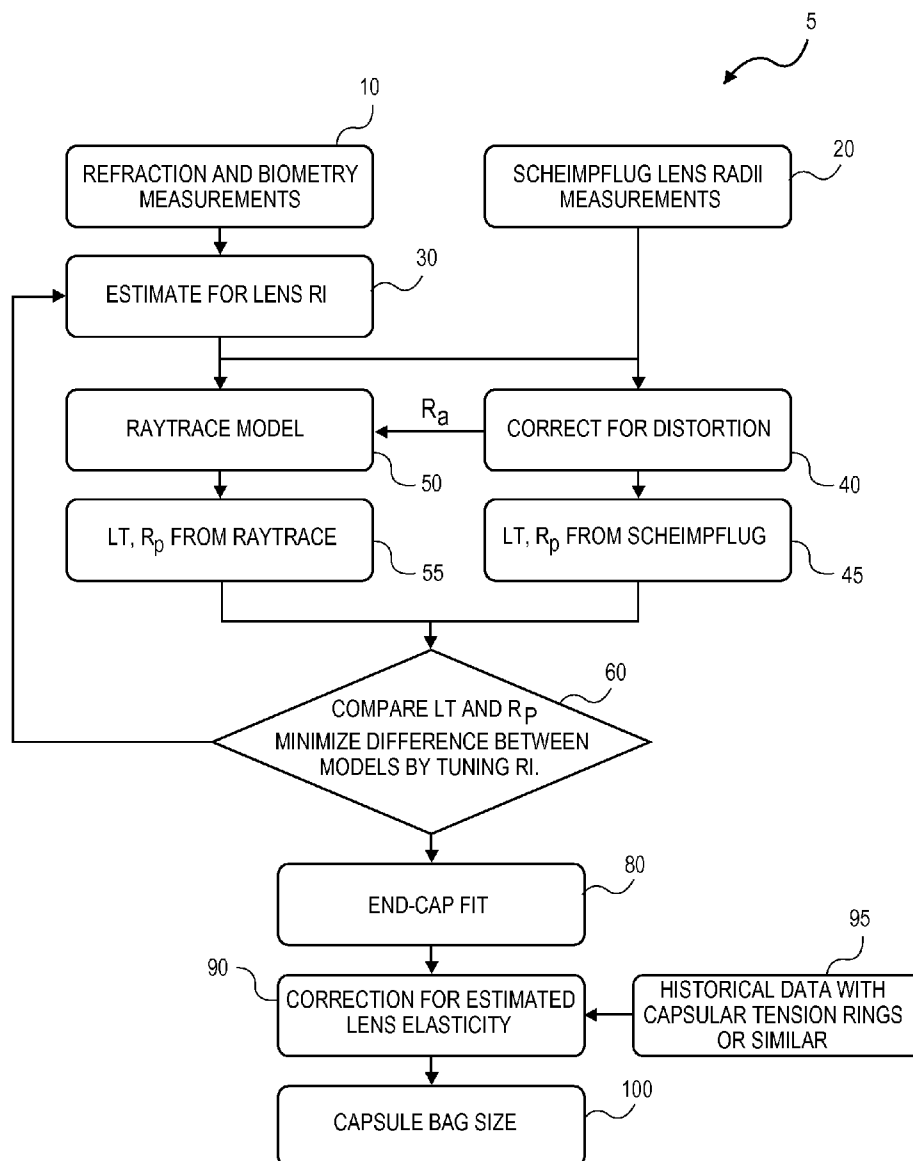(19) **United States**

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(54) **LENS CAPSULE SIZE ESTIMATION**

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(57) **ABSTRACT**

Methods of estimating the size of an ocular lens capsule.

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| REFRACTION AND BIOMETRY MEASUREMENTS |

