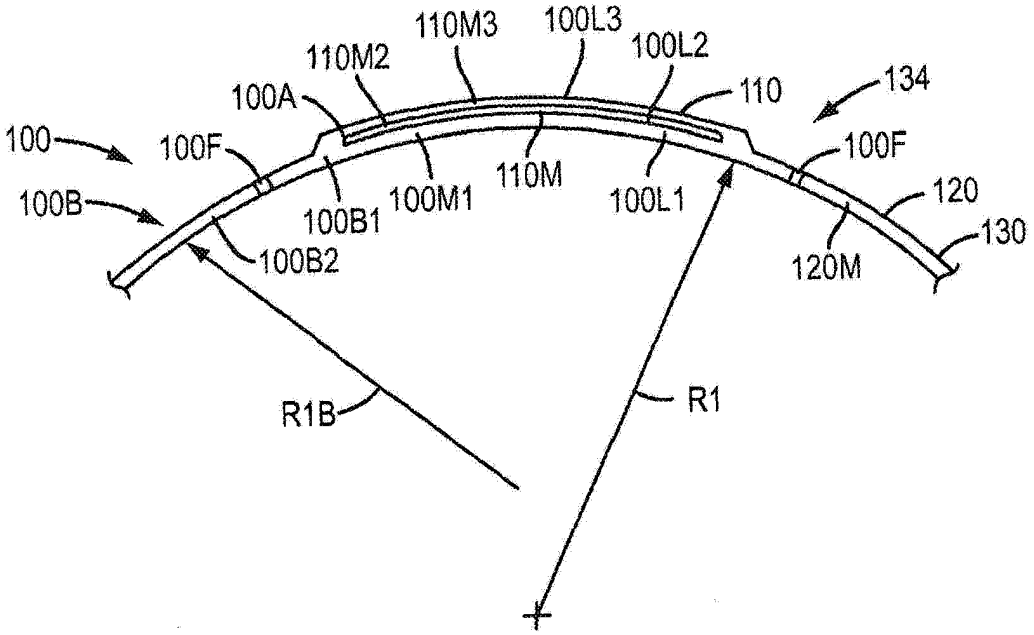


图 1C2

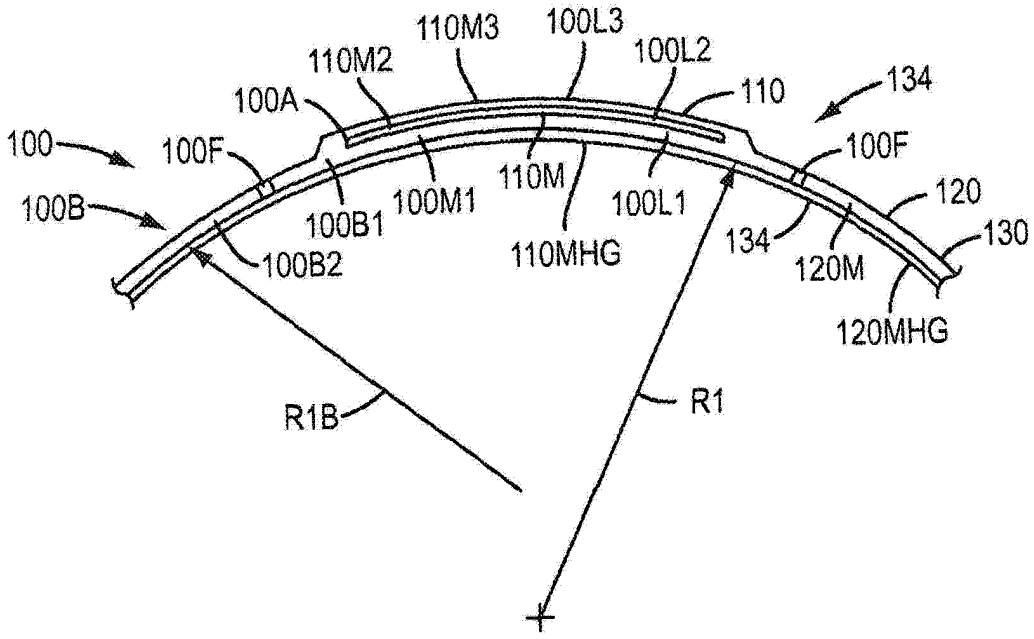


图 1C2A

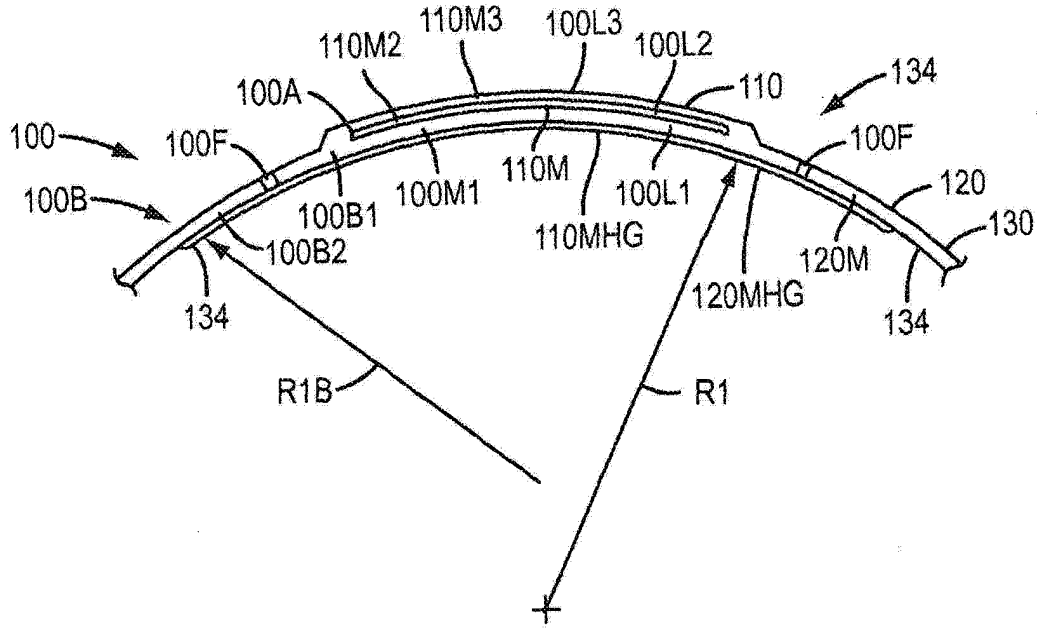


图 1C2B

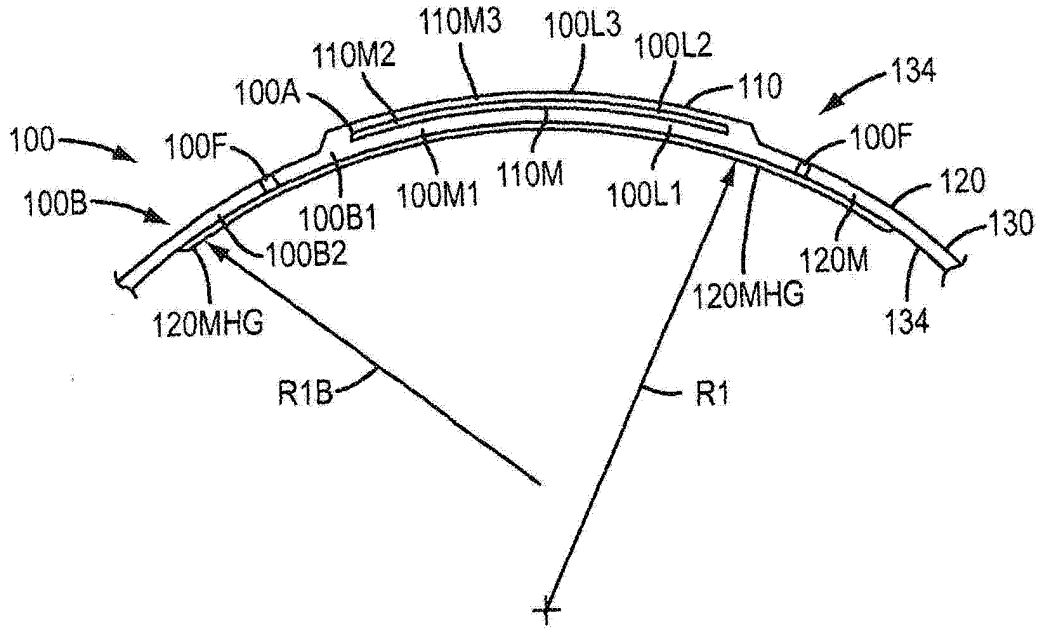


图 1C2C

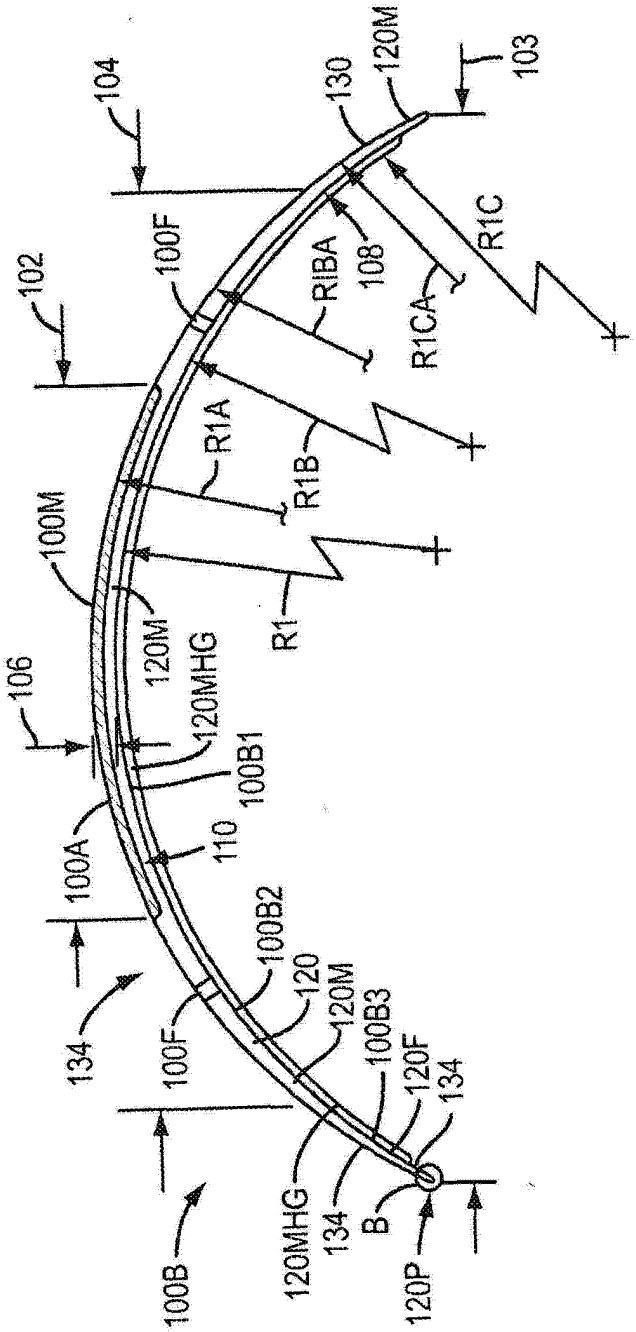


图 1C3

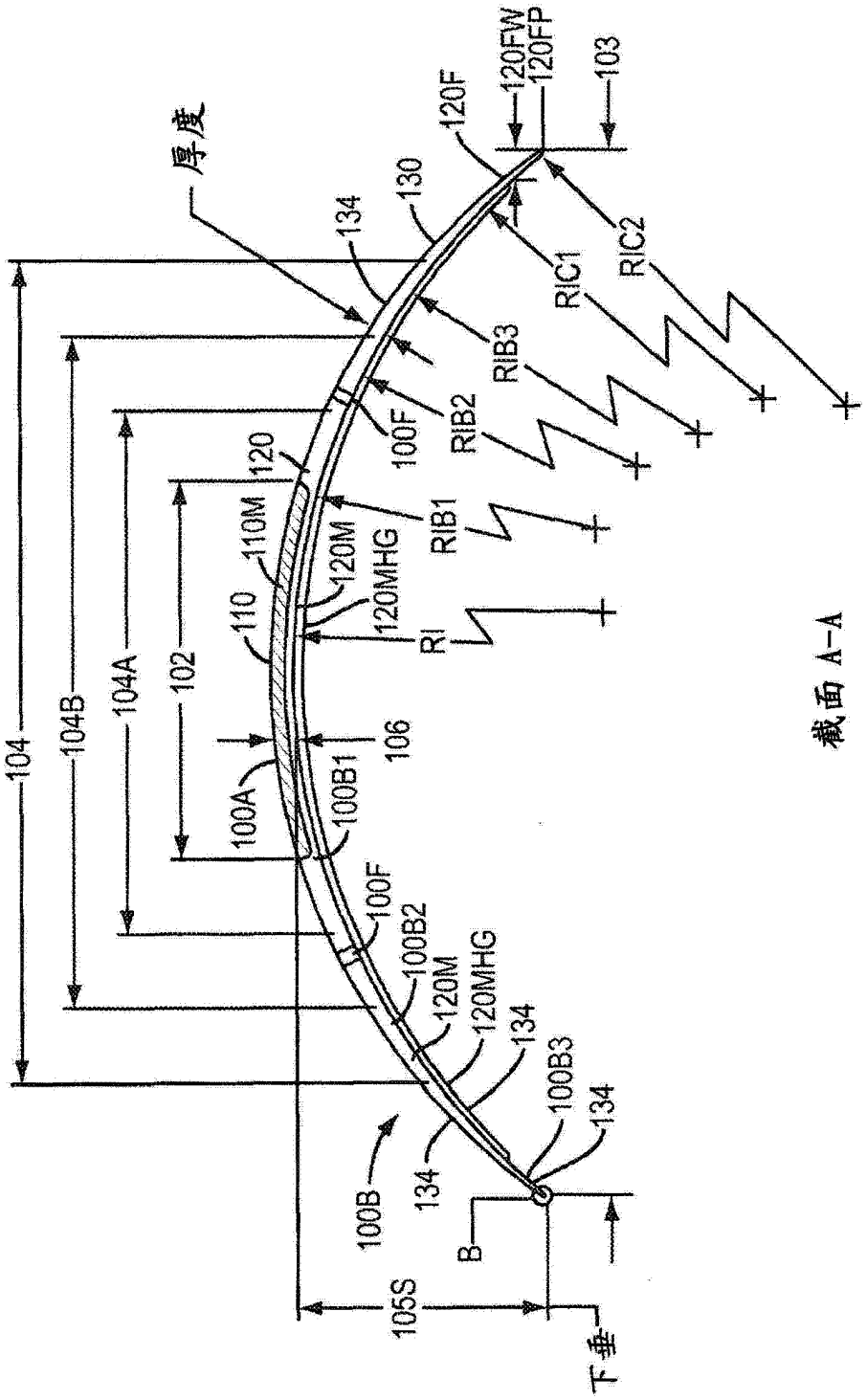


图 1C4

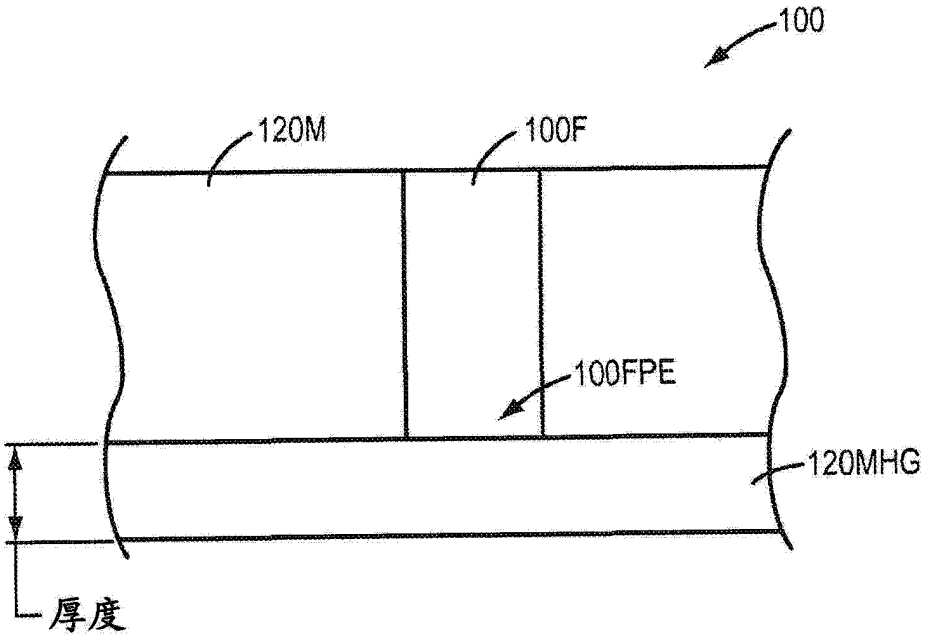


图 1C5

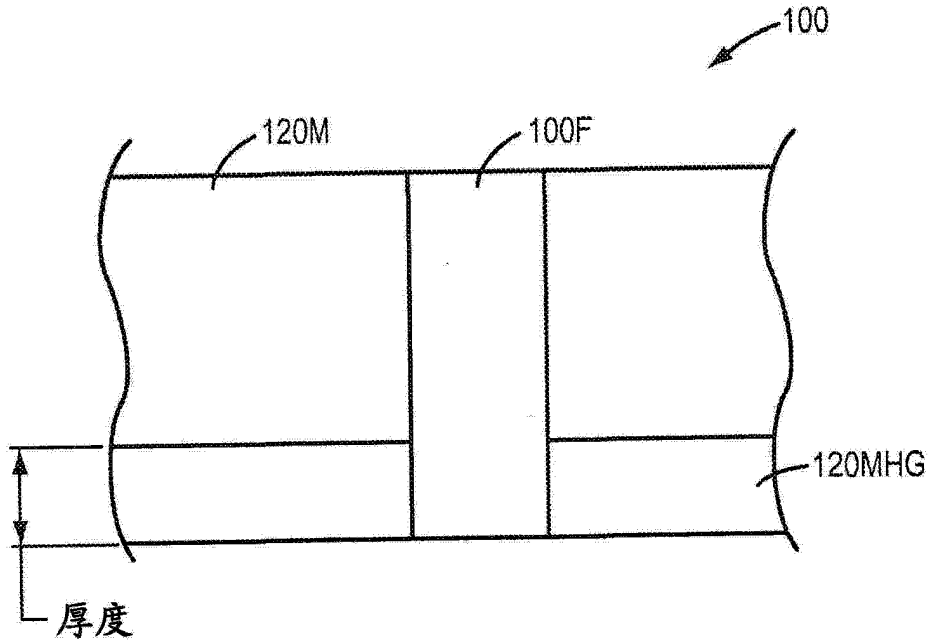


图 1C6

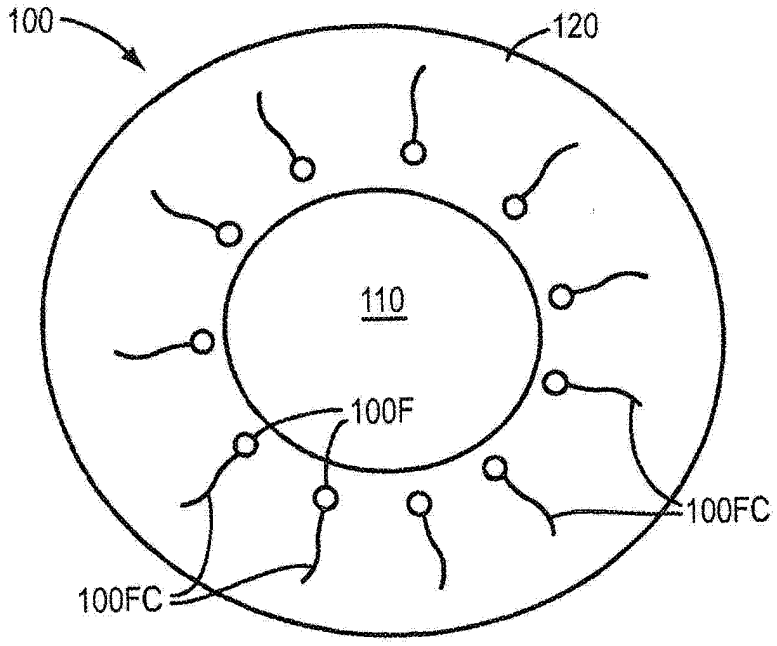


