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(54) **Title:** CORNEAL INLAY DESIGN AND METHODS OF CORRECTING VISION

(57) **Abstract:** Methods of designing corneal implants, such as inlays, to compensate for a corneal response, such as epithelial remodeling of the epithelial layer, to the presence of the implant. Additionally, methods of performing alternative corneal vision correction procedures to compensate for an epithelial response to the procedure. Methods of compensating for a corneal response when performing a vision correction procedure to create a center near region of the cornea for near vision while providing distance vision peripheral to the central near zone.

CORNEAL INLAY DESIGN AND METHODS OF CORRECTING VISION

BACKGROUND OF THE INVENTION

[0001]   Abnormalities in the human eye can lead to vision impairment such as myopia (near-sightedness), hyperopia (farsightedness), astigmatism, and presbyopia. A variety of devices and procedures have been developed to attempt to address these abnormalities.

[0002]   One type of device that has been proposed is a corneal implant, such as an onlay, which is placed on top of the cornea such that the outer layer of the cornea (i.e., the epithelium), can grow over and encompass the onlay. An inlay is a corneal implant that is surgically implanted within the cornea beneath a portion of corneal tissue by, for example, cutting a flap in the cornea and positioning the inlay beneath the flap. An inlay can also be positioned within a pocket formed in the cornea.

[0003]   Inlays can alter the refractive power of the cornea by changing the shape of the anterior surface of the cornea, by creating an optical interface between the cornea and an implant by having an index of refraction different than that of the cornea (i.e., has intrinsic power), or both. The cornea is the strongest refracting optical element in the eye, and altering the shape of the anterior surface of the cornea can therefore be a particularly useful method for correcting vision impairments caused by refractive errors.

[0004]   LASIK (laser-assisted in situ keratomileusis) is a type of refractive laser eye surgery in which a laser is used to remodel a portion of the cornea after lifting a previous cut corneal flap.

[0005]   Presbyopia is generally characterized by a decrease in the eye's ability to increase its power to focus on nearby objects due to, for example, a loss of elasticity in the crystalline lens that occurs over time. Ophthalmic devices and/or procedures (e.g., contact lenses, intraocular lenses, LASIK, inlays) can be used to address presbyopia using three common approaches. With a monovision prescription, the diopter power of one eye is adjusted to focus distant objects and the power of the second eye is adjusted to focus near objects. The appropriate eye is used to clearly view the object of interest. In the next two approaches, multifocal or bifocal optics are used to simultaneously, in one eye, provide powers to focus both distant and near objects. One common multifocal design includes a central zone of higher diopter power to focus near objects, surrounded by a peripheral zone of the desired lower power to focus distant objects. In a modified monovision prescription, the diopter power of one eye is adjusted to focus distance objects, and in the second eye a multifocal optical design is induced by the intracorneal inlay.

The subject therefore has the necessary diopter power from both eyes to view distant objects, while the near power zone of the multifocal eye provides the necessary power for viewing near objects. In a bilateral multifocal prescription, the multifocal optical design is induced in both eyes. Both eyes therefore contribute to both distance and near vision.

[0006]   Regardless of the vision correction procedure and/or devices implanted, it is important to understand the cornea's natural response to the procedure to understand how the cornea will attempt to reduce or minimize the impact of the vision correction procedure.

[0007]   Specific to understanding a response to an inlay, Watsky et al. proposed a simple biomechanical response in Investigative Ophthalmology and Visual Science, vol. 26, pp. 240-243 (1985). In this biomechanical model ("Watsky model"), the anterior corneal surface radius of curvature is assumed to be equal to the thickness of the lamellar corneal material (i.e., flap) between the anterior corneal surface and the anterior surface of a corneal inlay plus the radius of curvature of the anterior surface of the inlay.

[0008]   Reviews of clinical outcomes for implanted inlays or methods for design generally discuss relatively thick inlays (e.g., greater than 200 microns thick) for which the above simple biomechanical response model has some validity. This is because the physical size of the inlay dominates the biomechanical response of the cornea and dictates the primary anterior surface change. When an inlay is relatively small and thin, however, the material properties of the cornea contribute significantly to the resulting change in the anterior corneal surface. Petroll et al. reported that implantation of inlays induced a thinning of the central corneal epithelium overlying the inlay. "Confocal assessment of the corneal response to intracorneal lens insertion and laser in situ keratomileusis with flap creation using IntraLase," J. Cataract Refract. Surg., vol. 32, pp 1119-1128 (July 2006).

[0009]   Huang et al. reported central epithelial thickening after myopic ablation procedures and peripheral epithelial thickening and central epithelial thinning after hyperopic ablation procedures. "Mathematical Model of Corneal Surface Smoothing After Laser Refractive Surgery," America Journal of Ophthalmology, March 2003, pp 267-278. The theory in Huang does not address correcting for presbyopia, nor does it accurately predict changes to the anterior surface which create a center near portion of the cornea for near vision while allowing distance vision in an area of the cornea peripheral to the center near portion. Additionally, Huang reports on removing cornea tissue by ablation as opposed to adding material to the cornea, such as an intracorneal inlay.

[0010]   What is needed is an understanding of the cornea's response to the correction of presbyopia, using, for example, a corneal inlay. An understanding of the corneal response

allows the response to be compensated for when performing the procedure on the cornea and/or implanting an implant within the cornea to alter the cornea. A need also exists for understanding the cornea's response to an inlay which creates a center zone for near vision while providing distance vision peripheral to the central zone.

SUMMARY OF THE INVENTION

[0011]   One aspect of the invention is a method of correcting vision. The method includes determining a desired shape change for the anterior surface of the cornea to correct vision, selecting a corneal inlay with a thickness profile which will produce the desired shape change to the anterior surface of the cornea, implanting the inlay within the cornea to thereby produce the desired shape change in the anterior surface of the cornea, wherein selecting the inlay with the thickness profile which will produce the desired shape change to the anterior surface of the cornea compensates for epithelial remodeling of the epithelial layer of the cornea in response to implanting the inlay within the cornea.

[0012]   In some embodiments determining a desired shape change for the anterior surface of the cornea comprises determining a desired shape change for a central portion of an anterior surface of the cornea, wherein the central portion is disposed along the optical axis of the cornea.

[0013]   In some embodiments determining a desired shape change for a central portion of an anterior surface of the cornea comprises determining a desired shape change for a central portion of the anterior surface of the cornea while avoiding a shape change of a peripheral region of the anterior surface of the cornea disposed peripherally to the central portion, and wherein a diameter of an interface between the central portion and the peripheral portion is smaller than the diameter of the pupil.

[0014]   In some embodiments determining a desired shape change for the anterior surface of the cornea comprises determining a shape change which steepens a center portion of the cornea to provide for near vision and which provides for distance vision in a region peripheral to the central portion, and wherein implanting the inlay within the cornea induces the steepening to the central portion to provide for near vision while providing for distance vision peripheral to the central portion.

[0015]   In some embodiments determining a desired shape change for the anterior surface of the cornea to correct vision comprises determining a desired corneal power change to correct for presbyopia, for example, between about 1.5 diopters and about 3.5 diopters.

[0016]   In some embodiments the thickness profile comprises at least one of a central thickness, a diameter, an anterior radius of curvature, and a posterior radius of curvature, and wherein selecting a corneal inlay with a thickness profile comprises selecting at least of one of

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the central thickness, diameter, anterior radius of curvature, and posterior radius of curvature to compensate for epithelial remodeling of the epithelial layer of the cornea in response to implanting the inlay within the cornea. In some embodiments selecting at least of one of the central thickness, diameter, anterior radius of curvature, and posterior radius of curvature to compensate for epithelial remodeling comprises selecting a corneal inlay with a central thickness of about 50 microns or less, and in some embodiments the central thickness is between about 25 microns to about 40 microns. In some embodiments selecting at least of one of the central thickness, diameter, anterior radius of curvature, and posterior radius of curvature to compensate for epithelial remodeling comprises selecting a corneal inlay with a diameter of between about 1 mm and about 3 mm, and in some embodiments is between about 1.5mm and about 2mm.

[0017]   In some embodiments implanting the inlay within the cornea comprising creating a flap in the cornea and positioning the inlay under the flap, while in some embodiments implanting the inlay within the cornea comprising forming a pocket in the cornea and positioning the inlay within the pocket.

[0018]   In some embodiments compensating for epithelial remodeling of the epithelial layer of the cornea comprises compensating for an epithelial thinning above the inlay along the optical axis of the cornea and/or compensating for epithelial remodeling of the epithelial layer of the cornea comprises compensating for an epithelial thickening peripheral to the inlay.

[0019]   In some embodiments wherein compensating for epithelial remodeling of the epithelial layer of the cornea in response to implanting the inlay within the cornea comprises compensating for the epithelial layer remodeling to reduce the change in shape of the anterior surface of the cornea in response to implanting the inlay within the cornea.

[0020]   In some embodiments determining a desired shape change for the anterior surface of the cornea comprises determining a desired elevation change diameter for a central portion of the anterior surface of the cornea, and wherein selecting a corneal inlay with a thickness profile which will produce the desired elevation change diameter to the anterior surface of the cornea comprises selecting an inlay diameter, and wherein selecting the inlay diameter comprises selecting an inlay diameter that is the desired elevation change diameter minus about 1.8 mm to about 2.4 mm, and can be about 2 mm.

[0021]   In some embodiments determining a desired shape change for the anterior surface of the cornea comprises determining a desired central elevation change for a central portion of the anterior surface of the cornea, and wherein selecting a corneal inlay with a thickness profile which will produce the desired central elevation change to the anterior surface of the cornea comprises selecting an inlay central thickness, and wherein selecting an inlay central thickness

comprises selecting an inlay central thickness that is about 3 to about 7 times the desired central elevation change, and can be about 5 times the desired central elevation change.

[0022]   In some embodiments implanting the inlay within the cornea comprises producing a central elevation change to Bowman's layer.

[0023]   In some embodiments the inlay has a index of refraction different than the index of refraction of the cornea to thereby provide intrinsic power to the inlay.