| SCHEIMPFLUG LENS RADII MEASUREMENTS | 20

30

| ESTIMATE FOR LENS RI |

| RAYTRACE MODEL | R_a | CORRECT FOR DISTORTION |

50   40

| LT, R_p FROM RAYTRACE | LT, R_p FROM SCHEIMPFLUG |

55   45

60
COMPARE LT AND R_p
MINIMIZE DIFFERENCE BETWEEN
MODELS BY TUNING RI.

| END-CAP FIT | 80

95

90 | CORRECTION FOR ESTIMATED LENS ELASTICITY | ← | HISTORICAL DATA WITH CAPSULAR TENSION RINGS OR SIMILAR |

| CAPSULE BAG SIZE | 100

FIG. 1

FIG. 2

150

$$AP = Ra + Rp - LT$$

160

$$CBD = \frac{\sqrt{((Ra + Rp)^2 - AP^2) \times (AP^2 - (Ra - Rp)^2)}}{AP}$$

Rp

AP

Ra

Rp

CBD

LT

Ra

FIG. 3

LT

170

170

LT

170

170

CBD

CBD
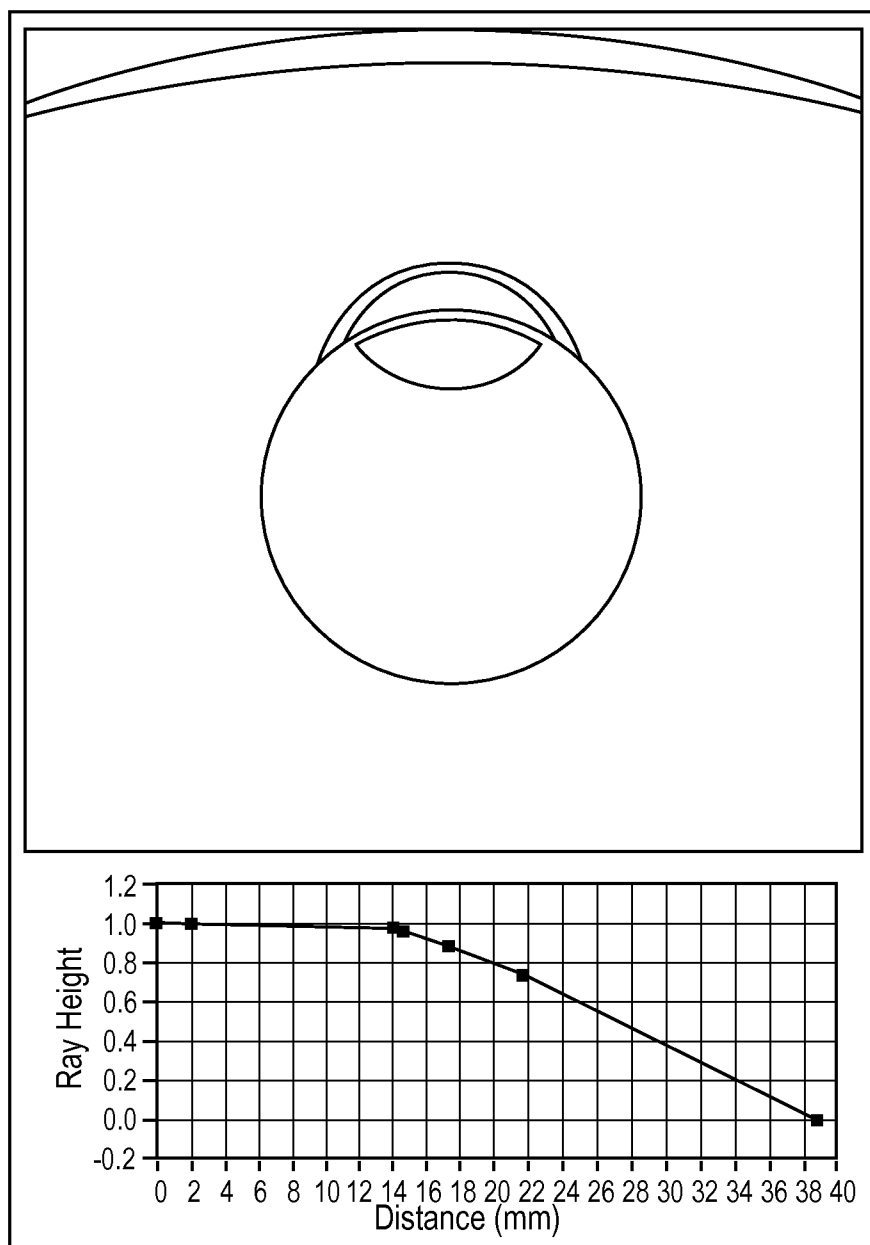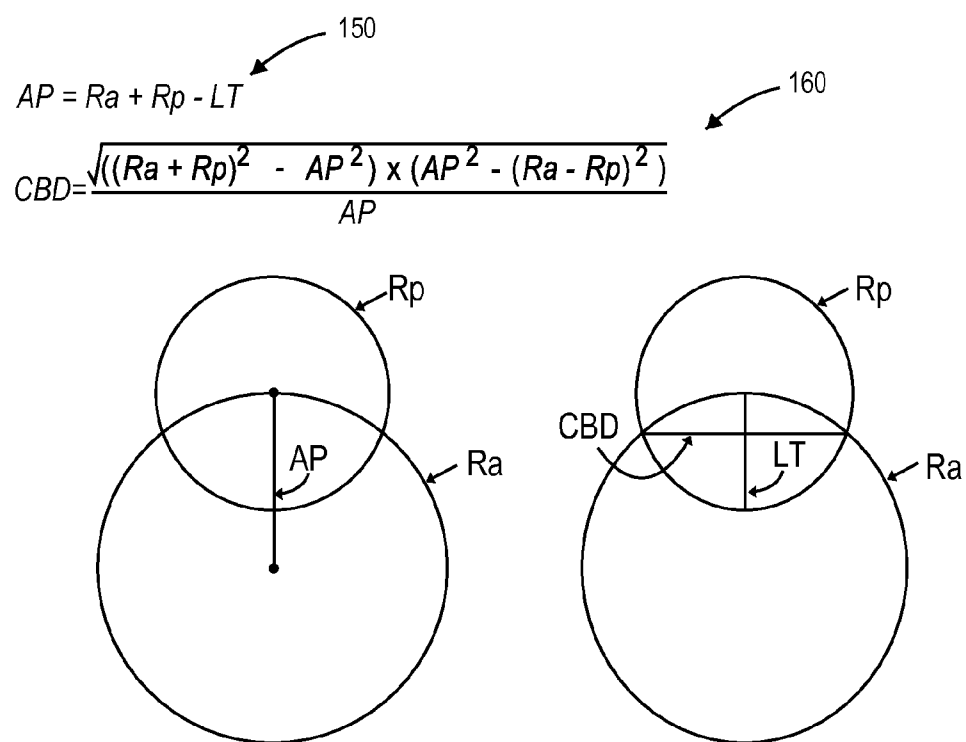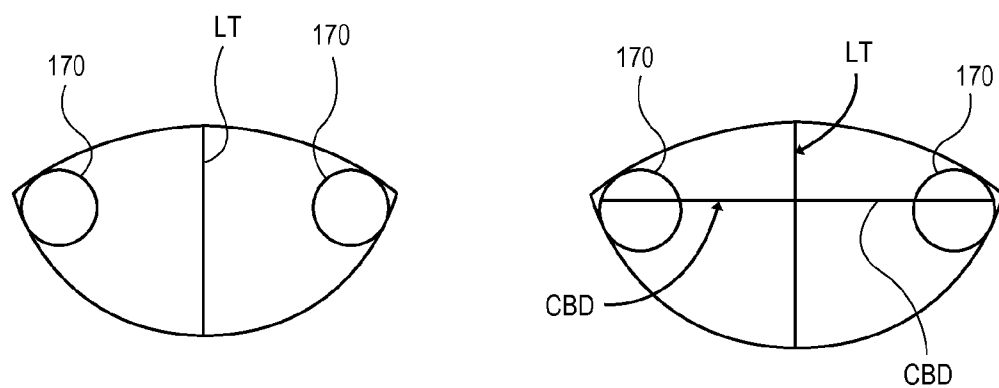
FIG. 4