图 1D

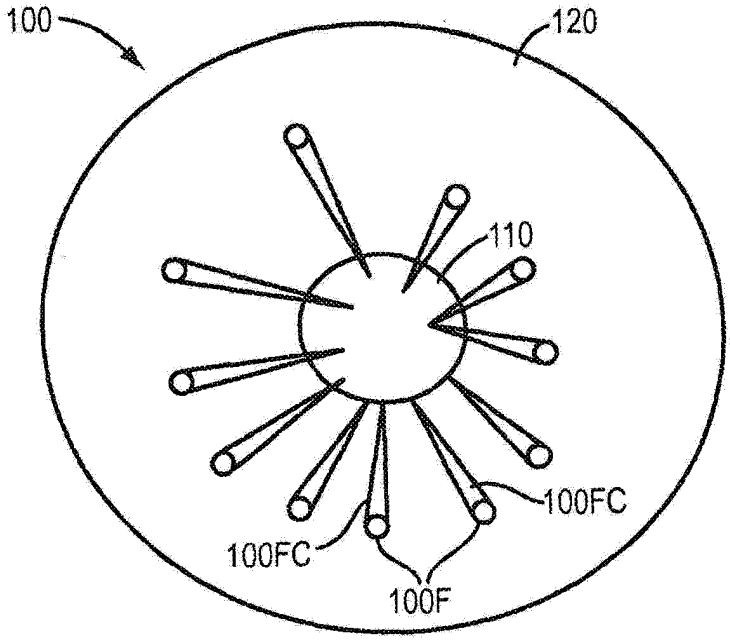


图 1E

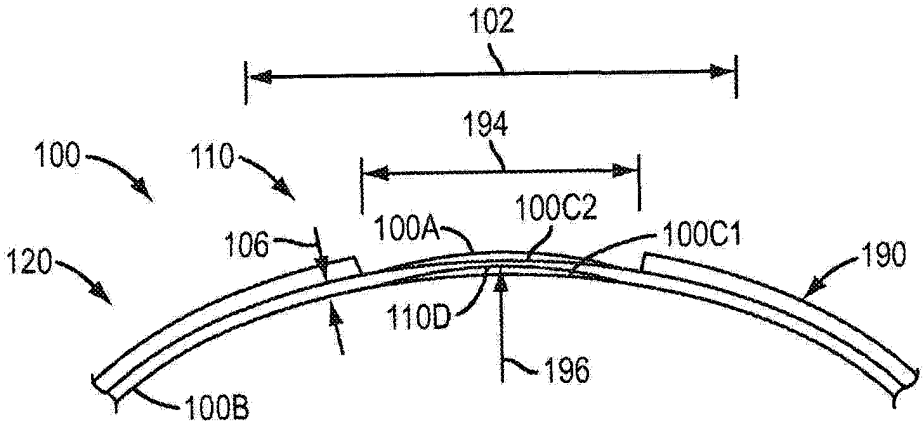


图 1F

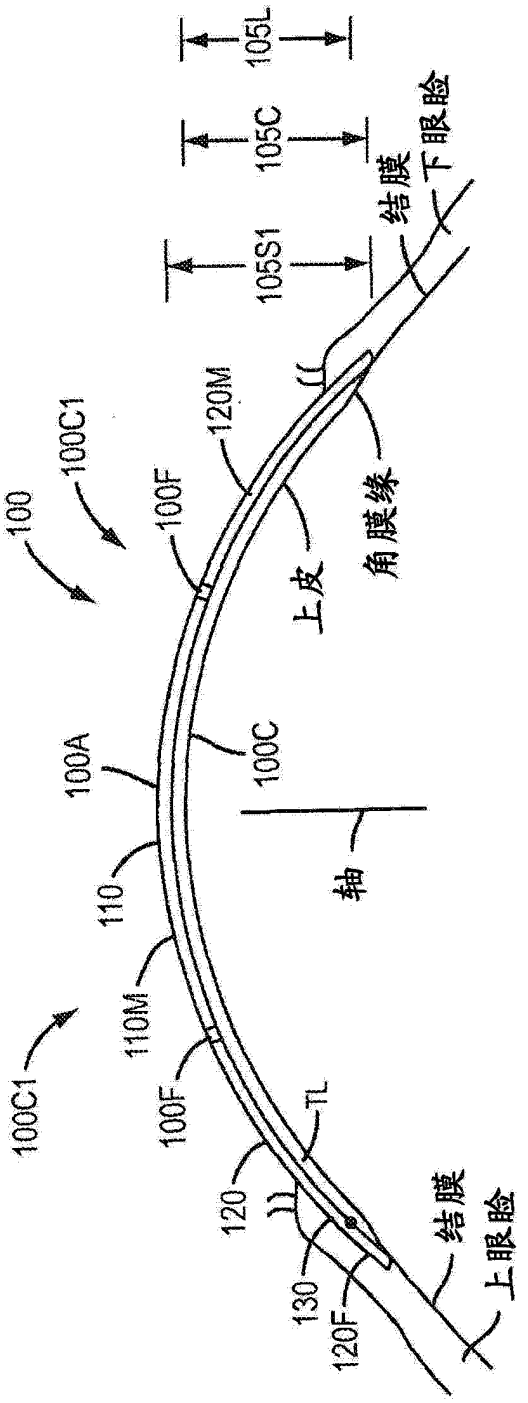


图 2A

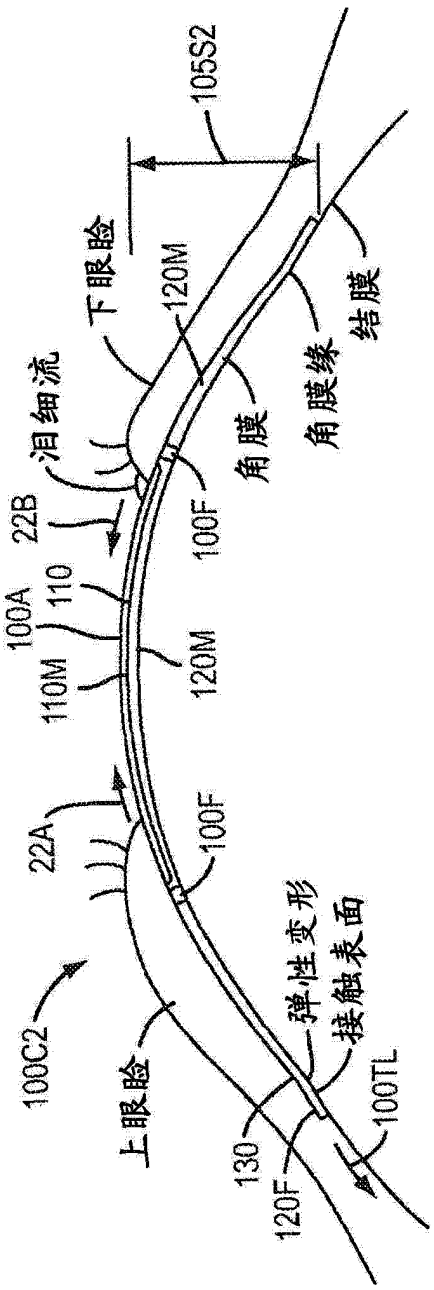


图 2B

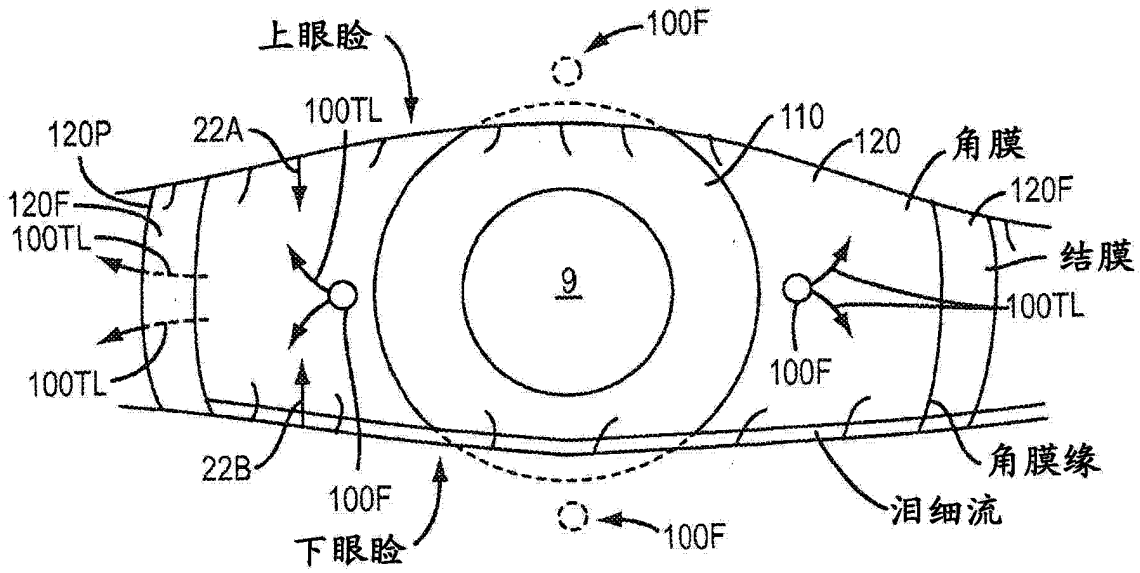


图 2C

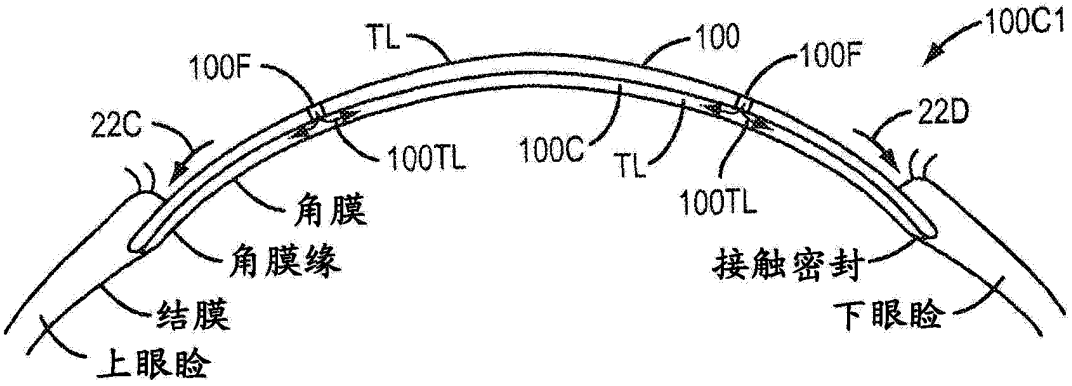


图 2D

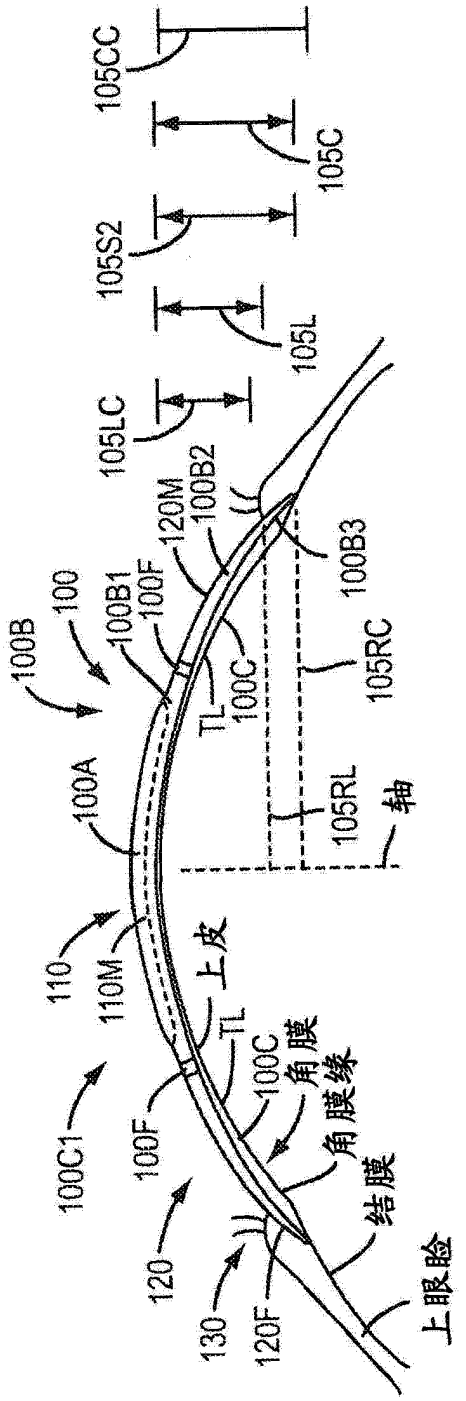


图 2E

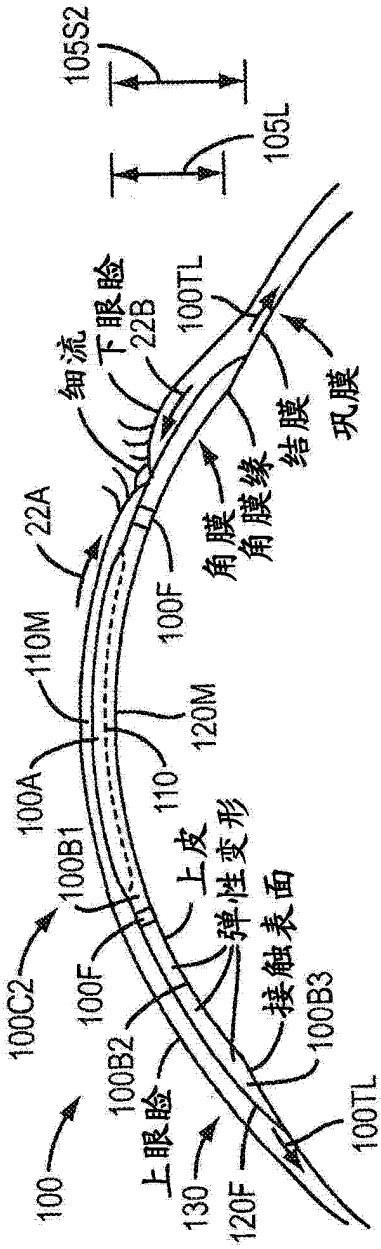


图 2F

