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(54) Title: SYSTEMS AND METHODS FOR FITTING CONTACT LENSES

OS

Clinical Input and Diagnostic Lens Lookup				Clearance Preferences and Observations				Over-Refraction Entry and Lens Parameter Calculation									
Input	Clinical Input Values	Dx Lens Parameters	Dx Lens Values	Fit Point or Point	Preferred Pre-compression Clearance at Control Point	Observed Clearance at Control Point	Sag change required to Preference	Lens order Parameters	Dx Lens SAG Microns	Calculated Rx Lens Sag Microns	Calculated Rx Lens Parameters	Clinical input	Clinical Input Values	Calculated Parameters	Rx Calculated Values		
Fit K or Reference Sphere	44.75	BCR	7.75	Apex	250	150	100	BCR	1440	1540	7.34	BCR of SCOR Lens	7.75	BCR	7.34	Cylinder	Axis
Profile or Cornea	0	PCZD	0.950	6.0	250	250	0	PCZD	950	912	0.900	Power of SCOR Lens	-4.00	Power	-9.30	-1.00	97
HWD	11.8	LZD	0.500	11.6	200	150	50	LZD	800	580	0.575	DR Sphere	-3.00	PCZD	0.900		
Dx Vault Lens Identifier	0 0000 -44	SLZA	44	12.8	100	50	50	SLZA	928	908	46	DR Cylinder	-1.00	LZD	0.575		
	Dx Lens/Vault	2918	13.8 Deep	100	150	50	LZD Deep	900	880	0.675	DR Flats	97	LZD Deep	0.675			
					Orientation Angle	15			Rx Lens/Vault (mm)	4000	4010			SLZA	46		
					Calculated Vault for Rx	4015								Orientation Angle	15		

FIG. 15

(57) Abstract: Fitting systems and methods and software and calculators are provided that measure and/or use two or more pre-determined clearance preference values from specific observation points or chords of the lens, and make two or more observations of clearance of the lens from the eye. By using the difference between the pre-determined clearance preference values and the observations at the specific observation points to modify the disclosed sagittal depths of at least two zones, a final lens is selected. In accordance with various embodiments of the present disclosure, a landmark indicator may be provided on a contact lens to assist the observation of clearances of two or more chords of a lens or eye.

TITLE: SYSTEMS AND METHODS FOR FITTING CONTACT LENSES

INVENTORS: JEROME A. LEGERTON; TIMOTHY O. KOCH

FIELD OF INVENTION

[0001] The present disclosure relates to contact lenses, and more specifically, to systems and methods for fitting contact lenses.

BACKGROUND OF THE INVENTION

[0002] As contact lenses designs have developed and become more complex through the years, so too has the complexity of fitting the lenses. For example, contact lenses with multiple zones, starting at the center of the lens (often, an "optic zone") with one or more additional zones transitioning to the perimeter of the lens are common.

[0003] In such lenses, each zone serves a different purpose as it relates to the wearer's eye, and as such, the zones frequently have geometries which are different from one another, and often quite complex. Moreover, even within a particular zone, the geometry may vary from meridian to meridian. For example, contact lenses configured as such have particularly selected variations in order to improve or facilitate rotational stability, reduce flexure and/or improve lens centration.

[0004] There is a need for a design and system of fitting contact lenses that is easily understood so that the fitter can succeed in the determination of the successful lens parameters with minimal time and equipment, along with a reduced number of lens reorders, and achieve successful wearing by the patient.

[0005] Because of the complex geometries of modern contact lenses and because the fitting of such lenses can be challenging, selecting a lens with the wrong parameters can result in misalignment of the lens on corneal and/or scleral surfaces (in the case of scleral lenses). This inability to achieve a proper lens fit

may also cause higher order aberrations that reduce the visual acuity of the wearer.

[0006] Accordingly, methods and systems which allow lens fitting practitioners to quickly and confidently fit contact lens are desired. The present disclosure addresses these needs and other limitations of the prior art.

SUMMARY OF THE INVENTION

[0007] In accordance with various embodiments, the present disclosure provides methods and systems that allow a fitter to determine and successfully fit a contact lens with minimal time and equipment, along with a reduced number of lens reorders. In this regard, in accordance with various aspects of the present disclosure, fitting systems and methods are provided that allow full disclosure and communication of the sagittal depths of each zone of the lens, as well as the widths of each zone of the lens. Additionally, systems and methods, for example in the form of software and calculators as described herein, include teaching the measurement and/or use of two or more pre-determined clearance preference values from specific observation points or chords of the lens, and making two or more observations of clearance of the lens from the eye, and preferably three, four or more of such observations. By using the difference between the pre-determined clearance preference values and the observations at the specific observation points or chords to modify the disclosed sagittal depths of at least two zones of a lens to produce a final lens.

[0008] The present disclosure contemplates communicating the determination of a total sag of a lens for an eye by using the difference of a pre-determined apical clearance value and an observed clearance value and the known sagittal depth of the lens used for the observation. Additionally, the sagittal contribution of a peripheral zone as a component in a mathematical calculation of a total sag of a

lens may be communicated and/or reported to various users of the systems and methods contemplated herein.

[0009] In accordance with various embodiments of the present disclosure, a landmark indicator may be provided on a contact lens to assist the observation of clearances of two or more chords of a lens or eye.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The exemplary embodiments of the present disclosure will be described in conjunction with the appended drawing figures in which like numerals denote like elements and:

[0011] FIG. 1 illustrates the zones of a contact lens in accordance with an exemplary embodiment of the present disclosure;

[0012] FIG. 2 illustrates a contact lens comprising two peripheral zones in accordance with an exemplary embodiment of the present disclosure;

[0013] FIG. 3 illustrates a peripheral zone defined by an angle in accordance with an exemplary embodiment of the present disclosure;

[0014] FIG. 4A illustrates a half lens in cross section in accordance with an exemplary embodiment of the present disclosure;

[0015] FIG. 4B illustrates a close up of the edge contour zone of the lens in FIG. 4A;

[0016] FIG. 5 illustrates an exemplary table containing lens parameters corresponding to a particular identifier in accordance with the present disclosure;

[0017] FIG. 6 is an exemplary look-up table for selecting a fitting lens in accordance with the present disclosure;

[0018] FIG. 7 is an image illustrating a scleral landing zone with clearance at an origin and an edge aligned with the conjunctiva;

[0019] FIG. 8 is an image illustrating a scleral landing zone that is "toe down" having an angle that is too deep;

- [0020] FIG. 9 is an image illustrating a scleral landing zone that is “heel down” having an angle that is too shallow;
- [0021] FIG. 10 shows an overlay of lenses illustrating an exemplary range of scleral landing zone angles;
- [0022] FIG. 11 shows a contact lens with a lens edge, cornea, and pupil with an inadequate dual elevation difference showing superior and inferior clearance;
- [0023] FIG. 12 shows the contact lens of FIG. 11 on the eye looking down and showing clearance in the superior portion;
- [0024] FIG. 13 shows a contact lens with no edge lift demonstrating proper dual elevation difference in contrast to the drawings of FIGS. 11 and 12 demonstrating the difference between a dual elevation lens and a non-dual elevation lens on the same eye;
- [0025] FIG. 14 is a table with estimates of the sagittal contribution of each Scleral Landing Zone Angle from its origin (12.8 mm) to the chord of the Total Sagittal Depth Value or TSDV (14.6 mm) at the mid-point of the Scleral Landing Zone in accordance with the present disclosure;
- [0026] FIG. 15 is a worksheet for manually recording diagnostic set lens parameters, clearance preferences and observed clearance values in accordance with the present disclosure;
- [0027] FIG. 16 is a table with the sagittal depth of a range of base curve radii for a chord of 9 mm in accordance with the present disclosure;
- [0028] FIG. 17 is a top view of a contact lens having a landmark indicator in accordance with the present disclosure; and
- [0029] FIG. 18 is a top view of a contact lens having orientation marks in the shallow meridian in accordance with the present disclosure.

DETAILED DESCRIPTION

[0030] The present disclosure relates to systems and methods for fitting contact lenses, particularly those with two or more zones and having geometries of varying complexity. One skilled in the art will appreciate that various aspects of the disclosure may be realized by any number or types of contact lenses, including but not limited to various orthokeratology lenses, scleral lens, and the like, as well as contact lenses known as “rigid,” “semi-rigid,” “soft” and/or hybrid bimodulus lenses of the same. Likewise, materials or methods configured to perform the intended functions may vary yet fall within the scope of the present disclosure. For example, in accordance with exemplary embodiments, the lenses can be comprised of one or more of fluorosilicon acrylate, silicon acrylate, polymethylmethacrylate, a silicon hydrogel, or another suitable material. In general, any gas permeable, biocompatible material is suitable for use herein and other materials or methods not specifically listed herein may be incorporated herein to perform the intended functions. It should also be noted that the drawings herein are not all drawn to scale, but may be exaggerated to illustrate various aspects of the disclosure, and in that regard, the drawings should not be limiting.

[0031] Additionally, systems and methods disclosed herein may be described herein in terms of functional block components, optional selections and various steps. It should be appreciated that such functional blocks may be realized by any number of hardware and/or software components configured to perform the specified functions. For example, the systems and methods described herein may employ various integrated circuit components, e.g., memory elements, processing elements, logic elements, look-up tables, and/or the like, which may carry out a variety of functions under the control of one or more microprocessors or other control devices. Similarly, the software elements of the systems and methods may be implemented with any programming or scripting language such

as C, C++, Java, COBOL, assembler, PERL, Visual Basic, SQL Stored Procedures, extensible markup language (XML), with the various algorithms being implemented with any combination of data structures, objects, processes, routines or other programming elements. Further, it should be noted that the systems and methods may employ any number of conventional techniques for data transmission, signaling, data processing, network control, and/or the like. Still further, the systems and methods could be used to detect or prevent security issues with a client-side scripting language, such as JavaScript, VBScript or the like.

[0032] Software elements may be loaded onto a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions that execute on the computer or other programmable data processing apparatus create means for implementing the functions specified in the flowchart block or blocks. These computer program instructions may also be stored in a computer-readable memory that can direct a computer or other programmable data processing apparatus to function in a particular manner, such that the instructions stored in the computer-readable memory produce an article of manufacture including instruction means which implement the function specified in the flowchart block or blocks. The computer program instructions may also be loaded onto a computer or other programmable data processing apparatus to cause a series of operational steps to be performed on the computer or other programmable apparatus to produce a computer-implemented process such that the instructions which execute on the computer or other programmable apparatus provide steps for implementing the functions specified in the flowchart block or blocks.

[0033] Still further, systems and methods disclosed herein may incorporate web- and browser-based interfaces, native mobile applications, and application

programming interfaces (APIs). Practitioners will appreciate that there are a number of methods for displaying data within a browser-based document. Data may be represented as standard text or within a fixed list, scrollable list, drop-down list, editable text field, fixed text field, modal, data visualization and live/real-time data updates, and/or the like. Likewise, there are a number of methods available for modifying data in a web page such as, for example, free text entry using a keyboard, selection of menu items, check boxes, option boxes, and/or the like.

[0034] Browser applications may comprise Internet browsing software installed within a computing unit or system to conduct searches for products and services, review information, conduct or initiate online transactions and/or facilitate electronic communications. These computing units or systems may take the form of a computer or set of computers, although other types of computing units or systems may be used, including laptops, notebooks, hand held computers and other mobile devices, set-top boxes, workstations, computer-servers, main frame computers, mini-computers, PC servers, pervasive computers, network sets of computers, and/or the like.

[0035] Operating systems such as, by way of example only, Windows, OS2, UNIX, Linux, Solaris, MacOS, Android, Palm OS, iPhone OS etc.) as well as various conventional support software and drivers typically associated with computers are contemplated as are any suitable mobile device (e.g., a mobile device that includes short messaging service (SMS) functionality), phone, personal computer, network computer, workstation, minicomputer, mainframe or the like.

[0036] The above being noted, in accordance with various aspects of the present disclosure, fitting systems and methods are provided that allow full disclosure and communication of the sagittal depths of each zone of the lens, as well as the

widths of each zone of the lens. Additionally, systems and methods, for example in the form of software and calculators as described above and in more detail below, include teaching the measurement and/or use of two or more pre-determined clearance preference values from specific observation points or chords of the lens, and making two or more observations of clearance of the lens from the eye, and preferably three, four or more of such observations. By using the difference between the pre-determined clearance preference values and the observations at the specific observation points or chords to modify the disclosed sagittal depths of at least two zones of a lens to produce a final lens.

[0037] The above-noted systems and methods may be used in connection with a wide variety of contact lenses, and may be particularly beneficial used in connection with so called scleral contact lenses. Examples of such lenses and exemplary geometries of the same are described below, but should be considered as merely exemplary, and not limiting of the scope of the disclosure herein.

EXEMPLARY LENSES

[0038] An exemplary lens in accordance with the present disclosure may be used with humans or animals, having corneas of varying diameters. In some embodiments, the lens has a diameter smaller than the visible iris diameter, while in some embodiments, for example, in scleral contact lenses, the lens has a diameter larger than the visible iris diameter. In exemplary embodiments, the diameter of the lens is between about 7 mm and about 24 mm, and generally the diameter of the lens is between about 9.5 mm and about 18 mm. One skilled in the art will appreciate that a lens diameter according to the present disclosure may be much larger or smaller, depending on the intended purpose and the size of the cornea, and in some embodiments, the sclera, to be fitted with the lens.

