US010709548B2

(12) **United States Patent**
Culbertson et al.

(10) **Patent No.: US 10,709,548 B2**
(45) **Date of Patent: Jul. 14, 2020**

(54) **METHOD AND APPARATUS FOR CREATING OCULAR SURGICAL AND RELAXING INCISIONS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/668,696**

(22) Filed: **Mar. 25, 2015**

(65) **Prior Publication Data**

US 2015/0196429 A1 Jul. 16, 2015

Related U.S. Application Data

(62) Division of application No. 13/569,103, filed on Aug. 7, 2012, now Pat. No. 9,233,024, which is a division

(Continued)

(51) **Int. Cl.**

A61F 2/16 (2006.01)
A61F 9/00 (2006.01)

(Continued)

(52) **U.S. Cl.**

CPC ***A61F 2/1613*** (2013.01); ***A61F 2/16*** (2013.01); ***A61F 2/1637*** (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC A61F 9/008; A61F 2/1613; A61F 2/16; A61F 2/1637; A61F 2/1648;

(Continued)

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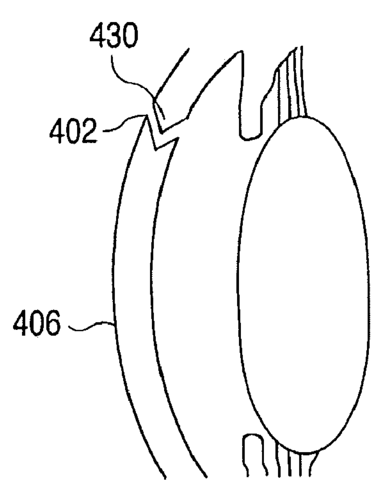
(57) **ABSTRACT**

A scanning system for treating target tissue in a patient's eye includes an ultrafast laser source configured to deliver a laser beam comprising a plurality of laser pulses; an Optical Coherence Tomography (OCT) device configured to generate signals which may be used to create an image of the cornea and limbus of the eye of the patient; a scanner configured to focus and direct the laser beam in a pattern within the cornea or limbus to create incisions therein; and a controller operatively coupled to the laser source and scanner configured to control the scanner to adjust the position of the laser beam based upon the signals from the OCT device to create a cataract incision in the cornea or limbus that provides access for lens removal instrumentation to a crystalline lens of the patient's eye, and a relaxation incision in the cornea or limbus.

17 Claims, 6 Drawing Sheets



Related U.S. Application Data

of application No. 12/048,186, filed on Mar. 13, 2008, now Pat. No. 9,233,023.

(60) Provisional application No. 60/906,944, filed on Mar. 13, 2007.

(51) **Int. Cl.**
A61F 9/007 (2006.01)
A61F 9/008 (2006.01)
A61F 9/009 (2006.01)

(52) **U.S. Cl.**
CPC ***A61F 2/1648*** (2013.01); ***A61F 2/1662*** (2013.01); *A61F 9/00* (2013.01); *A61F 9/008* (2013.01); *A61F 9/009* (2013.01); *A61F 9/00754* (2013.01); *A61F 9/00812* (2013.01); *A61F 9/00825* (2013.01); *A61F 2002/1683* (2013.01); *A61F 2002/16901* (2015.04); *A61F 2009/0087* (2013.01); *A61F 2009/0088* (2013.01); *A61F 2009/00859* (2013.01); *A61F 2009/00872* (2013.01); *A61F 2009/00887* (2013.01); *A61F 2009/00897* (2013.01); *A61F 2220/0016* (2013.01)

(58) **Field of Classification Search**
CPC A61F 9/00825; A61F 2002/1683; A61F 2009/00859; A61F 2009/0087; A61F 2009/00872; A61F 2009/0088; A61F 2009/00887; A61F 2009/00897; A61F 9/00; A61F 9/0825; A61F 2220/0016; A61F 9/00754; A61F 9/009; A61F 2/1662
See application file for complete search history.

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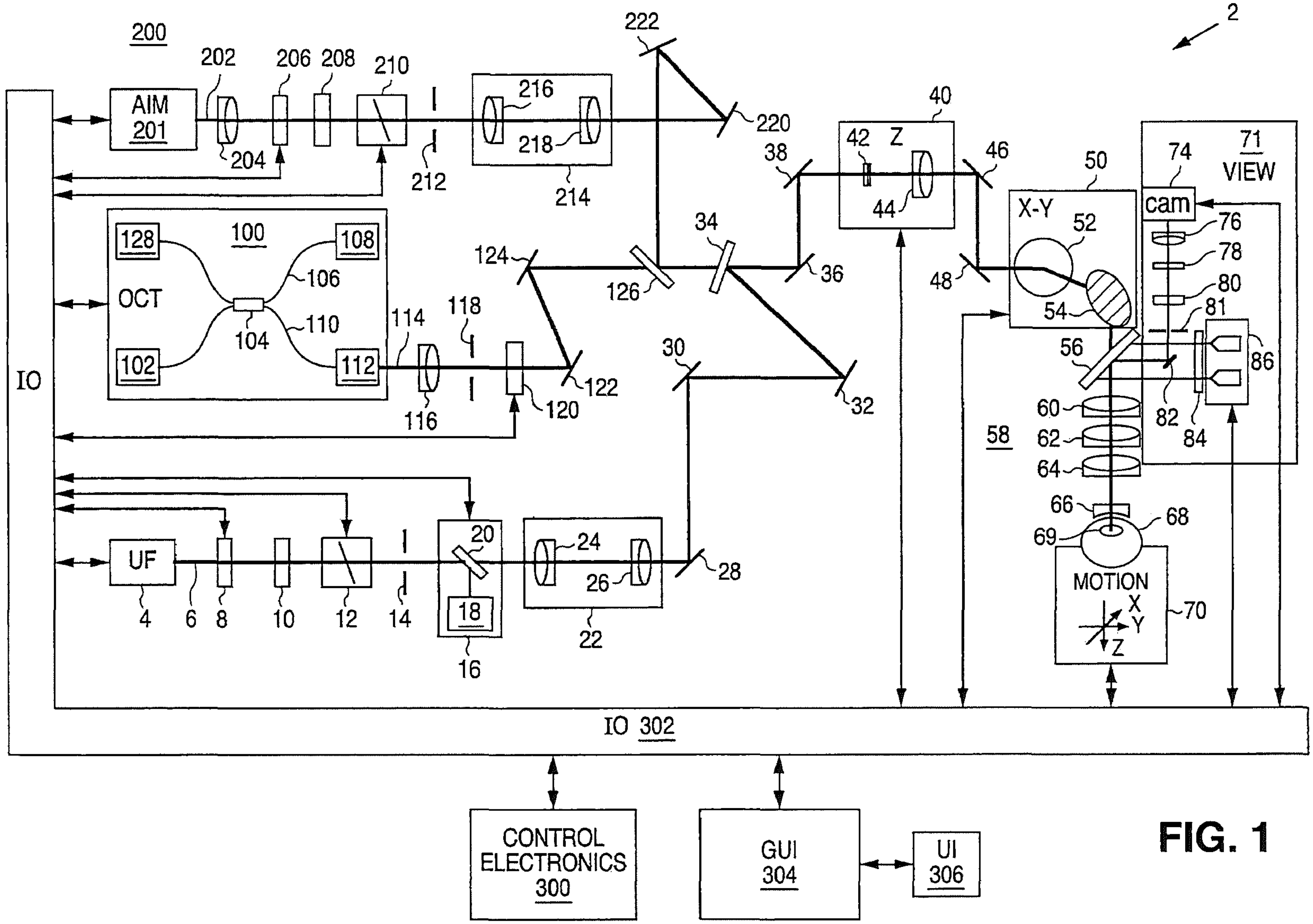
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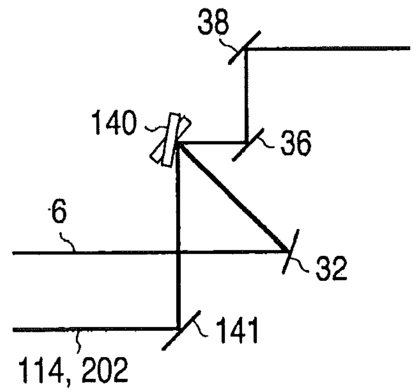
FIG. 1