LENS CAPSULE SIZE ESTIMATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 12/872,314, filed Aug. 31, 2010, now U.S. Pat. No. 8,447,086, which application claims priority under 35 U.S.C §119 to U.S. Provisional Patent Application No. 61/238,606, filed Aug. 31, 2009, which is incorporated herein by reference.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0003] An intraocular lens ("IOL") can be used to replace a native lens of the eye when the native lens has been clouded by a cataract, or when the native lens loses part or all of its ability to accommodate. Non-accommodating IOLs have been described, including fixed monofocal IOLs and multifocal IOLs. Accommodating IOLs have also been described, which have accommodative capabilities similar to a native lens.

[0004] To replace a native lens with an IOL, the native lens is first removed from the capsular bag (typically by emulsification), leaving the capsular bag in the eye. The IOL is then implanted within the capsular bag. It is generally beneficial to ensure that the IOL to be implanted is appropriately sized based on the size of the patient's capsular bag. It may be even more important to ensure that an accommodating IOL is appropriately sized because, unlike a non-accommodating IOL, an accommodating IOL accommodates in response to changes in shape of the capsular bag. The accommodative response of an accommodating IOL may therefore depend on the appropriateness of the fit between the IOL and the capsular bag. Determining, or estimating, the size of the capsular bag before implanting the IOL is therefore generally beneficial, and may even greatly enhance the accommodative response of an accommodating IOL.