[0039] Lenses in accordance with the present disclosure may have any suitable cross-sectional thickness and the cross-sectional thickness may vary across the surface of the lens. In exemplary embodiments, the cross-sectional thickness ranges from about 0.05 to about 0.5 mm. One skilled in the art will appreciate that a lens cross-sectional thickness according to the present disclosure may be much thinner or thicker.

[0040] An exemplary lens may be materially and/or structurally configured for daytime use only, nighttime use only, or 24 hour use for a single day or a plurality of days.

[0041] Lenses in accordance with the present disclosure may include virtually any contact lenses, whether to correct refractive errors, for a corneal reshaping program, or for other uses. In general, typical lenses contemplated by the present disclosure are those having two or more zones.

[0042] For example, in general, an exemplary scleral lens in accordance with the present disclosure and with reference to FIG. 1 comprises a central zone 110, at least one peripheral (or annular) zone 120, and an edge contour zone or "landing zone" 140. Each of the zones may be spherical or aspherical. A lens in accordance with the present disclosure further comprises an anterior surface and a posterior surface. "Anterior surface" refers to the surface meant to contact an eyelid, and "posterior surface" refers to the surface meant to contact a cornea, and in some embodiments, a sclera, or other portion of the eye. Examples of scleral lens designs may be found in United States Patent No. 8,113,653 entitled "SCLERAL CONTACT LENS AND METHODS FOR MAKING AND USING THE SAME" and United States Patent No. 8,113,652 entitled "CONTACT LENS WITH MERIDIONAL SAGITTAL VARIATION AND METHODS FOR MAKING AND USING THE SAME," both of which issued February 14, 2012, and both of which are herein incorporated in their entirety by reference.

CENTRAL ZONE

[0043] In accordance with exemplary embodiments, the central zone 110 is generally concentric with and comprises the center of the lens. In exemplary embodiments, the central zone 110 is configured to have a conventional spherical geometry and has a diameter comparable to the visible pupil diameter, for example, from about 2 to about 10 mm, and generally, from about 3.5 to about 9 mm. In various exemplary embodiments, the central zone 110 may be configured to have a conventional aspheric, multifocal or toric geometry.

[0044] In various exemplary embodiments, the central zone 110 has a posterior surface having a curvature determined by the correction or reshaping to be imparted to the cornea or based upon other desirable properties and/or effects. For example, an exemplary lens comprises a central zone 110 configured to correct an intended refractive error. The radius of curvature of the central zone 110 may be chosen based upon characteristics of an eye for which the lens is being designed, and particularly related to the amount of correction required. In various exemplary embodiments, the central zone 110 may be flatter than the radius of curvature of the cornea. In general, a central base curve is chosen to align the curvature of the central cornea so as to be relatively parallel when suspended in front of it.

[0045] In exemplary embodiments, the central zone 110 is configured independent from the peripheral zone(s) 120. In accordance with exemplary embodiments, the posterior surface of the central zone 110 need not be configured to spatially match the topography of the cornea, while in other exemplary embodiments, the posterior surface of the central zone 110 indeed may be configured to completely or partially spatially match the topography of the cornea.

PERIPHERAL ZONES

[0046] In exemplary embodiments, the central zone is surrounded by at least one peripheral zone 120, which may be defined by an angle. In accordance with exemplary embodiments, a peripheral zone 120 is generally concentric with the central zone 110. In some embodiments, a peripheral zone 120 is a generally annular or ring-shaped portion of the lens, overlying the cornea and/or sclera and found beyond the central zone 110. In some embodiments, a peripheral zone 120 has a constant width circumferentially, for example, from about 0.1 mm to about 10 mm. In other embodiments, a peripheral zone 120 has a variable width circumferentially.

[0047] In various exemplary embodiments, the central zone 110 is surrounded by a plurality of peripheral zones (for example, 2, 3, 4, 5, 6, 7, 8, etc.), and each may be defined by an angle. For example, and as shown in FIG. 2, an exemplary lens 200 in accordance with the present disclosure comprises a central zone 210, a first peripheral zone 220, a second peripheral zone 230, and an edge contour zone 240.

[0048] In the context of a scleral lens, the second and third peripheral zones 220, 230 may be a Peripheral Corneal Zone (PCZ) and Limbal Zone (LZ), respectively. The Peripheral Corneal Zone is the first zone peripheral to the central zone 110 and is designed to raise or lower the posterior lens surface to maintain uniform clearance from a chord of 9 mm to 11.6 mm. Adjustments in this zone convert the lens to being oblate or prolate as needed independent of the base curve radius. The Limbal Zone is the second zone peripheral to the central zone 110 and will raise and lower the posterior lens surface to achieve the desired apical and Limbal Clearance when the correct base curve radius, PCZ depth and Landing Zone Angle are in place. The Limbal Zone meets the Scleral Landing Zone at a chord of 12.8 mm which is outside the average corneal diameter.

[0049] The Scleral Landing Zone may have either a rotationally symmetric design or a Dual Elevation design with a deep meridian and a shallow meridian. The Limbal Zone Depth (LZD) of the deep meridian may be varied to create a prescribed greater depth than the shallow meridian to promote circumferential scleral alignment. The Dual Elevation feature is designed and selected to compensate for a near universal elevation difference found in the sclera of human eyes at a chord of approximately 14.6 mm. This feature results in a lens fit which spreads the lens contact and pressure on the sclera in a uniform manner. The Dual Elevation feature may also improve lens centration and produces a lens that is rotationally stable. The convex to the eye Scleral Landing Zone design provides simultaneous clearance at its origin (12.8 mm) and pre-compression edge lift when the proper Landing Zone Angle is selected. The most peripheral portion of the Scleral Landing Zone is shaped to provide the posterior portion of the lens edge.

[0050] In various embodiments, an anterior central curve, an independent variable, may be selected to provide the necessary optical power to correct any residual refractive error not corrected by the optical and mechanical effect of the posterior base curve and the tear lens forming between it and the cornea. The anterior central curve may be spherical, aspherical, toric, multifocal or free-form to correct higher order aberrations.

[0051] In exemplary embodiments, an angle defining a peripheral zone may be measured at a hinge point at the junction of the first peripheral zone 120 (i.e., the next most central zone) and the next peripheral zone. In exemplary embodiments, a hinge point may be located anterior to, or rest upon the surface of the eye.

[0052] For example, in an exemplary embodiment as illustrated in FIG. 3, a scleral contact lens 300 has a posterior surface comprising a central zone 310 and at

least one peripheral zone, wherein: a peripheral zone 330 is defined by an angle 350; the angle 350 is formed by an intersection of a line 360 and a cross-dimensional chord 390; the line 360 connects a hinge point 370 at the junction of a next most central zone 320 and the peripheral zone 330, and a most peripheral point 380 of the peripheral zone 330, the hinge point 370 and the most peripheral point 380 both being located on a semi-meridian of the contact lens 300; and the cross-dimensional chord 390 passes through the hinge point 370. As used herein, a cross-dimensional chord is perpendicular to the central axis of an exemplary scleral lens.

[0053] One skilled in the art will appreciate that while an angle defining a peripheral zone may be measured at a hinge point, the angle may be measured at any number of points. For instance, in an embodiment, a peripheral zone is defined by one or a plurality of cone angles, for example, having an apex coincident with the central axis of, or otherwise anterior or posterior to, an exemplary scleral lens. In another embodiment, the use of a convex curve conforms to an angle wherein the extended radius of curvature intersects the axis of the central zone of the lens.

[0054] In an exemplary embodiment, a peripheral zone defined by an angle is curved in either a concave or convex direction or is uncurved. In the event a peripheral zone is curved, its radius of curvature, conic constant and/or polynomial expression may be specified along with the angle of the chord of its arc.

[0055] In an exemplary embodiment, a peripheral zone defined by an angle is further defined by a sigmoid, conic constant and/or polynomial expression. In an exemplary embodiment, a peripheral zone serves as a connecting zone to adjust the sagittal depth to a desired amount such that the lens can substantially touch the cornea, lightly touch the cornea under the central zone or can be suspended

a desired amount above the cornea. The connecting zone depth is determined to bring the lens within an intended proximity to the cornea.

[0056] In the event the portion of the eye underlying the peripheral zone defined by an angle is not circumferentially uniform in elevation, the angle for a plurality of semi-meridians or transverse sections can be varied to create a transverse undulation of a peripheral zone to allow the peripheral zone of the lens to have an equivalent lens eye relationship. For similar reasons, alternatively, or additionally, the curve for a plurality of semi-meridians or transverse sections can be varied, as shown, for example, in FIG. 3, wherein peripheral zone 330 is convex toward the surface of the eye in a semi-meridian and concave toward the surface of the eye in the alternate semi-meridian.

[0057] The rotational transition between semi-meridians or transverse sections having differing angles and/or curves may be linear or otherwise uncurved, or defined by a sigmoid, conic constant or other polynomial expression. Moreover, the rotational transition between semi-meridians or transverse sections having differing angles and/or curves may vary radially.

[0058] In accordance with exemplary embodiments, the most peripheral zone may be comprised of meridians modified by any mathematical means of smoothly diminishing the difference between the edge sagittal depth location at full diameter (to planar) that would derive by continuation of the curvature of a given meridian passing through the most peripheral zone to the full diameter of the edge in comparison to the edge that would be projected from one selected meridian whose edge sagittal depth location has been chosen to be the common edge. However, in other embodiments the difference need not be diminished to planar at full diameter, and moreover, need not be a common edge selected from one meridian.

[0059] In exemplary embodiments, the meridian(s) projecting to the common edge are those yielding the least ultimate sagittal depth at the full edge diameter but may in some cases be chosen by other criteria. Such methods of diminishing the difference may be as simple as projecting the difference that would arise in the absence of reconciliation and using a stepwise linear function to gradually eliminate the projected difference over the course of transitioning from the most outer diameter of peripheral zone to a point at or near the full edge diameter where all meridians coincide in sagittal depth to generate a common edge for the lens. Any mathematical means however would suffice and may additionally incorporate terms designed to minimize sharp junctions or to modify the rate of diminishment to control where along the course of transition the most rapid diminishment occurs. Such functions may include polynomials, power series, logarithmic functions or averaging functions among others. Such functions may be applied to each defined meridian as required by the difference of the projected sagittal depth at full diameter for that meridian from the sagittal depth at full diameter of the meridian selected to define the common edge.

EDGE CONTOUR ZONE

[0060] As noted above, an exemplary lens in accordance with the present disclosure comprises a central zone 110, at least one peripheral zone 120, and an edge contour zone 140 (or scleral landing zone). In exemplary embodiments, the edge contour zone 140 provides an edge lift at the termination of the lens that may allow the aqueous tear film to pass under the lens and exchange the post lens film.

[0061] In exemplary embodiments, a peripheral zone is curved in either a concave or convex direction or is uncurved in an effort to produce a light and uniform conjunctival pressure with a lens edge termination that is lifted above the conjunctiva.

[0062] For example, as shown in FIGS. 4A and 4B (FIG 4B illustrates a close up of the edge contour zone of the lens in FIG. 4A), a lens 400, configured to at least partially rest upon a typical eye surface 401, comprises (i) a central zone 410 having a semi-chord length of approximately 4.0 mm, (ii) a first peripheral zone 420 having a width of approximately 1.25 mm, and (iii) a second peripheral zone 430 having a width of approximately 2.5 mm. The first peripheral zone has a longer radius of curvature than the central zone and the second peripheral zone is convex toward the eye to provide an edge lift 402 at the edge contour zone.

[0063] In accordance with exemplary embodiments, notwithstanding the curvature changes in the peripheral zone(s), the lens returns to at least one of circular, planar, and untilted at its edge contour zone. Such return may thereby reduce conjunctival pressure and/or conjunctival epithelial flap occurrence, as well as provide benefits such as improved circulation and exchange of the post lens tear film, and improved regulation of the edge lift circumferentially.

EXEMPLARY METHODS OF FITTING

[0064] As described herein, methods of applying the present disclosure can include the use of corneal topography elevation data along with measurements of images taken by optical coherence tomography, Scheimpflug imaging, or other biometric instrumentation, which may be digitally read by the device as opposed to the practitioner.

[0065] In this regard, as mentioned above, a practitioner may use two or more pre-determined clearance preference values from specific observation points or chords of the lens, and by making two or more observations of clearance of the lens from the eye and using the difference between the pre-determined clearance preference values and the observations at the specific observation points or chords to modify the disclosed sagittal depths of at least two zones of a lens, a final lens may be selected.

[0066] In accordance with various aspects of the present disclosure, contact lenses contemplated herein are fitted to substantially avoid touching the cornea and to come to rest on the bulbar conjunctiva outside of the limbus of the eye and may be accomplished by the lens design and the manner in which the lens is fitted. In the presently described embodiment, the goal in fitting is a well-centered lens having a base curve that is usually flatter (longer) than the flattest meridian of the cornea by approximately 0.50 to 2.00 Diopters. A well-fit lens will have proper sagittal depth to prevent z-axis tilt and achieve centration over the corneal apex. A well-fit lens will also have a proper sagittal depth profile to prevent bearing at the Limbal Zone – Scleral Landing Zone junction (12.8 chord) and avoids significant impingement of the bulbar conjunctiva at the edge of the lens. The lens will demonstrate central corneal clearance, peripheral corneal clearance, limbal clearance, and landing zone-scleral tangential correspondence.