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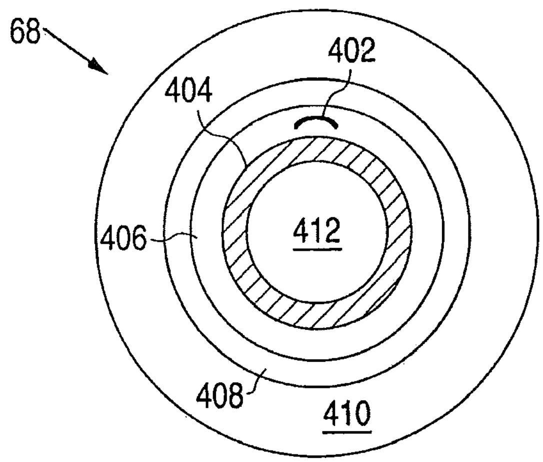
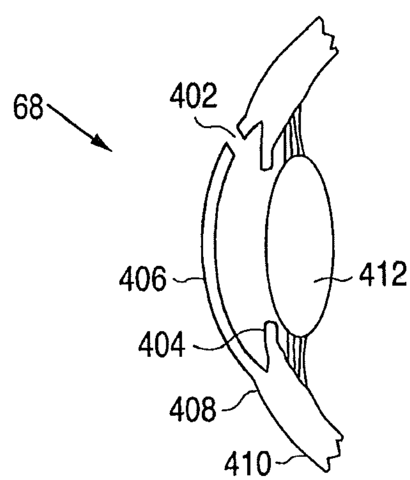


FIG. 5A



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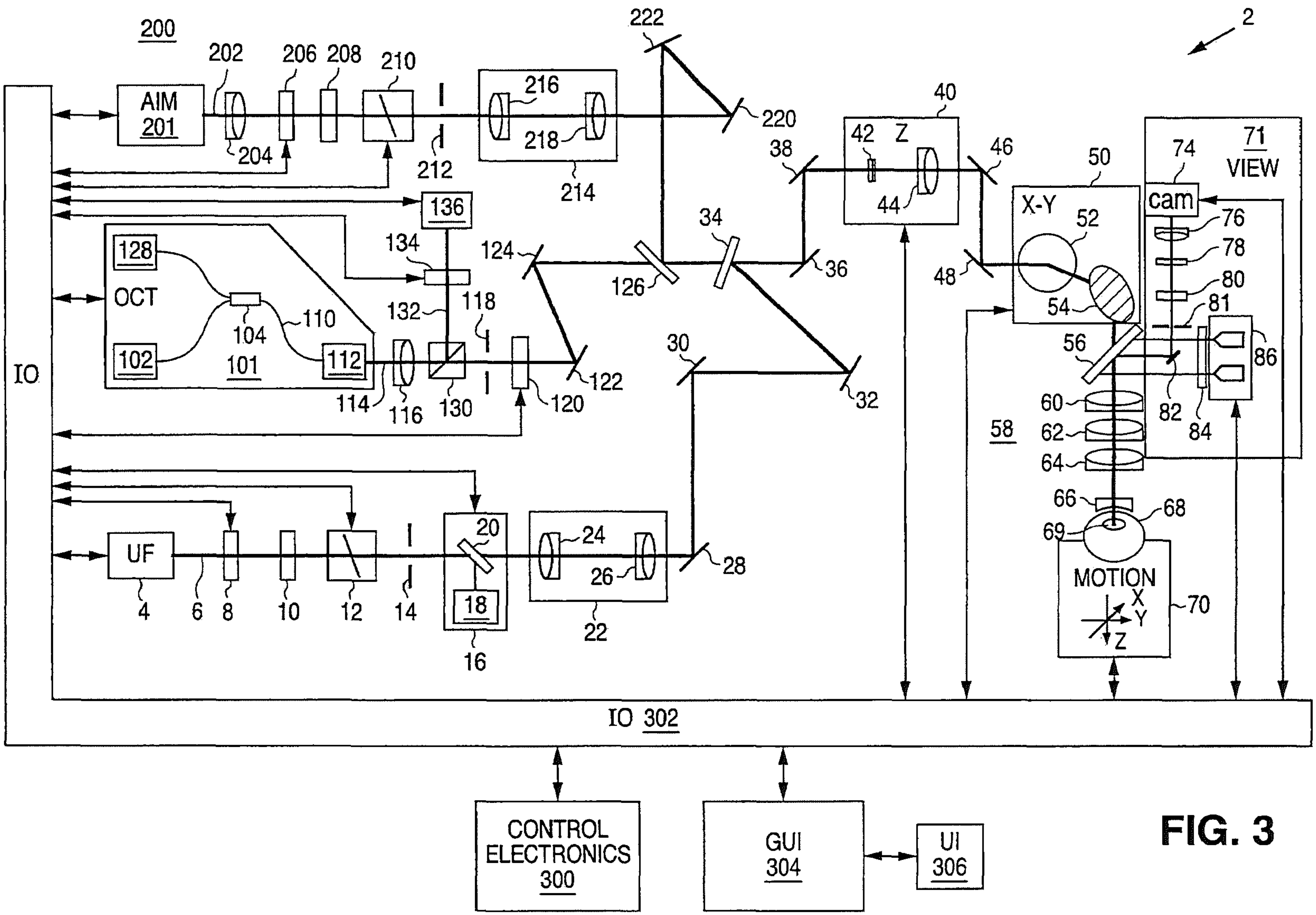
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FIG. 3

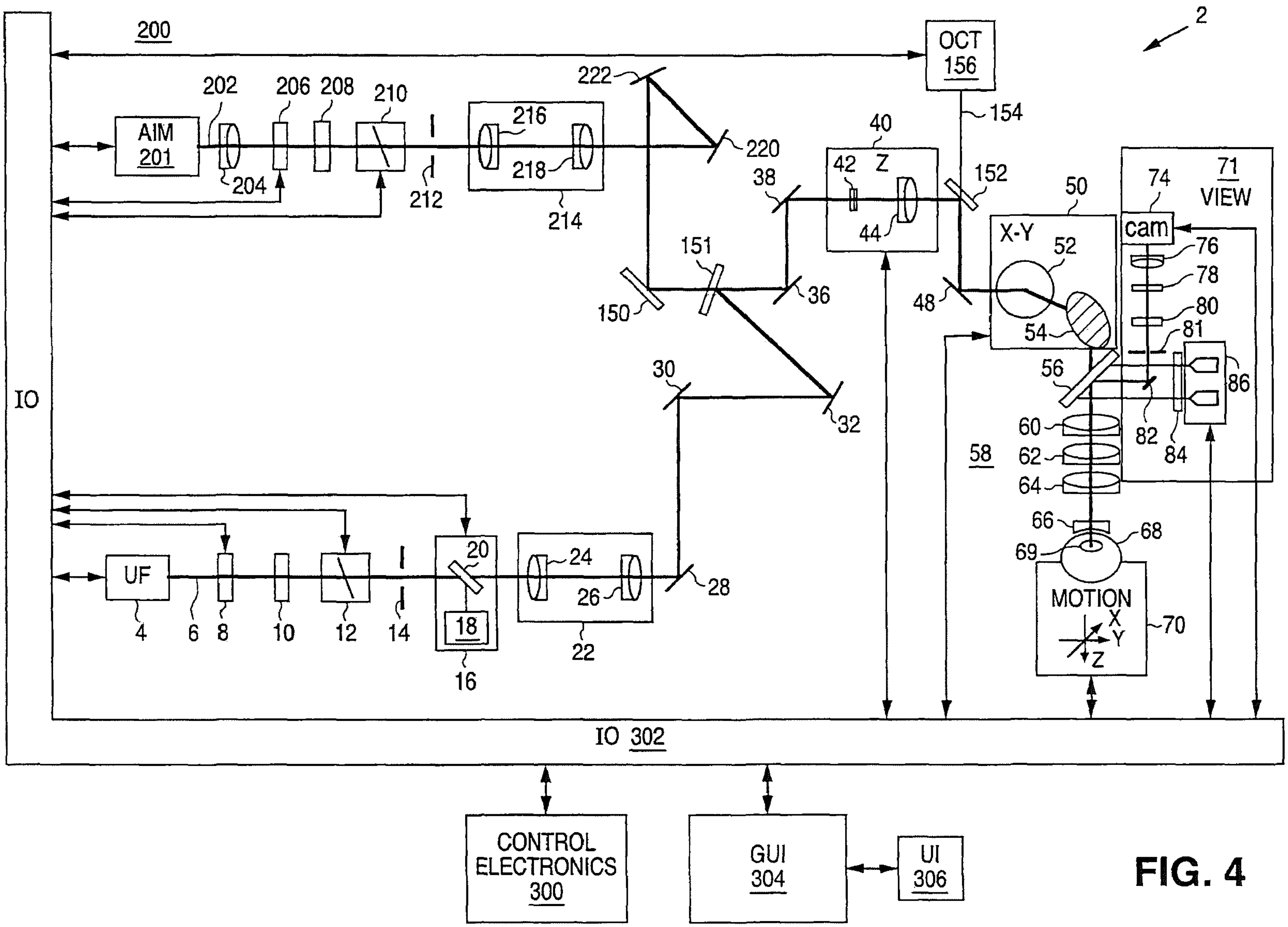
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FIG. 4