[0005] Techniques have been described to estimate the size of a capsular bag, but they have shortcomings which result in a need for improved methods of estimating the capsular bag size. For example, magnetic resonance imaging (MRI) can be used to non-invasively measure the dimensions of the capsular bag. The image resolution is, however, typically about ±0.1 mm or more. Moreover, the MRI slice thickness is generally too thick to get an accurate estimation of the true equatorial diameter of the lens capsule since there are typically only 3-5 images taken across the lens. Attempting to decrease the slice thickness creates a longer scanning time and this creates images with more motion noise as the patient's eye slightly moves over the course of the scan. Additionally, the access to, cost, and analysis of a MRI scan makes this technique prohibitive for IOL applications.

[0006] While optical coherence tomography (OCT) could be used to non-invasively measure the anterior lens radius, current clinical OCT devices do not have the capability to image a significant portion of the lens radii due to the iris. OCT measurements are currently made along or parallel to the optical axis of the eye. Therefore, the area of the lens surfaces that can be imaged is limited by the iris. Accurately calculating lens radii is highly dependent on the amount of lens surface (arc length) that can be imaged as well as ensuring axial alignment so that the true lens center is being imaged. As understood, OCT methods, unlike Scheimpflug methods, currently do not rotationally 'scan' the lens which is needed in order to reconstruct the true shape of the lens since asymmetries may be present. Like Scheimpflug imaging, OCT images also require distortion correction due to the different indices of refraction that the light travels through. OCT may a potential method if the issues mentioned above can be addressed.

[0007] Invasive methods such as capsular tension rings (see, e.g., Vass, C. et al. Prediction of pseudophakic capsular bag diameter based on biometric variables. J Cataract Refract Surg. 1999; 25:1376-1381, which is incorporated by reference herein) and capsule measurement rings (see, e.g., Tehrani, M. et al. Capsule measuring ring to predict capsular bag diameter and follow its course after foldable intraocular lens implantation, J Cataract Refract Surg. 2003; 29:2127-2134, which is incorporated by reference herein) have been used to estimate capsule size. These methods involve the implantation of a flexible, incomplete (<360°) ring which has an unrestrained diameter greater than the diameter of the capsular bag. When the ring is placed in the capsular bag after lens removal, the ring stretches out the capsule like a low-stiffness spring. By measuring the distance between features on the ring before and after implantation, a measurement of the stretched capsule diameter can be made. Since these methods are invasive and are deforming the capsular bag they can only obtain an equivalent diameter measurement and not a true volumetric measurement of the capsular bag, unlike Scheimpflug imaging (and possibly small-slice thickness MRI and rotationally scanning OCT). Additionally, invasive methods are not ideal as the correct size of the replacement IOL must be available at the time of measurement as opposed to non-invasive methods which allow the surgeon time to acquire the appropriate device or revise the treatment strategy.

SUMMARY OF THE INVENTION

[0008] One aspect of the disclosure is a method of estimating the size of an ocular lens capsule. The method includes obtaining patient data of a subject; imaging an anterior surface of an ocular lens and a posterior surface of the ocular lens; estimating a refractive index of the ocular lens; correcting the image of the anterior surface of the ocular lens for distortion to determine a radius of curvature of the anterior surface of the ocular lens; correcting the image of the posterior surface of the ocular lens for distortion to determine a radius of curvature of the posterior surface of the ocular lens; determining a thickness of the ocular lens using the corrected images of the anterior and posterior surfaces; estimating an estimated radius of curvature of the posterior surface of the ocular lens and an estimated lens thickness using the estimated refractive index, the patient data, and the radius of curvature of the anterior surface of the ocular lens; determining a difference between the determined radius of curvature of the posterior surface and the estimated radius of curvature of the posterior surface, and determining a difference between the thickness of the lens and the estimated lens thickness; minimizing at least one of the differences by repeating the estimating step and the determining step with an

adjusted estimated refractive index; creating a geometric model of the capsule using the radii of curvature of the anterior surface, the posterior surface, and the lens thickness; and selecting an intraocular lens for implantation based on the computed geometric model.