[0067] In accordance with various exemplary non-limiting embodiments, fitting methods and systems disclosed herein use the following parameters:

Optic Zone = 9.0 mm
Peripheral Corneal Zone Width = 1.3 mm
Limbal Zone Width = 0.6 mm
Harmonic optic zone area thickness = $0.29 \text{ mm} \pm 0.02$
Scleral Landing Zone apex = 12.8 mm
Convex to the eye curvature in the Scleral Landing Zone
Dual Elevation landing zone with 200 micron difference between shallow and deep meridian
Overall total sagittal depth value chord diameter = 14.6 mm
Overall Diameter = 16.4 mm (for corneal diameters larger than 12.8, a larger overall diameter may be required)

[0068] By selecting the Peripheral Corneal Zone Depth and Limbal Zone Depth, full corneal and limbal clearance can be maintained after lenses used in connection with the present disclosure compress the bulbar conjunctiva. Fitting herein includes using fitting set lenses that are greater in depth than the eye being fit. The use of the fitting set lenses allows determination of:

- 1) the Scleral Landing Zone angle; and
- 2) the amount of the Dual Elevation needed to achieve equal contact with the sclera circumferentially.

[0069] In accordance with various aspects of the present disclosure, there are seven primary fitting objectives:

- 1) Provide a landing zone angle that demonstrates pre-conjunctival-compression clearance at its origin (12.8 mm) and scleral correspondence at the edge.
- 2) Determine the Limbal Zone Depth to provide the preferred pre-conjunctival compression limbal clearance at 11.6 mm (the chord of the landmark indicator).
- 3) Determine the need for the Dual Elevation feature in the limbal zone depth and estimate the number of microns of Dual Elevation difference needed.
- 4) Determine the total sagittal depth value for the respective eye. The total sagittal depth value will always equal the sum of the sagittal depth values for each of the four zones. It will also equal the sag of the respective eye plus the preferred pre-conjunctival compression apical clearance.
- 5) Determine the Peripheral Corneal Zone Depth that demonstrates pre-conjunctival-compression clearance at the optic zone junction
- 6) Provide a base curve radius that is longer than the apical radius and that aligns the underlying cornea to provide equivalent clearance at the corneal apex and at the 9.0 mm optic zone junction.
- 7) Provide the lens power in sphere and cylinder that provides optimum visual acuity and clarity.

PRE-COMPRESSION CLEARANCE PREFERENCES

[0070] Fitting in accordance with the present disclosure may be based on the use of two or more pre-compression clearance preferences which are combined with the respective pre-compression clearance observations of a lens having known sagittal values to calculate the values of the zones (e.g., four zones) of a final suggested lens. The starting point is to determine practitioner preferences based on the practitioner's training and experience in fitting scleral contact lenses.

[0071] Apical clearance, optic zone clearance, and limbal clearance are generally constant regardless of the eye being fit, while the Scleral Landing Zone junction clearance preference varies based on the corneal diameter (Horizontal Visible Iris Diameter or "HVID"). Preference values may vary from one practitioner to the other and may vary from one eye to the next.

PRE-COMPRESSION CLEARANCE OBSERVATIONS

[0072] In accordance with the present disclosure, a suggested fitting set lens is applied to an eye and observations of the post-lens fluorescein tear layer are made, for example, within 15 minutes of lens application. In the presently described embodiment, there are four clearance observations (though more or less may be made as appropriate):

- 1) Apical Clearance estimated by comparison to the known lens thickness and average corneal thickness
- 2) Clearance at the edge of the optic zone (9.0 mm chord)
- 3) Clearance at the Limbal Zone junction (11.6 mm chord) which is at the location of a 11.6 landmark indicator
- 4) Clearance at the junction or hinge of the Scleral Landing Zone (12.8 mm chord)

[0073] The apical clearance is used to calculate the total sagittal depth value TSDV of each eye being fit. The prescribed TSDV equals the fitting set lens

TSDV combined with the difference between the preferred apical clearance and the observed pre-compression apical clearance:

$$\text{Rx TSDV} = \text{Fitting set TSDV} + (\text{Preferred Apical Clearance} - \text{Observed Apical Clearance})$$

[0074] The prescribed TSDV will rarely change for a given eye and is generally first determined without instrumentation by the apical clearance observation of a lens having a known TSDV. Clearance observations are recorded for use in calculating the final lens values for each of the lens zones. The use of the other three clearance observations will be discussed hereinbelow in an exemplary fitting procedure.

FULL DISCLOSURE OF SAGITTAL DEPTH

[0075] In accordance with various aspects of the present disclosure, there is full disclosure of all values for the lens design parameters. The disclosure includes providing the sagittal depth contribution of the base curve radius over the chord of the optic zone, the peripheral corneal zone depth over the width of the peripheral corneal zone, the limbal zone depth over the width of the limbal zone and the sagittal depth of the Scleral Landing Zone from its junction or hinge to the middle of the Scleral Landing Zone.

[0076] The total of the depths of the four zones equals the TSDV of each fitting set lens and prescription lens. The full disclosure of the depths combined with a system for calculating values for a lens prescription based on clinical observations provides a means for precise fitting of each eye as follows:

$$\text{TSDV} = \text{BCR sag} + \text{PCZD} + \text{LZD} + \text{SLZD}$$

CALCULATORS

[0077] In accordance with various aspects of the present disclosure, a calculating tool is provided for calculating the final lens parameters from the known sagittal depth of each lens. As described in more detail below, calculators as contemplated herein use the pre-compression clearance preferences, pre-compression clearance observations, and the sagittal depth values for each zone to calculate the final suggested lens values for each zone. Various embodiments may also include a power calculation that uses the known base curve radius and lens power along with entered values for the sphero-cylindrical over-refraction. Calculators may be embodied in software found on conventional multi- or single-purpose computers, mobile devices, kiosks, or the like.

CONTOUR ELEVATION SYSTEM

[0078] Those skilled in the art will appreciate that the growing body of knowledge of scleral contour supports that the sclera is, as a rule, unequal in elevation. Further, evidence suggests that the sclera becomes more unequal in elevation at greater chord diameters. Early research using fringe topography revealed that the average eye has an elevation difference of approximately 300 microns at a chord of 13.5 mm. System and methods contemplated herein may use lenses having a 200 micron Dual Elevation feature in the limbal zone depth meridional difference. The 200 micron difference continues through the 14.6 mm tangential landing diameter. Lenses in accordance with the present disclosure may be ordered with no Dual Elevation feature or with values other than the 200 micron difference. Alternatively, lenses in accordance with the present disclosure may include non-orthogonal (not 90 degrees apart) differences to facilitate contour elevation fitting that is driven by clinical observations of the need for varying elevations in the Scleral Landing Zone.

FITTING SET CONFIGURATION

[0079] In an embodiment, a fitting set in accordance with the present disclosure has a series of lenses having six different TSDVs. For example, these may include four prolate TSDVs: 3600, 3900, 4200, and 4800; and two oblate TSDVs, 3600 and 4400 though many other combinations and configurations may likewise be employed. Each lens in a unique TSDV series has a different single landing zone angle circumferentially. The angles may be increments of 3 degrees from 38 to 50 degrees. Each lens may have a 200 micron Dual Elevation feature in the limbal zone depth or by incorporating two different scleral landing zone angles.

[0080] Set lens identifiers may be included. For example:

- 1) P or O: Prolate or Oblate
- 2) TSDV in microns: 3600, 3900, 4200, 4400, 4800
- 30 Scleral Landing Zone Angle: -38, -41, -44, -47, -50

[0081] Thus, an exemplary identifier of "P 3600-44" means Prolate, 3600 TSDV, -44 degree SLZA. An example of a table containing exemplary lens parameters corresponding to a particular identifier is illustrated in FIG. 5.

FITTING SET LENS SELECTION

[0082] In an exemplary embodiment, the starting lens for eyes with regular corneas is determined from the flat keratometry value. The best-fit or reference sphere from corneal topography is used for irregular cornea eyes. Using a base curve radius that is longer (flatter) than the flat keratometry measurement is preferred. In various embodiments, lenses may be ordered in 0.01 mm steps. The Peripheral Corneal Zone Depth (PCZD) and Limbal Zone Depth (LZD) of the fitting set lenses are based on the suggested base curve radius and corneal elevation in the shallow meridian. The starting or suggested Scleral Landing Zone Angle (SLZA) for the fitting set lenses is a mean value based on biometric

ocular contour measurement distribution statistics. The prescribed SLZA will be determined from fitting set lens observations.

[0083] In accordance with exemplary methods herein, a fitting set lens is first determined by reference to a look-up table such as that illustrated in FIG. 6. For example, for flat keratometry equal to 43.75, the lens identifier is P 3600-44. In the above noted exemplary fitting set of FIG. 5, this corresponds to a selected lens having the following values:

BCR: 8.00 PCZD: 0.750 LZD: 0.550 SLZA: - 44 Power: -3.00

[0084] Lenses and the containers in which they are contained in accordance with the present disclosure may have unique identifiers that may be checked to ensure the correct lens is selected.

[0085] In accordance with alternative embodiments, instrumentation providing sagittal height data at a given chord may allow for an alternate method of determining the first lens to apply with regard to the TSDV series and/or the starting Scleral Landing Zone Angle as different from the biometric mean.

GENERAL EVALUATION STEPS

[0086] In accordance with exemplary methods of the present disclosure, the selected lenses are placed on the eye with the lens filled with care product and fluorescein and the practitioner looks for the presence of a bubble under the lens. If a bubble greater than about 1 mm in diameter is present, the lens is removed and re-applied and the preceding inspection is made again. If upon inspection no bubble(s) are found, an evaluation can be conducted immediately or, alternatively, the lens may be allowed to equilibrate for about 5 to 15 minutes before evaluation. While there is not necessarily a need to wait to make a post compression evaluation, in accordance with various embodiments, systems and

methods contemplated herein can be used for post-compression observations. For example, a practitioner may calculate a “re-order” lens after post-compression observations using methods disclosed herein, or additional calculator and/or software for such post-compression preferences.

[0087] Next, the key Scleral Landing Zone observations are made, including observing :

- a. Clearance at landing zone junction (12.8 mm chord) as a function of the HVID.
- b. Edge alignment with bulbar conjunctiva with no impingement
- c. Consistency of edge alignment circumferentially: Equal lens-eye relationship circumferentially is desired.

[0088] Then, observations of the key corneal zone are made:

- a. Apical clearance: Compared to pre-compression clearance preference.
- b. Clearance at optic zone junction (9 mm chord); desired clearance is approximately the same as apical clearance.
- c. Clearance over limbus at the 11.6 mm landmark indicator (described below) compared to pre-compression clearance preference.

[0089] After these observations, the final lens can be calculated from the pre-compression clearance values, observed clearance values and known TSDV. More specific examples of the fitting procedures are described below.

STEP 1: FITTING THE SCLERA

[0090] In accordance with various aspects of the present disclosure, the evaluation starts with fitting the sclera. Exemplary fitting sets provide five Landing Zone Angles for each TSDV (sagittal depth value at 14.6). Look-up tables list the

middle or mean landing zone angle for human eyes derived from biometric data which is -44 degrees for example, for a 16.4 mm lens.

[0091] After observing that the fitting set lens demonstrates full corneal clearance, the first observation is to see if there is an obvious shallow scleral meridian. The shallow meridian can also be referred to as the meridian that is highest in elevation. This is the meridian that the lens contacts first. In some cases the lens cannot reach the deep meridian of the sclera because the shallow meridian is holding the lens too far from the deep meridian.

[0092] The first observations are intended to study the lens-eye relationship in the shallow scleral meridian. For example, with reference to FIG. 7, the practitioner should observe to see if the lens is aligned with the conjunctiva and if there is clearance of the lens at the beginning of the Scleral Landing Zone (12.8 mm) and estimate the clearance in microns. An optic section may be useful for this observation. The lens thickness may also be used as a gauge for estimating the same.

[0093] The second observation is the position of the lens edge relative to the bulbar conjunctiva. The posterior lens edge should be flush or exhibit minor lift when viewed immediately after lens application and before conjunctival compression.

[0094] The proper Scleral Landing Zone Angle balances the two observations. As the clearance at the origin of the Scleral Landing Zone goes down, the edge lift will increase. Conversely, as the clearance at the origin of the Scleral Landing Zone goes up, the edge lift decreases. The Scleral Landing Zone can be imagined like a foot with the toes at the edge. A Scleral Landing Zone Angle that is too great can be referred to as "toe down" (see FIG. 8), while a Scleral Landing Zone Angle that is too small can be referred to as "heel down" (see FIG. 9).

[0095] The pre-conjunctival-compression objective is to select a Scleral Landing Zone Angle that demonstrates clearance at its origin (12.8 mm) of approximately 150 microns while also demonstrating scleral correspondence at the edge. The proper SLZA will provide a point of greatest contact with the underlying sclera near the midpoint of the zone itself (approximate chord of 14.6 mm). Clearance will be visible at the junction with the Limbal Zone. Simultaneously, the lens edge will appear to lay upon the sclera and not impinge into it. The middle of the Scleral Landing Zone is the fulcrum upon which the lens can teeter when the SLZA is increased or decreased.

[0096] An observation of a lens edge that sinks into the conjunctiva in conjunction with high clearance at the origin of the Scleral Landing Zone indicates an angle that is too great in value. If the observation is being made with the 44 degree SLZA, then the prescription should be an SLZA less than 44 degrees. The 41 degree SLZA lens in the same TSDV may be applied and evaluated. If the 41 degree lens looks good, the SLZA selection process is finished. If the 41 degree SLZA now looks heel down by having very little clearance at the origin of the Scleral Landing Zone and too much edge lift, then the correct angle is between 41 and 44 degrees. An interpolation judgement can be made to decide whether to order 42 or 43 degrees. FIG. 10 illustrates an overlay of lenses illustrating an exemplary range of angles.