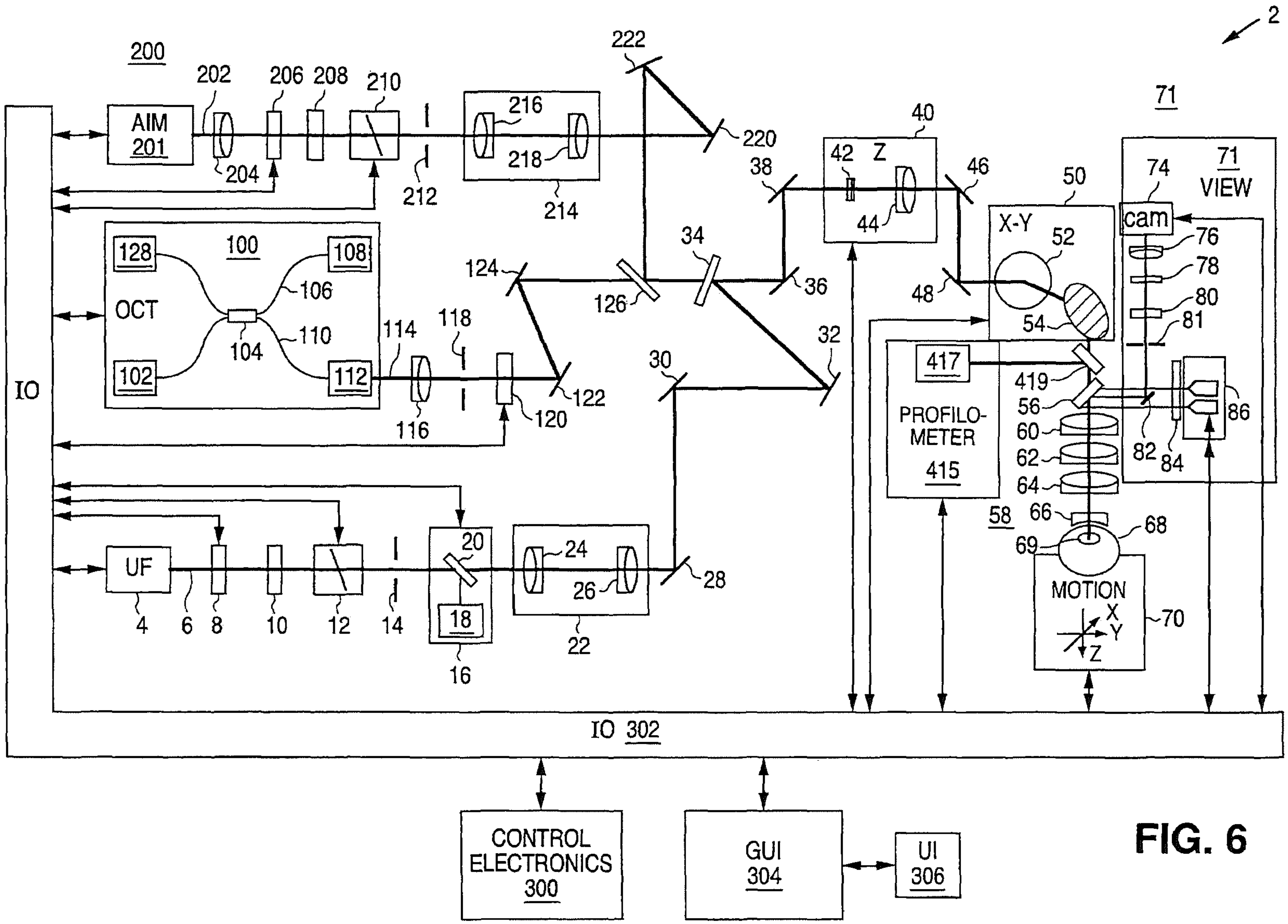
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FIG. 6

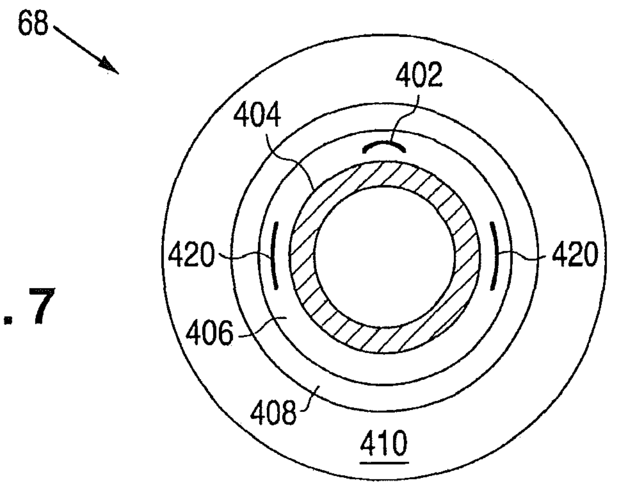

FIG. 7

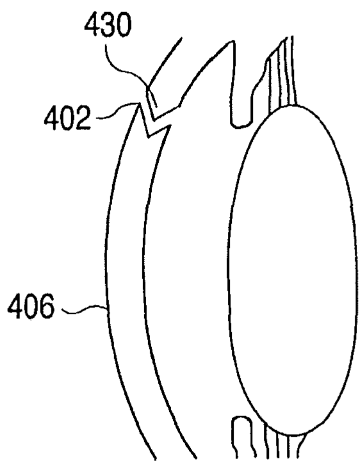

FIG. 8

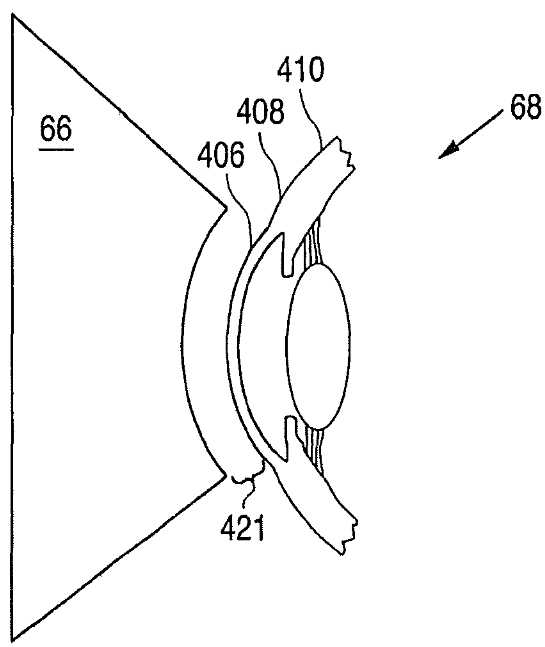

FIG. 9

METHOD AND APPARATUS FOR CREATING OCULAR SURGICAL AND RELAXING INCISIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 13/569,103, filed Aug. 7, 2012, which is a divisional of U.S. patent application Ser. No. 12/048,186, filed Mar. 13, 2008, which claims the benefit under 35 USC § 119 of U.S. Provisional Application No. 60/906,944, filed Mar. 13, 2007, now expired, which is incorporated by reference as if set forth fully herein.

FIELD OF THE INVENTION

The present invention relates to ophthalmic surgical procedures and systems.

BACKGROUND OF THE INVENTION

Cataract extraction is one of the most commonly performed surgical procedures in the world with estimated 2.5 million cases performed annually in the United States and 9.1 million cases worldwide in 2000. This was expected to increase to approximately 13.3 million estimated global cases in 2006. This market is composed of various segments including intraocular lenses for implantation, viscoelastic polymers to facilitate surgical maneuvers, disposable instrumentation including ultrasonic phacoemulsification tips, tubing, and various knives and forceps. Modem cataract surgery is typically performed using a technique termed phacoemulsification in which an ultrasonic tip with an associated water stream for cooling purposes is used to sculpt the relatively hard nucleus of the lens after performance of an opening in the anterior lens capsule termed anterior capsulotomy or more recently capsulorhexis. Following these steps as well as removal of residual softer lens cortex by aspiration methods without fragmentation, a synthetic foldable intraocular lens (IOLs) is inserted into the eye through a small incision.