One aspect of the invention is a method of performing a corrective procedure on a cornea to correct for presbyopia. The method includes determining a desired stromal tissue alteration to correct presbyopia, altering the stromal layer of the cornea to correct the presbyopia, wherein altering the stromal layer of the cornea to correct the presbyopia comprises compensating for epithelial remodeling of the epithelial layer of the cornea in response to the stromal layer alteration.

[0024]   In some embodiments altering the stromal layer of the cornea to correct the presbyopia comprises altering the stromal layer using a laser, and may include ablating cornea tissue, such as in a LASIK procedure.

[0025]   In some embodiments altering the stromal layer of the cornea to correct the presbyopia comprises weakening stromal tissue, and in some cases corrects for presbyopia.

[0026]   In some embodiments altering the stromal layer of the cornea to correct the presbyopia comprises positioning a foreign substance within the cornea, such as an intracorneal inlay. The inlay can modify the shape of the anterior surface of the cornea by steepening a central portion to provide near vision while providing distance vision in a region of the cornea peripheral to the central portion.

[0027]   One aspect of the invention is a method of correcting vision. The method includes determining a desired shape change for the anterior surface of the cornea, wherein the desired shape change comprises a central zone of increased steepness for providing near vision, performing a vision correction procedure to increase the steepness of a central portion of the anterior surface of the cornea to provide near vision while providing distance vision in a region of the cornea peripheral to the central portion, wherein performing a vision correction procedure compensates for epithelial remodeling to the anterior surface of the cornea.

[0028]   In some embodiments performing a vision correction procedure to increase the steepness of a central portion of the anterior surface of the cornea to provide near vision while providing distance vision in a region of the cornea peripheral to the central portion comprises positioning an intracorneal inlay within corneal tissue. Positioning an intracorneal inlay within

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corneal tissue comprises positioning the inlay within stroma tissue at a depth of about 200

microns or less measured from the anterior surface of the cornea.

INCORPORATION BY REFERENCE

[0029]   All publications and patent applications mentioned in this specification are herein

incorporated by reference to the same extent as if each individual publication or patent

application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030]   The novel features of the invention are set forth with particularity in the appended

claims. A better understanding of the features and advantages of the present invention will be

obtained by reference to the following detailed description that sets forth illustrative

embodiments, in which the principles of the invention are utilized, and the accompanying

drawings of which:

[0031]   Figure 1 shows an exemplary intracorneal inlay which can be implanted within

cornea tissue according to methods herein.

[0032]   Figures 2 and 3 show an exemplary steepening of a central portion of the anterior

surface of the cornea after an inlay has been implanted within the cornea.

[0033]   Figure 4 illustrates how an inlay as described herein can be implanted within a cornea

to provide center near vision and peripheral distance vision in an eye.

[0034]   Figure 5 illustrates the locations of epithelial thinning and thickening after an inlay

has been implanted within a cornea.

[0035]   Figure 6 illustrates the shape change of Bowman's layer and the anterior surface of

the cornea in response to an inlay being implanted within the cornea.

[0036]   Figures 7 and 9 present clinical data (e.g., distance and near visual acuity and the

refractive effect created by the inlay) and the change in anterior corneal surface elevation derived

from pre-op and post-op wavefront measurements of patients in which an inlay was implanted.

[0037]   Figures 8 and 10 chart the changes in elevation of the anterior surface of the cornea

(i.e., the difference in elevation between pre-op and post-op) versus the radius of the anterior

surface of the cornea for patients in which an inlay was implanted.

DETAILED DESCRIPTION OF THE INVENTION

[0038]   This disclosure relates to methods of vision correction and methods of compensating

for a cornea's response to the vision correction procedure to invoke a desired corneal shape

change. The disclosure includes methods of correcting presbyopia. In some embodiments the

methods include implanting a corneal inlay within cornea tissue to correct for presbyopia while compensating for the inlay's presence within the cornea. The disclosure also provides methods of increasing the curvature of a central portion of the anterior surface of the cornea to provide near vision in the central portion while providing distance vision peripheral to the central

5   portion. In some particular embodiments an inlay is implanted in the cornea to cause the central portion to increase in curvature to provide near vision.

[0039]   The cornea can be generally considered to be comprised of, from the anterior A to posterior P direction, the epithelium, Bowman's layer, stroma, Descemet's membrane, and the endothelium. The epithelium is a layer of cells that can be thought of as covering the surface of

10   the cornea and it is only about five (5) cells thick with a thickness of about 50 microns. The stroma is the thickest layer of the cornea and gives the cornea much of its strength, and most refractive surgeries involve manipulating stroma cells. Descemet's membrane and the endothelium are considered the posterior portion of the cornea and are generally not discussed herein. The instant disclosure focuses the discussion on the epithelium, Bowman's layer, and the

15   stroma.

[0040]   As disclosed herein a cornea's response to a vision correction procedure is generally described as a "physiological response," or variations thereof. The physiological response may include any biomechanical response, which is the corneal response due to an interaction with and/or alteration to Bowman's layer. A physiological response as used herein may also include

20   an epithelial response, which includes a natural remodeling of the epithelial layer in response to a vision correction procedure.

[0041]   In some embodiments a corneal inlay is used to correct for presbyopia. Figure 1 is a side cross-sectional view of an exemplary corneal inlay 10 with diameter D, central thickness T along the central axis CA of the inlay, anterior surface 12, posterior surface 18, outer edge 16,

25   and optional beveled portion 14. Anterior surface 12 has an anterior radius of curvature, and posterior surface 18 has a posterior radius of curvature. Outer edge 16 connects posterior surface 18 and beveled portion 14. The beveled portion may be considered a part of the anterior surface or may be considered a separate surface between the anterior surface and the posterior surface. Exemplary inlay 10 can be used to treat, for example without limitation, presbyopia.

30   [0042]   Inlay 10 can have any features or parameters described herein or in any of the following Patent Applications and Patents: U.S. Patent Application No. 11/738,349, filed April 20, 2007, (U.S. Patent Application No. US 2008/0262610 A1), U.S. Patent Application No. 11/381,056, filed May 1, 2006 (Patent Application Pub. US 2007/0255401 A1), U.S. Patent Application No. 11/554,544, filed October 30, 2006 (Patent Application Pub. US 2007/0203577

A1), U.S. Patent Application No. 11/293,644, filed December 1, 2005 (Patent Application Pub. US 2007/0129797 A1), U.S. Patent Application No. 11/421,597, filed June 1, 2006 (Patent Application Pub. US 2007/0280994 A1), 10/924,152, filed August 23, 2004 (Patent Application Pub. US 2005/0178394 A1), U.S. Patent Application No. 11/106,983, filed April 15, 2005

5   (Patent Application Pub. US 2005/0246016 A1), U.S. Patent Application No. 10/837,402, filed April 30, 2004 (Patent Application Pub. US 2005/0246015 A1), U.S. Patent Application No. 10/053,178, filed November 7, 2001 (Patent No. 6,623,522), U.S. Patent Application No. 10/043,975, filed October 19, 2001 (Patent No. 6,626,941), U.S. Patent Application No. 09/385,103, filed August 27, 1999 (Patent No. 6,361,560), and U.S. Patent Application No.

10   09/219,594, filed December 23, 1998 (Patent No. 6,102,946), all of which are incorporated by reference herein.

[0043]   Inlay 10 can be implanted within the cornea by known procedures such as by cutting a flap 25 (see Figure 2) in the cornea, lifting the flap 25 to expose the corneal bed, placing the inlay 10 on the exposed cornea bed, and repositioning the flap 25 over the inlay 10. When flap

15   25 is cut, a small section of corneal tissue is left intact, creating a hinge for flap 25 so that flap 25 can be repositioned accurately over the inlay 20. After the flap 25 is repositioned over the inlay, the flap adheres to the corneal bed. In some embodiments in which an inlay is positioned beneath a flap, the inlay is implanted between about 100 microns and about 200 microns deep in the cornea. In some embodiments the inlay is positioned at a depth of between about 130

20   microns to about 160 microns. In some particular embodiments the inlay is implanted at a depth about 150 microns.

[0044]   The inlay can also be implanted by creating a pocket in the cornea and positioning the inlay within the formed pocket. Pockets are generally created deeper in the cornea than flaps, which can help in preventing nerve damage. In some embodiments in which a pocket is formed,

25   the inlay is implanted at a depth of between about 150 microns and about 300 microns. In some embodiments the inlay is positioned at a depth of between about 200 microns to about 250 microns.

[0045]   The inlay should be positioned on the corneal bed with the inlay centered on the subject's pupil or visual axis. Inlay 10 can be implanted in the cornea at a depth of about 50% or

30   less of the cornea thickness measured from the anterior surface of the cornea (approximately 250 μm or less). The flap 25 may be cut using, for example, a laser (e.g., a femtosecond laser) or a mechanical keratome. Additional methods or details of implanting the inlay can be found in, for example, U.S. Patent Application No. 11/293,644, filed December 1, 2005 (Patent Application

Pub. US 2007/0129797 A1) and U.S. Patent Application No. 11/421,597, filed June 1, 2006 (Patent Application Pub. US 2007/0280994 A1), which are incorporated by reference herein.

[0046] As can be seen in Figure 2, inlay 10, once implanted within the cornea, changes the refractive power of the cornea by altering the shape of the anterior surface of the cornea from pre-operative shape 35 (shown with dashed line) to post-operative shape 40 (shown as a solid line). In Figure 2, the inlay changes the shape of a central portion of the anterior surface of the cornea, while a peripheral portion of the anterior surface peripheral to the central portion does not change shape. Figure 2 shows an elevation change in the central portion of the anterior surface of the cornea. The elevation change includes a steepening of the central portion. The curvature of the central zone is increased to provide for near vision in the central portion, while the shape of the peripheral zone does not change and provides for distance vision peripheral to the central zone. The inlay in Figure 2 can be used to correct for presbyopia because the central zone's increased curvature increases the eye's ability to focus on near objects.