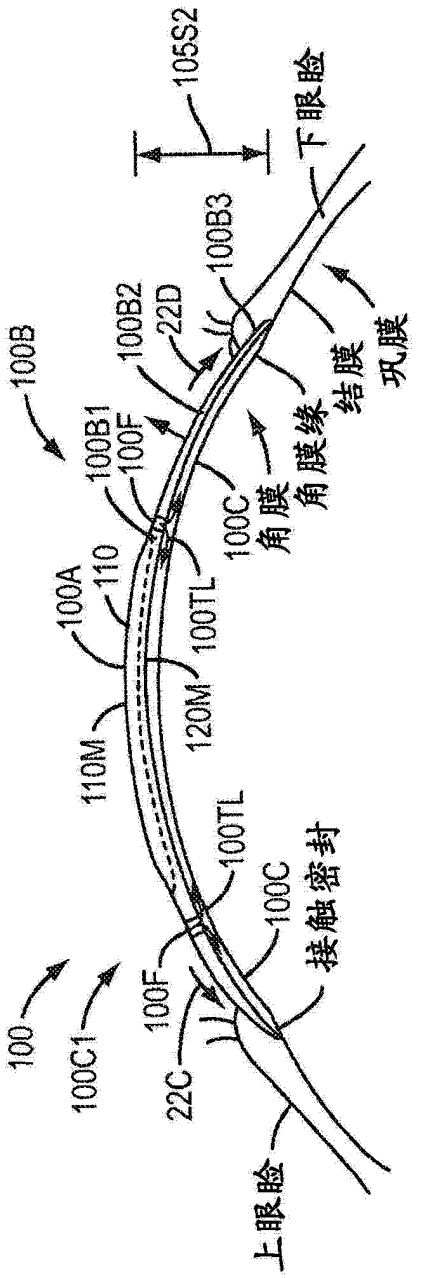


图 2G

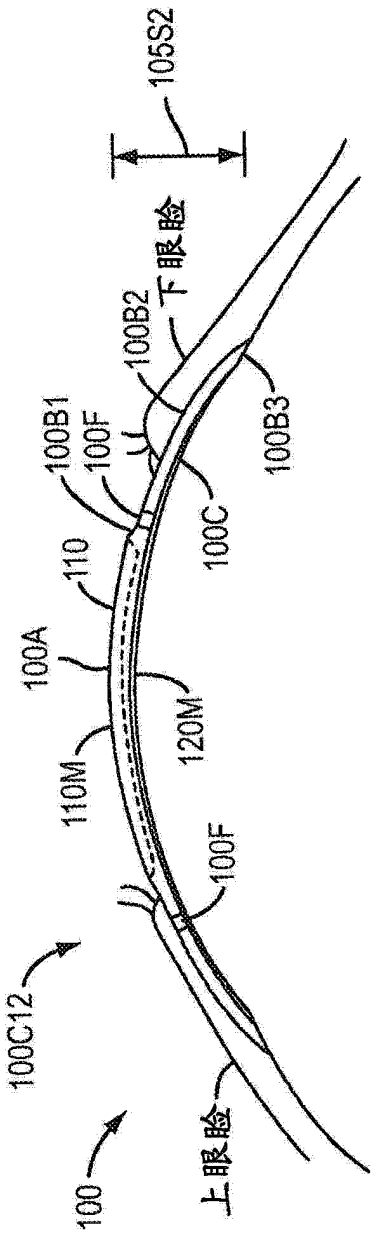


图 2H

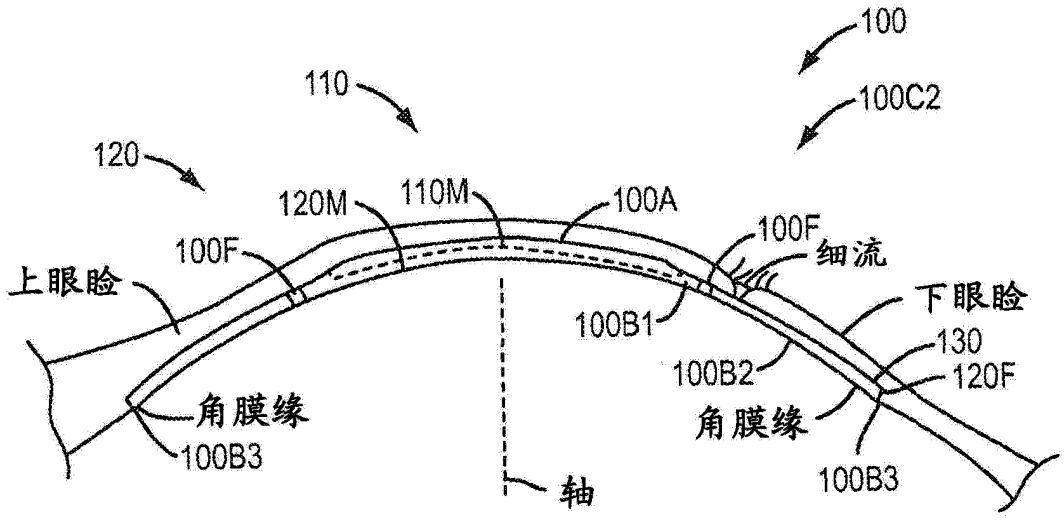


图 2F1

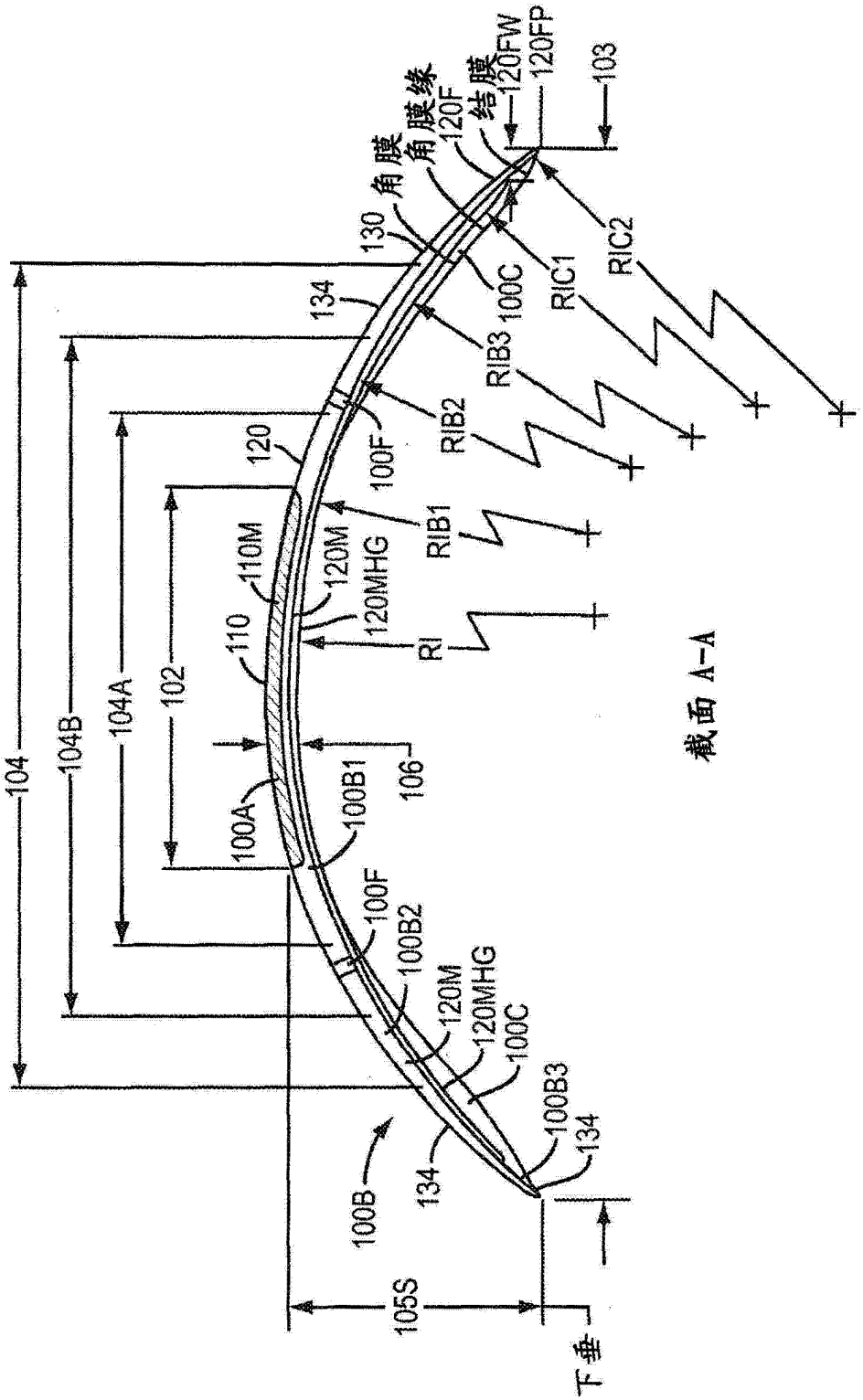


图 2I

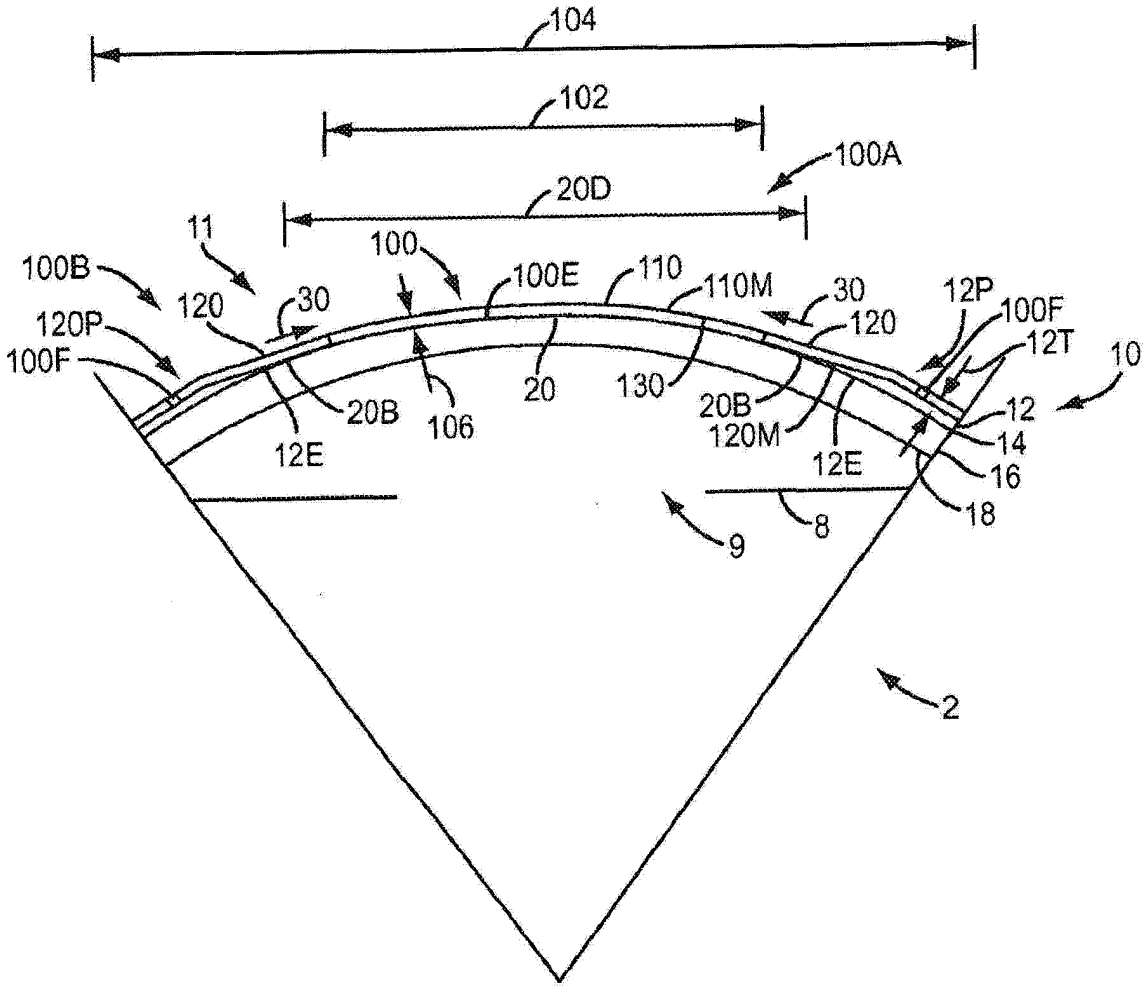


图 3A

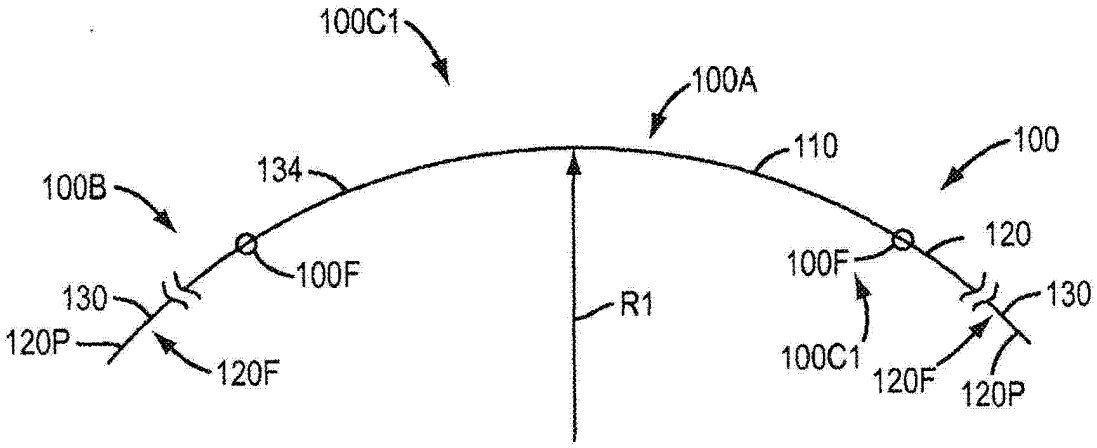


图 3B

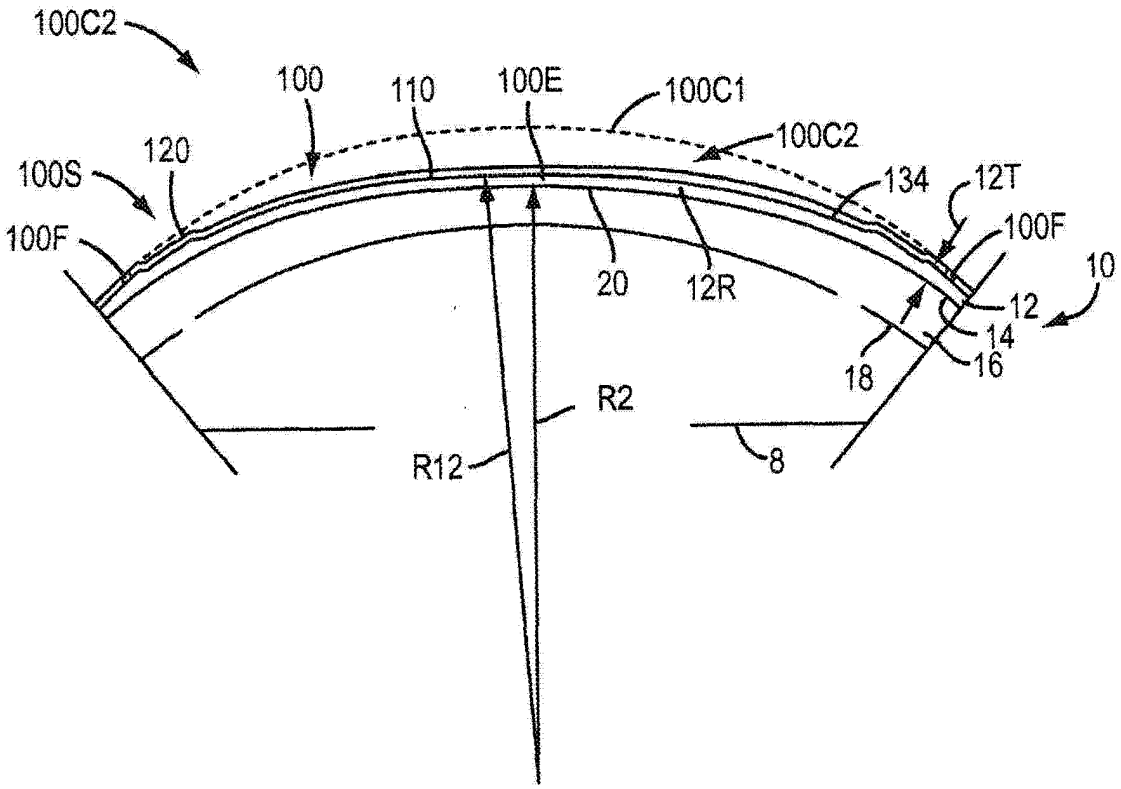


图 3C

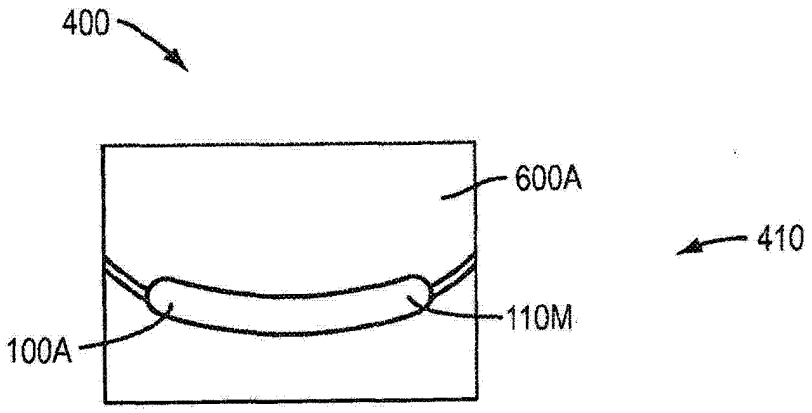


图 4A

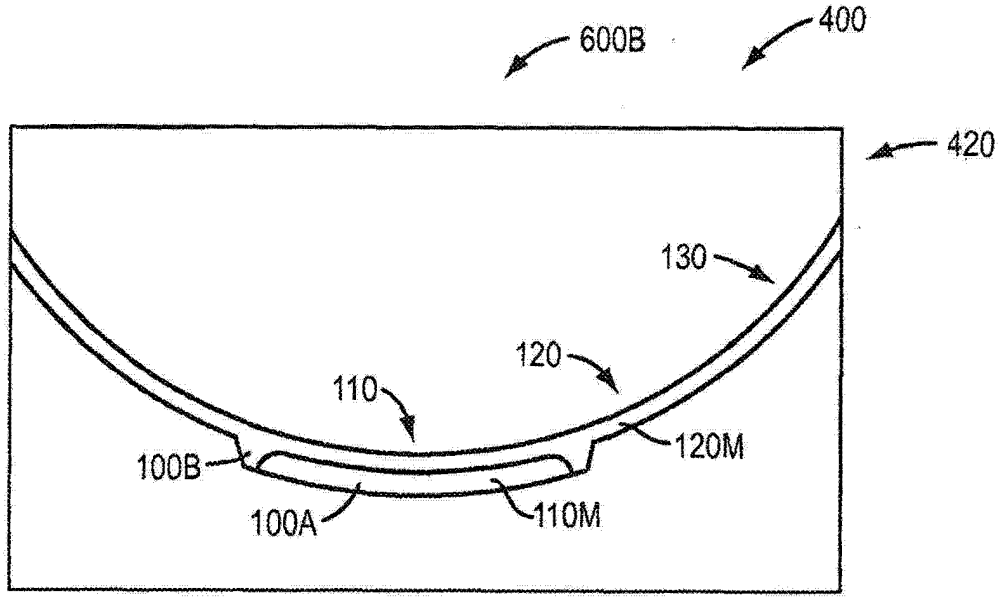


图 4B