Many cataract patients are astigmatic. Astigmatism can occur when the cornea has a different curvature one direction than the other. IOLs are not presently used to correct beyond 5 D of astigmatism, even though many patients have more severe aberrations. Correcting it further often involves making the corneal shape more spherical, or at least more radially symmetrical. There have been numerous approaches, including Corneaplasty, Astigmatic Keratotomy (AK), Corneal Relaxing Incisions (CRI), and Limbal Relaxing Incisions (LRI). All are done using manual, mechanical incisions. Presently, astigmatism cannot easily or predictably be corrected fully using standard techniques and approaches. About one third of those who have surgery to correct the irregularity find that their eyes regress to a considerable degree and only a small improvement is noted. Another third of the patients find that the astigmatism has been significantly reduced but not fully corrected. The remaining third have the most encouraging results with most or all of the desired correction achieved.

What is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of corneal shaping that may be associated with invasive cataract and other ophthalmic pathologies.

SUMMARY OF THE INVENTION

Rapid and precise opening formation in the cornea and/or limbus are possible using a scanning system that implements

patterned laser cutting. The patterned laser cutting improves accuracy and precision, while decreasing procedure time.

A scanning system for treating target tissue in a patient's eye includes a light source for generating a light beam, a scanner for deflecting the light beam to form first and second treatment patterns of the light beam under the control of a controller, and a delivery system for delivering the first treatment pattern to the target tissue to form a cataract incision therein that provides access to an eye chamber of the patient's eye. The delivery system is also for delivering the second treatment pattern to the target tissue to form a relaxation incision along or near limbus tissue or along corneal tissue anterior to the limbus tissue of the patient's eye to reduce astigmatism thereof.

A method of treating target tissue in a patient's eye includes generating a light beam, deflecting the light beam using a scanner to form first and second treatment patterns, delivering the first treatment pattern to the target tissue to form an incision that provides access to an eye chamber of the patient's eye, and delivering the second treatment pattern to the target tissue to form a relaxation incision along or near limbus tissue or along corneal tissue anterior to the limbus tissue of the patient's eye to reduce astigmatism thereof.

Other objects and features of the present invention will become apparent by a review of the specification, claims and appended figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic diagram of the optical beam scanning system.

FIG. **2** is an optical diagram showing an alternative beam combining scheme.

FIG. **3** is a schematic diagram of the optical beam scanning system with an alternative OCT configuration.

FIG. **4** is a schematic diagram of the optical beam scanning system with another alternative OCT combining scheme.

FIG. **5**A is a top view of a patient's eye showing a cataract incision.

FIG. **5**B is a side cross sectional view of a patient's eye showing the cataract incision.

FIG. **6** is a schematic diagram of the optical beam scanning system with a profilometer subsystem.

FIG. **7** is a top view of a patient's eye showing corneal relaxing incisions.

FIG. **8** is a side cross sectional view of a patient's eye showing an incision with a specialized geometry.

FIG. **9** is a side cross sectional view of a contact lens in proximity to a patient's eye.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The techniques and systems disclosed herein provide many advantages over the current standard of care. Specifically, rapid and precise openings in the cornea and/or limbus are formed using 3-dimensional patterned laser cutting. The accuracy and precision of the incisions are improved over traditional methods, while the duration of the procedure and the risk associated with creating incisions are both reduced. The present invention can utilize anatomical and optical characterization and feedback to perform astigmatic keratotomy such as limbal and corneal relaxing incisions in conjunction with the creation of surgical incision that provides the surgeon access to the anterior chamber of an eye. The surgical incision may be made completely, or partially, depending upon the clinical situation. A wavefront sensor, interferometer, surface profiler, or other such device may be used to yield prescriptions for correcting the astigmatism or other visual aberrations. Likewise, these same devices may be used to verify the surgical correction of the patterned scanning system, even adjusting it during the treatment procedure to produce the desired outcome. Furthermore, the present invention may be used in multiple sessions to coordinate the healing of the astigmatic correction, and drive the corrective treatment over the course of the wound healing process. The present invention also provides for the image guided alignment of the incision.

There are surgical approaches provided by the present invention that enable the formation of very small and geometrically precise opening(s) and incision(s) in precise locations in and around the cornea and limbus. The incisions enable greater precision or modifications to conventional ophthalmic procedures as well as enable new procedures. The incision is not limited only to circular shapes but may be any shape that is conducive to healing or follow on procedures. These incisions might be placed such that they are able to seal spontaneously; or with autologous or synthetic tissue glue, photochemical bonding agent, or other such method. Furthermore, the present invention provides for the automated generation of incision patterns for optimal effect.

Another procedure enabled by the techniques described herein provides for the controlled formation of an incision or pattern of incisions. Conventional techniques are confined to areas accessible from outside the eye using mechanical cutting instruments and thus can only create incisions from anterior to posterior segments of tissue. In contrast, the controllable, patterned laser techniques described herein may be used to create an incision in virtually any position and in virtually any shape. Matching incisions may be made in both the anterior and posterior sections. The present invention is uniquely suited to perform such matching incisions.

Furthermore, these incisions may be tailored to complement an asymmetric IOL that is being inserted as part of the procedure or has been previously inserted. The present invention enables the measurement of the IOL placement and subsequent automated calculation and generation of these complimentary corneal or limbus incisions. The controllable, patterned laser techniques described herein have available and/or utilize precise lens measurement and other dimensional information that allows the incision or opening formation while minimizing impact on surrounding tissue.

The present invention can be implemented by a system that projects or scans an optical beam into a patient's eye **68**, such as system **2** shown in FIG. **1** which includes an ultrafast (UF) light source **4** (e.g. a femtosecond laser). Using this system, a beam may be scanned in a patient's eye in three dimensions: X, Y, Z. In this embodiment, the UF wavelength can vary between 1010 nm to 1100 nm and the pulse width can vary from 100 fs to 10000 fs. The pulse repetition frequency can also vary from 10 kHz to 250 kHz. Safety limits with regard to unintended damage to non-targeted tissue bound the upper limit with regard to repetition rate and pulse energy; while threshold energy, time to complete the procedure and stability bound the lower limit for pulse energy and repetition rate. The peak power of the focused spot in the eye **68** and specifically within the crystalline lens **69** and anterior capsule of the eye is sufficient to produce optical breakdown and initiate a plasma-mediated ablation process. Near-infrared wavelengths are preferred because linear optical absorption and scattering in biological tissue is reduced across that spectral range. As an example, laser **4** may be a repetitively pulsed 1035 nm device that produces 500 fs pulses at a repetition rate of 100 kHz and an individual pulse energy in the ten microjoule range.

The laser **4** is controlled by control electronics **300**, via an input and output device **302**, to create optical beam **6**. Control electronics **300** may be a computer, microcontroller, etc. In this example, the entire system is controlled by the controller **300**, and data moved through input/output device IO **302**. A graphical user interface GUI **304** may be used to set system operating parameters, process user input (UI) **306** on the GUI **304**, and display gathered information such as images of ocular structures.

The generated UF light beam **6** proceeds towards the patient eye **68** passing through half-wave plate, **8**, and linear polarizer, **10**. The polarization state of the beam can be adjusted so that the desired amount of light passes through half-wave plate **8** and linear polarizer **10**, which together act as a variable attenuator for the UF beam **6**. Additionally, the orientation of linear polarizer **10** determines the incident polarization state incident upon beam combiner **34**, thereby optimizing beam combiner throughput.

The UF beam proceeds through a shutter **12**, aperture **14**, and a pickoff device **16**. The system controlled shutter **12** ensures on/off control of the laser for procedural and safety reasons. The aperture sets an outer useful diameter for the laser beam and the pickoff monitors the output of the useful beam. The pickoff device **16** includes of a partially reflecting mirror **20** and a detector **18**. Pulse energy, average power, or a combination may be measured using detector **18**. The information can be used for feedback to the half-wave plate **8** for attenuation and to verify whether the shutter **12** is open or closed. In addition, the shutter **12** may have position sensors to provide a redundant state detection.