[0047] In some embodiments the inlay has properties similar to those of the cornea (e.g., index of refraction around 1.376, water content of 78%, etc.), and may be made of hydrogel or other clear bio-compatible material. The inlay can be comprised of a variety of materials including, for example and without limitation, Lidofilcon A, Poly-HEMA (hydroxyethyl methylacrylate), poly sulfone, silicone hydrogel. In some embodiments the inlay comprises from about 20% to about 50% HEMA (hydroxyethyl methylacrylate), from about 30% to about 85% NVP (N-vinyl pyrrolidone), and/or about 0% to about 25% PVP (polyvinyl pyrrolidone). Other formulations of such materials cover compositions ranging from about 15% to about 50% MMA (methyl methylacrylate), from about 30% to about 85% NVP, and/or about 0% to about 25% PVP (polyvinyl pyrrolidone).

[0048] In some embodiments the water content of these compositions ranges from about 65% to about 80%. In one particular embodiment the inlay comprises about 78% NVP and about 22% MMA(methyl methacrylate), allymethacrylate as a crosslinker, and AIBN (azobisisobutylonitrile) as the initiator. Exemplary additional details and examples of the inlay material can be found in U.S. Patent Application No. 11/738,349, filed April 20, 2007, (U.S. Patent Application No. US 2008/0262610 A1), which is incorporated by reference herein. In some embodiments the inlay has an index of refraction of approximately 1.376 +/- .0.008, which is substantially the same as the cornea. As a result, the inlay does not have intrinsic diopter power. The inlay can, however, have an index of refractive that is substantially different than the index of refraction of the cornea such that the inlay has intrinsic diopter power (in addition to changing the curvature of the anterior surface of the cornea). Exemplary details of a lens with

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intrinsic diopter power and methods of use, the features of which can be incorporated into the methods herein, are described in U.S. Patent Application No. 11/381,056, filed May 1, 2006 (Patent Application Pub. US 2007/0255401 A1), which is incorporated herein by reference.

[0049]   Figure 3 illustrates a cross-sectional side view of an exemplary biomechanical effect of inlay 210 on the shape of the post-operative anterior corneal surface 240. Inlay 210 has center thickness 265, edge thickness 250, anterior surface 215, and posterior surface 220. The "effect" zone (which may also be referred to herein as "central zone"), or the region of the anterior surface whose curvature is altered due to the presence of the inlay, extends peripherally beyond the diameter of inlay 210. The "effect" zone comprises the geometric projection of the inlay diameter on the anterior surface 260 and "an outer effect zone" 255 peripheral to the projection of the inlay diameter. The effect zone has a center thickness 275.

[0050]   Figure 4 illustrates an exemplary embodiment in which an inlay is used to provide near vision while providing distance vision to correct for presbyopia. The eye comprises cornea 110, pupil 115, crystalline lens 120, and retina 125. In Figure 4, implanting the inlay (not shown) centrally in the cornea creates a small diameter "effect" zone 130 in the cornea. Both the inlay diameter and effect zone diameter are smaller than the pupil 115 diameter. The "effect" zone 130 provides near vision by increasing the curvature of the anterior corneal surface in a central region of the cornea, and therefore the diopter power of the "effect" zone 130. The region of the cornea peripheral to the "effect" zone 135 has a diameter less than the diameter of the pupil and provides distance vision. The subject's near vision is therefore improved while minimizing the loss of distance vision in the treated eye.

[0051]   An exemplary advantage of this type of inlay is that when concentrating on nearby objects 140, the pupil naturally becomes smaller (e.g., near point miosis) making the inlay effect even more effective. Near vision can be further increased by increasing the illumination of a nearby object (e.g., turning up a reading light). Because the "effect" zone 130 is smaller than the diameter of pupil 115, light rays 150 from distant object(s) 145 by-pass the inlay and refract using the region of the cornea peripheral to the "effect" zone to create an image of the distant objects on the retina 125. This is particularly true with larger pupils. At night, when distance vision is most important, the pupil naturally becomes larger, thereby reducing the inlay effect and maximizing distance vision.

[0052]   A subject's natural distance vision is in focus only if the subject is emmetropic (i.e., does not require correction for distance vision). Many subjects are ammetropic, requiring either myopic or hyperopic refractive correction. Especially for myopes, distance vision correction can be provided by myopic Laser in Situ Keratomileusis (LASIK) or other similar corneal refractive

procedures. After the distance corrective procedure is completed, the small inlay can be implanted in the cornea to provide near vision. Since LASIK requires the creation of a flap, the inlay may be inserted concurrently with the LASIK procedure. The inlay may also be inserted into the cornea after the LASIK procedure as the flap can be re-opened. This type of inlay may therefore be used in conjunction with other refractive procedures, such as LASIK for correcting myopia or hyperopia.

[0053]   In some embodiments (e.g., as shown in Figure 4) an inlay is implanted to create an effect zone that is less than the pupil diameter and is used for correcting presbyopia. Presbyopia is generally characterized by a decrease in the ability of the eye to increase its power to focus on nearby objects due to, for example, a loss of elasticity in the crystalline lens over time. Typically, a person suffering from Presbyopia requires reading glasses to provide near vision. For early presbyopes (e.g., about 45 to 55 years of age), at least 1 diopter is typically required for near vision. For complete presbyopes (e.g., about 60 years of age or older), between 2 and 3 diopters of additional power is required. In an exemplary embodiment, a small inlay (e.g., about 1 to about 3 mm in diameter) is implanted centrally in the cornea to induce an "effect" zone on the anterior corneal surface (e.g., about 2 to about 4 mm in diameter) that is smaller than the optical zone of the cornea for providing near vision while also allowing distance vision in a region of the cornea peripheral to the effect zone.

[0054]   The first step in correcting the vision of a subject by altering the cornea is generally determining the desired post-operative shape of the anterior corneal surface which will provide the desired refractive power change (i.e., determining the shape change for the anterior surface of the cornea). The shape of the desired anterior surface may be the result of a biomechanical response as well as epithelial remodeling of the anterior corneal surface as a result of the vision correction procedure. Corneal epithelial remodeling will be described in more detail below. Based on a biomechanical response and an epithelial response, the vision correction procedure is performed (e.g., implanting an inlay) to induce the desired anterior surface change.

[0055]   This disclosure includes an exemplary method of determining a desired anterior corneal shape to provide for corrective vision. One particular embodiment in which the method includes implanting an inlay within the cornea to provide for center near and peripheral distance will be described. In some embodiments a central zone on the anterior corneal surface with a sharp transition is preferred (i.e., substantially without an outer effect zone which can be seen in Figure 3). A sharp transition maximizes both the near and distance power efficiencies. In practice, the effects of epithelial remodeling typically prevent "sharp" transitions. Empirically,

the anterior surface change induced by the inlay can be given by a symmetric polynomial of at least eighth order:

$$Elev(r) = a0 + a2 \times r^2 + a4 \times r^4 + a6 \times r^6 + a8 \times r^8 \qquad \text{Eq 1.}$$

[0056]   Where "Elev" is the change in anterior corneal surface elevation due to the inlay, a0, a2, a4, a6 and a8 are the coefficients governing the shape

And "r" is the radial extent location from the center of the anterior surface change.

[0057]   The elevation change discussed herein is azimuthally symmetric in plane perpendicular to the axis of the cornea. But orthogonal asymmetries may be included with more complex inlay designs, attempting to correction of corneal astigmatism, pre-existing in the subject's eye. Physically, there are useful restrictions on the form of the elevation expression. At r = 0, the elevation change is maximal and is central height "hctr". From the symmetry, at r = 0, the first derivative of elevation expression must be zero. The extent of the inlay-induced change is limited to a maximal radius (r_z), where Elev(r_z) = 0. And because the elevation smoothly transitions to the original cornea at r_z, the first derivative may also be zero; i.e., dElev(r_z)/dr = 0.

[0058]   With these restrictions, the elevation change can be characterized by four independent parameters: hctr, r_z, a6 and a8. And the remaining coefficients are given by:

a0 = hctr

a2 = 2 * alpha / rz ^ 2 - beta / 2 / rz

a4 = beta / 2 / rz ^ 3 - alpha / rz ^ 4

Where:

alpha = -hctr - a6 * rz ^ 6 - a8 * rz ^ 8

beta = -6 * a6 * rz ^ 5 - 8 * a8 * rz ^ 7

[0059]   Thus, the ideal anterior corneal elevation change can be expressed by four independent parameters: hctr, r_z, a6 and a8.

[0060]   Table 1 provides ideal anterior corneal surface changes for three spectacle ADD powers (1.5 diopters, 2.0 diopters, and 2.5 diopters) and for three pupil sizes (small, nominal and large) when using near vision.

TABLE 1: Examples of Ideal Anterior Corneal Surface Change Designs

Design Type	Pupil Size	ADD	"hctr"	rad zone	a6 (mm^{-5})	a8 (mm^{-7})

(mm)		(diopters)	(microns)	(mm)		
MaxN @ 2.5	small	1.5	4.30	1.39	-4.500E-04	2.800E-04
MaxN @ 3.0	nominal	1.5	5.06	1.50	-2.830E-04	1.466E-04
MaxN @ 3.5	large	1.5	6.24	1.66	-3.374E-04	9.972E-05
MaxN @ 2.5	small	2.0	5.38	1.36	-2.450E-03	8.100E-04
MaxN @ 3.0	nominal	2.0	7.15	1.55	-1.830E-03	4.420E-04
MaxN @ 3.5	large	2.0	10.70	1.87	-6.014E-04	1.108E-04
MaxN @ 2.5	small	2.5	6.58	1.38	-2.247E-03	7.904E-04
MaxN @ 3.0	nominal	2.5	9.87	1.68	-7.639E-04	1.950E-04
MaxN @ 3.5	large	2.5	13.70	1.97	-3.658E-04	7.109E-05

[0061]   Performing the optical ray-trace optimization to derive the optimal anterior corneal elevation change (Elev) requires a model eye which mimics the key optical functions of the human eye. The finite eye model by Navarro (Accommodation dependent model of the human eye with aspherics, R. Navarro. Et al, JOSA Vol 2 No 8 1985 p. 1273-1281) provides one such model. For these design purposes, the Navarro provides anatomically correct values for the corneal physical and optical properties and provides total eye properties such as normal values for the total eye spherical aberrations, chromatic aberration and Stiles-Crawford effect. Other model eyes can be also used if they specify these criteria.