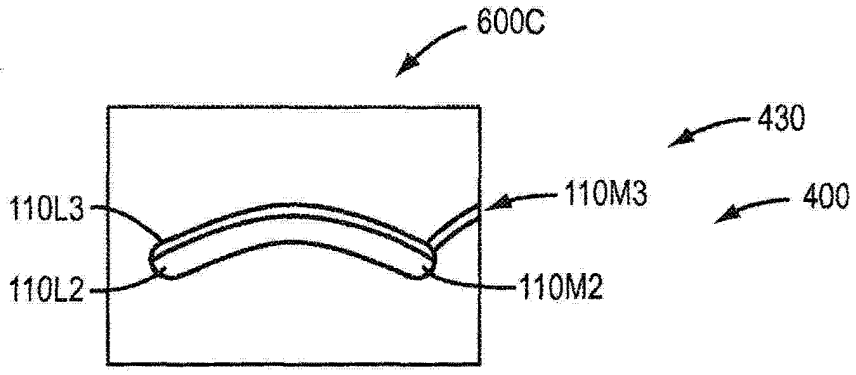


图 4C

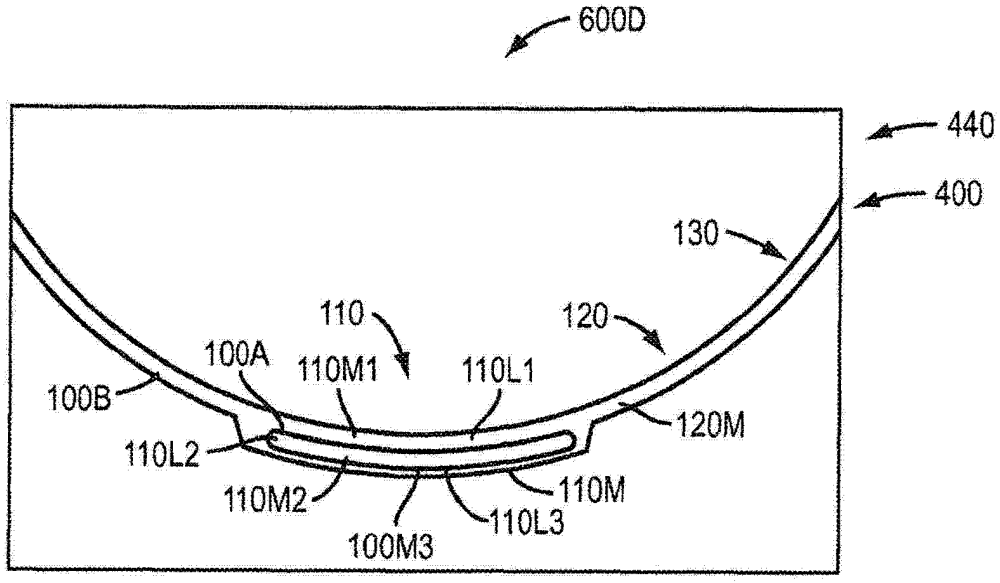


图 4D

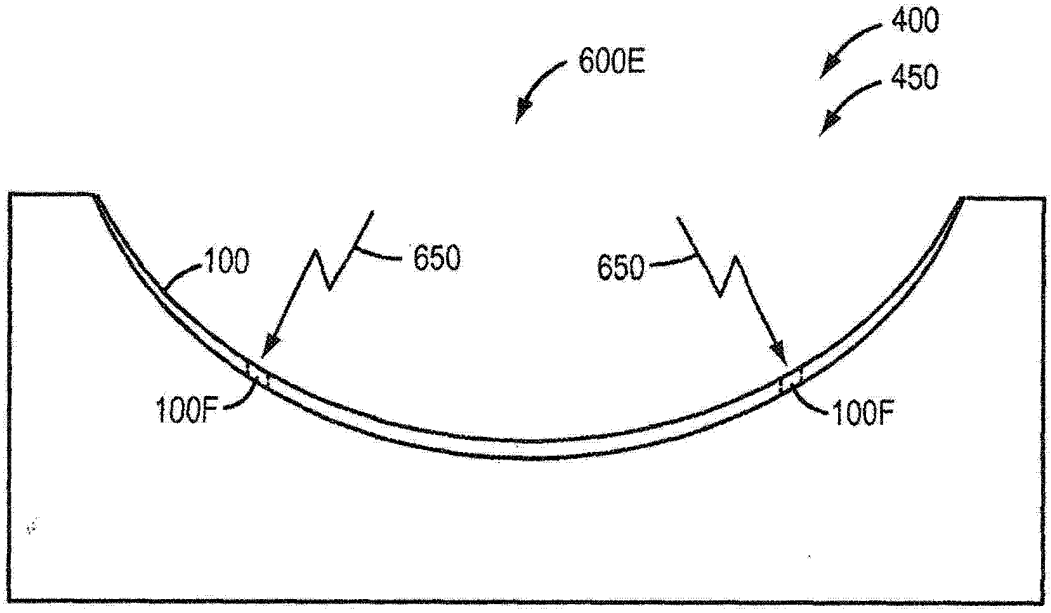


图 4E

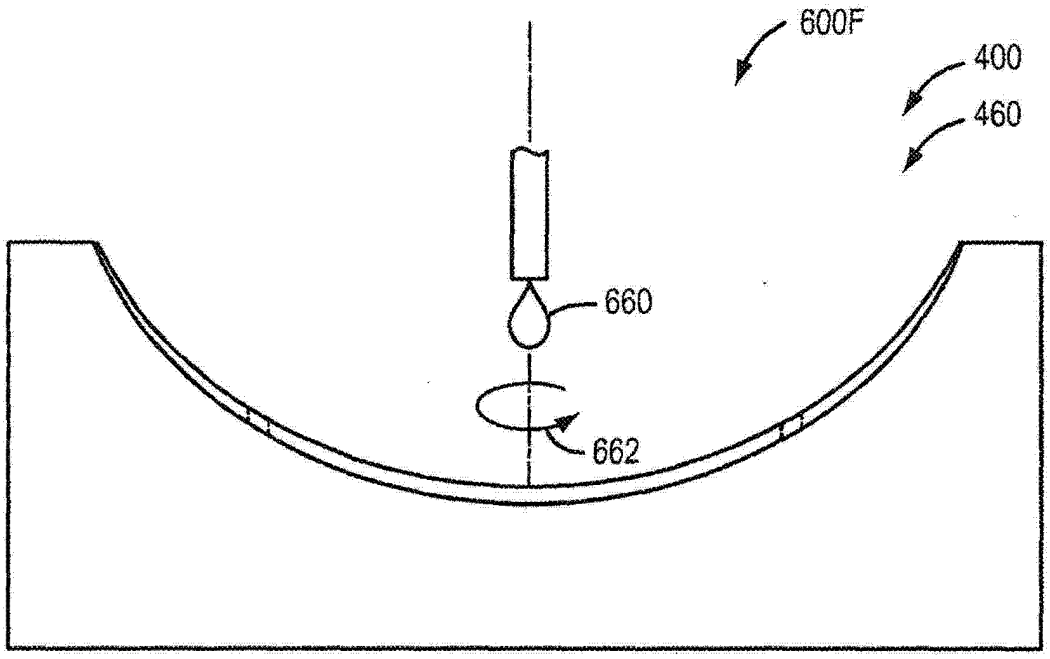


图 4F

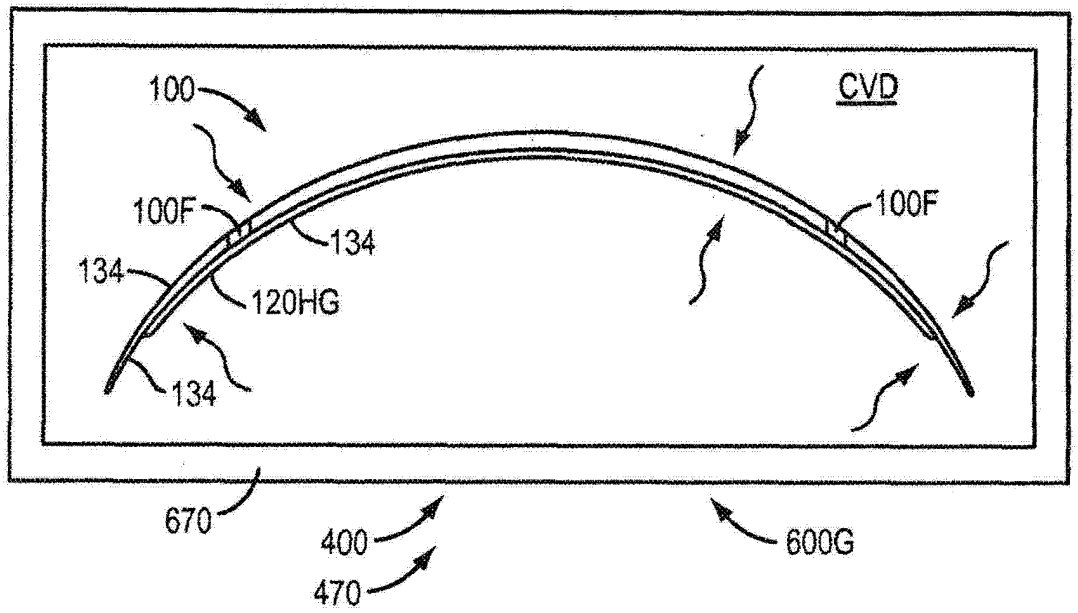


图 4G

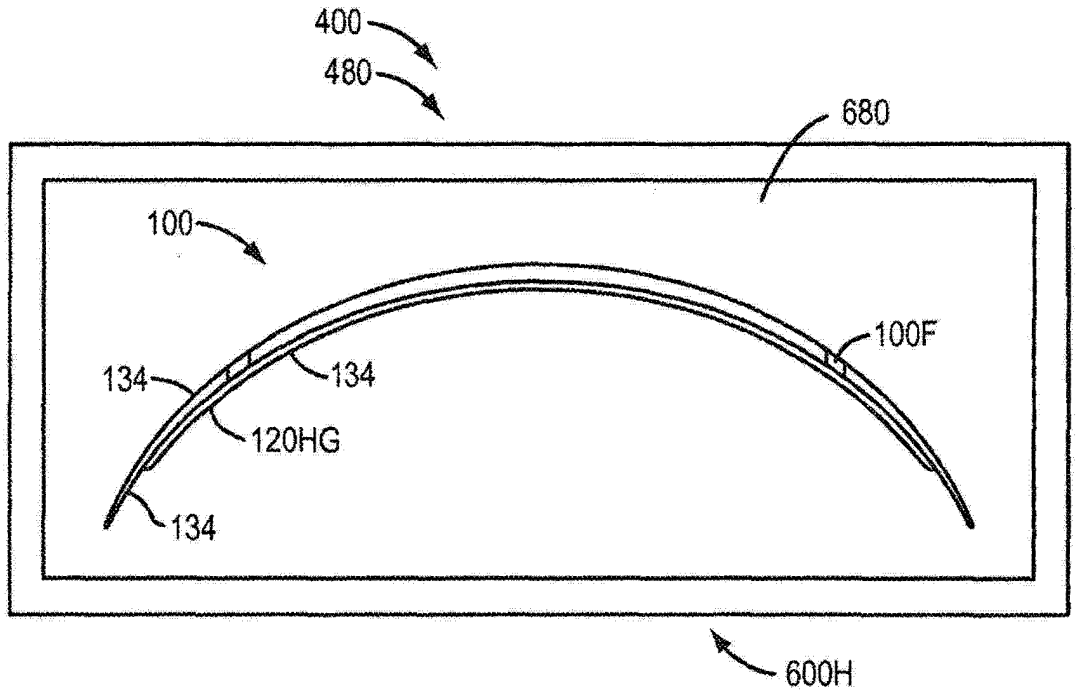


图 4H

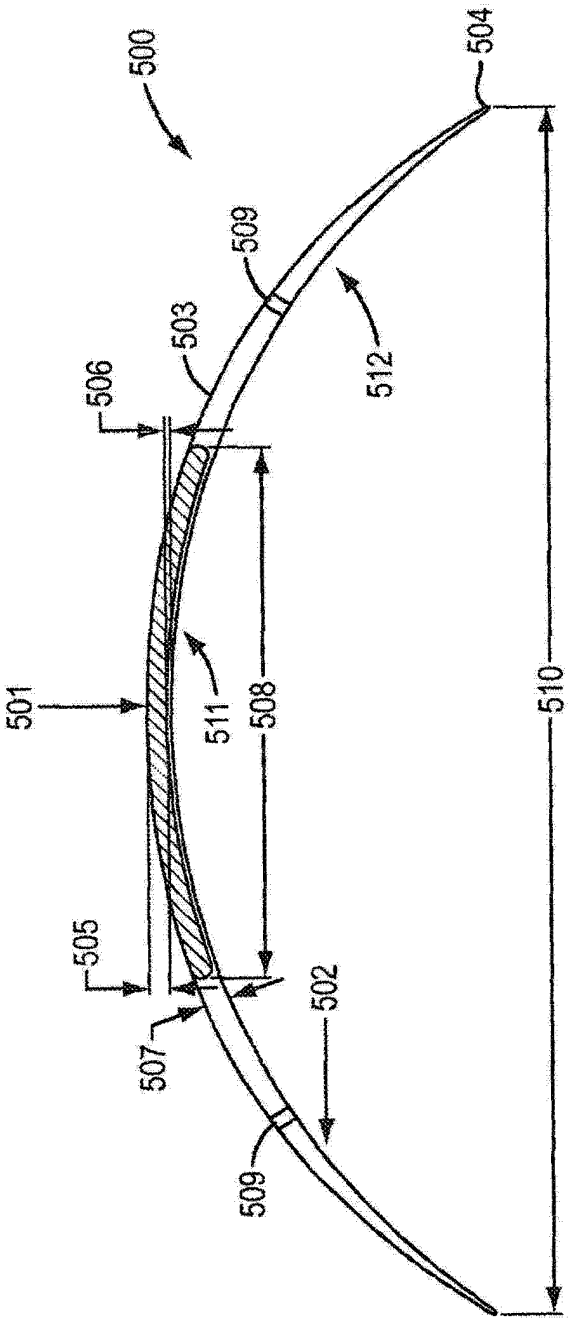


图 5

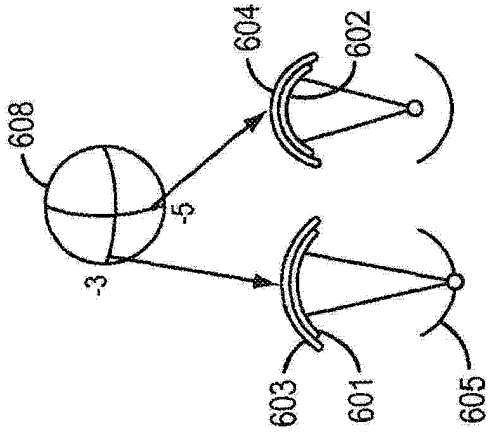


图 6A

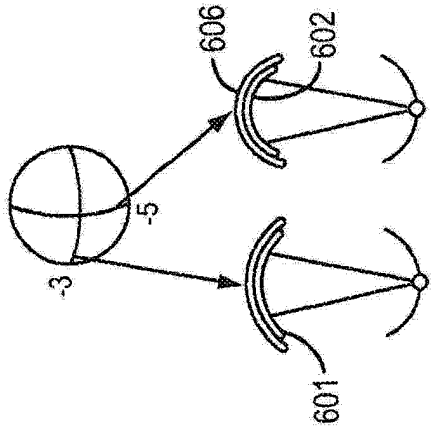


图 6B