The beam passes through a beam conditioning stage **22**, in which beam parameters such as beam diameter, divergence, circularity, and astigmatism can be modified. In this illustrative example, the beam conditioning stage **22** includes a 2 element beam expanding telescope comprised of spherical optics **24** and **26** in order to achieve the intended beam size and collimation. Although not illustrated here, an anamorphic or other optical system can be used to achieve the desired beam parameters. The factors used to determine these beam parameters include the output beam parameters of the laser, the overall magnification of the system, and the desired numerical aperture (NA) at the treatment location. In addition, the optical system **22** can be used to image aperture **14** to a desired location (e.g. the center location between the 2-axis scanning device **50** described below). In this way, the amount of light that makes it through the aperture **14** is assured to make it through the scanning system. Pickoff device **16** is then a reliable measure of the usable light.

After exiting conditioning stage **22**, beam **6** reflects off of fold mirrors **28**, **30**, & **32**. These mirrors can be adjustable for alignment purposes. The beam **6** is then incident upon beam combiner **34**. Beam combiner **34** reflects the UF beam **6** (and transmits both the OCT **114** and aim **202** beams described below). For efficient beam combiner operation, the angle of incidence is preferably kept below 45 degrees and the polarization where possible of the beams is fixed. For the UF beam **6**, the orientation of linear polarizer **10** provides fixed polarization.

Following the beam combiner **34**, the beam **6** continues onto the z-adjust or Z scan device **40**. In this illustrative example the z-adjust includes a Galilean telescope with two lens groups **42** and **44** (each lens group includes one or more lenses). Lens group **42** moves along the z-axis about the collimation position of the telescope. In this way, the focus position of the spot in the patient's eye **68** moves along the z-axis as indicated. In general there is a fixed linear relationship between the motion of lens **42** and the motion of the focus. In this case, the z-adjust telescope has an approximate 2.times.beam expansion ratio and a 1:1 relationship of the movement of lens **42** to the movement of the focus. Alternatively, lens group **44** could be moved along the z-axis to actuate the z-adjust, and scan. The z-adjust is the z-scan device for treatment in the eye **68**. It can be controlled automatically and dynamically by the system and selected to be independent or to interplay with the X-Y scan device described next. Mirrors **36** and **38** can be used for aligning the optical axis with the axis of z-adjust device **40**.

After passing through the z-adjust device **40**, the beam **6** is directed to the x-y scan device by mirrors **46** & **48**. Mirrors **46** & **48** can be adjustable for alignment purposes. X-Y scanning is achieved by the scanning device **50** preferably using two mirrors **52** & **54** under the control of control electronics **300**, which rotate in orthogonal directions using motors, galvanometers, or any other well known optic moving device. Mirrors **52** & **54** are located near the telecentric position of the objective lens **58** and contact lens **66** combination described below. Tilting these mirrors **52/54** causes them to deflect beam **6**, causing lateral displacements in the plane of UF focus located in the patient's eye **68**. Objective lens **58** may be a complex multi-element lens element, as shown, and represented by lenses **60**, **62**, and **64**. The complexity of the lens **58** will be dictated by the scan field size, the focused spot size, the available working distance on both the proximal and distal sides of objective **58**, as well as the amount of aberration control. An f-theta lens **58** of focal length 60 mm generating a spot size of 10 .mu.m, over a field of 10 mm, with an input beam size of 15 mm diameter is an example. Alternatively, X-Y scanning by scanner **50** may be achieved by using one or more moveable optical elements (e.g. lenses, gratings) which also may be controlled by control electronics **300**, via input and output device **302**.

The aiming and treatment scan patterns can be automatically generated by the scanner **50** under the control of controller **300**. Such patterns may be comprised of a single spot of light, multiple spots of light, a continuous pattern of light, multiple continuous patterns of light, and/or any combination of these. In addition, the aiming pattern (using aim beam **202** described below) need not be identical to the treatment pattern (using light beam **6**), but preferably at least defines its boundaries in order to assure that the treatment light is delivered only within the desired target area for patient safety. This may be done, for example, by having the aiming pattern provide an outline of the intended treatment pattern. This way the spatial extent of the treatment pattern may be made known to the user, if not the exact locations of the individual spots themselves, and the scanning thus optimized for speed, efficiency and accuracy. The aiming pattern may also be made to be perceived as blinking in order to further enhance its visibility to the user.

An optional contact lens **66**, which can be any suitable ophthalmic lens, can be used to help further focus the optical beam **6** into the patient's eye **68** while helping to stabilize eye position. The positioning and character of optical beam **6** and/or the scan pattern the beam **6** forms on the eye **68** may be further controlled by use of an input device such as a joystick, or any other appropriate user input device (e.g. GUI **304**) to position the patient and/or the optical system.

The UF laser **4** and controller **300** can be set to target the surfaces of the targeted structures in the eye **68** and ensure that the beam **6** will be focused where appropriate and not unintentionally damage non-targeted tissue. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT), Purkinje imaging, Scheimpflug imaging, or ultrasound may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), Purkinje imaging, Scheimpflug imaging, ultrasound, or other known ophthalmic or medical imaging modalities and/or combinations thereof. In the embodiment of FIG. **1**, an OCT device **100** is described, although other modalities are within the scope of the present invention. An OCT scan of the eye will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information is then be loaded into the control electronics **300**, and used to program and control the subsequent laser-assisted surgical procedure. The information may also be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes used for cutting the lens capsule and segmentation of the lens cortex and nucleus, and the thickness of the lens capsule among others.

The OCT device **100** in FIG. **1** includes a broadband or a swept light source **102** that is split by a fiber coupler **104** into a reference arm **106** and a sample arm **110**. The reference arm **106** includes a module **108** containing a reference reflection along with suitable dispersion and path length compensation. The sample arm **110** of the OCT device **100** has an output connector **112** that serves as an interface to the rest of the UF laser system. The return signals from both the reference and sample arms **106**, **110** are then directed by coupler **104** to a detection device **128**, which employs either time domain, frequency or single point detection techniques. In FIG. **1**, a frequency domain technique is used with an OCT wavelength of 920 nm and bandwidth of 100 nm.

Exiting connector **112**, the OCT beam **114** is collimated using lens **116**. The size of the collimated beam **114** is determined by the focal length of lens **116**. The size of the beam **114** is dictated by the desired NA at the focus in the eye and the magnification of the beam train leading to the eye **68**. Generally, OCT beam **114** does not require as high an NA as the UF beam **6** in the focal plane and therefore the OCT beam **114** is smaller in diameter than the UF beam **6** at the beam combiner **34** location. Following collimating lens **116** is aperture **118** which further modifies the resultant NA of the OCT beam **114** at the eye. The diameter of aperture **118** is chosen to optimize OCT light incident on the target tissue and the strength of the return signal. Polarization control element **120**, which may be active or dynamic, is used to compensate for polarization state changes which may be induced by individual differences in corneal birefringence, for example. Mirrors **122** & **124** are then used to direct the OCT beam **114** towards beam combiners **126** & **34**. Mirrors **122** & **124** may be adjustable for alignment purposes and in particular for overlaying of OCT beam **114** to UF beam **6** subsequent to beam combiner **34**. Similarly, beam combiner **126** is used to combine the OCT beam **114** with the aim beam **202** described below.

Once combined with the UF beam **6** subsequent to beam combiner **34**, OCT beam **114** follows the same path as UF beam **6** through the rest of the system. In this way, OCT beam **114** is indicative of the location of UF beam **6**. OCT beam **114** passes through the z-scan **40** and x-y scan **50** devices then the objective lens **58**, contact lens **66** and on into the eye **68**. Reflections and scatter off of structures within the eye provide return beams that retrace back through the optical system, into connector **112**, through coupler **104**, and to OCT detector **128**. These return back reflections provide the OCT signals that are in turn interpreted by the system as to the location in X, Y Z of UF beam **6** focal location.

OCT device **100** works on the principle of measuring differences in optical path length between its reference and sample arms. Therefore, passing the OCT through z-adjust **40** does not extend the z-range of OCT system **100** because the optical path length does not change as a function of movement of **42**. OCT system **100** has an inherent z-range that is related to the detection scheme, and in the case of frequency domain detection it is specifically related to the spectrometer and the location of the reference arm **106**. In the case of OCT system **100** used in FIG. **1**, the z-range is approximately 1-2 mm in an aqueous environment. Extending this range to at least 4 mm involves the adjustment of the path length of the reference arm within OCT system **100**. Passing the OCT beam **114** in the sample arm through the z-scan of z-adjust **40** allows for optimization of the OCT signal strength. This is accomplished by focusing the OCT beam **114** onto the targeted structure while accommodating the extended optical path length by commensurately increasing the path within the reference arm **106** of OCT system **100**.