[0062]   To include the anterior corneal elevation change (Elev) in the Navarro eye model, the Elev surface is added to the anterior surface of the Navarro eye model. Calculations of the image quality created by the anterior surface change to the eye model are accomplished using any of many commercial ray-trace software packages. For the examples provided, the Zemax-EE Optical Design Program (2008) from the Zemax Development Corporation was used.

[0063]   The objective of the ray-trace optimization is to find the elevation surface parameters (hctr, r_z, a6 and a8) that maximize the optical performance for a given set of assumptions. There are many optical metrics of image quality used in optical design. Of these, the Modulation Transfer Function (MTF) is particularly useful for optical designs, simultaneously using two zones of optical power. The MTF is the efficiency of transferring the contrast of the original object to the contrast of the image of the object on the human retina. The MTF efficiency (modulation) is plotted as a function of the spatial frequency information in the image of the object. The spatial frequency can be thought of as one divided by the size of features in the image. Thus, large spatial frequencies represent very fine features in the image, and low spatial

frequencies represent very large features in the image. The image quality is maximized when the MTF values at selected spatial frequencies have their highest values.

[0064]   The assumptions are derived from the inlay's design requirement to provide a good distance image from light rays passing through the peripheral region between the pupil diameter and the inlay's effect zone (r_z), and a good near image for light rays passing through the central effect zone. Thus, the ray-trace program is set with at least two configurations. In the first, the object for the eye model is set to infinity (e.g., looking at a distant object). In the second configuration, the object is set at a near distance. The typical distance of near work and ophthalmic prescription is 40 cm, which corresponds to a spectacle ADD of 2.5 diopters.

[0065]   For each configuration, the model eye's pupil size must be set. Of the many choices, two are the most logical. In the first, the pupil size is set the same for both configurations and goal of the optimization is to find the elevation parameters which give equal distance and near image quality. The second choice is to set separate pupil sizes for the distance and near configurations. The near configuration pupil size is set to subject's pupil size in a well illuminated setting i.e., the peripheral distance zone is effectively zero. This condition provides the maximal near distance capability. The distance configuration pupil size is set to the subject's night-time or dim-light pupil size, where distance vision is maximized. For the examples provided herein, the latter method was used, using different pupil sizes for the distance and near configurations. Note that regardless of the method chosen, the same range of ideal elevation profiles (e.g., Table 1) will be found.

[0066]   The human pupil size varies for a given set of illumination conditions, with two important trends. As an individual ages, the nighttime pupil size decreases. Additionally, when looking at a near object, the pupil diameter reduces by about 0.5 mm. Based on literature and clinical experience, the near configuration pupil in bright lighting is considered "small" if approximately 2.5 mm in diameter, "nominal" if approximately 3.0 mm, and "large" if approximately 3.5 mm in diameter. For the distance configuration, the nighttime pupil sizes vary greatly, and any loss of distance vision is compensated for by the fellow eye. Thus, one nighttime pupil size is sufficient for design purposes and a diameter of 5.0 mm is suggested by the literature / clinical experience.

[0067]   The optimization tools of the ray-trace software program are now utilized. The elevation parameters (hctr, r_z, a6 and a8) are varied until the MTF of the near configuration is maximized while simultaneously maximizing the MTF of the distance configuration. The ideal design is clearly a function of the assumed pupil sizes. In practice, subject may be screened

preoperatively, allowing the surgeon to select the inlay design most appropriate for the subject's pupil size range and desired visual outcome.

[0068]   In this particular method of implanting an inlay, once the desired anterior surface change has been determined, the inlay to be implanted is selected, taking into account and compensating for a biomechanical response and an epithelial response due to the presence of the inlay. Exemplary biomechanical interactions which can be taken into consideration can be found in U.S. Patent Application No. 11/738,349, filed April 20, 2007, to which this application claims priority and which is incorporated by reference herein.

[0069]   Empirical data presented herein below provides details of some aspects of a biomechanical response and an epithelial response due to the presence of an intracorneal inlay.

[0070]   Petroll et al. noted that intracorneal inlays induced epithelial thinning of the epithelium overlying the inlay. Figure 5 illustrates a cross-section side view of inlay 500 positioned within the cornea stroma layer. Imaging a portion of the cornea with optical coherence tomography (OCT) has shown that after an inlay is positioned within the cornea, the epithelial layer attempts to reduce an induced change in shape in the anterior surface of the cornea. There has been a noticed epithelial thinning 502 radially above the inlay, and an epithelial thickening 504 at locations slightly beyond the diameter of the inlay. The epithelial layer remains unchanged in outer region 506. This epithelial remodeling appears to be a natural response by the epithelial layer to smooth out, or reduce, the induced increase in curvature of the anterior surface of the cornea. By thinning in region 502 and thickening in region 504, the epithelium remodels and attempts to return the anterior surface to its pre-operative shape. Epithelial remodeling in this context is the epithelial layer's way of attempting to reduce the change induced by the implantation of a foreign object within the cornea. The thinning and thickening have each been observed to be about 10 microns.

[0071]   This epithelial remodeling will adjust the shape of the anterior surface of the cornea after the inlay has been implanted. This will adjust the refractive effect of the inlay. In the examples described above, epithelial remodeling will attempt to reduce an induced steepening in curvature of the central effected zone by thinning a central region of the epithelium and thickening a peripheral portion of the epithelium. Understanding the epithelial remodeling is therefore important to understand how an inlay will ultimately change the shape of the anterior surface of the cornea. In some embodiments, therefore, selecting an inlay to be implanted within the cornea to be used for center near vision comprises selecting an inlay that will compensate for epithelial remodeling and still cause the anterior surface of the cornea to adjust to the desired shape. Huang et al. describes the effects of epithelial remodeling as it relates to ablation of

cornea tissue (i.e., removal of tissue). Huang, however, fails to address an epithelial remodeling after the addition of material to the cornea, such as an intracorneal inlay. An embodiment herein focuses on the epithelial remodeling after the addition of material to the cornea.

[0072]   Figure 6 illustrates a cross-sectional side view of a portion of a cornea before and after implantation of an intracorneal inlay 600. The change in the central region of Bowman's layer "DCenBow" is shown by the difference in the two arrows. Similarly, the changes in a peripheral region of Bowmans' layer "DPerBow", the central anterior surface of cornea "DCenCor", and a peripheral region of the anterior surface of cornea "DPerCorn" are represented.

[0073]   Figure 7 presents clinical data (e.g., distance and near visual acuity and the refractive effect created by the inlay) and the change in anterior corneal surface elevation derived from pre-op and post-op wavefront measurements of nine patients in whom a 1.5 mm diameter inlay with an average center thickness of about 32 microns (ranging from 30 microns to 33 microns) was implanted. The "Postop ucnVA" column shows the post-operative uncorrected near visual acuity. The second "PostuncNL" column shows the lines of uncorrected near visual acuity change (positive represents a gain while negative represents a loss). The "PostOp ucDVA" column shows the post-operative uncorrected distance visual acuity. The "PostucDL" column shows the lines of uncorrected distance visual acuity change (positive represents a gain while negative represents a loss). The "InlayADDeff" column shows the refractive effect of the inlay calculated from clinical refraction data. The "InlayCen2.5mmSph" column shows the refractive effect of the inlay, centered on the inlay for a 2.5 mm diameter pupil, calculated from Tracey wavefront data. The "Diff Fit Ht" column shows the central anterior corneal elevation change (i.e., the difference between post-op and pre-op) calculated from Tracey wavefront data. The "Diff Eff Dia" column shows the effect zone diameter. Figure 8 charts the changes in elevation of the anterior surface of the cornea (i.e., the difference in elevation between pre-op and post-op) versus the radius of the anterior surface of the cornea for the nine patients in whom the 1.5mm diameter inlay was implanted.

[0074]   Figure 9 presents clinical data the change in anterior corneal surface elevation derived from pre-op and post-op wavefront measurements of seven patients in whom a 2.0 mm diameter inlay with an average center thickness of about 32 microns (ranging from 31 microns to 33 microns) was implanted. The column headings are the same as those shown in Figure 8. Figure 10 charts the changes in elevation of the anterior surface of the cornea (i.e., the difference in elevation between pre-op and post-op) versus the radius of the anterior surface of the cornea for the seven patients in whom the 2.0 mm diameter inlay was implanted.

[0075]   As shown in the data there is patient-to-patient variability with respect to the
epithelial remodeling of the cornea. The designs and methods described herein, however, show
effectiveness despite this variability.

[0076]   A merely exemplary method for designing or selecting an implantable cornea device
such as a small inlay to provide for central near vision and peripheral distance visions, which
also compensates for epithelial remodeling or other physiological responses to the inlay will now
be given. One step in the method is determining a maximum effect zone diameter (d_{eff}) that is an
acceptable tradeoff between the near vision improvement and the loss of distance vision.
Considerations include the pupil size of the specific subject or a group of characteristic subjects
(e.g., subjects within a particular age range) while reading or viewing nearby objects, and the
pupil size for distance viewing, especially at night. Based on the analysis of pupil sizes recorded
in subjects with various intracorneal inlays, consideration of the distance and near visual acuities,
review of literature on pupil size changes, and supplemental theoretical ray-trace analysis of
theoretical eyes with the intracorneal inlay, in some embodiments the desired effect zone
diameter is between about 2.0 mm and about 4.0 mm. In an exemplary application, the inlay is
placed in one eye to provide near vision while distance correction by other means is performed
on both the inlay eye and the fellow eye. In this example, both eyes contribute to distance
vision, with the non-inlay eye providing the sharpest distance vision. The eye with the inlay
provides near vision.

[0077]   An additional step in the method is to determine the inlay diameter. As shown above,
the "effect" zone increases with inlay diameter. Based on empirical data discussed above in
Figure 7 regarding implanting an inlay with a diameter of 1.5 mm, the inlay can be selected to
have a diameter between about 1.5 mm and about 2.9 mm less than the diameter of the desired
effect zone diameter. Excluding the 3.0 mm effect zone diameter from patient 7, the inlay can be
selected to have a diameter between about 2.2 mm and 2.9 mm less than the diameter of the
desired effect zone diameter. Based on the average effect zone diameter of 3.9 mm from all nine
patients, in some embodiments the inlay is selected to have a diameter of about 2.4mm less than
the effect zone diameter.