[0009] In some embodiments the method further comprises computing a capsular bag diameter from the geometric model.

[0010] In some embodiments estimating the refractive index comprises estimating a refractive index of the ocular lens using the patient data.

[0011] In some embodiments the method further comprises fitting end caps into the geometric model to compute the capsular bag diameter.

[0012] In some embodiments the method further comprises using an estimated lens elasticity to compute the capsular bag diameter.

[0013] In some embodiments imaging an anterior surface of an ocular lens and a posterior surface of the lens comprises imaging the anterior surface of an ocular lens and a posterior surface of the lens with a Scheimpflug imaging system.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0015] FIG. 1 illustrates an exemplary method of estimating a capsule bag size.

[0016] FIG. 2 illustrates performing a raytrace to determine an estimate for the radius of curvature of the posterior surface of the lens using an estimate for the refractive index of the lens, refraction and biometry data, as well as the radius of curvature of the anterior surface of the lens computed from Scheimpflug imaging.

[0017] FIG. 3 illustrates a geometric model for computing the capsular bag diameter.

[0018] FIG. 4 describes an optional end-cap fitting to refine the capsular bag diameter measurement.

DETAILED DESCRIPTION OF THE INVENTION

[0019] The disclosure herein relates generally to methods of estimating the size of a capsular bag in an eye. The methods herein can be used to determine an appropriately-sized IOL to be implanted in a subject following the estimation, but the methods are not limited to this use. As used herein, capsular bag "size" includes, without limitation, any dimension of a capsular bag, a general shape of the bag or portions of the bag, volume, etc.

[0020] The estimation methods described herein can be performed on a capsule bag when the capsule is in a subject (in vivo), on an artificial capsular bag which is part of an artificially created eye, or on a native capsule bag which is part of an eye from a subject (such as an animal) which has been removed from the subject. The methods are performed while the lens is still within the capsule, but in some instances some measurements may be made after the lens has been removed from the capsule.

[0021] FIG. 1 shows an exemplary embodiment of a method of estimating a capsule bag size. While method 5

comprises a plurality of steps, it is understood that in alternative embodiments of estimating a capsule size not all of the steps included in method 5 need to be included in the estimation of the capsule size. It is also understood that in alternative embodiments the order of the steps in method 5 need not necessarily be adhered to in estimating a capsule size. In some embodiments not only do all of the steps from method 5 not need to be performed, but the order in which they are performed may be different than the order shown in FIG. 1.

[0022] Method 5 includes step 10 which comprises obtaining refraction and/or biometry measurements from the subject using, for example without limitation, A-scan, OCT, or other clinical methods. The information obtained in step 10 can include, without limitation, manifest refraction (spectacle correction to achieve emmotropia), corneal power, corneal thickness, keratometry (k-values that can be converted to corneal radius of curvature), axial length, anterior chamber depth, lens thickness, the white-to-white distance, wavefront maps that assist in separating corneal aberrations from lens aberrations or a combination thereof, cataract density, age, gender, and ethnicity. The information obtained in step 10 can be broadly considered patient data.

[0023] Method 5 also includes step 20 which comprises obtaining images of the anterior, and if possible, posterior radii of curvature of the native lens using a Scheimpflug imaging system. The accuracy for the measurement of the posterior lens radius of curvature is based on the amount of the lens that can be visualized, a factor of the dilation of the iris.

[0024] The Scheimpflug imaging system that may be used to image the anterior and posterior radii of curvature can be, without limitation, the NIDEK EAS-1000 (NIDEK Co. Ltd, Gamagori, Japan), the Topcon SL-45 (Topcon Medical Systems Inc., Paramus, N.J.), the Pentacam (OCULUS Optikgerate GmbH, Wetzlar, Germany), and the GALILEI dual Scheimpflug analyzer (Ziemer Ophthalmology, Port, Switzerland). These and other Scheimpflug imaging systems are described in Dubbelman M, van der Heijde G L, Weeber H A, The thickness of the aging human lens obtained from corrected Scheimpflug images, Optom Vis Sci, 2001; 78:411-416, and Rosales P, Marcos S, Pentacam Scheimpflug quantitative imaging of the native lens and intraocular lens, J Refractive Surgery, 2009; 25: 422-428, the entire disclosures of which, including their references, are incorporated by reference herein.