Because of the fundamental differences in the OCT measurement with respect to the UF focus device due to influences such as immersion index, refraction, and aberration, both chromatic and monochromatic, care must be taken in analyzing the OCT signal with respect to the UF beam focal location. A calibration or registration procedure as a function of X, Y Z should be conducted in order to match the OCT signal information to the UF focus location and also to the relate to absolute dimensional quantities.

Observation of an aim beam may also be used to assist the user to directing the UF laser focus. Additionally, an aim beam visible to the unaided eye in lieu of the infrared OCT and UF beams can be helpful with alignment provided the aim beam accurately represents the infrared beam parameters. An aim subsystem **200** is employed in the configuration shown in FIG. **1**. The aim beam **202** is generated by a an aim beam light source **201**, such as a helium-neon laser operating at a wavelength of 633 nm. Alternatively a laser diode in the 630-650 nm range could be used. The advantage of using the helium neon 633 nm beam is its long coherence length, which would enable the use of the aim path as a laser unequal path interferometer (LUPI) to measure the optical quality of the beam train, for example.

Once the aim beam light source generates aim beam **202**, the aim beam **202** is collimated using lens **204**. The size of the collimated beam is determined by the focal length of lens **204**. The size of the aim beam **202** is dictated by the desired NA at the focus in the eye and the magnification of the beam train leading to the eye **68**. Generally, aim beam **202** should have close to the same NA as UF beam **6** in the focal plane and therefore aim beam **202** is of similar diameter to the UF beam at the beam combiner **34** location. Because the aim beam is meant to stand-in for the UF beam **6** during system alignment to the target tissue of the eye, much of the aim path mimics the UF path as described previously. The aim beam **202** proceeds through a half-wave plate **206** and linear polarizer **208**. The polarization state of the aim beam **202** can be adjusted so that the desired amount of light passes through polarizer **208**. Elements **206** & **208** therefore act as a variable attenuator for the aim beam **202**. Additionally, the orientation of polarizer **208** determines the incident polarization state incident upon beam combiners **126** and **34**, thereby fixing the polarization state and allowing for optimization of the beam combiners' throughput. Of course, if a semiconductor laser is used as aim beam light source **200**, the drive current can be varied to adjust the optical power.

The aim beam **202** proceeds through a shutter **210** and aperture **212**. The system controlled shutter **210** provides on/off control of the aim beam **202**. The aperture **212** sets an outer useful diameter for the aim beam **202** and can be adjusted appropriately. A calibration procedure measuring the output of the aim beam **202** at the eye can be used to set the attenuation of aim beam **202** via control of polarizer **206**.

The aim beam **202** next passes through a beam conditioning device **214**. Beam parameters such as beam diameter, divergence, circularity, and astigmatism can be modified using one or more well known beaming conditioning optical elements. In the case of an aim beam **202** emerging from an optical fiber, the beam conditioning device **214** can simply include a beam expanding telescope with two optical elements **216** and **218** in order to achieve the intended beam size and collimation. The final factors used to determine the aim beam parameters such as degree of collimation are dictated by what is necessary to match the UF beam **6** and aim beam **202** at the location of the eye **68**. Chromatic differences can be taken into account by appropriate adjustments of beam conditioning device **214**. In addition, the optical system **214** is used to image aperture **212** to a desired location such as a conjugate location of aperture **14**.

The aim beam **202** next reflects off of fold mirrors **222** & **220**, which are preferably adjustable for alignment registration to UF beam **6** subsequent to beam combiner **34**. The aim beam **202** is then incident upon beam combiner **126** where the aim beam **202** is combined with OCT beam **114**. Beam combiner **126** reflects the aim beam **202** and transmits the OCT beam **114**, which allows for efficient operation of the beam combining functions at both wavelength ranges. Alternatively, the transmit and reflect functions of beam combiner **126** can be reversed and the configuration inverted. Subsequent to beam combiner **126**, aim beam **202** along with OCT beam **114** is combined with UF beam **6** by beam combiner **34**.

A device for imaging the target tissue on or within the eye **68** is shown schematically in FIG. **1** as imaging system **71**. Imaging system includes a camera **74** and an illumination light source **86** for creating an image of the target tissue. The imaging system **71** gathers images which may be used by the system controller **300** for providing pattern centering about or within a predefined structure. The illumination light source **86** for the viewing is generally broadband and incoherent. For example, light source **86** can include multiple LEDs as shown. The wavelength of the viewing light source **86** is preferably in the range of 700 nm to 750 nm, but can be anything which is accommodated by the beam combiner **56**, which combines the viewing light with the beam path for UF beam **6** and aim beam **202** (beam combiner **56** reflects the viewing wavelengths while transmitting the OCT and UF wavelengths). The beam combiner **56** may partially transmit the aim wavelength so that the aim beam **202** can be visible to the viewing camera **74**. Optional polarization element **84** in front of light source **86** can be a linear polarizer, a quarter wave plate, a half-wave plate or any combination, and is used to optimize signal. A false color image as generated by the near infrared wavelength is acceptable.

The illumination light from light source **86** is directed down towards the eye using the same objective lens **58** and contact lens **66** as the UF and aim beam **6**, **202**. The light reflected and scattered off of various structures in the eye **68** are collected by the same lenses **58** & **66** and directed back towards beam combiner **56**. There, the return light is directed back into the viewing path via beam combiner and mirror **82**, and on to camera **74**. Camera **74** can be, for example but not limited to, any silicon based detector array of the appropriately sized format. Video lens **76** forms an image onto the camera's detector array while optical elements **80** & **78** provide polarization control and wavelength filtering respectively. Aperture or iris **81** provides control of imaging NA and therefore depth of focus and depth of field. A small aperture provides the advantage of large depth of field which aids in the patient docking procedure. Alternatively, the illumination and camera paths can be switched. Furthermore, aim light source **200** can be made to emit in the infrared which would not directly visible, but could be captured and displayed using imaging system **71**.

Coarse adjust registration is usually needed so that when the contact lens **66** comes into contact with the cornea, the targeted structures are in the capture range of the X, Y scan of the system. Therefore a docking procedure is preferred, which preferably takes in account patient motion as the system approaches the contact condition (i.e. contact between the patient's eye **68** and the contact lens **66**. The viewing system **71** is configured so that the depth of focus is large enough such that the patient's eye **68** and other salient features may be seen before the contact lens **66** makes contact with eye **68**.

Preferably, a motion control system **70** is integrated into the overall control system **2**, and may move the patient, the system **2** or elements thereof, or both, to achieve accurate and reliable contact between contact lens **66** and eye **68**. Furthermore, a vacuum suction subsystem and flange may be incorporated into system **2**, and used to stabilize eye **68**. The alignment of eye **68** to system **2** via contact lens **66** may be accomplished while monitoring the output of imaging system **71**, and performed manually or automatically by analyzing the images produced by imaging system **71** electronically by means of control electronics **300** via IO **302**. Force and/or pressure sensor feedback may also be used to discern contact, as well as to initiate the vacuum subsystem.

An alternative beam combining configuration is shown in the alternate embodiment of FIG. **2**. For example, the passive beam combiner **34** in FIG. **1** can be replaced with an active combiner **140** in FIG. **2**. The active beam combiner **34** can be a moving or dynamically controlled element such as a galvanometric scanning mirror, as shown. Active combiner **140** changes it angular orientation in order to direct either the UF beam **6** or the combined aim and OCT beams **202**,**114** towards the scanner **50** and eventually eye **68** one at a time. The advantage of the active combining technique is that it avoids the difficulty of combining beams with similar wavelength ranges or polarization states using a passive beam combiner. This ability is traded off against the ability to have simultaneous beams in time and potentially less accuracy and precision due to positional tolerances of active beam combiner **140**.

Another alternate embodiment is shown in FIG. **3** which is similar to that of FIG. **1** but utilizes an alternate approach to OCT **100**. In FIG. **3**, OCT **101** is the same as OCT **100** in FIG. **1**, except that the reference arm **106** has been replaced by reference arm **132**. This free-space OCT reference arm **132** is realized by including beam splitter **130** after lens **116**. The reference beam **132** then proceeds through polarization controlling element **134** and then onto the reference return module **136**. The reference return module **136** contains the appropriate dispersion and path length adjusting and compensating elements and generates an appropriate reference signal for interference with the sample signal. The sample arm of OCT **101** now originates subsequent to beam splitter **130**. The potential advantages of this free space configuration include separate polarization control and maintenance of the reference and sample arms. The fiber based beam splitter **104** of OCT **101** can also be replaced by a fiber based circulator. Alternately, both OCT detector **128** and beam splitter **130** might be moved together as opposed to reference arm **136**.