[0078]   Based on empirical data discussed above in Figure 9 regarding implanting an inlay
with a diameter of 2.0 mm, the inlay can be selected to have a diameter between about 1.6 mm
and about 2.4 mm less than the diameter of the desired effect zone diameter. In some
embodiments the inlay can be selected to have a diameter between about 1.8 mm and about 2.4
mm less than the diameter of the desired effect zone diameter. Based on the average effect zone
diameter of 4.0 mm from all seven patients, in some embodiments the inlay is selected to have a

diameter of about 2.0 mm less than the effect zone diameter. In this manner an inlay diameter can be selected which compensates for epithelial remodeling.

[0079]   An additional step is to determine the inlay's posterior radius of curvature. The inlay is positioned on a lamellar bed, which is the anterior aspect of the cornea underneath the flap (in embodiments in which a flap is created). The posterior curvature of the inlay should match the curvature of the lamellar bed to prevent diffuse material from filling in gaps between the inlay and the lamellar bed, which can lead to optical opacities. For inlays which are "stiffer" (i.e., greater modulus of elasticity) than the cornea, pre-operative estimates of the bed curvature are used to select the inlay with the appropriate posterior curvature. In the preferred embodiment, the inlay is more flexible (i.e., modulus of elasticity less than or equal to about 1.0 MPa) than the cornea (corneal modulus about 1.8 MPa), and the inlay will bend and conform to the bed curvature when placed under the flap. Analysis of the posterior shape of the implanted inlays by means of Optical Coherence Topography suggests that bed radius of curvature ranges between 6 mm and 9 mm. To avoid any possibility of a gap beneath the inlay, in some embodiments the posterior radius of curvature is about 10 mm.

[0080]   An additional optional step is to determine the inlay edge thickness. A finite edge thickness 16 (see Figure 1) creates a gap under the flap at the peripheral edge of the inlay, potentially leading to biochemical changes resulting in opacities in the cornea. Thus, in some embodiments the edge thickness is minimized and preferably is less than about 20 microns. In some embodiments the edge thickness is less than about 15 microns.

[0081]   An additional step is determining the inlay center thickness (see "T" in Figure 1). Based on the clinical data above shown in Figure 7 in which a 1.5 mm diameter inlay is implanted (average center thickness of about 32 microns), the inlay center thickness is selected to be between about 3.0 and about 7 times the desired central anterior elevation change. Based on the average of 6.6 microns in central anterior elevation change, in one particular embodiment the inlay center thickness is determined to be about 5 times the desired central anterior elevation change. This data therefore shows a factor of about 5 for the inlays with a diameter of 1.5 mm.

[0082]   Based on the clinical data above shown in Figure 9 in which a 2.0 mm diameter inlay is implanted (average center thickness of about 32 microns), the inlay center thickness is selected to be between about 4.5 and about 6.0 times the desired central anterior elevation change. Based on the average of 6.2 microns in central anterior elevation change, in one particular embodiment the inlay center thickness is determined to be about 5 times the desired central anterior elevation change. This data therefore shows a factor of about 5 for the inlays with a diameter of 2.0 mm.

[0083]   An additional step is determining the inlay anterior radius of curvature. The inlay's anterior surface shape and curvature influence the shape and curvature of the portion of the cornea's anterior surface above the inlay and the outer effect zone. A range of anterior radii of curvatures, based on empirical evidence (some of which can be found in U.S. Patent Application No. 11/738,349, filed April 20, 2007, (U.S. Patent Application No. US 2008/0262610 A1, which is incorporated herein by reference) is between about 5.0 mm and about 10.0 mm. In some embodiments the selected anterior radius of curvature is between about 6 mm and about 9 mm. In particular embodiments the anterior radius of curvature is about 7.7 mm or about 8.5 mm. While spherical anterior and posterior surfaces have been described herein, non-spherical surfaces may be desirable. Such aspheric anterior inlay surfaces may be either flatter or steeper compared to a spherical surface.

[0084]   An optional additional step is to determine an optional edge taper or bevel. Exemplary bevels are described in detail in co-pending U.S. Patent Application No. 11/106,983, filed April 15, 2005 (Patent Application Pub. US 2005/0246016 A1), the disclosure of which is incorporated by reference herein. The shape of the bevel and the curvature of the anterior surface affect how fast the anterior surface outer effect zone returns to the original anterior corneal surface and influences the anterior corneal surface's outer effect zone shape. The outer effect zone shape in turn determines the distribution of dioptic powers in the outer effect zone region and the retinal image quality for primarily intermediate and near objects. The subtleties of the taper zone shape become most important when a sophisticated biomechanical model of the inlay and corneal interaction has been derived.

[0085]   The above method is merely exemplary and not all of the steps need be included in selecting inlay parameters. For example, the inlay need not have a bevel and therefore selecting a bevel length or shape need not be performed when selecting an inlay profile to compensate for epithelial remodeling.

[0086]   While portions of the disclosure above have highlighted selecting an inlay with specific features to compensate for an epithelial response, this disclose also includes methods of compensating for an epithelial response from a variety of other vision correcting intracorneal procedures. The discussion herein focuses on procedures that alter the stroma layer and for which the epithelial layer remodels to reduce the effect of the intracorneal procedure. One category of vision correction procedures that alter the stroma are procedures which remodel the cornea tissue. For example, corneal ablation procedures such as LASIK are included in this category. Remodeling the corneal tissue can be done with lasers, such as ultraviolet and shorter wavelength lasers. These lasers are commonly known as excimer lasers which are powerful

sources of pulsed ultraviolet radiation. The active medium of these lasers are composed of the noble gases such as argon, krypton and xenon, as well as the halogen gases such as fluorine and chlorine. Under electrical discharge, these gases react to build excimer. The stimulated emission of the excimer produces photons in the ultraviolet region.

5 [0087]   Procedures that alter the stroma layer also include procedures that weaken corneal tissue without ablating the tissue. 20/10 Perfect Vision has developed the intraCOR® treatment, for example, an intrastromal correction of presbyopia using a femtosecond laser. Procedures that introduce a foreign body or matter into the cornea, such as an inlay, are also included in this category. It is also contemplated that a flowable media, such as a fluid or uncured polymeric 10 composition, could be positioned within the cornea as well to be used to correct vision.

[0088]   These additional cornea procedures will provoke an epithelial response which in some embodiments is compensated for when performing the procedures. For example, corneal ablation procedures remove corneal tissue which changes the curvature of the anterior surface of the cornea. The epithelial layer then remodels to try and reduce the shape change. Performing 15 the procedure to compensate for this epithelial remodeling will therefore allow the procedure to produce the desired change to the cornea.

[0089]   While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to 20 those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

CLAIMS

WHAT IS CLAIMED IS:

1.   A method of correcting vision, comprising:

5   determining a desired shape change for the anterior surface of the cornea to correct
vision;

        selecting a corneal inlay with a thickness profile which will produce the desired shape
change to the anterior surface of the cornea,

        implanting the inlay within the cornea to thereby produce the desired shape change in the

10   anterior surface of the cornea,

        wherein selecting the inlay with the thickness profile which will produce the desired
shape change to the anterior surface of the cornea compensates for epithelial remodeling of the
epithelial layer of the cornea in response to implanting the inlay within the cornea.

15   2.   The method of claim 1 wherein determining a desired shape change for the anterior
surface of the cornea comprises determining a desired shape change for a central portion of an
anterior surface of the cornea, wherein the central portion is disposed along the optical axis of
the cornea.

20   3.   The method of claim 1 wherein determining a desired shape change for a central portion
of an anterior surface of the cornea comprises determining a desired shape change for a central
portion of the anterior surface of the cornea while avoiding a shape change of a peripheral region
of the anterior surface of the cornea disposed peripherally to the central portion, and wherein a
diameter of an interface between the central portion and the peripheral portion is smaller than the

25   diameter of the pupil.

4.   The method of claim 1 wherein determining a desired shape change for the anterior
surface of the cornea comprises determining a shape change which steepens a center portion of
the cornea to provide for near vision and which provides for distance vision in a region

30   peripheral to the central portion, and wherein implanting the inlay within the cornea induces the
steepening to the central portion to provide for near vision while providing for distance vision
peripheral to the central portion.

5.   The method of claim 1 wherein determining a desired shape change for the anterior surface of the cornea to correct vision comprises determining a desired corneal power change to correct for presbyopia.

6.   The method of claim 5 wherein determining a desired corneal power change to correct for presbyopia comprises determining the desired corneal power change to be between about 1.5 diopters and about 3.5 diopters.

7.   The method of claim 1 wherein the thickness profile comprises at least one of a central thickness, a diameter, an anterior radius of curvature, and a posterior radius of curvature, and wherein selecting a corneal inlay with a thickness profile comprises selecting at least of one of the central thickness, diameter, anterior radius of curvature, and posterior radius of curvature to compensates for epithelial remodeling of the epithelial layer of the cornea in response to implanting the inlay within the cornea.

8.   The method of claim 7 wherein selecting at least of one of the central thickness, diameter, anterior radius of curvature, and posterior radius of curvature to compensates for epithelial remodeling comprises selecting a corneal inlay with a central thickness of about 50 microns or less.

9.   The method of claim 8 wherein selecting a corneal inlay with a central thickness of about 50 microns or less comprises selecting a corneal inlay with a central thickness of about 25 microns to about 40 microns.

10.   The method of claim 7 wherein selecting at least of one of the central thickness, diameter, anterior radius of curvature, and posterior radius of curvature to compensates for epithelial remodeling comprises selecting a corneal inlay with a diameter of between about 1 mm and about 3 mm.

11.   The method of claim 10 wherein selecting a corneal inlay with a diameter of between about 1 mm and about 3 mm comprises selecting a corneal inlay with a diameter of between about 1.5 mm and about 2 mm.

12. The method of claim 1 wherein implanting the inlay within the cornea comprising creating a flap in the cornea and positioning the inlay under the flap.

13. The method of claim 1 wherein implanting the inlay within the cornea comprising forming a pocket in the cornea and positioning the inlay within the pocket.