[0097] Conversely, if the 44 degree SLZA fitting set lens has low clearance at the 12.8 mm chord and high edge lift, the 44 degree SLZA is too low an angle (heel down). In this case, the 47 degree SLZA fitting set lens in the same TSDV may be applied to repeat the observation. An angle between 44 and 47 may be selected if the 47 degree SLZA now appears to have excess clearance at the origin of the Scleral Landing Zone while showing the edge to impinge the bulbar conjunctiva (toe down).

[0098] It is possible that the 41 degree SLZA will be too great an angle on some eyes and the 38 degree SLZA will need to be applied for observation. Consistent with this, it is possible that the 47 degree SLZA will not be great enough for some eyes and the 50 degree LZA will need to be applied for observation.

EVALUATING THE DUAL ELEVATION REQUIREMENT

[0099] The completion of the fitting the sclera step is fulfilled with the objective of determining the need for the Dual Elevation feature and to estimate the number of microns of Dual Elevation difference needed. This determination is based on the observation of the circumferential lens edge to sclera relationship. In the Scleral Landing Zone Angle evaluation step above, the observation is made in the shallow or highest meridian of the sclera which is often near horizontal or visible within the palpebral fissure. The Dual Elevation observation is an attempt to see the difference between the highest meridian and the lowest (deepest) meridian. It is common for the lens to tip or tilt to achieve a three point touch. Intentional tipping of the lens to "reach" a deep semi-meridian will raise or elevate the semi-meridian 180 degrees away. The amount it is raised is about twice the actual difference.

[00100] The observation of a space or an excessive edge lift in the two deep semi-meridians or the one semi-meridian 180 degrees from a semi meridian that is tipped to reach one deep point is the focus of the estimation of the difference in the depth of the deep meridian from the shallow meridian. Biometric data demonstrates that the average eye has 300 microns of difference between the deep and shallow meridian. With reference to FIG. 11, a contact lens with a lens edge (outer ring), cornea (middle ring), and pupil (inner ring) are illustrated. The two arcs between the cornea and the lens edge represent clearance or lift in the inferior and superior regions which indicates the need for the dual elevation sagittal difference. FIG. 12 illustrates the eye looking down and showing the

clearance in the superior portion. FIG. 13 illustrates a lens with no edge lift demonstrating proper dual elevation difference in contrast to the drawings of FIGS. 11 and 12 demonstrating the difference between a dual elevation lens and a non-dual elevation lens on the same eye.

[00101] Too much or too little dual elevation will demonstrate clearance or edge lift in the meridian or semi meridian where the lens is not deep enough. Usually when there is deficient dual elevation the excessive clearance will be in the superior and inferior portions (the vertical meridian). Too much dual elevation is more likely to show edge lift or clearance in nasal and/or temporal portions.

[00102] The standard Dual Elevation TSDV lens has a 200 micron difference. In extreme cases as much as 800 microns of Dual Elevation sagittal difference is needed due to potential extreme scleral elevation differences at the chord of 14.6 mm. It is possible that some eyes will not require any Dual Elevation feature.

STEP 2: EVALUATING AND SELECTING THE LIMBAL ZONE DEPTH

[00103] In accordance with various aspects of the present disclosure, there may be an emphasis on evaluating the lens from the periphery to the center rather than the apex to the periphery. Since scleral contact lenses only touch the sclera, it is prudent to fit the sclera first and then move inward. With the proper SLZA and Dual Elevation requirement in hand the next zone to evaluate is the Limbal Zone.

[00104] The determination of the Limbal Zone Depth is based on the observation of the clearance at the limbus of the eye as assisted by the 11.6 landmark indicator. This observation can be made even if the Landing Zone Angle is not correct. The objective is to prescribe a lens with a preferred limbal clearance in microns when the proper Landing Zone Angle is in place. The micron changes in sagittal depth with the SLZA change is integrated with the observed limbal clearance to determine the final Limbal Zone Depth.

[00105] For example, if a 3600 TSDV lens is applied and the SLZA is observed to be correct, and the limbal clearance is 300 microns while the preferred limbal clearance is 200 microns, then the LZD must be decreased 100 microns. This change of 100 microns lowers all zones inside of the Limbal Zone. Hence, the apical clearance along with the entire optic zone (OZ) and the Peripheral Corneal Zone will lower by the same 100 microns. This reduction of everything inside must be compensated for later in the context of the preferred and observed clearances for those zones.

[00106] Alternatively, if the SLZA is not correct and an adjustment in the angle will be made, this adjustment directly impacts the height of the lens inside of the Scleral Landing Zone. The sagittal change with an SLZA change must be considered when the final Limbal Zone Depth is determined. Changing the SLZA to a greater angle will raise the lens inside and will require a reduction to the LZD for each angle of change. Changing the SLZA to a lesser angle will lower the lens inside and will require an addition to the LZD for each angle of change. FIG. 14 illustrates a table with estimates of the sagittal contribution of each Scleral Landing Zone Angle from its origin (12.8 mm) to the chord of the TSDV (14.6 mm) at the mid-point of the Scleral Landing Zone.

[00107] Reference to the table of FIG. 14 is made by looking up the fitting set lens value observed on the eye and the intended prescribed value. For example, if the 44 degree LZA is too shallow and a 46 degree LZA is prescribed. The limbal clearance will be increased by the difference. The difference is equal to $0.998 - 0.928 = 70$ microns. Hence, the deeper SLZA will raise all zones inside of it by 70 microns. The changes in SLZA are compensated in the Limbal Zone Depth only since the adjustment in the LZD is manifest at all points inward from it. The impact of SLZA changes is managed in the Limbal Zone Depth adjustment.

[00108] If the SLZA is increased the LZD must decrease the same number of microns to maintain the desired limbal, peripheral corneal and apical clearance. Conversely, if the SLZA is decreased the LZD must increase the same number of microns to maintain the desired limbal peripheral corneal, and apical clearance.

[00109] No changes in the Peripheral Corneal Zone Depth or the base curve radius are required when changes are made in the Scleral Landing Zone Angle. In this manner, the Scleral Landing Zone and the Limbal Zone are paired to make equal and opposite changes in LZD when the SLZA is changed.

STEP 3: EVALUATING AND SELECTING THE BASE CURVE RADIUS

[00110] In accordance with the present disclosure, next, the observed pre-compression apical clearance, 9.0 clearance and the 11.6 clearance are recorded. The decision to change the Base Curve Radius is a function of the difference between the observed apical clearance and the observed 9.0 clearance. If they are close in clearance then no change in BCR should be made. If the apical clearance is significantly thinner than the 9.0 clearance, a shorter (steeper) BCR will produce a more uniform clearance profile. Conversely, if the apical clearance is significantly greater than the 9.0 clearance, then a longer (flatter) BCR will produce a more uniform clearance profile. If there is no obvious difference between the apical clearance and the 9.0 clearance, then it is appropriate to assign equal values to the two clearance observations. Changes in BCR are regarded as of lower importance and may serve a secondary purpose like controlling the final lens power. For example, in a high minus prescription the lens power may be reduced by selecting a longer (flatter) BCR.

[00111] An increase in BCR lowers the apical clearance. A decrease (steepening) adversely changes the observed relationship between the apical clearance and the optic zone junction clearance (9.0 chord). Minor changes in BCR generally

do not have a significant impact however. A change in BCR will require an adjustment to the PCZD as discussed in the next step.

STEP 4: CALCULATING THE TSDV OF EACH EYE

[00112] In accordance with various aspects of the present disclosure, the TSDV of an eye is calculated by adding the difference between the preferred apical clearance and the observed apical clearance to the known TSDV of the fitting set lens used for the observations. For example: A P 3600-44 is observed to have 100 microns of apical clearance and the preferred pre-compression clearance is 250 microns. Stated otherwise:

$$\text{TSDV} = 3600 + (250 - 100) = 3600 + 150 = 3750$$

[00113] Thus, this eye has a TSDV of 3750. This eye requires a lens having a TSDV of 3750 to have 250 microns of pre-compression apical clearance. In other words, the sum of the sagittal depth values of all four zones of a 16.4 mm lens must equal 3750. At the same time, the proper scleral landing and the desired pre-compression clearances must exist in all chords of the lens. In this regard, the proper scleral landing was determined in step 1, the proper Limbal Zone depth in Step 2, the apical clearance and the optic zone (9.0) clearance were equalized in step 3, and the TSDV is calculated now in step 4.

STEP 5: EVALUATING AND SELECTING THE PERIPHERAL CORNEAL ZONE DEPTH (PCZD)

[00114] Next, the Peripheral Corneal Zone Depth (PCZD) can be determined even if the Scleral Landing Zone Angle, the Limbal Zone Depth and the Base Curve Radius of the fitting set lens are not correct for final values. Because the above steps were conducted, the correct values for three of the four zones are known,

namely, the proper SLZA and whether it should be Dual Elevation or not, the proper LZD with the clearance observation and after determining any changes in the SLZA, and whether the BCR needed changes independent of the other zones. In the final step, the TSDV was calculated to provide the proper apical clearance for each given eye.

[00115] The total of all the sagittal depths of all the zones must equal the TSDV. Since three of the four zones have been determined and their sagittal depth values are known, the PCZD is derived from totaling their depths and subtracting the sum from the known TSDV.

[00116] In accordance with various embodiments, the PCZD may be automatically modulated as needed to make the lens prolate or oblate to equalize the 9.0 and the 11.6 clearance after the apical clearance is equalized with the 9.0 clearance by a change in the BCR.

[00117] The PCZD is the primary adjusting zone to produce the desired apical clearance after any adjustment to the SLZA, LZD and BCR. For example, a P 3600-44 lens may be applied and predetermined preferred clearance values and observed clearance values are recorded manually, for example, in a worksheet such as illustrated in FIG. 15.

[00118] As seen in FIG. 15, the insufficient Scleral Landing Zone (12.8) clearance indicates a need for a greater SLZA; -44 increased to -46. This raises the entire lens by 70 microns. Additionally, while the preferred Limbal Clearance is 200 microns, only 100 microns is observed. The SLZA change raises the lens 70 of the 100 microns so the LZD must still be increased by another 30 microns. The reported LZD of the observed lens is 0.550 (550 microns), so the new LZD must be 580 microns. In accordance with various aspects, this may be rounded to the nearest 25 microns. Thus, the suggested final LZD is then 575 microns.

[00119] Further, the apical clearance is 300 microns, significantly greater than the 9.0 clearance of 200 microns (100 microns) so the BCR needs to be longer (flatter) to equalize. The BCR table indicates increasing the BCR from 8.0 to 8.2 to decrease the apical clearance relative to the 9.0 clearance by 100 microns.

[00120] Thus:

$$\text{TSDV of this eye} = 3600 + (250-300) = 3600 - 50 = 3550$$

[00121] In other words, the known values are:

$$\text{TSDV} = 3550$$

$$\text{SLZA} = -46 \text{ degrees with a derived sag of } 0.998 \text{ (998 microns)}$$

$$\text{LZD} = 550 + 30 = 580 \text{ rounded to } 0.575$$

$$\text{BCR} = 8.25 \text{ with a derived sag of } 1335 \text{ microns}$$

[00122] The PCZD will equal the remainder when the sum of the SLZA sag, LZD, and BCR sag are subtracted from the TSDV:

$$\text{PCZD} = \text{TSDV} - (\text{SLZAsag} + \text{LZD} + \text{BCRsag})$$

[00123] In this example the $\text{PCZD} = 3550 - (1335 + 575 + 998) = 3550 - 2908 = 642$. As noted above, the LZD and PCZD may be rounded to the nearest 25 microns. Thus, the resultant suggested TSDV 16.4 mm lens parameters are:

$$\text{BCR: } 8.25$$

$$\text{PCZD: } 0.650$$

$$\text{LZD: } 0.550$$

$$\text{SLZA: } -46$$

[00124] The Table in FIG. 16 provides the sagittal depth of a range of base curve radii for the chord of 9 mm. Reference to the Table of FIG. 16 is useful for changing the PCZD when the BCR is changed to maintain the same TSDV. In this regard, one can look up the fitting set lens sag at the chord of the OZ (9.0 mm) which was observed on the eye and then look up the sag for the intended or prescribed BCR.

[00125] For example, if the fitting set lens has an 8.0 mm BCR, and a BCR of 8.40 mm will be prescribed, the Peripheral Corneal Zone Depth must be adjusted to

maintain the desired apical clearance and TSDV. The final lens with the 8.40 mm BCR will be shallower by the difference. The difference is equal to $1.307 - 1.386 = -79$ microns. Hence, the longer (flatter) BCR will lower the lens over the corneal apex by 79 microns. There is a need to compensate for this in the Peripheral Corneal Zone Depth in an equal and opposite direction. In this example, the decreased sagittal depth from the flatter BCR is compensated by making the PCZD deeper. This adjustment is automatically managed in the PCZD calculation using the difference between the TSDV and the sum of the BCRsag, LZD, and SLZAsag.

[00126] No changes in the Limbal Zone Depth are indicated when changes are made in the base curve radius. In this manner, the Peripheral Corneal Zone and the Optic Zone are paired to make equal and opposite changes in PCZD when the BCR is changed.

[00127] As those skilled in the art will appreciate, the BCR in some irregular corneas are not well predicted by keratometry or the reference sphere from corneal topography. Observations of the fluorescein pattern may show a significant difference in the apical clearance and the clearance at the optic zone junction. In such cases, a change in base curve radius is indicated to attempt to equalize the apical and optic zone junction clearances. For example, if there is too little apical clearance with an abundance of clearance at the optic zone junction, a shorter base curve radius is indicated.