FIG. **4** shows another alternative embodiment for combining OCT beam **114** and UF beam **6**. In FIG. **4**, OCT **156** (which can include either of the configurations of OCT **100** or **101**) is configured such that its OCT beam **154** is coupled to UF beam **6** after the z-scan **40** using beam combiner **152**. In this way, OCT beam **154** avoids using the z-adjust. This allows the OCT **156** to possibly be folded into the beam more easily and shortening the path length for more stable operation. This OCT configuration is at the expense of an optimized signal return strength as discussed with respect to FIG. **1**. There are many possibilities for the configuration of the OCT interferometer, including time and frequency domain approaches, single and dual beam methods, swept source, etc, as described in U.S. Pat. Nos. 5,748,898; 5,748,352; 5,459,570; 6,111,645; and 6,053,613 (which are incorporated herein by reference.)

The present invention provides for creating the incision to allow access for the lens removal instrumentation, typically referred to as the "cataract incision." This is shown as cataract incision **402** on the patient's eye **68** illustrated in FIGS. **5**A & **5**B. In these figures cataract incision **402** is made to eye **68** to provide access to crystalline lens **412** through cornea **406** while pupil **404** is dilated. The incision **402** is shown in cornea **406**, but could be alternately placed in limbus **408** or sclera **410**. The incision may be made with adjustable arcuate dimensions (both radius and extent), radial orientation and depth. A complete cut may not be desirable in all situations, such as in an unsterile field where opening the eye to the environment poses further risks of endophthalmitis, for example. In this case, the present invention may provide a cataract incision that only partially penetrates cornea **406**, limbus **408** and/or sclera **410**. The resident imaging apparati in system **2** may also provide input for planning the incision. For example, imaging system **71** and/or OCT **100** could identify the limbal boundary, and guide the incision to follow it along at a predetermined depth. Furthermore, surgeons often have difficulty in starting the incision at the correct location relative to limbus **410** when employing cold steel techniques, as well as keeping the knife straight to avoid incisions that ultimately penetrate both cornea **406** and sclera **410**. Such angled incisions prove more likely to have torn edges and significantly higher risks of endophthalmitis.

The present invention may make use of the integrated OCT system **100** to discern limbus **408** and sclera **410** relative to cornea **406** by virtue of the large optical scattering differences between them. These can be directly imaged using OCT device **100**, and the location of the transition (limbus **408**) from clear (cornea **406**) to scattering (sclera **410**) can be determined and used by CPU **300** of system **2** to guide the placement of the laser-created incisions. The scanner position values corresponding to this transition define the location of limbus **408**. Thus, once registered to each other, OCT **100** can guide the position of beam **6** relative to limbus **408**. This same imaging approach may be used to discern the thickness of the tissue, as well. Thus, the depth of the incisions and their disposition within the tissue may be precisely defined. With that in mind, the choice of wavelength for OCT device **100** preferably accounts for the requirement of scleral measurement. Wavelengths in the range of 800-1400 nm are especially suited for this, as they are less scattered in tissue (and penetrate to depths of .about.1 mm) while not suffering from linear optical absorption by water or other tissue constituents that would otherwise diminish their performance.

Standard cataract incisions typically require .about.30.degree. of limbal angle as seen from directly above the eye. Such incisions have been shown to induce from 0-1.0 D of astigmatism, on average. Thus, achieving postoperative emmetropia can be made more difficult. To address astigmatism, the present invention may also produce Astigmatic Kerototomy (AK) incisions. Such incisions are routinely used to correct astigmatism by relaxing an asymmetrically shaped cornea along its steep axis. Similar to the cataract incision, such relaxing incisions (RIs) must be accurately placed along or nearby the limbus and are known as Limbal Relaxing Incisions (LRIs). Relaxing incisions, however, are only partially penetrating incisions. They should leave at least 200 .mu.m of tissue thickness in order to maintain its ongoing structural integrity. Similarly, Corneal Relaxing Incisions (CRIs) are incisions that are placed anterior to the limbus in the clear corneal tissue to serve the same clinical purpose of astigmatic correction. In addition to the specific clinical details, the circumferential orientation and angular extent are also influenced by the cataract incision. Thus, with the present invention, the RIs may be planned and executed in conjunction with the cataract incision to achieve a better visual correction than otherwise possible. To optimize the entire treatment, the cataract incision should not be placed at or near the steep axis of the cornea. If it is, only one RI is traditionally recommended. There are a variety of nomograms based upon empirical observations that are currently used by clinicians to prescribe the placement and extent of RIs. These include, but are not limited to, the Donnenfeld, Gills, Nichamin, and Koch nomograms.

FIG. **6** illustrates system **2** as shown in FIG. **1**, but with a sub-system to characterize the astigmatism of the patient's cornea. Specifically, a profilometer **415** distal to X-Y scanner **50** is included to allow for a continuous unobstructed view of the cornea of patient's eye **68**. Profilometer **415** and its sensor **417** are added to system **2** via beam combiner **419** and are connected as shown in FIG. **6** to the system controller **300** through input/output bus **302**. As compared to the configuration described in FIG. **1**, in this embodiment, contact lens **66** or its disposition relative to cornea **406** of eye **68** may have to be modified, or compensated for, to suit the profilometer's mode of operation. This is because profilometer **415** requires the cornea to be in its natural state, not forced into contact with a surface and possibly conforming to its shape, to accurately measure cornea **406** and provide data to system **2** for calculation and registration via input/output bus **302** and control electronics **300**. Alternately, contact lens **66** may be removed from contact with the eye, and the diagnostic and therapeutic portions of system **2** made to traverse gap **421** to eye **68** as shown in FIG. **9**. The change in relationship between eye **68** and system **2** made by removing contact lens **66** must then be accounted for in ranging and registration of beams **6**, **114**, and **202**. The use of OCT **100** to discern the location and shape of cornea **406** is especially useful in this regard, as the reflection from cornea **406** will provide a very strong signal making registration straight forward.

In this embodiment, profilometer **415** may be used to prescribe an astigmatic keratotomy to correct the shape of a patient's cornea to diminish its astigmatism. The profilometer **415** may be a placido system, triangulation system, laser displacement sensor, interferometer, or other such device, which measures the corneal topography also known as the surface profile or the surface sag (i.e. sagitta) of the cornea as a function of the transverse dimension to some defined axis. This axis is typically the visual axis of the eye but can also be the optical axis of the cornea. Alternately, profilometer **415** may be replaced by a wavefront sensor to more fully optically characterize the patient's eye. A wavefront sensing system measures the aberration of the eye's optical system. A common technique for accomplishing this task is a Shack-Hartmann wavefront sensor, which measures the shape of the wavefronts of light (surfaces of constant phase) that exit the eye's pupil. If the eye were a perfect optical system, these wavefronts would be perfectly flat. Since the eye is not perfect, the wavefronts are not flat and have irregular curved shapes. A Shack-Hartmann sensor divides up the incoming beam and its overall wavefront into sub-beams, dividing up the wavefront into separate facets, each focused by a microlens onto a subarray of detection pixels. Depending upon where the focal spot from each facet strikes its subarray of pixels, it is then possible to determine the local wavefront inclination (or tilt). Subsequent analysis of all facets together leads to determination of the overall wavefront form. These deviations from the perfectly overall flat wavefront are indicative of the localized corrections that can be made in the corneal surface. The measurements of the wavefront sensor may be used by controller **300** to automatically prescribe an astigmatic keratotomy via predictive algorithms resident in the system, as mentioned above.