14. The method of claim 1 wherein compensating for epithelial remodeling of the epithelial layer of the cornea comprises compensating for an epithelial thinning above the inlay along the optical axis of the cornea.

15. The method of claim 1 wherein compensating for epithelial remodeling of the epithelial layer of the cornea comprises compensating for an epithelial thickening peripheral to the inlay.

16. The method of claim 1 wherein compensating for epithelial remodeling of the epithelial layer of the cornea in response to implanting the inlay within the cornea comprises compensating for the epithelial layer remodeling to reduce the change in shape of the anterior surface of the cornea in response to implanting the inlay within the cornea.

17. The method of claim 1 wherein determining a desired shape change for the anterior surface of the cornea comprises determining a desired elevation change diameter for a central portion of the anterior surface of the cornea, and wherein selecting a corneal inlay with a thickness profile which will produce the desired elevation change diameter to the anterior surface of the cornea comprises selecting an inlay diameter, and

wherein selecting the inlay diameter comprises selecting an inlay diameter that is the desired elevation change diameter minus about 1.8 mm to about 2.4 mm.

18. The method of claim 17 wherein selecting the inlay diameter comprises selecting an inlay diameter that is the desired elevation change diameter minus about 2 mm.

19. The method of claim 1 wherein determining a desired shape change for the anterior surface of the cornea comprises determining a desired central elevation change for a central portion of the anterior surface of the cornea, and wherein selecting a corneal inlay with a thickness profile which will produce the desired central elevation change to the anterior surface of the cornea comprises selecting an inlay central thickness, and

wherein selecting an inlay central thickness comprises selecting an inlay central thickness that is about 3 to about 7 times the desired central elevation change.

20.   The method of claim 19 wherein selecting an inlay central thickness comprises selecting an inlay central thickness that is about 5 times the desired central elevation change.

21.   The method of claim 1 wherein implanting the inlay within the cornea comprises producing a central elevation change to Bowman's layer.

22.   The method of claim 1 wherein the inlay has a index of refraction different than the index of refraction of the cornea to thereby provide intrinsic power to the inlay.

23.   A method of performing a corrective procedure on a cornea to correct for presbyopia, comprising:

determining a desired stromal tissue alteration to correct presbyopia;

altering the stromal layer of the cornea to correct the presbyopia,

wherein altering the stromal layer of the cornea to correct the presbyopia comprises compensating for epithelial remodeling of the epithelial layer of the cornea in response to the stromal layer alteration.

24.   The method of claim 23 wherein altering the stromal layer of the cornea to correct the presbyopia comprises altering the stromal layer using a laser.

25.   The method of claim 24 wherein altering the stromal layer using a laser comprises remodeling the cornea with the laser.

26.   The method of claim 25 wherein remodeling the cornea with the laser comprises ablating corneal tissue.

27.   The method of claim 26 wherein ablating corneal tissue comprises performing a LASIK procedure.

28.   The method of claim 24 wherein altering the stromal layer using a laser comprises altering the stromal layer using a UV laser.

29.   The method of claim 24 wherein altering the stromal layer using a laser comprises altering the stromal layer using a femtosecond laser.

5   30.   The method of claim 23 wherein altering the stromal layer of the cornea to correct the presbyopia comprises weakening stromal tissue.

31.   The method of claim 23 wherein altering the stromal layer of the cornea to correct the presbyopia comprises positioning a foreign substance within the cornea.

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32.   The method of claim 31 wherein positioning a foreign substance within the cornea comprises positioning an inlay within the cornea, the method further comprising modifying the shape of the anterior surface of the cornea by positioning the inlay within the cornea.

15   33.   The method of claim 32 wherein modifying the shape of the anterior surface of the cornea comprises steepening a central portion to provide near vision while providing distance vision in a region of the cornea peripheral to the central portion.

34.   A method of correcting vision, comprising:
20   determining a desired shape change for the anterior surface of the cornea, wherein the desired shape change comprises a central zone of increased steepness for providing near vision;
          performing a vision correction procedure to increase the steepness of a central portion of the anterior surface of the cornea to provide near vision while providing distance vision in a region of the cornea peripheral to the central portion,
25   wherein performing a vision correction procedure compensates for epithelial remodeling to the anterior surface of the cornea.

35.   The method of claim 34 wherein performing a vision correction procedure to increase the steepness of a central portion of the anterior surface of the cornea to provide near vision while
30   providing distance vision in a region of the cornea peripheral to the central portion comprises positioning an intracorneal inlay within corneal tissue.

36.   The method of claim 35 wherein positioning an intracorneal inlay within corneal tissue comprises positioning the inlay within stroma tissue at a depth of about 200 microns or less measured from the anterior surface of the cornea.