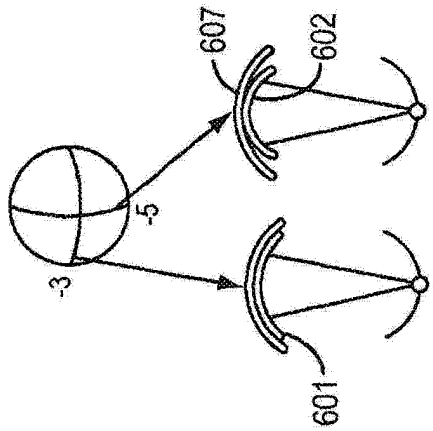


图 6C

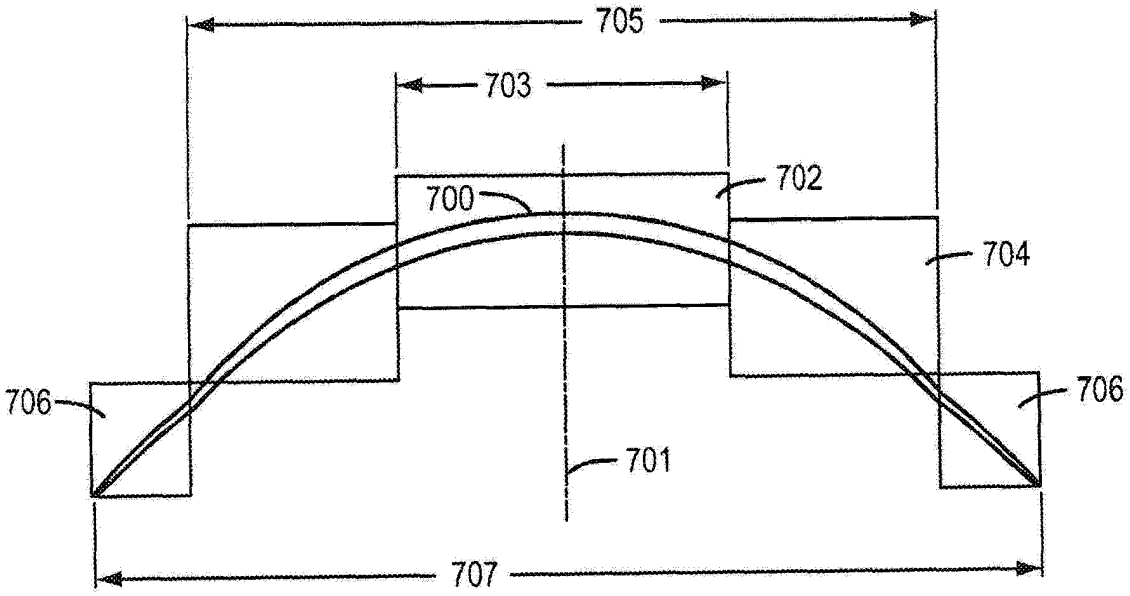


图 7

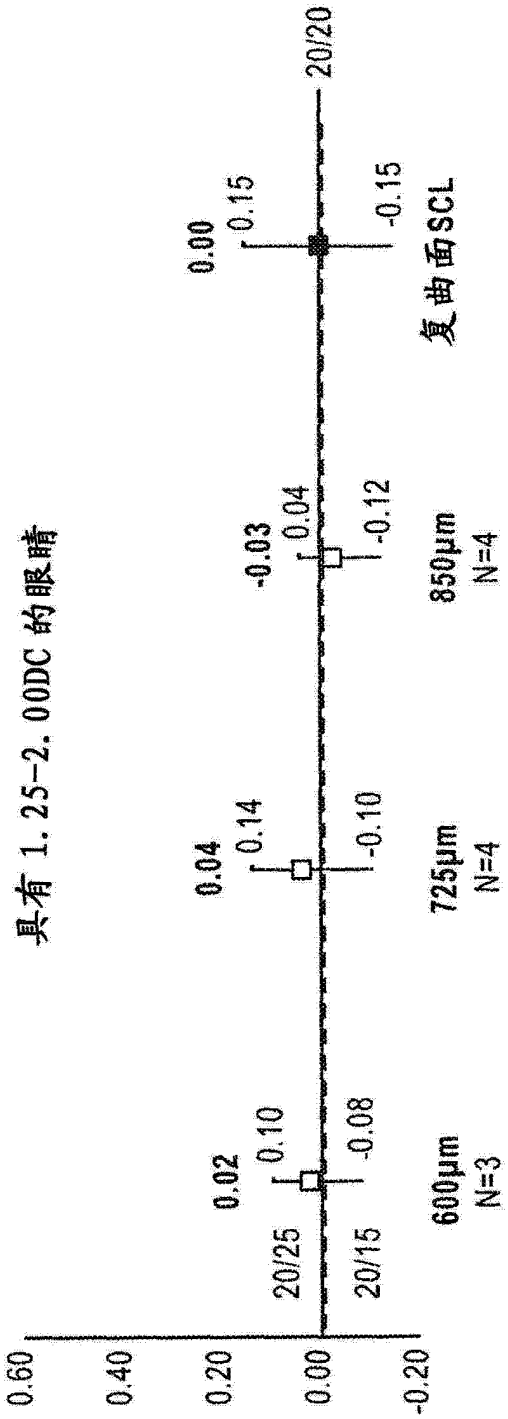


图 8A

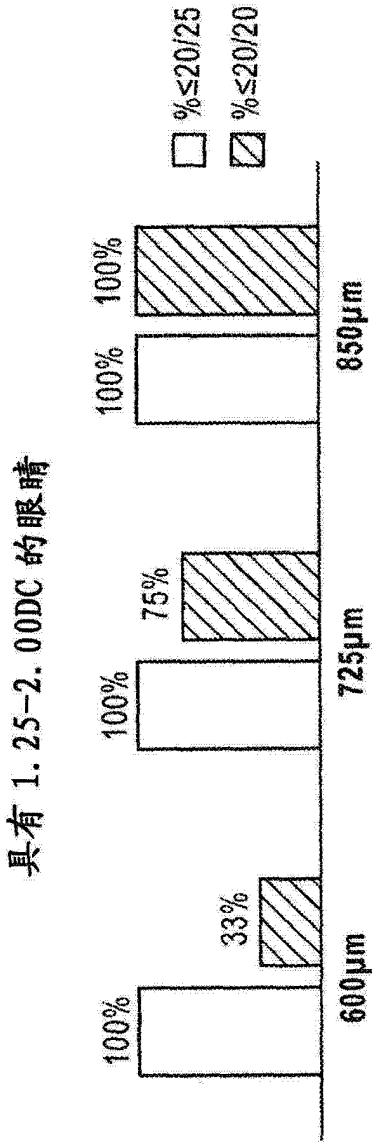


图 8B

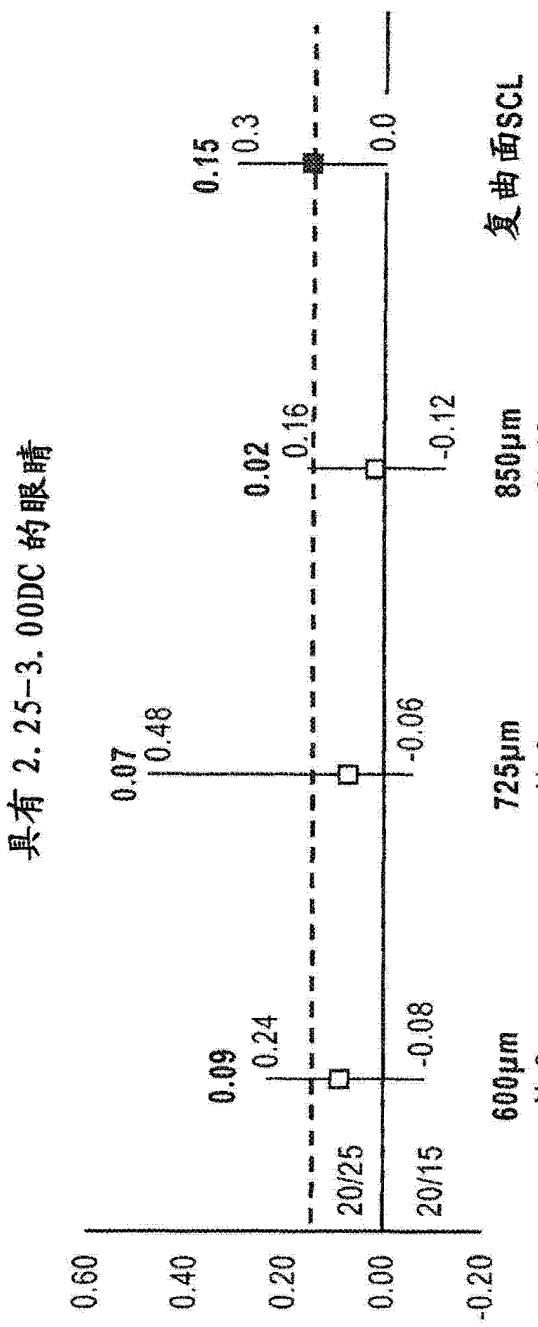


图 9A

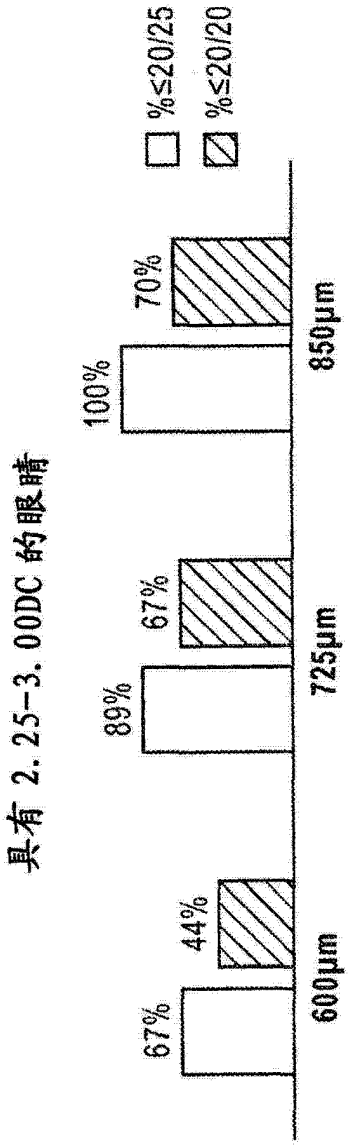


图 9B

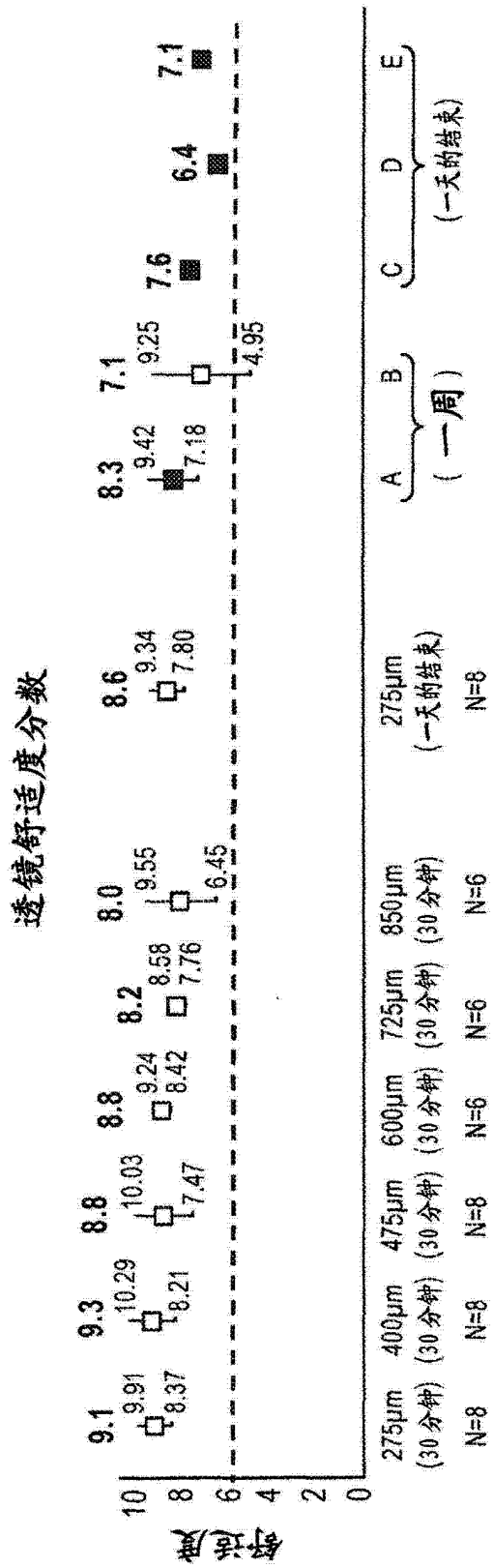


图 10A

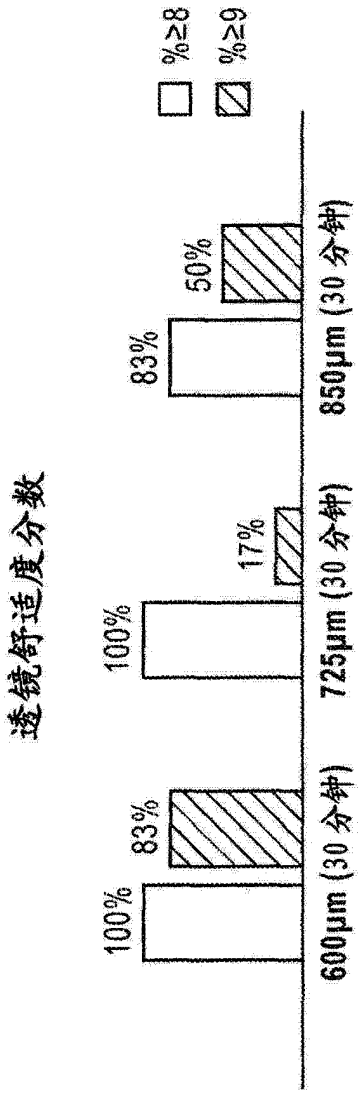


图 10B

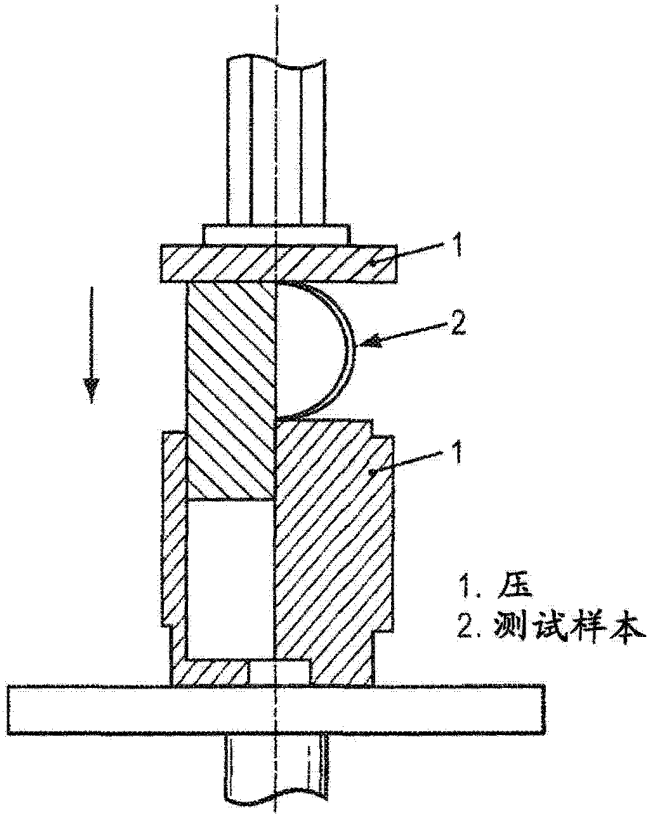