[0025] Method 5 also includes step 30 which comprises estimating the refractive index ("RI") of the lens from any combination of biometry and patient data obtained in step 10 (e.g., cataract density, age, gender, ethnicity, etc.).

[0026] Method 5 also includes step 40 which comprises correcting the Scheimpflug images from step 20 for distortion due to imaging through the cornea, anterior chamber, and through the lens. When photographing the anterior and posterior surface of the native lens to measure the anterior and posterior radii of curvature, Scheimpflug imaging systems currently do not account for one or more types of distortion in the imaging process. One type of distortion that is corrected in step 40 is the optical distortion caused by refraction from different ocular surfaces. The radius of curvature of the anterior surface of the lens needs to be corrected for the distortion caused by both the anterior and posterior surfaces of the cornea, while the radius of curvature of the posterior surface of the lens needs to be corrected for the anterior and posterior surfaces of the cornea as well as the anterior surface of the

native lens and the refractive index of the native lens (equivalent or gradient refractive index).

[0027] The images are corrected to determine the radius of curvature of the anterior surface of the lens ("Ras"), radius of curvature of the posterior surface of the lens ("Rps") and the lens thickness ("LTs"). The subscript "s" is used herein to denote that these measurements are computed from Scheimpflug imaging.

[0028] Correcting the Scheimpflug images at step 40 can be accomplished by a raytracing method using estimated refractive indices. For example, methods of correcting for optical distortion are discussed in Dubbleman and Rosales, which are both incorporated by reference herein. For example, Rosales describes correcting the optical distortion by means of raytracing to reconstruct the anterior and posterior surfaces of the lens (see, e.g., FIG. 2 in Rosales). It is noted that the corrective algorithm used may be specific to the particular type of Scheimpflug photography system being used to image the lens (due to the optical path within the instrument), or the corrective algorithm may be able to be applied to more than one particular imaging system.

[0029] Method 5 also includes step 50 of performing a raytrace (different than the raytrace performed in step 40) to determine at step 55 an estimate for the radius of curvature of the posterior surface of the lens ("Rp") and the lens thickness ("LT") using an estimate for the RI of the lens (from step 30), the subject's refraction and biometry data, as well as Ras. FIG. 2 illustrates an exemplary model for performing a raytrace from step 50. FIG. 2 shows the radii that define the spectacles (glasses), the cornea, the crystalline lens, and the retina. The y-axis in the graph in FIG. 2 is the ray height from a paraxial raytrace and if the model parameters are adjusted correctly the ray height should be zero at the final point corresponding to the retina to ensure that the image is in-focus.

[0030] Method 5 also includes step 60 which comprises comparing the resultant lens thicknesses and radii of curvature of the posterior surface of the lens from the two models (i.e., comparing the results from step 45 and step 55). Step 60 further includes minimizing the difference between one or more of the measurements by repeating the modeling while iteratively changing the refractive index.

[0031] Once satisfactory agreement between the models is found after iteratively modifying the refractive index, step 70 (not shown in FIG. 1, but which, in method 5, follows step 60 and occurs before step 80) is performed, which fits the anterior radius, posterior radius, and lens thickness to a simple geometric model to compute the capsule bag diameter ("CBD"). FIG. 3 illustrates the method of computing the CBD. This is done by assuming the centers of the circles with radii Rp and Ra are aligned on-axis, as is shown in FIG. 3. The distance between the centers, AP, is calculated using equation 150, and the distance between the intersections of the circles (CBD) is calculated using equation 160.

[0032] Method 5 also includes optional step 80 of fitting end-caps 170 (see FIG. 4) to further refine the CBD measurement. The end caps are mathematically calculated by adjusting the lens anterior and posterior surfaces so that the first derivatives are zero at the lens equator and both surfaces meet at this location. It is a polynomial approximation with fraction exponents that become the dominant terms as the surfaces extend to the lens equator.

[0033] Once the capsule geometry is reconstructed through the described method using end caps, the capsular bag volume or any other measurement related to the capsule geometry can be determined.

[0034] Method 10 also includes optional step 90 which comprises correcting for estimated lens elasticity. If enough capsular tension ring or similar data has been collected (step 95), this correction may be applied to account for the elasticity of the capsule by comparing the data from step 95 with the prior CBD result.

[0035] Once the capsule size is estimated at step 100, an appropriately sized IOL can be selected, from a kit of IOLs, to be implanted based on the capsule size estimation. For example, if the volume of the capsule has been estimated during the method, the IOL to be implanted can be selected at least in part based on the estimated volume of the capsule. Alternatively, the capsule size estimation method may be used to manufacture or design a patient-specific IOL.