A
16
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18
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T
D
CA
P
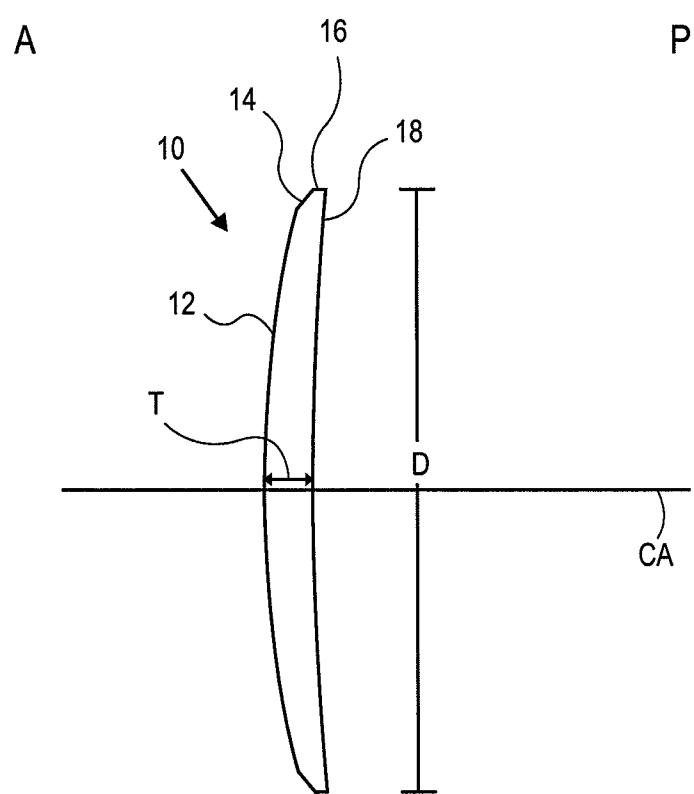
FIG. 1
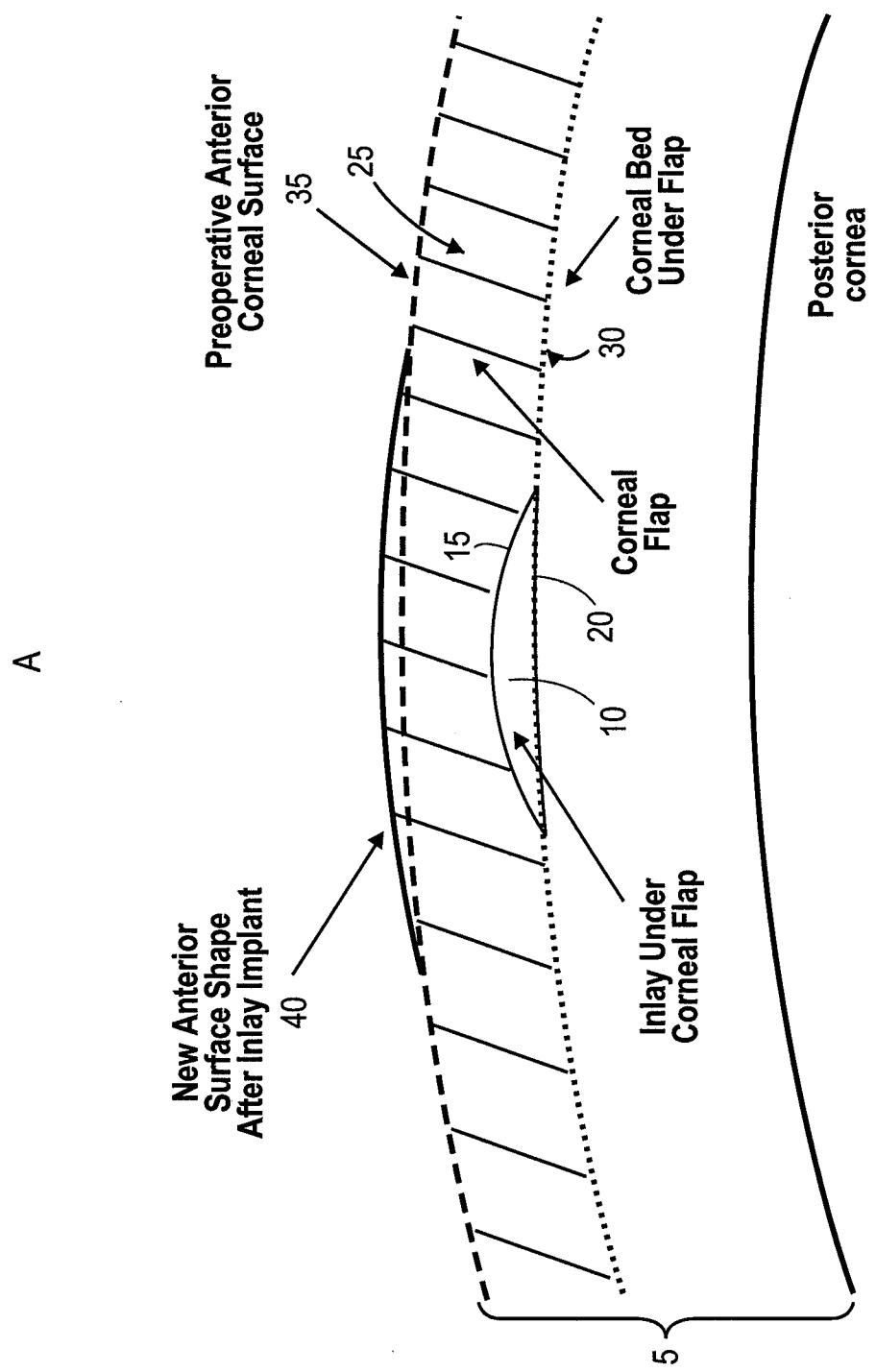
FIG. 2
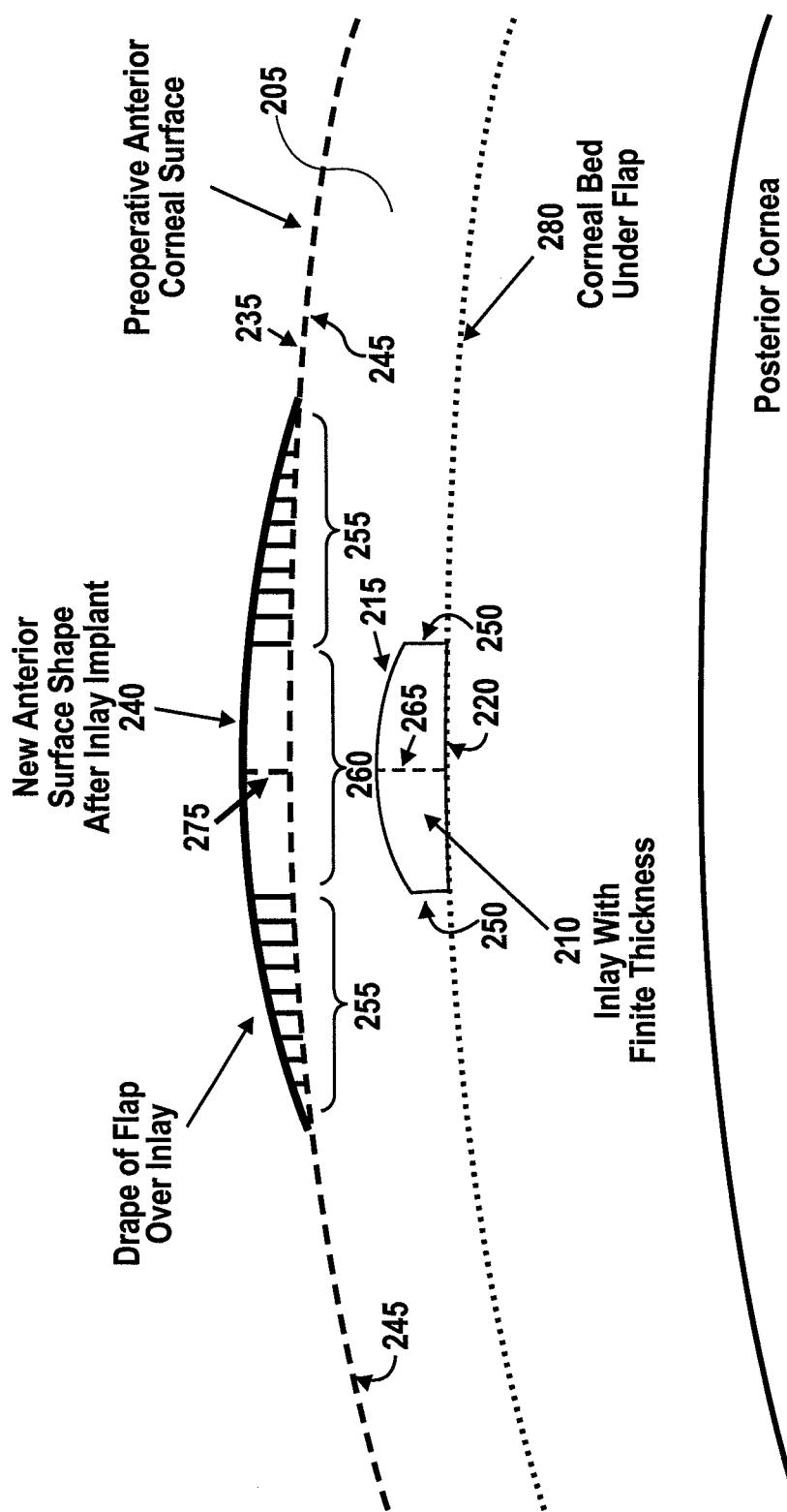
FIG. 3
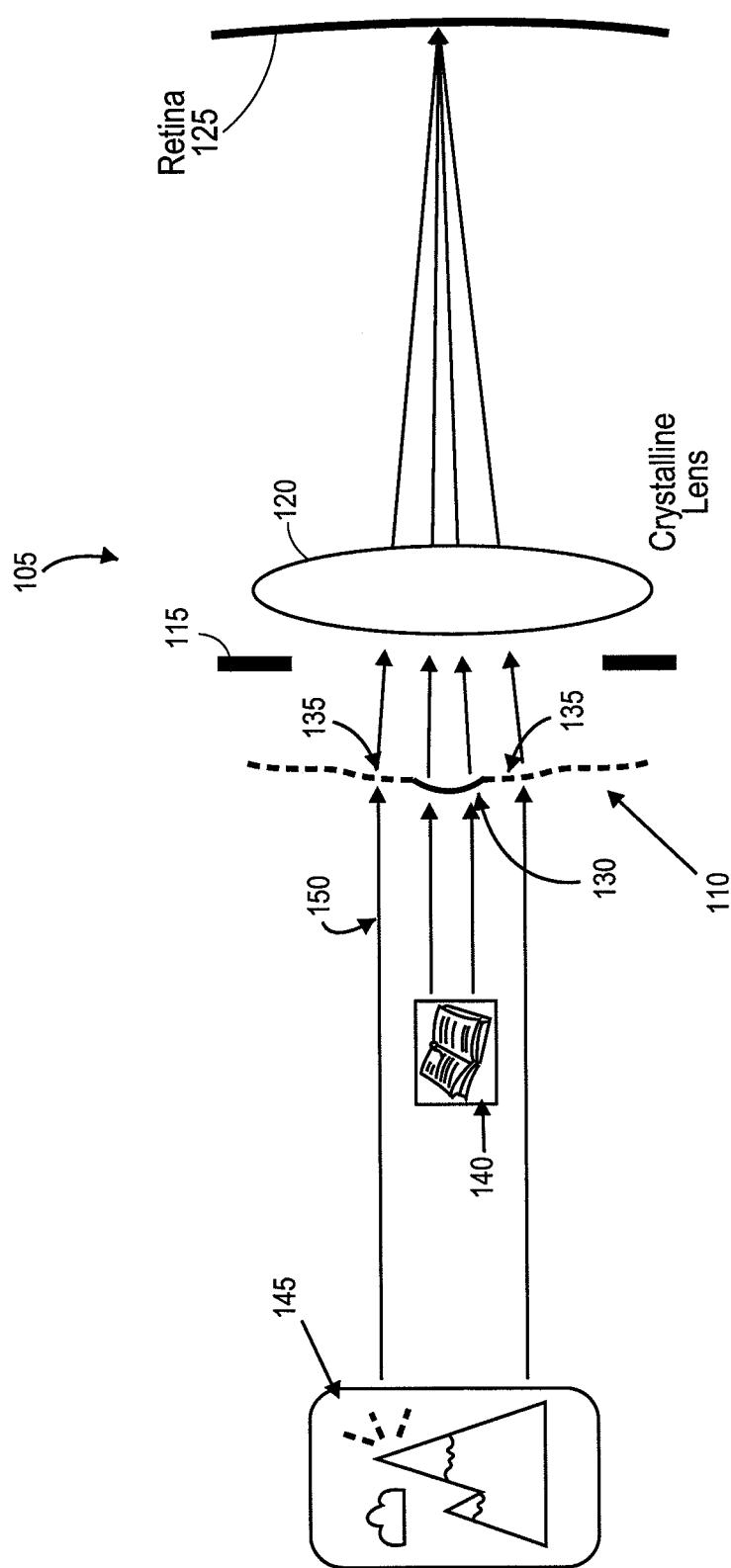
FIG. 4
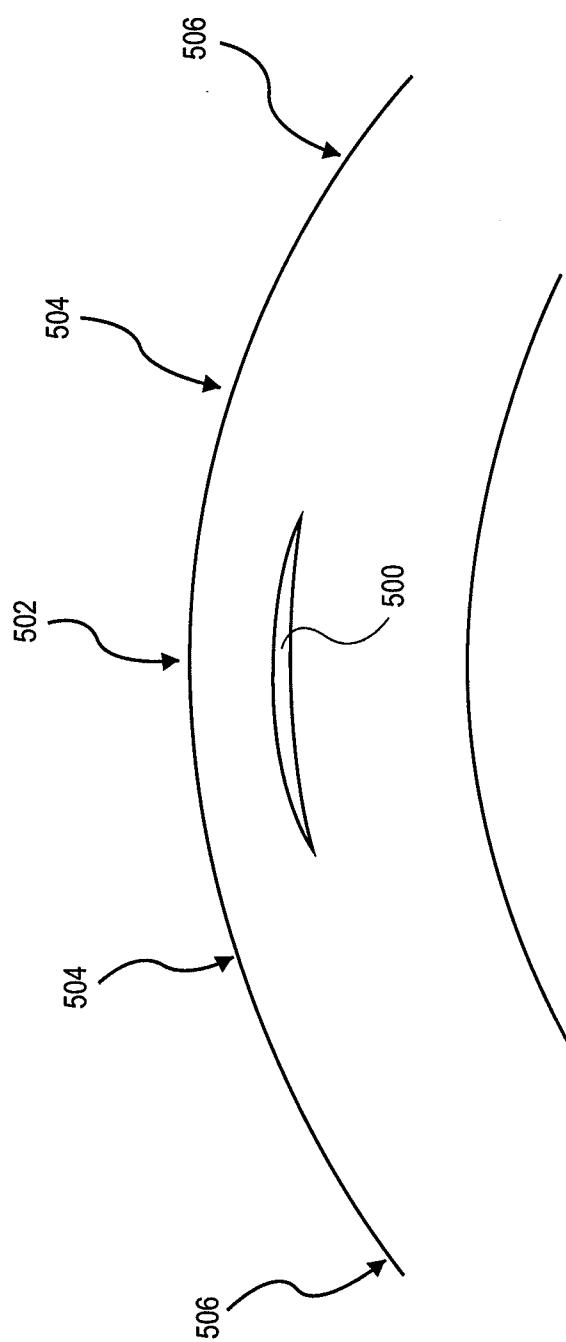
FIG. 5
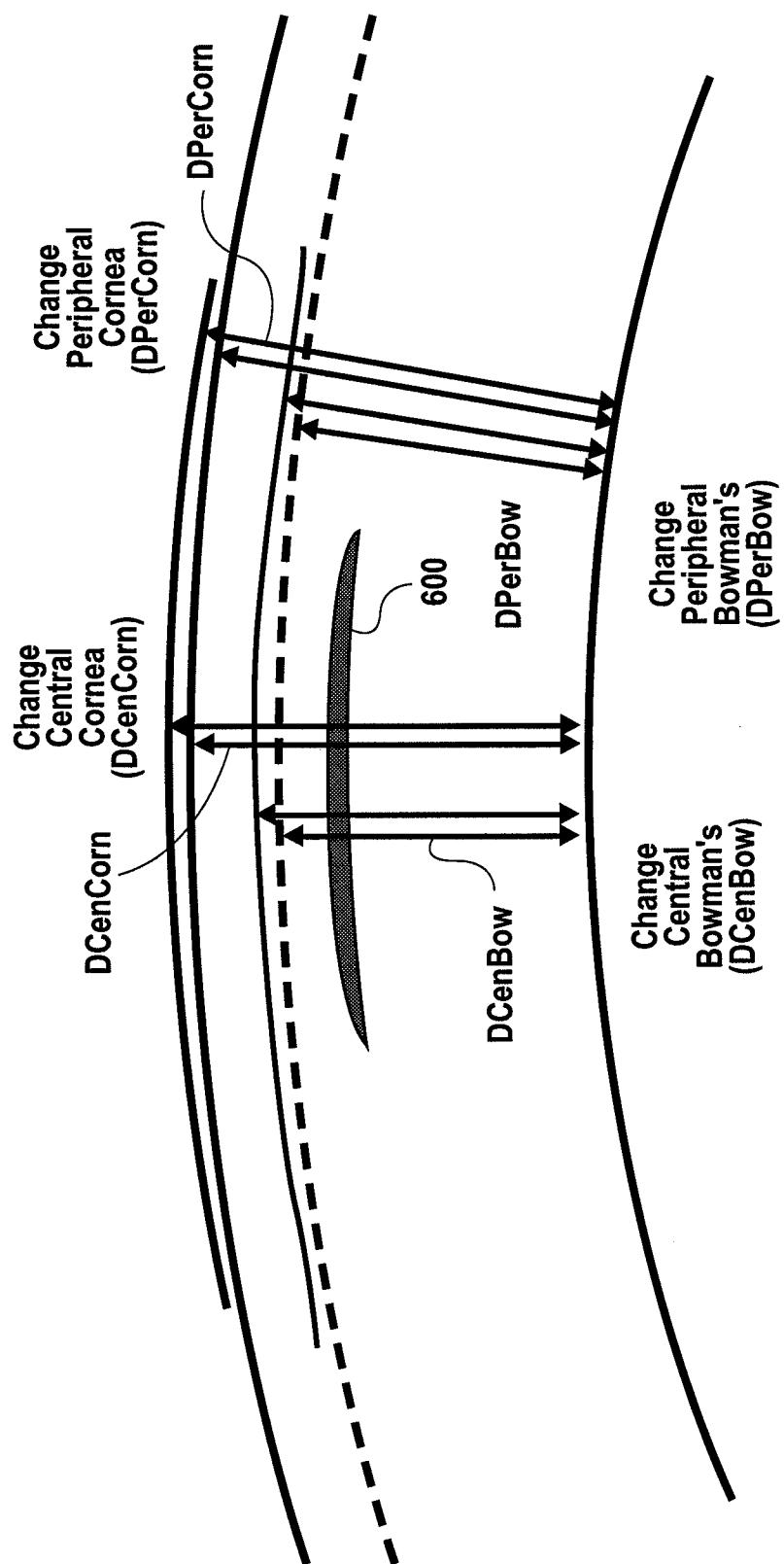
FIG. 6