FIG. **7** shows a possible configuration of such an astigmatic keratotomy. In this example, eye **68** is shown and a set of relaxing incisions RI **420** are made at locations within the area of the cornea **406**. Likewise, as is known in the art, such relaxing incisions may be made in the limbus **408**, or sclera **410**. Astigmatism is present when the cornea is not spherical; that is, it is steeper in one meridian than other (orthogonal) meridian. Determining the nature of the corneal shape is important, whether the astigmatism is "with-the-rule," "against-the-rule," or oblique. In "with-the-rule" astigmatism, the vertical meridian is steeper than the horizontal meridian; in "against-the-rule" astigmatism, the horizontal meridian is steeper than the vertical meridian. Limbal relaxing incisions (LRIs) are a modification of astigmatic keratotomy (AK), a procedure to treat astigmatism. LRIs are placed on the far peripheral aspect of the cornea (the limbus), resulting in a more rounded cornea. Astigmatism is reduced, and uncorrected vision is improved. LRIs can correct astigmatism up to 8 diopters (D); however, the use of LRIs is presently routinely reserved for corrections of 0.5-4 D of astigmatism. Although LRIs are a weaker corrective procedure compared to corneal relaxing incisions (CRIs), LRIs produce less postoperative glare and less patient discomfort. In addition, these incisions heal faster. Unlike CRIs, making the incision at the limbus preserves the perfect optical qualities of the cornea. LRIs are also a more forgiving procedure, and surgeons often get excellent results, even with early cases.

The desired length, number, and depth of relaxing incisions **420** can be determined using nomograms. A starting point nomogram can titrate surgery by length and number of

LRIs. However, the length and placement can vary based on topography and other factors. The goal is to reduce cylindrical optical power and to absolutely avoid overcorrecting with-the-rule astigmatism, because against-the-rule astigmatism should be minimized. Relaxing incisions formed in the sclera, limbus, or cornea are generally used for cases of with-the-rule astigmatism and low against-the-rule astigmatism. When using the relaxing incision in conjunction with against-the-rule astigmatism, the LRI can be moved slightly into the cornea, or, alternatively, the LRI could be placed opposite another relaxing incision in the sclera, limbus or cornea. For patients who have with-the-rule astigmatism or oblique astigmatism, the relaxing incision is made temporally, and the LRIs are placed at the steep axis. The placement of the LRI should be customized to the topography of the cornea. In cases of asymmetric astigmatism, the LRI in the steepest axis can be elongated slightly and then shortened the same amount in the flatter of the 2 steep axes. Paired LRIs do not have to be made in the same meridian. Patients with low (<1.5 D) against-the-rule astigmatism receive only a single LRI in the steep meridian, placed opposite to the cataract incision. However, if astigmatism is greater than 1.5 D, a pair of LRIs should be used. In against-the-rule astigmatism cases, one pair of LRIs may be incorporated into the cataract incision. The length of the LRI is not affected by the presence of the cataract incision. This is difficult to perform precisely with present methods. In low with-the-rule astigmatism cases, a single 6-mm LRI (0.6 mm in depth) is made at 90.degree. The LRI can be independent of the cataract incision in with-the-rule astigmatism cases (if the cataract incision is temporal and the LRI is superior).

Furthermore, unlike traditional cold steel surgical approaches to creating incisions that must start at the outside and cut inwards, using a light source for making these incisions allows for RI **420** to be made from the inside out and thus better preserve the structural integrity of the tissue and limit the risk of tearing and infection. Moreover, the cataract incision **402** and the relaxation incision(s) **420** can be made automatically using the imaging and scanning features of system **2**. A pair of treatment patterns can be generated that forms incisions **402** and **420**, thus providing more accurate control over the absolute and relative positioning of these incisions. The pair of treatment patterns can be applied sequentially, or simultaneously (i.e. the pair of treatment patterns can be combined into a single treatment pattern that forms both types of incisions). For proper alignment of the treatment beam pattern, an aiming beam and/or pattern from system **2** can be first projected onto the target tissue with visible light indicating where the treatment pattern(s) will be projected. This allows the surgeon to adjust and confirm the size, location and shape of the treatment pattern(s) before their actual application. Thereafter, the two or three dimensional treatment pattern(s) can be rapidly applied to the target tissue using the scanning capabilities of system **2**.

Specialized scan patterns for creating alternate geometries for cataract incisions **402** that are not achievable using conventional techniques are also possible. An example is illustrated in FIG. **8**. A cross-sectional view of an alternate geometry for cataract incision **402** is shown to have a bevel feature **430**. Bevel feature **430** may be useful for wound healing, sealing, or locking. Such 3-dimensional cataract incisions **402** can be achieved accurately and quickly utilizing the 3-dimensional scanning ability of system **2**. Although a beveled incision is shown, many such geometries are enabled using the present invention, and within its scope. As before, the incision **402** is shown in cornea **406**, but could be alternately placed in limbus **408** or sclera **410**.

For large fields as when incisions are made in the outer most regions such as the limbus or sclera, a specialized contact lens can be used. This contact lens could be in the form of a gonioscopic mirror or lens. The lens does not need to be diametrically symmetric. Just one portion of the lens can be extended to reach the outer regions of the eye such as the limbus **408** and sclera **410**. Any targeted location can be reached by the proper rotation of the specialized lens.

It is to be understood that the present invention is not limited to the embodiment(s) described above and illustrated herein, but encompasses any and all variations falling within the scope of the appended claims. For example, references to the present invention herein are not intended to limit the scope of any claim or claim term, but instead merely make reference to one or more features that may be covered by one or more of the claims. All the optical elements downstream of scanner **50** shown in FIGS. **1**, **3** and **4** form a delivery system of optical elements for delivering the beam **6**, **114** and **202** to the target tissue. Conceivably, depending on the desired features of the system, some or even most of the depicted optical elements could be omitted in a delivery system that still reliably delivers the scanned beams to the target tissue.

What is claimed is:

1. A scanning system for treating target tissue in a patient's eye, comprising:

a) an ultrafast laser source configured to deliver a laser beam comprising a plurality of laser pulses;
b) an Optical Coherence Tomography (OCT) device configured to generate signals which may be used to create an image of the cornea and limbus of the eye of the patient;
c) a scanner configured to focus and direct the laser beam in a pattern within the cornea or limbus to create incisions therein; and
d) a controller operatively coupled to the laser source and scanner programmed to determine a treatment pattern based upon the signals from the OCT device, the treatment pattern forming a cataract incision in the cornea that provides access for lens removal instrumentation to a crystalline lens of the patient's eye and one or more relaxation incisions in the cornea or limbus, wherein the cataract incision has an arcuate extent of less than 360 degrees in a top view, wherein the cataract incision includes a bevel shape in a cross-sectional view, the bevel shape including a first segment and a second segment which intersect each other at an angle, the cataract incision being entirely located in the cornea and intersecting both an anterior surface and a posterior surface of the cornea, and to control the scanner to scan the position of the laser beam in the treatment pattern.

2. The system of claim **1**, wherein the controller is programmed to operate the laser source and scanner such that at least one of the incisions only partially extends through the target tissue.

3. The system of claim **1**, further comprising: a profilometer for measuring a surface profile of a surface of the cornea of the patient's eye, wherein the controller is programmed to determine the treatment pattern in response to the measured surface profile.

4. The system of claim **1**, wherein the OCT device is configured to measure scattering properties from different locations on the patient's eye, wherein the controller is programmed to determine the treatment pattern in response to the scattering properties.

5. The system of claim **1**, wherein the controller is programmed to operate the laser source and scanner to create incisions within the tissue at a depth based upon the signals from the OCT device.

6. The system of claim **1**, wherein the scanner comprises a Z-scan device operable to move a focus position of the laser beam along a z-axis and a X-Y scan device operable to move the focus position of the laser beam laterally relative to the z-axis.

7. The system of claim **6**, wherein the OCT device produces an OCT beam that passes through the Z-scan device and the X-Y scan device.

8. The system of claim **1**, wherein the ultrafast laser source is configured to deliver a laser beam having a wavelength between 1010 nm to 1100 nm.

9. The system of claim **1**, wherein the ultrafast laser source is configured to deliver laser pulses having pulse lengths of 100 fs to 10000 fs.

10. The system of claim **1**, wherein the ultrafast laser source is configured to deliver a plurality of laser pulses having a pulse repetition frequency of 10 kHz to 250 kHz.

11. The system of claim **1**, wherein the OCT device comprises an OCT light source configured to generate a light beam having wavelengths of 800 nm to 1400 nm.

12. The system of claim **1**, wherein the OCT device comprises a broadband OCT light source.

13. The system of claim **1**, wherein the OCT device is a frequency domain OCT device.

14. The system of claim **13**, wherein the frequency domain OCT device comprises a swept light source.

15. The system of claim **1**, further comprising a wavefront sensing system configured to measure the optical aberration of the eye.

16. The system of claim **15**, wherein the wavefront sensing system comprises a Shack-Hartmann wavefront sensor configured to measure a shape of a wavefront of light that exits the eye's pupil.

17. The system of claim **16**, wherein a correction to the shape of the cornea is made based on the shape of the wavefront.

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