EVALUATING AND SELECTING THE LENS POWER

[00128] In accordance with various aspects of the present disclosure, two exemplary methods are provided for determining lens power. The first is empirical by use of the Jessen Formula and the second is by over-refraction and use of the fitting set lens base curve radius and power. A common practice in scleral lens fitting of irregular cornea eyes is to use a fitting set lens with the known lens values

and an over refraction. Generally, it is preferred to have a BCR and lens power that minimizes the dioptric power of the over refraction. High over refractions are adjusted for the vertex distance of the refraction. Even so, the higher the over-refraction power the more likely the need for a re-order to refine power.

[00129] The amount of apical clearance of the lens also impacts the quality of the vision and, in some cases, impacts the over-refraction results. It is preferable that an over-refraction be conducted with a fitting set lens that demonstrates less than 400 microns of apical clearance. In accordance with various aspects, a practitioner's preference for use of the over-refraction sphere value only or the over refraction spherocylindrical spherical equivalent may be incorporated into power selection.

[00130] In an exemplary embodiment, power selection using over-refraction with a lens of known base curve radius and power and with no change in the BCR is as follows:

Lens Identifier: P 4800 -44; Known BCR = 7.0, known Power = -9.00

Spherocylindrical over refraction: +6.00 – 1.00 X 97

Preference to use the over-refraction sphere in minus cylinder form:

Rx Lens BCR = 7.0 (therefore no change due to BCR change)

Rx Lens Power = Dx Lens power + Vertex adjusted over-refraction sphere

A look up table or formula for vertex adjustment may be used (in this case +6.00 adjusted for a 13 mm vertex distance = +6.50)

Rx Lens Power = -9.00 +6.50 = -2.50

[00131] In an exemplary embodiment, power selection using over-refraction with a lens of known base curve radius and power and with a change in the BCR is as follows:

Lens Identifier: P 4200 -47; Known BCR = 7.5, known Power = -5.00

Spherocylindrical over refraction: -4.50 – 0.75 X 83

Preference to use the over-refraction sphere only and in minus cylinder form:

Rx Lens BCR = 8.4 (effect of the flatter BCR must be integrated)

Rx Lens Power = Dx Lens power + Vertex adjusted over-refraction sphere -
Change in tear lens power

A look up table or formula for vertex adjustment may be used (in this case
+/-4.50 adjusted for a 13 mm vertex distance = -4.25)

The change in the radius from 7.50 (45.00 D) to 8.40 (40.18 D) = 40.18 –
45.00 = -4.82 D tear lens power

Rx Lens Power = -5.00 + (-4.25) – (-4.82) = - 4.43 D (may round to - 4.50)

FRONT SURFACE TORIC FOR RESIDUAL ASTIGMATISM

[00132] In accordance with various aspects of the present disclosure and with reference briefly to FIG. 18, lenses used with the methods and systems disclosed herein may have orientation marks 1050 located in the peripheral corneal zone between the 9 and 11 mm chords. The orientation marks 1050 may be placed during back surface manufacturing on the shallow meridian of dual elevation design lenses. Alternatively, the orientation marks 1050 may be placed on the front surface by use of scribing, drilling, laser marking or pigment deposition. Because the shallow meridian of most human eyes is relatively horizontal, the marks will be visible without retracting the lids when the lens settles onto the shallow meridian during the diagnostic fitting. The angular position of the orientation marks 1050 when the lens is on eye is required for placing the cylindrical power axis in the prescribed lens.

[00133] A practitioner may use an optic section in conjunction with the protractor feature found on most ophthalmic biomicroscopes (slit lamps) to determine the orientation angle of the lens fitted. In this regard, the section is narrowed and the light source rotated until the optic section aligns with the orientation marks 1050. At that point, the angle on the protractor is noted. After that, the practitioner misaligns the light source and repeats the alignment several times to gather

repeated measures. The measurement after over-refraction represents the longest settling time of the lens on the eye.

[00134] Most eyes will demonstrate residual astigmatism due to Javal's Rule. Irregular cornea eyes usually have greater amounts and more unusual axes to the residual astigmatism due to the presence of posterior corneal irregularity. In some cases the residual astigmatism represents a higher order aberration equivalent. Just as a spherical equivalent represents the best sphere in the absence of cylinder, cylinder represents the best cylinder in the absence of correction for coma, trefoil and other higher order aberrations.

[00135] Since most eyes will demonstrate this residual astigmatism, including the cylindrical component in 16.4 lenses as contemplated herein will be common. Residual astigmatism correction of 0.75 diopters is typically clinically significant. Improved visual acuity or at least subjective clarity will be demonstrated when 0.75 diopters of astigmatism is corrected.

[00136] The recommended cylinder power is the amount measured in the spherocylindrical over refraction. Vertex adjusting each meridian may result a minor adjustment in the cylinder power. Generally speaking, the vertex adjustment of the sphere allows for use of the over-refraction cylinder power.

TSDV CALCULATION SYSTEM

[00137] In accordance with various embodiments of the present disclosure, a calculator and/or application (software) provide a means of entering the fitting set lens parameters, preferred clearance values and clinical observations of clearance and are then used to calculate a final lens by the formulas and methods described above. The same steps may be implemented in such calculators and software applications:

1. Enter flat keratometry value or reference sphere from topography
2. Enter whether the cornea is Prolate or Oblate
3. Enter measured HVID

4. The lens identifier of the suggested fitting set lens is automatically selected from a look up table
5. The parameters and sagittal depth values for the respective fitting set lens are automatically selected from look up tables
6. Enter or accept preferred clearance preferences
7. Apply the suggested fitting set lens OR over-ride the suggested identifier and select an alternate lens and apply it
8. Enter the refined HVID from the observation of the 11.6 mm landmark indicator and the cornea
9. Enter the clearance observations
10. The parameters of a suggested final lens that is calculated to provide preferred clearances is reported
11. Enter over-refraction findings with the fitting set lens and angular position of the orientation marks
12. The final power is calculated using the vertex distance formula for the over-refraction and any change in power due to a change in base curve radius.

[00138] The calculation system may be used during a first fitting or when observing a lens that has been ordered and placed on an eye. The lens identifier for an ordered lens may depart from the identifier used for a fitting set lens. In an exemplary embodiment, the lens identifier for the prescribed lens may be a series of numbers or letters corresponding to the values for the parameters for each zone of the lens. The calculation system may be configured to automatically select the parameter values from the lens identifier for the prescribed lens.

[00139] In an alternate embodiment, the lens identifier for an ordered lens may be the order number assigned by the manufacturer when the lens order was processed. Respectively, the calculation system may be connected by electronic means to the database of the manufacturer to automatically select and populate the parameter values from the order number assigned by the manufacturer. The calculation system may also be used by entering post-compression preference values in conjunction with post compression clearance observations to calculate a final set of lens parameters according to the present invention.

LANDMARK INDICATOR

[00140] As mentioned above, in accordance with various embodiments of the present disclosure and with reference to FIG. 17, a landmark indicator may be provided on a contact lens to assist the observation of clearances of two or more chords of a lens or eye. For example, it is generally known that the average diameter of a human cornea is about 11.8 mm. Thus, by placing a visible indicator 1010 in the lens proximate a point slightly smaller than the average diameter of 11.8 mm, for example, 11.6 mm (or 5.8 mm radius measured from the center of the lens) a practitioner has a reference point relating to both gauging the size of the cornea, as well as calculating the location of various junctions or hinge points in multi-zone contact lenses. These hinge or junction points are the locations where there is a difference in the geometric derivation of the lens between zones.

[00141] In accordance with various aspects of the present disclosure, the size of the cornea can be assessed by observing whether the outer edge of the cornea of the eye extends beyond, falls short, or is underneath the indicator 1010. By so observing, the practitioner can determine whether the cornea is larger or smaller than average, which may be beneficial when selecting and fitting lenses using the systems and methods described herein, as well as fitting other lenses not discussed expressly herein. For example, the corneal diameter value may be used to modify the clearance preference values for the hinge point of the scleral landing zone.

[00142] As contemplated herein, a 16.4 diameter scleral lens may have four zones: an optic zone 1002 with a typical diameter of about 9 mm, a peripheral corneal zone 1004 with a typical width of about 1.3 mm (which by combining this zone with the optic zone 1002 results in a diameter of about 11.6 mm, the location of the indicator 1010), a limbal zone 1006 with a width of about 0.6 mm, and a scleral landing zone 1008 with a width of about 1.8 mm, all of which, when combined

result in a 16.4 mm lens. At the beginning and end of each of these zones is a hinge point where elevational changes in the zones occur. The practitioner can use the indicator 1010 to determine the approximate size of the cornea, which gives an initial reference point for implementing the methods and systems disclosed herein, for example, by first selecting a first lens from a fitting set, making observations of actual clearances between the lens and the eye, and making calculations (whether manual or with a calculator or software) to select a final lens.

[00143] Landmark indicators 1010 in accordance with the present disclosure comprise any indicator in or on a lens that can act as a reference point for a practitioner. In the embodiment illustrated in FIG. 17, the indicator 1010 comprises a continuous ring at a specific diameter (e.g., 11.6 mm or 5.8 mm radius from center). However, the ring need not be continuous. For example, the indicator 1010 may have a series of points, dashes or arcs formed at 5.8 mm radius from the center of the eye. Alternatively, the indicators 1010 may also be found at only one point 5.8 mm from the center. As one skilled in the art will appreciate, any number of configurations of the indicators 1010 may be used and fall with the present scope to the extent it assists a practitioner in gaging the diameter of a cornea.

[00144] In various embodiments, landmark indicators 1010 may be formed in or marked on lenses in any suitable manner. For example, in some embodiments, a landmark ring may be formed by diamond turning the lens to create the ring. In alternative embodiments, other machining methods may be used. In still other embodiments, the indicators 1010 may be configured by using dyes, inks or other visual indicators applied to a surface of or embedded with the lens. In any event, it should be appreciated that any method of including an indicator which can act

as a reference point for the cornea as contemplated herein falls within the present scope.

[00145] Finally, the foregoing disclosure is illustrative of the present disclosure and is not to be construed as limiting the disclosure. Although one or more embodiments of the disclosure have been described, persons of ordinary skill in the art will readily appreciate that numerous modifications could be made without departing from the scope and spirit of the disclosure. As such, it should be understood that all such modifications are intended to be included within the scope of this disclosure. The written description and drawings illustrate the present disclosure, and are not to be construed as limited to the specific embodiments disclosed.

CLAIMS

We claim:

1. A fitting method for a contact lens comprising the steps of:
selecting a fitting lens with sagittal depth values;
determining at least two clearance preference values for specific observation points on the fitting lens;
making at least two observations of clearance of the contact lens from an eye at the specific observation points; and
using a difference between the at least two clearance preference values and the at least two observations of clearance of the contact lens at the specific observation points to modify sagittal depths of at least two zones to produce a final lens.
2. A fitting method for a contact lens according to claim 1, wherein the contact lens is a scleral lens.
3. A fitting method for a contact lens according to claim 1, wherein more than two clearance preference values and observations of clearance at the specific observation points are observed.
4. A fitting method for a contact lens according to claim 1, wherein the fitting method is performed using a fitting calculator.
5. A fitting method for a contact lens according to claim 1, wherein the fitting method is performed using a software application.

6. A fitting method for a contact lens according to claim 1, wherein the fitting method is performed using a worksheet.

7. A fitting method for a contact lens according to claim 1, wherein at least one of (a) the sagittal depths of each zone of the contact lens and (b) a width of each zone of the contact lens is fully disclosed.

8. A fitting method for a contact lens according to claim 1, wherein the contact lens comprises a central zone, at least one peripheral zone, and an edge contour zone.

9. A fitting method for a contact lens according to claim 8, wherein the contact lens further comprises a second peripheral zone.

10. A fitting method for a contact lens according to claim 1, wherein the contact lens comprises a central zone, a peripheral corneal zone, a limbal zone, and a scleral landing zone.

11. A fitting method for a contact lens according to claim 1, wherein the contact lens has a dual elevation configuration based on a relationship of a scleral landing zone to a sclera.

12. A fitting method for a contact lens according to claim 1, wherein particular contact lenses from a fitting set are identified based on a identifier table having individual contact lens parameters.

13. A fitting method for a contact lens according to claim 1, wherein a contact lens is selected from a fitting set based on a look-up table.

14. A fitting method for a contact lens according to claim 1, further comprising an observation worksheet for manually recording at least one of an right or left eye, contact lens sagittal depth values, corneal diameter value, observed orientation mark angular position, contact lens base curve radius, contact lens power, over refraction data, clearance preference values and clearance observation data.

15. A fitting method for a contact lens according to claim 1, wherein the contact lens further comprises a landmark indicator located at a radius corresponding to an average radius of a human cornea.

16. A fitting method for a contact lens according to claim 15, wherein the landmark indicator assists a practitioner with estimating a diameter of the human cornea.

17. A fitting method for a contact lens according to claim 15, wherein the landmark indicator assists a practitioner with observing clearances of two or more chords of a lens on an eye.

18. A fitting method for a contact lens according to claim 16, wherein the landmark indicator is located at about 11.6 mm.

19. A fitting method for a contact lens according to claim 17, wherein the landmark indicator is at least one of a ring, a point, a dash, an arc, a series of a series of points, a series of dashes, and a series of arcs.

20. A fitting method for a contact lens according to claim 1, wherein the contact lens comprises orientation marks located on a principal meridian of the contact lens.

21. A fitting method for a contact lens according to claim 20, wherein the orientation marks assist a practitioner with estimating an angular positioning of a lens on an eye.

22. A fitting method for a contact lens according to claim 20, wherein the orientation marks are located in a shallow meridian of the contact lens.