图 11

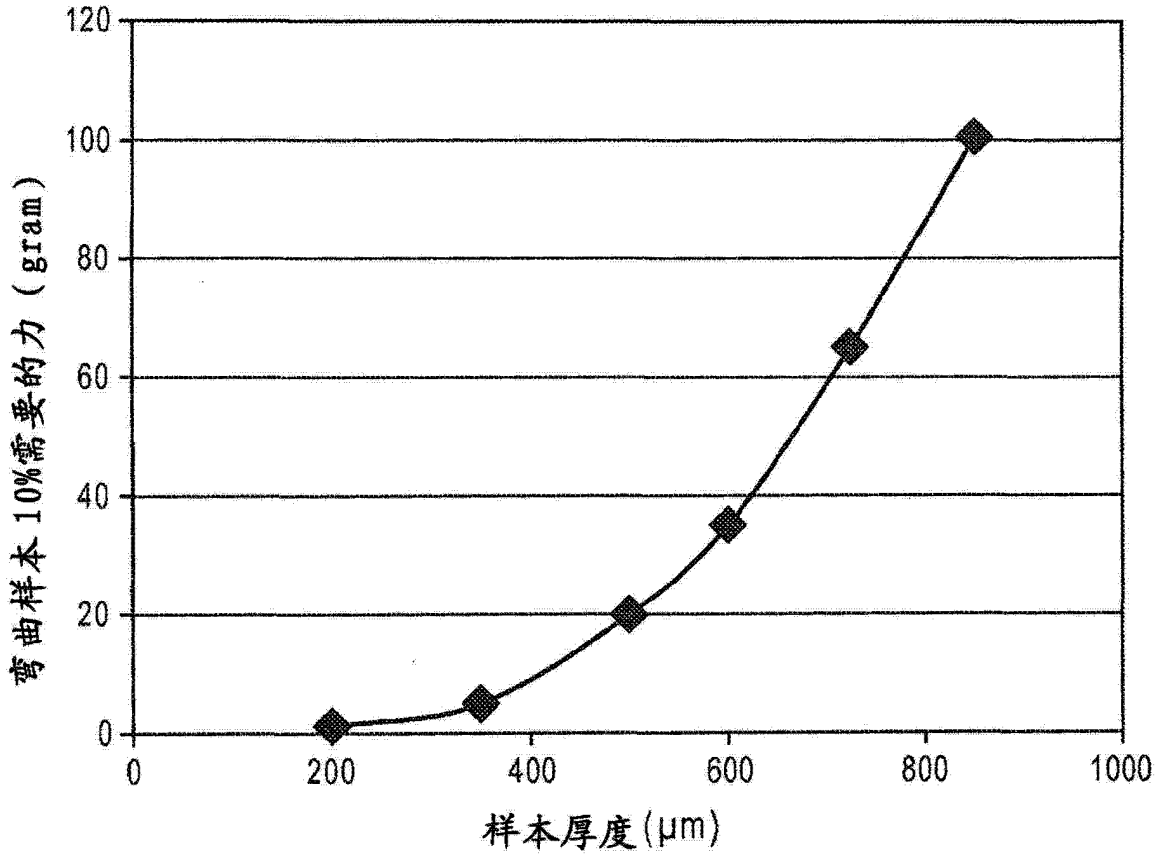


图 12

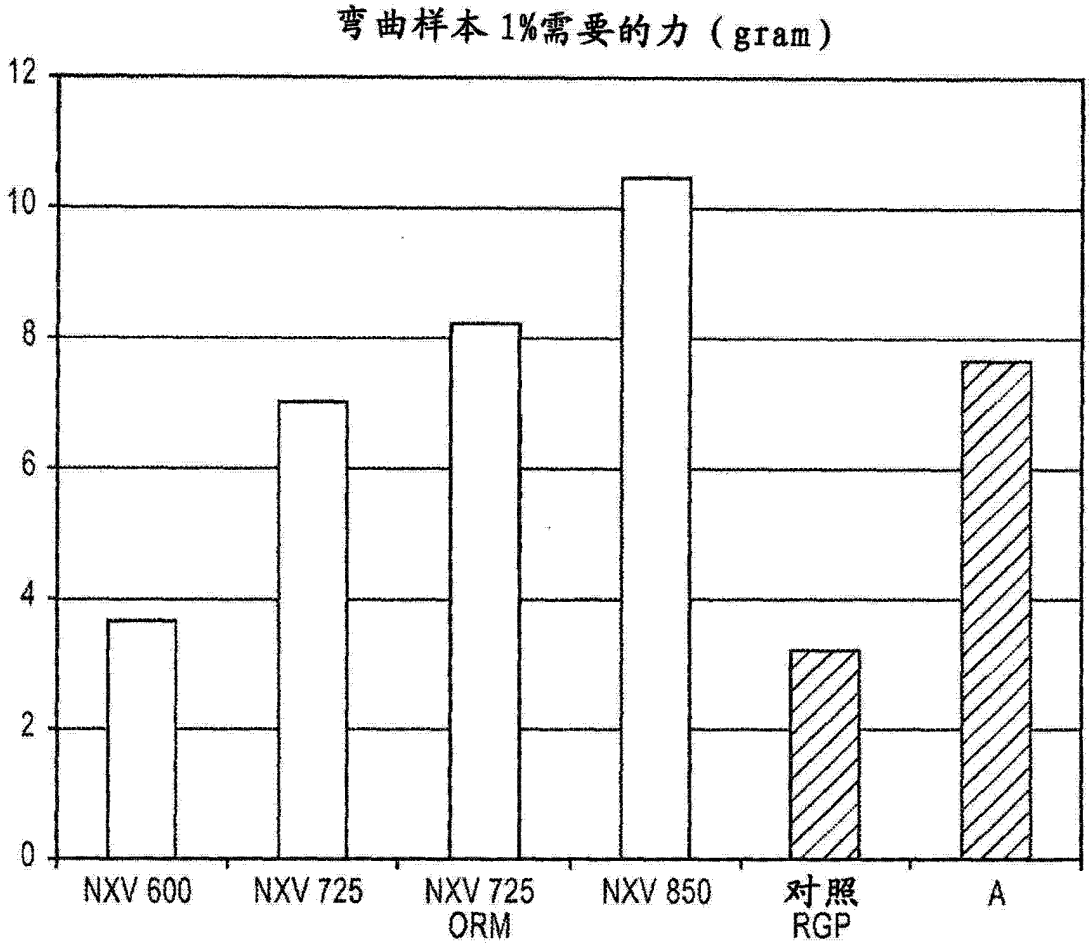


图 13

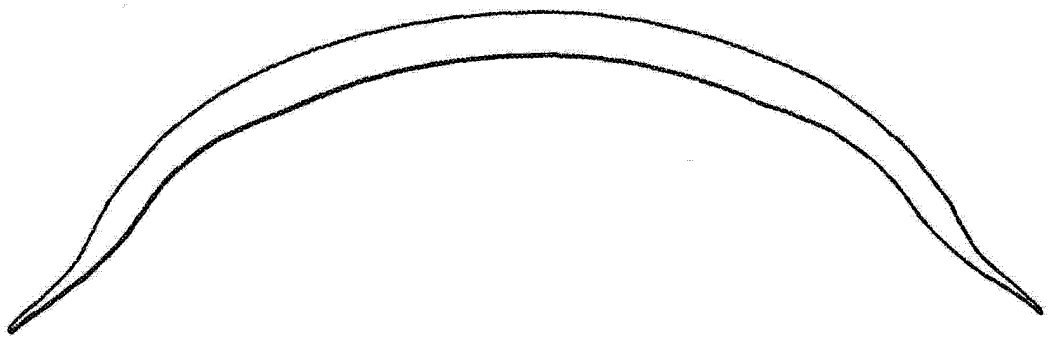


图 14A

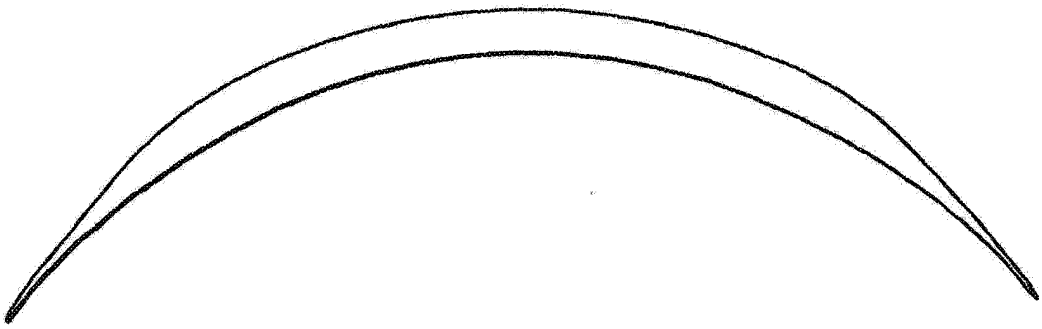


图 14B

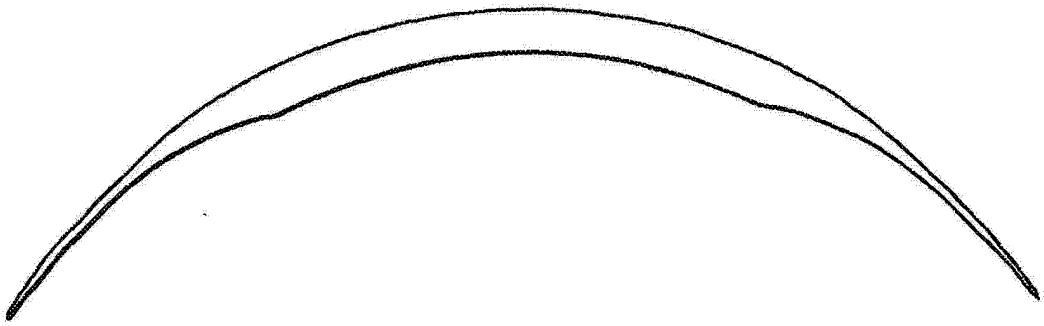


图 14C

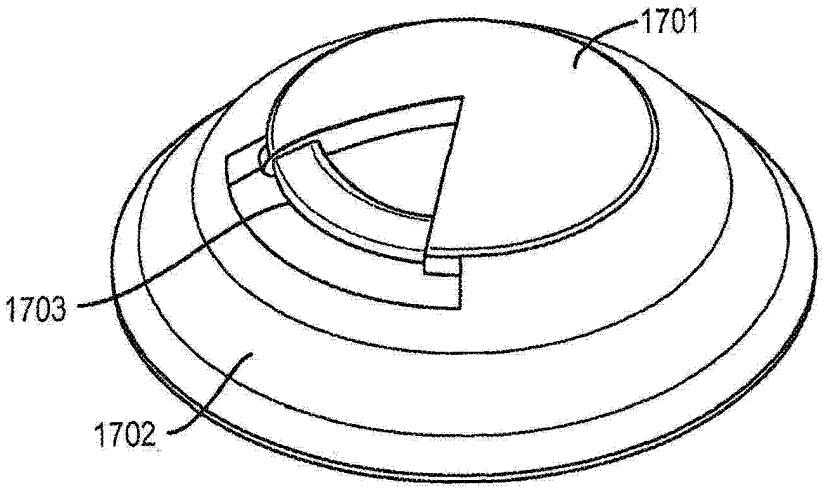


图 15A

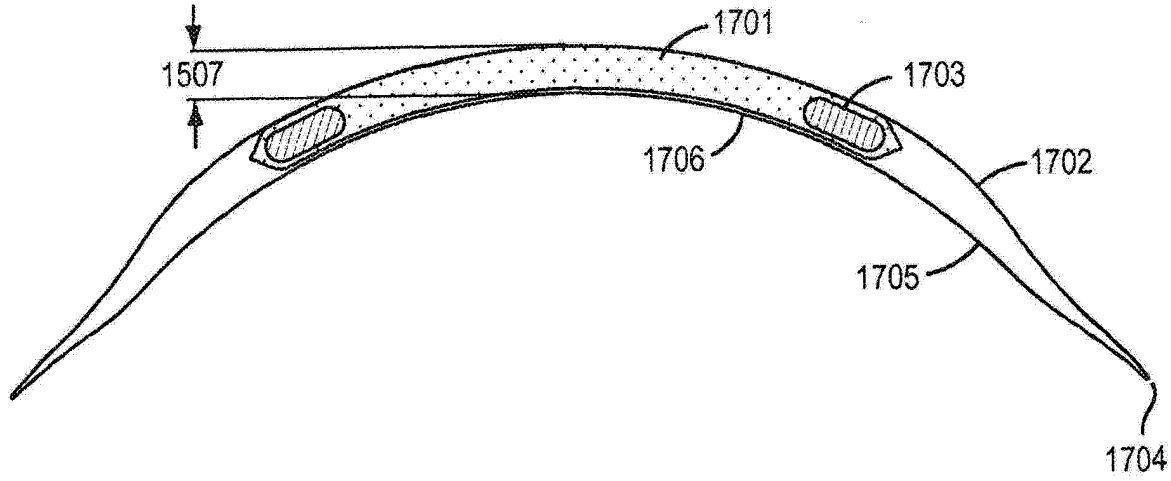


图 15B

Abstract

Ophthalmic lenses for correcting refractive error of an eye are disclosed. Ophthalmic lenses include a deformable inner portion and a deformable peripheral portion. When disposed over the optical region of an eye, the inner portion is configured so that engagement of the posterior surface against the eye deforms the posterior surface so that the posterior surface has a shape diverging form the refractive shape of the epithelium when viewing with the eye through the ophthalmic lens. The rigidity of the inner portion is greater than the rigidity of the peripheral portion and the ophthalmic lenses are configured to allow movement relative to the eye upon blinking of the eye and to be substantially centered on the optical region of the cornea following the blinking of the eye. Methods of correcting refractive errors of an eye (such as astigmatism or spherical aberration) using the ophthalmic lenses are also disclosed.