Subject	Postop ucnVA	PostucNL	PostOp ucDVA	PostucDL	InlayADDeff	InlayCen2.5mmSph	Diff Fit Ht	Diff Eff Dia
1	32	3	20	1	0.75	-2.32	5.9	3.7
2	40	3	40	-2	1.00	-2.72	6.7	3.7
3	28	4	51	-3	1.75	-2.47	8.2	4.4
4	25	3	64	-5	1.75	-2.99	9.3	4.3
5	27	3	25	-1	2.50	-2.19	6.2	3.9
6	21	5	25	-1	2.25	-2.78	6.7	3.8
7	22	4	32	-2	1.25	-2.38	5.3	3.0
8	28	5	32	-2	1.50	-1.99	4.7	3.8
9	24	5	40	-2	2.00	-2.37	6.2	3.9
Average =	27	4	37	-2	1.64	-2.47	6.6	3.9
Max =	40	5	64	1	2.50	-1.99	9.3	4.4
Min =	21	3	20	-5	0.75	-2.99	4.7	3.0
Stdev =	6	1	14	2	0.57	0.31	1.4	0.4

FIG. 7
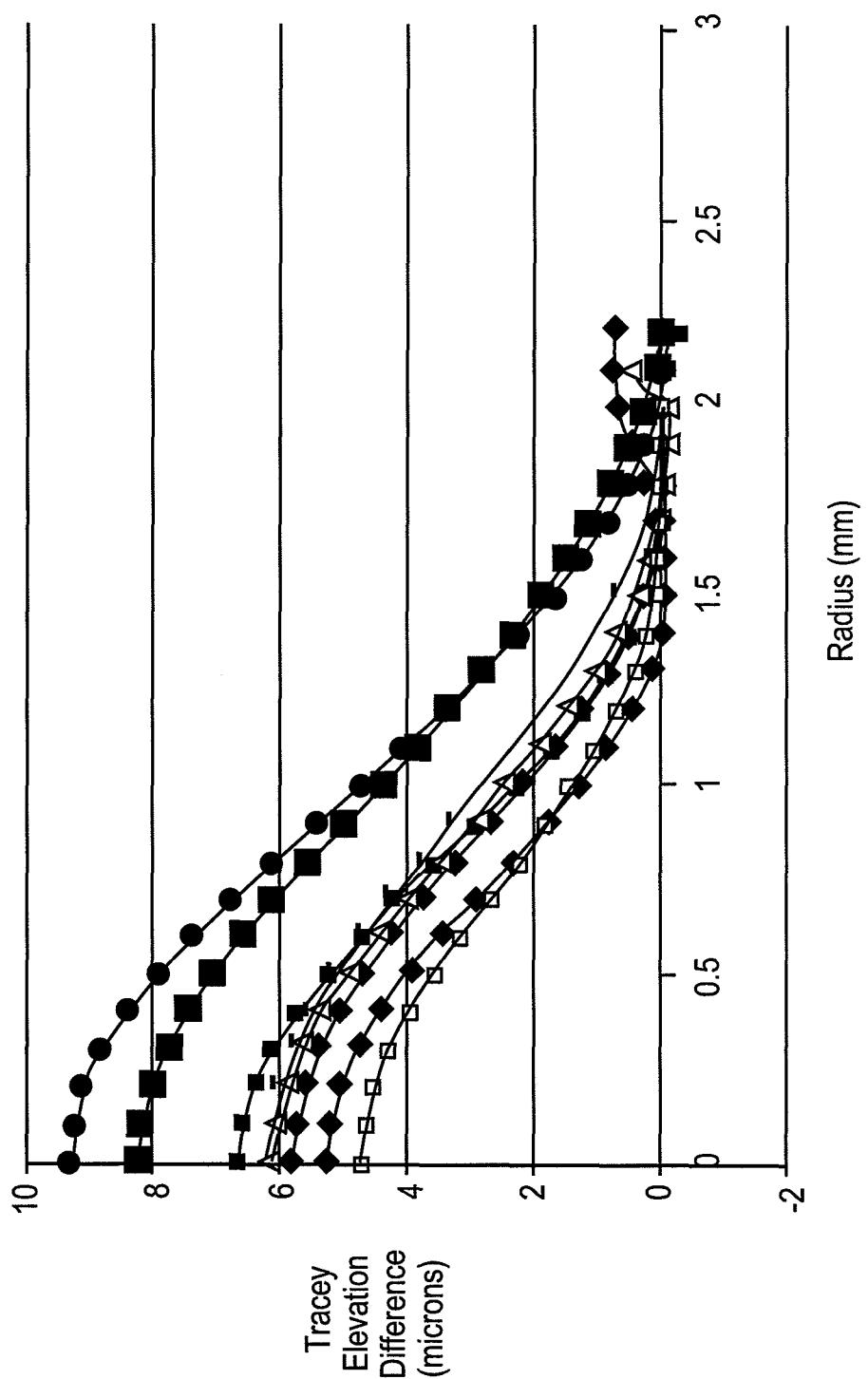
FIG. 8

Subject	Postop ucnVA	PostucNL	PostOP ucDVA	PostucDL	InlayADDeff	InlayCen2.5mmSph	Diff Fit Ht	Diff Eff Dia
1	20	4.4	40	-2.8	2.75	-2.68	6.7	3.6
2	25	4.6	35	-2.0	2.88	-1.87	6.3	4.2
3	25	5.4	33	-1.8	1.38	-1.82	5.5	4.0
4	20	6.0	42	-3.0	2.13	-2.34	6.9	4.0
5	25	5.8	29	-1.0	2.00	-1.82	6.0	4.4
6	21	4.8	80	-4.0	2.25	-1.60	5.8	3.8
7	20	5.0	32	-1.6	2.75	-2.38	6.3	4.2
Average =	22	5.1	42	-2.3	2.30	-2.08	6.2	4.0
Max =	25	6.0	80	-1.0	2.88	-1.60	6.9	4.4
Min =	20	4.4	29	-4.0	1.38	-2.68	5.5	3.6
Stdev =	3	0.6	18	1.0	0.53	0.39	0.5	0.3

FIG. 9

FIG. 10