23. A fitting method for a contact lens according to claim 20, wherein the orientation marks are at least one of a point or a dash.

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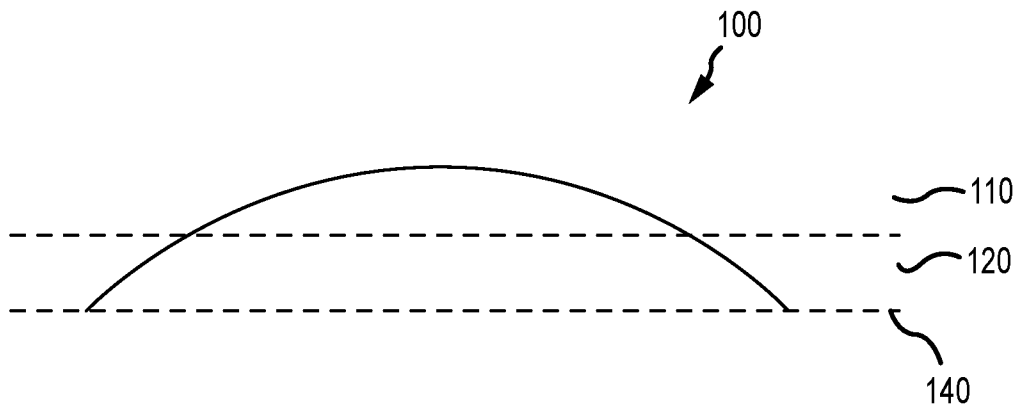


FIG.1

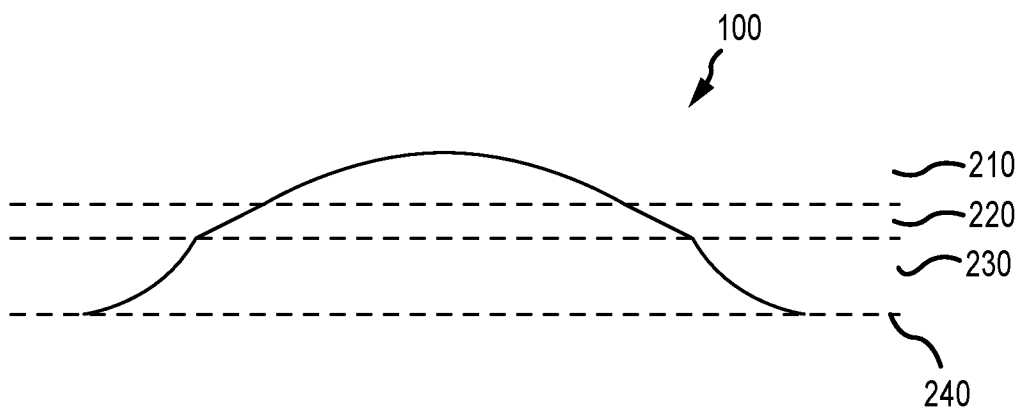


FIG.2

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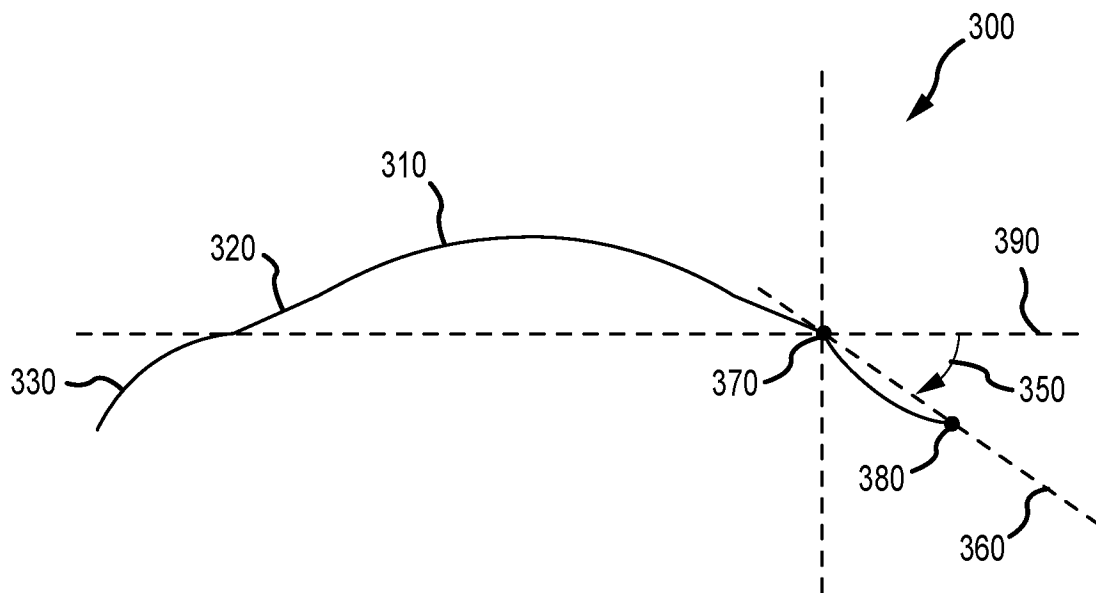