[0036] Exemplary IOLs which can be implanted in the capsule based on the capsule size estimation methods include those, without limitation, described in U.S. Pat. No. 7,122,053, U.S. Pat. No. 7,261,737, U.S. Pat. No. 7,247,168, U.S. Pat. No. 7,217,288, U.S. Pat. No. 6,935,743, U.S. Patent Application Publication 2007/0203578, U.S. Patent Application Publication 2007/0106377, U.S. Patent Application Publication 2005/0149183, U.S. Patent Application Publication 2007/0088433, U.S. Patent Application Publication, and U.S. Patent Application Publication 2008/0306588, all of which are incorporated by reference herein.

[0037] The current disclosure is also related to Provisional Patent Application No. 61/143,559, filed Jan. 9, 2009, entitled Lenses and Methods of Accounting for Different Lens Capsule Sizes and Changes to a Lens Capsule Post-Implantation, which is incorporated by reference herein.

[0038] One or more of the steps in the methods described herein can be performed by instructions on any computer-readable medium for use by or in connection with an instruction execution system, apparatus or device, such as a computer-based system, processor-containing system, or any system that can fetch the instructions from the instructions execution system, apparatus, or device and execute the instructions. A "computer-readable medium" as used herein can be any medium that can contain, store, communicate, propagate, or transport the program for use by or in connection with the instruction execution system, apparatus, or device. The computer readable medium can be, for example but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, device, or propagation medium. More specific examples (a non-exhaustive list) of the computer-readable medium would include the following: an electrical connection (electronic) having one or more wires, a portable computer diskette (magnetic), a random access memory (RAM) (magnetic), a read-only memory (ROM) (magnetic), an erasable programmable read-only memory (EPROM) (magnetic), an optical fiber (optical), portable optical disc such a CD, CD-R, CD-RW, DVD, DVD-R, or DVD-RW, or flash memory such as compact flash cards, secured digital cards, USB memory devices, memory stick, etc. Note that the computer-readable medium could even be paper or another suitable medium upon which the program is printed, as the program text can be electronically captured via optical scanning of the paper or other

medium, then compiled, interpreted or otherwise processed in a suitable manner if necessary, and then stored in a computer memory.

[0039] While preferred embodiments of the present disclosure have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the disclosure. It should be understood that various alternatives to the embodiments of the disclosure described herein may be employed in practicing the disclosure.

What is claimed is:

1. A method of estimating the size of an ocular lens capsule, comprising:

obtaining patient data of a subject;

imaging an anterior surface of an ocular lens and a posterior surface of the ocular lens;

estimating a refractive index of the ocular lens;

correcting the image of the anterior surface of the ocular lens for distortion to determine a radius of curvature of the anterior surface of the ocular lens;

correcting the image of the posterior surface of the ocular lens for distortion to determine a radius of curvature of the posterior surface of the ocular lens;

determining a thickness of the ocular lens using the corrected images of the anterior and posterior surfaces;

estimating an estimated radius of curvature of the posterior surface of the ocular lens and an estimated lens thickness using the estimated refractive index, the patient data, and the radius of curvature of the anterior surface of the ocular lens;

determining a difference between the determined radius of curvature of the posterior surface and the estimated radius of curvature of the posterior surface, and determining a difference between the thickness of the lens and the estimated lens thickness;

minimizing at least one of the differences by repeating the estimating step and the determining step with an adjusted estimated refractive index;

creating a geometric model of the capsule using the radii of curvature of the anterior surface, the posterior surface, and the lens thickness; and

selecting an intraocular lens for implantation based on the computed geometric model.

2. The method of claim 1 further comprising computing a capsular bag diameter from the geometric model.

3. The method of claim 1 wherein estimating the refractive index comprises estimating a refractive index of the ocular lens using the patient data.

4. The method of claim 1 wherein the method further comprises fitting end caps into the geometric model to compute the capsular bag diameter.

5. The method of claim 1 wherein the method further comprises using an estimated lens elasticity to compute the capsular bag diameter.

6. The method of claim 1 wherein imaging an anterior surface of an ocular lens and a posterior surface of the lens comprises imaging the anterior surface of an ocular lens and a posterior surface of the lens with a Scheimpflug imaging system.

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