FIG.3

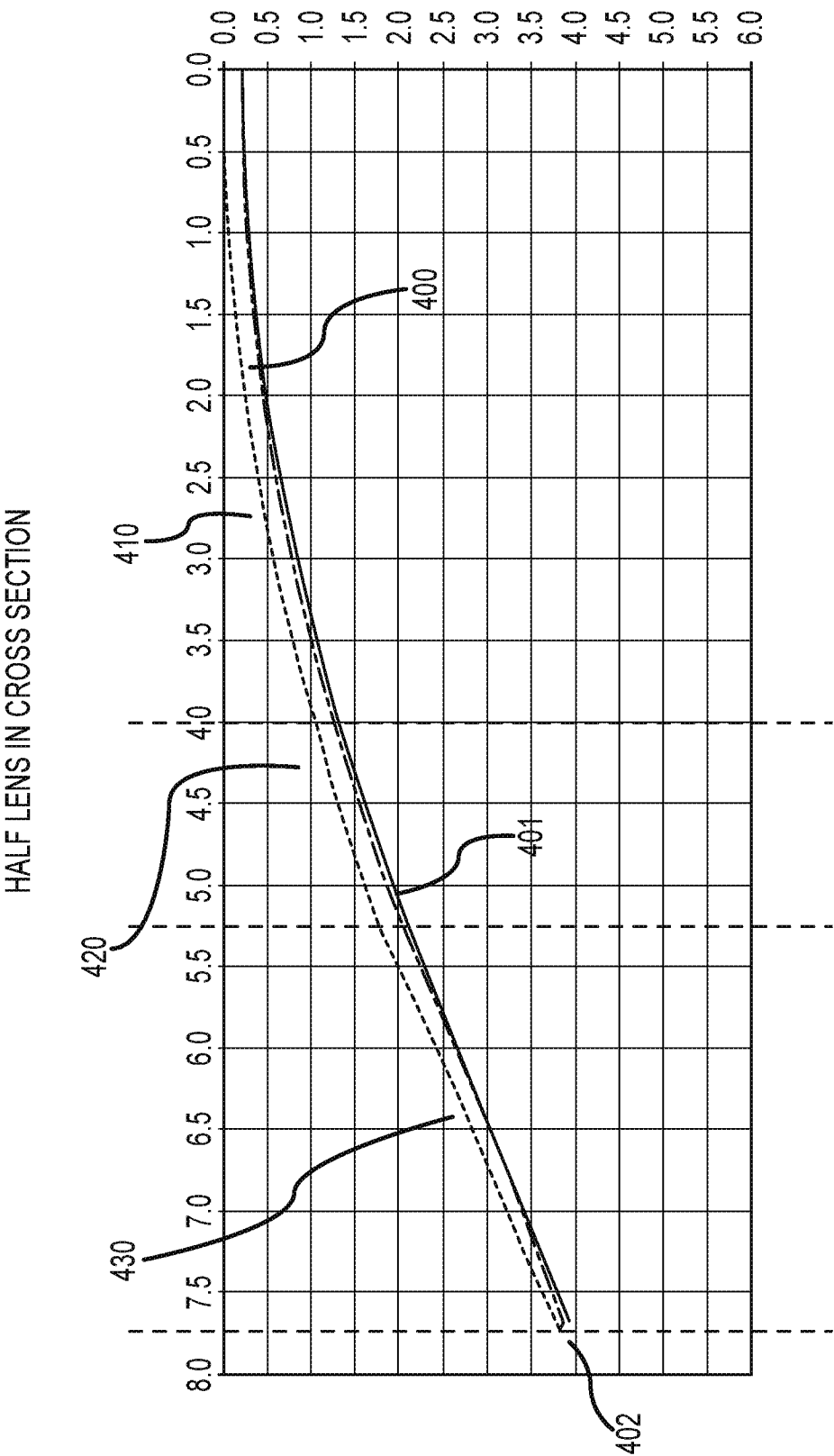


FIG.4A

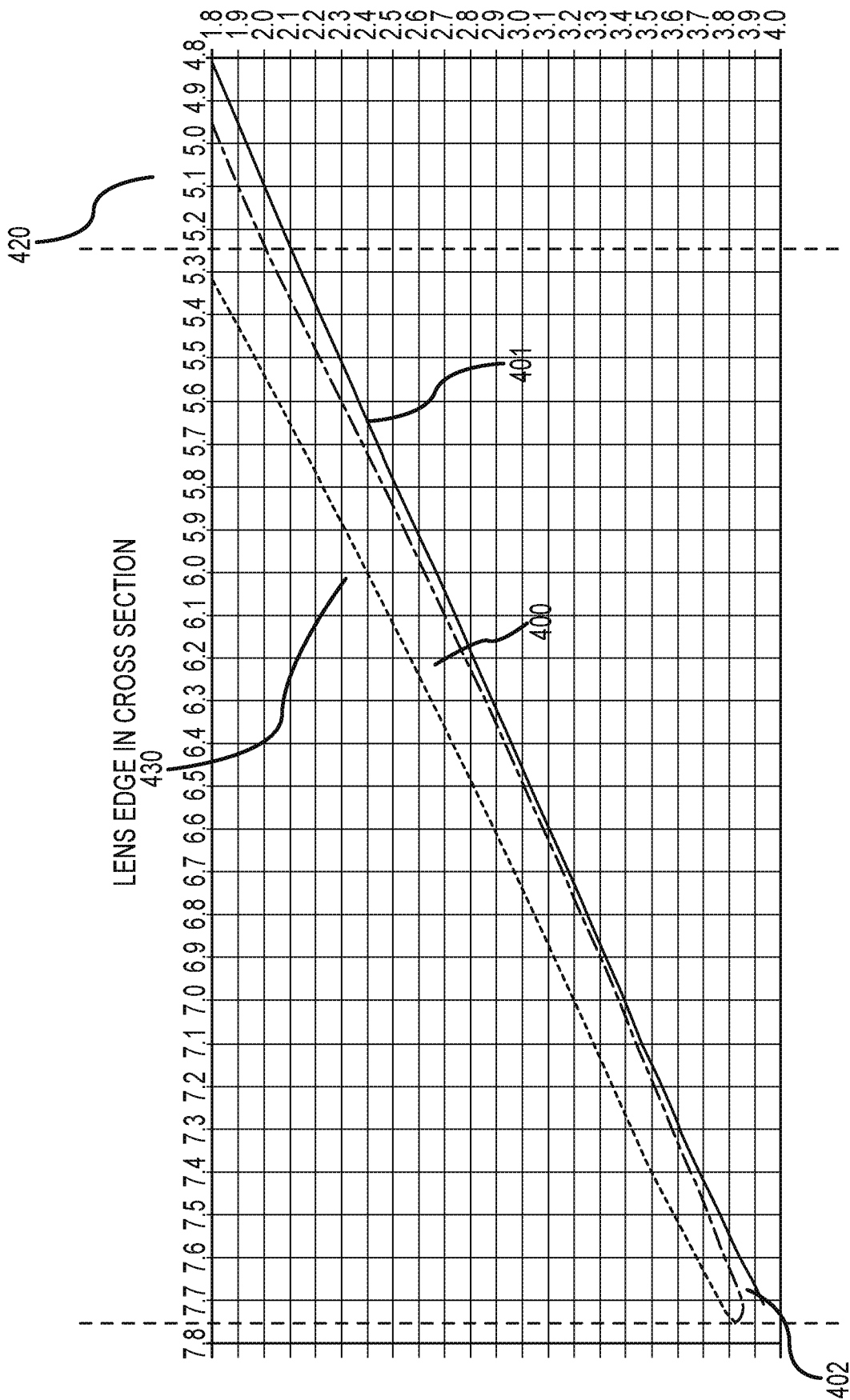


FIG.4B

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Lens Identifier Table

Identifier	Power	BCR	BCR SAG	PCZD	LZD	LZD Deep	SLZA	SLZD
P 3600-38	-3.00	8.0	1.386	0.825	0.650	0.850	-38	0.748
P 3600-41	-3.00	8.0	1.386	0.800	0.600	0.800	-41	0.834
P 3600-44	-3.00	8.0	1.386	0.750	0.550	0.750	-44	0.928
P 3600-47	-3.00	8.0	1.386	0.700	0.500	0.700	-47	1.035
P 3600-50	-3.00	8.0	1.386	0.625	0.450	0.650	-50	1.156
P 3900-38	-4.00	7.75	1.440	1.025	0.700	0.900	-38	0.748
P 3900-41	-4.00	7.75	1.440	1.000	0.650	0.850	-41	0.834
P 3900-44	-4.00	7.75	1.440	0.950	0.600	0.800	-44	0.928
P 3900-47	-4.00	7.75	1.440	0.900	0.550	0.750	-47	1.035
P 3900-50	-4.00	7.75	1.440	0.825	0.500	0.700	-50	1.156
P 4200-38	-5.00	7.5	1.500	1.075	0.900	1.100	-38	0.748
P 4200-41	-5.00	7.5	1.500	1.025	0.850	1.050	-41	0.834
P 4200-44	-5.00	7.5	1.500	1.000	0.800	1.000	-44	0.928
P 4200-47	-5.00	7.5	1.500	0.925	0.750	0.950	-47	1.035
P 4200-50	-5.00	7.5	1.500	0.850	0.700	0.900	-50	1.156
P 4800-38	-9.00	7.0	1.638	1.225	1.200	1.400	-38	0.748
P 4800-41	-9.00	7.0	1.638	1.200	1.150	1.350	-41	0.834
P 4800-44	-9.00	7.0	1.638	1.150	1.100	1.300	-44	0.928
P 4800-47	-9.00	7.0	1.638	1.100	1.050	1.250	-47	1.035
P 4800-50	-9.00	7.0	1.638	1.050	0.950	1.150	-50	1.156
O 3600-38	0.00	10.0	1.070	1.150	0.650	0.850	-38	0.748
O 3600-41	0.00	10.0	1.070	1.100	0.600	0.800	-41	0.834
O 3600-44	0.00	10.0	1.070	1.050	0.550	0.750	-44	0.928
O 3600-47	0.00	10.0	1.070	1.000	0.500	0.700	-47	1.035
O 3600-50	0.00	10.0	1.070	0.925	0.450	0.650	-50	1.156
O 4400-38	-3.00	9.0	1.206	1.325	1.100	1.300	-38	0.748
O 4400-41	-3.00	9.0	1.206	1.300	1.050	1.250	-41	0.834
O 4400-44	-3.00	9.0	1.206	1.275	1.000	1.200	-44	0.928
O 4400-47	-3.00	9.0	1.206	1.225	0.950	1.150	-47	1.035
O 4400-50	-3.00	9.0	1.206	1.150	0.900	1.100	-50	1.156

FIG.5

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Fitting Set Look-up Table

Flat K of Regular Cornea or Topography Reference Sphere of Irregular Cornea	Suggested Lens Identifier
49.00 and Steeper	P 4800 -44
46.00 to 48.87	P 4200 -44
44.00 to 45.87	P 3900 -44
42.00 TO 43.87	P 3600 -44
Flatter than 42.00	O 3600 -44
Oblate Deep	O 4400 -44

FIG.6

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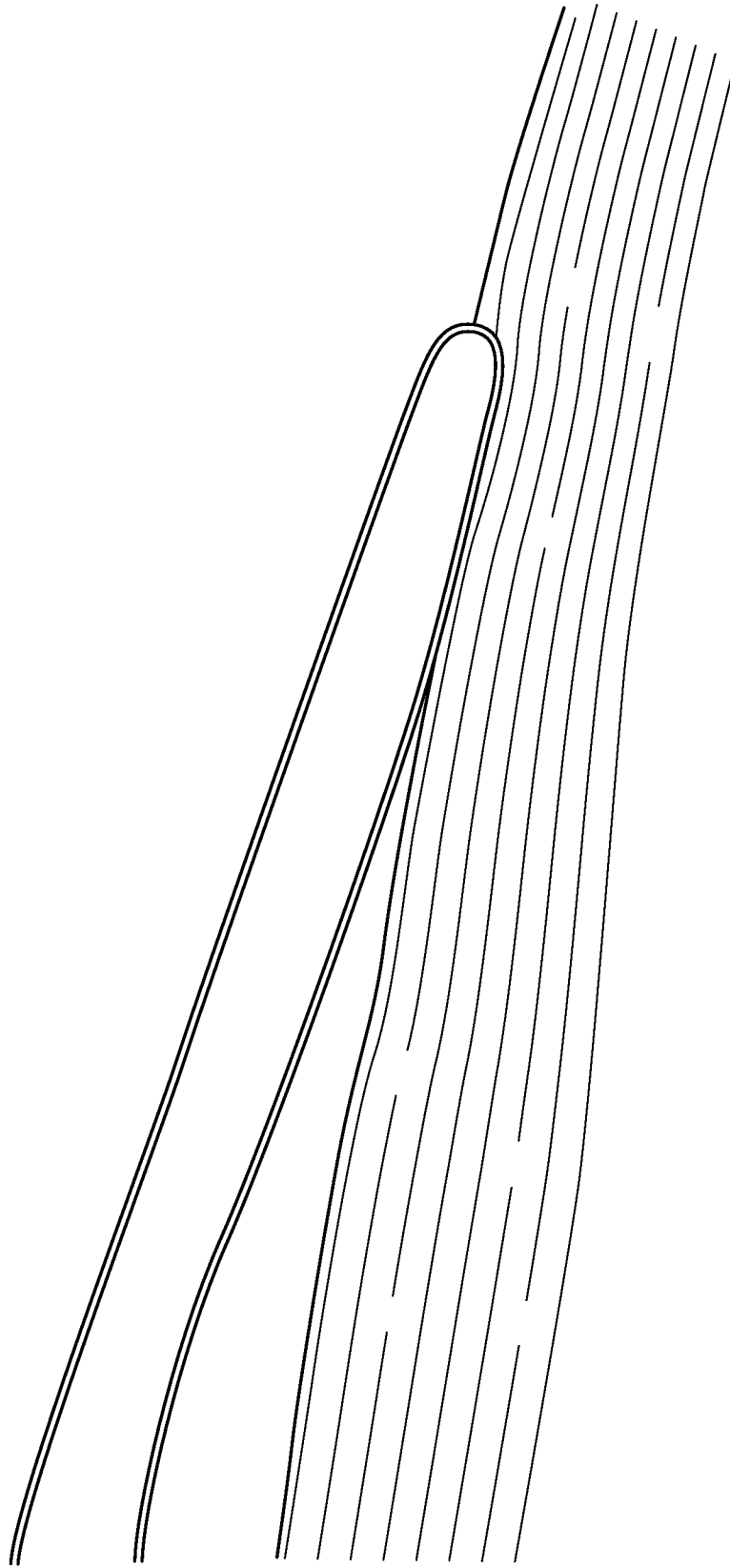


FIG.7

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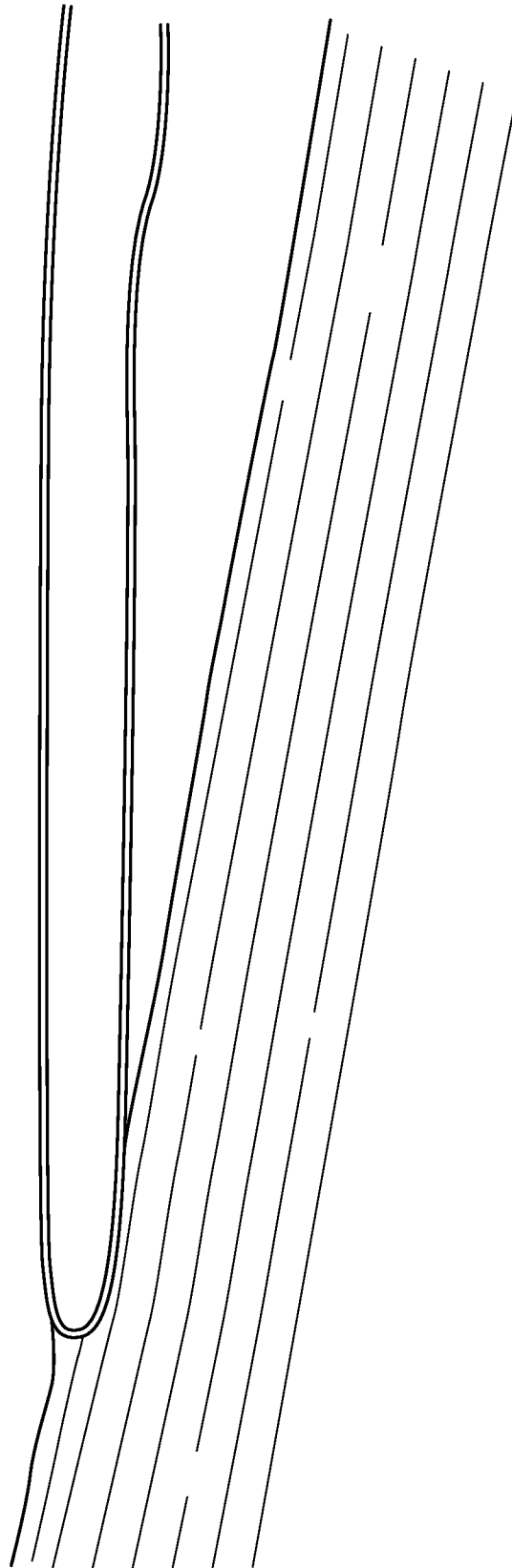


FIG.8

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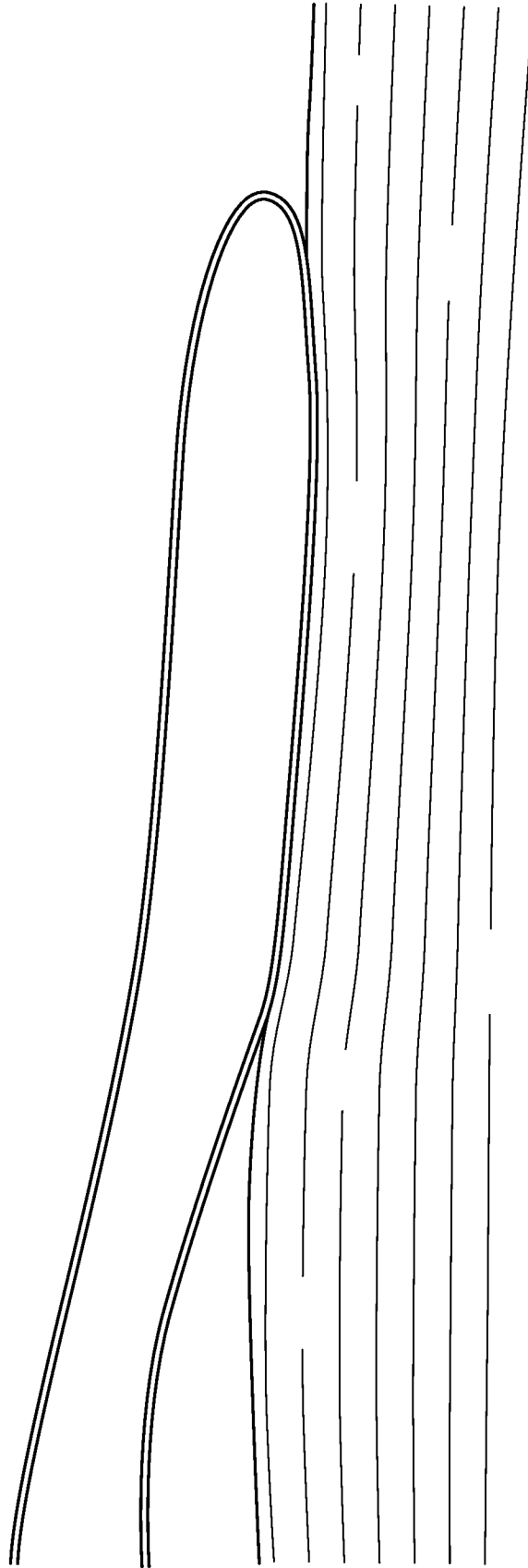


FIG.9

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FIG.10

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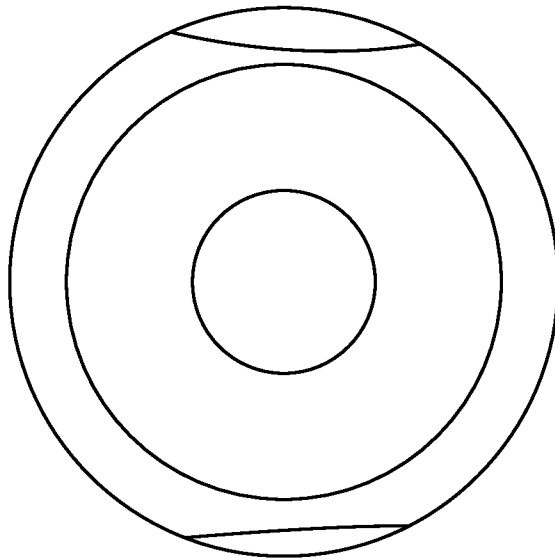


FIG.11

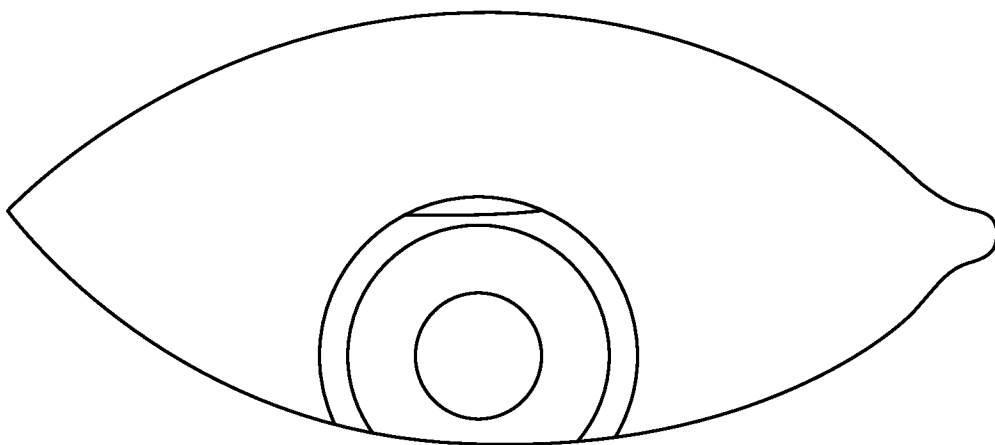


FIG.12

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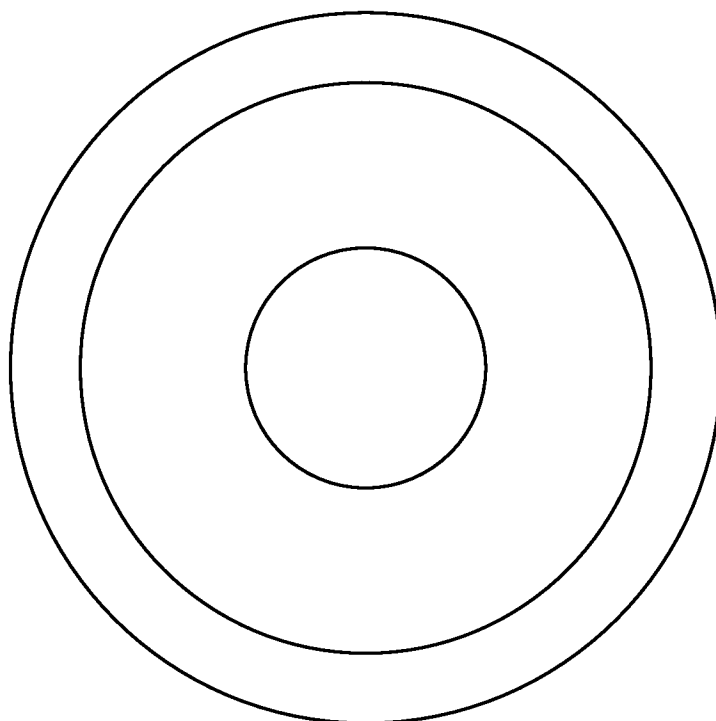


FIG.13

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**Estimates of Sagittal Contribution of Each
Scleral Landing Zone Angle**

SLZA with 12.8 Origin	SLZA Sag at 14.6 Chord
-35	0.670
-36	0.695
-37	0.721
-38	0.748
-39	0.776
-40	0.804
-41	0.834
-42	0.864
-43	0.896
-44	0.928
-45	0.962
-46	0.998
-47	1.035
-48	1.073
-49	1.114
-50	1.156
-51	1.200
-52	1.247
-53	1.296
-54	1.348
-55	1.404
-56	1.462
-57	1.525
-58	1.591
-59	1.663

FIG.14

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00

Clinical Input and Diagnostic Lens Lookup				Clearance Preferences and Observations				Over-Refraction Entry and Lens Parameter Calculation								
Vault	Clinical Input Values	Dx Lens Parameters	Dx Lens Values	Fit Control Point	Preferred Pre-compression Clearance at Control Point	Observed Clearance at Control Point	Sag change required for Preference	Lens order Parameters	Dx Lens SAG Microns	Calculated Rx Lens Sag Microns	Calculated Rx Lens Parameters	Clinical Input	Clinical input Values	Rx Calculated Parameters	Rx Calculated Values	
Flat K or Reference Sphere	41.00	BCR	10.0	Apex	250	100	150	BCR	1070	1220	8.91	BCR of SCOR Lens	18.00	BCR	8.91	Cylinder Axis
Prolate or Obate	0	PCZD	1.050	9.0	250	250	0	PCZD	1050	1107	1.100	Power of SCOR Lens	0.00	Power	-3.11	-1.75 82
HVID	11.9	LZD	0.500	11.6	200	250	-50	LZD	550	430	0.425	DR Sphere	+1.00	PCZD	1.100	
Dx Vault Lens Identifier	0 3600 -44	SLZA	-44	12.8	100	50	50	SLZA	928	998	-46	DR Cylinder	-1.75	LZD	0.425	
		Dx Lens IV Vault	3598	12.8 Deep	100	0	100	L20 Deep	750	558	0.575	DR Rats	82	L20 Deep	0.575	
					Orientation Angle	170			Rx Lens iVault Total	3755	3743			SLZA	-46	
					Calculated iVault for Rx	3750								Orientation Angle	170	

FIG.15

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OS

Clinical Input and Diagnostic Lens Lookup				Clearance Preferences and Observations			Over-Refraction Entry and Lens Parameter Calculation										
iVault	Clinical Input Values	Dx Lens Parameters	Dx Lens Values	Fit Control Point	Preferred Pre-compression Clearance at Control Point	Observed Clearance at Control Point	Sag change required for Preference	Lens order Parameters	Dx Lens SAG Microns	Calculated Rx Lens Sag Microns	Calculated Rx Lens Parameters	Clinical Input	Clinical input Values	Calculated Parameters	Rx Calculated Values		
Flat K or Reference Sphere	44.75	BCR	7.75	Apex	250	150	100	BCR	1440	1540	7.34	BCR of SCOR Lens	7.75	BCR	7.34	Cylinder Axis	
Prolate or Obate	0	PCZD	0.950	9.0	250	250	0	PCZD	950	912	0.900	Power of SCOR Lens	-4.00	Power	-9.30	-1.00 97	
HVID	11.8	LZD	0.500	11.6	200	150	50	LZD	600	580	0.575	DR Sphere	-3.00	PCZD	0.900		
Dx iVault Lens Identifier	0 3900 -44	SLZA	-44	12.8	100	50	50	SLZA	928	998	-46	DR Cylinder	-1.00	LZD	0.575		
				12.8 Deep	100	150	-50	L20 Deep	800	880	0.875	DR Rats	97	L20 Deep	0.875		
					Orientation Angle	15			Rx Lens iVault Total	4030	4013			SLZA	-46	Orientation Angle	1.5
					Calculated iVault for Rx	4018											

FIG.15

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Sagittal Depth Range of Base Curve Radii

Base Curve Radius	Optic Zone Diameter	Sagittal Depth
6.00	9.0	2.031
6.10	9.0	1.982
6.20	9.0	1.935
6.30	9.0	1.891
6.40	9.0	1.849
6.50	9.0	1.810
6.60	9.0	1.772
6.70	9.0	1.736
6.80	9.0	1.702
6.90	9.0	1.669
7.00	9.0	1.638
7.10	9.0	1.608
7.20	9.0	1.580
7.30	9.0	1.552
7.40	9.0	1.525
7.50	9.0	1.500
7.60	9.0	1.475
7.70	9.0	1.452
7.75	9.0	1.440
7.80	9.0	1.429
7.90	9.0	1.407
8.00	9.0	1.386

Base Curve Radius	Optic Zone Diameter	Sagittal Depth
8.20	9.0	1.345
8.40	9.0	1.307
8.50	9.0	1.289
8.60	9.0	1.271
8.80	9.0	1.238
9.00	9.0	1.206
9.20	9.0	1.176
9.40	9.0	1.147
9.60	9.0	1.120
9.80	9.0	1.094
10.00	9.0	1.070
10.30	9.0	1.035
10.60	9.0	1.003
11.00	9.0	0.963
11.50	9.0	0.917
12.00	9.0	0.876
13.00	9.0	0.804
14.00	9.0	0.743
15.00	9.0	0.691
16.00	9.0	0.646
18.00	9.0	0.572
20.00	9.0	0.513

FIG.16

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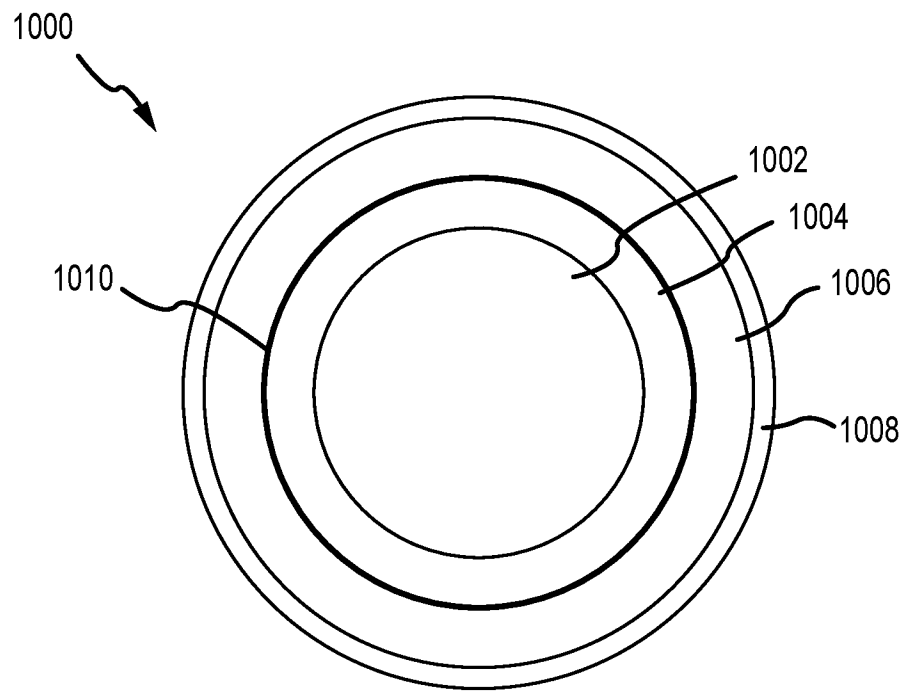


FIG.17

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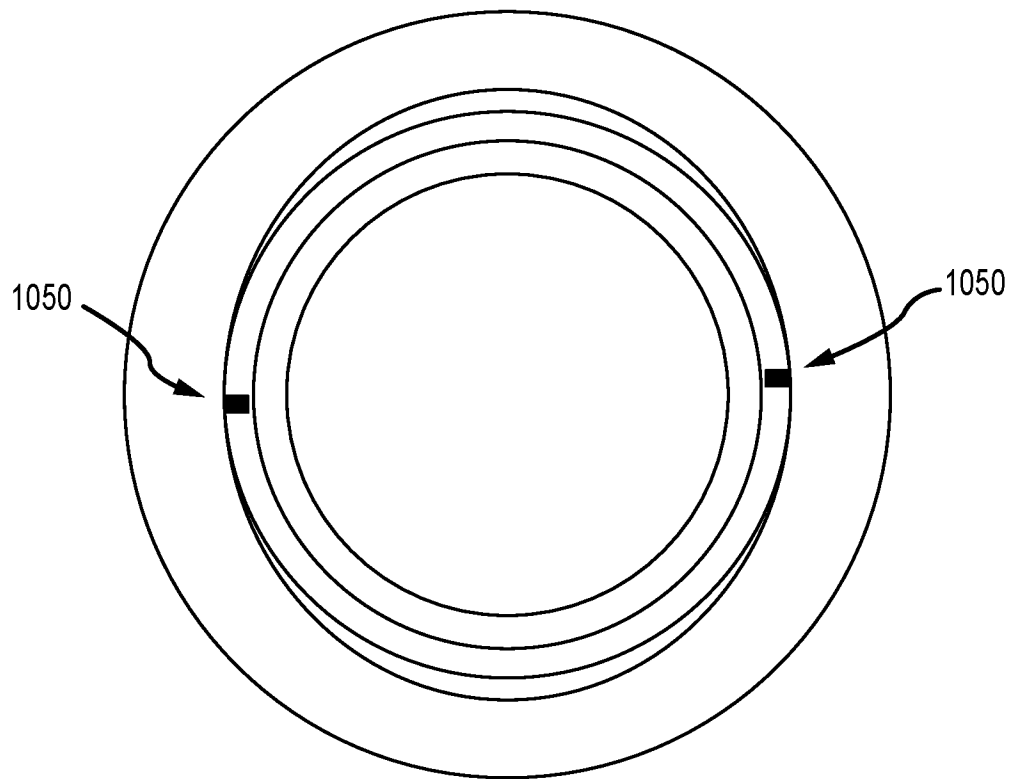


FIG.18

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2017/051262

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G02C 7/04; G2C 7/02; G06F 9/00; G06F 17/50 (2017.01)

CPC - G02C 7/047; G02C 7/02; G02C 7/04; G06F 9/00; G06F 17/50 (2017.02)

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)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---	US 8,794,759 B2 (LEGERTON et al) 05 August 2014 (05.08.2014) entire document	1, 3-9, 12, 13 ---
Y		2, 10, 11, 14-23
Y	US 8,113,653 B2 (LEGERTON et al) 14 February 2012 (14.02.2012) entire document	2, 10, 11
Y	US 8,694,352 B1 (HAWKINS et al) 08 April 2014 (08.04.2014) entire document	14
Y	US 6,086,202 A (CHATEAU et al) 11 July 2000 (11.07.2000) entire document	15-19
Y	US 5,936,704 A (GABRIELIAN et al) 10 August 1999 (10.08.1999) entire document	20-23
A	US 5,929,968 A (COTIE et al) 27 July 1999 (27.07.1999) entire document	1-23
A	US 7,862,176 B2 (GEMOULES et al) 04 January 2011 (04.01.2011) entire document	1-23
A	US 2013/0297015 A1 (JOHNS et al) 07 November 2013 (07.11.2013) entire document	1-23
A	US 4,193,672 A (TROMBLEY et al) 18 March 1980 (18.03.1980) entire document	1-23

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

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

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Date of the actual completion of the international search

31 May 2017

Date of mailing of the international search report

19 JUN 2017

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