

AUTOMATED CAPSULOTOMY**CROSS-REFERENCE TO RELATED APPLICATIONS**

The present application claims the benefit of US Provisional Application 63/053,650, entitled "Automatic posterior capsulotomy and combination device," filed July 19, 2020, whose disclosure is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention is related to ophthalmologic procedures, especially capsulotomy procedures.

BACKGROUND

10 In some cases, following the replacement of the natural lens of an eye, opacification of the posterior capsule of the eye occurs. In such cases, a posterior capsulotomy may be the treatment of choice.

US Patent 8,465,478 describes systems, apparatus, and methods for developing laser systems that can create a precise predetermined jigsaw capsulotomy. The systems, apparatus, and methods further provide laser systems that can use a single laser as a therapeutic laser and as laser radar and that reduce the patient-to-patient variability and doctor-to-doctor variability associated with hand-held apparatus for performing capsulorhexis and capsulotomies. There is further described a precise predetermined jigsaw shot pattern and shaped capsulotomy that is based at least in part on the shape of an IOL and in particular an accommodating IOL.

20 US Patent 8,845,625 describes systems and methods for cataract intervention. In one embodiment a system comprises a laser source configured to produce a treatment beam comprising a plurality of laser pulses; an integrated optical system comprising an imaging assembly operatively coupled to a treatment laser delivery assembly such that they share at least one common optical element, the integrated optical system being configured to acquire image information pertinent to one or more targeted tissue structures and direct the treatment beam in a 3-dimensional pattern to cause breakdown in at least one of the targeted tissue structures; and a controller operatively coupled to the laser source and integrated optical system, and configured to adjust the laser beam and treatment pattern based upon the image information, and distinguish two or more anatomical structures of the eye based at least in part upon a robust least squares fit

analysis of the image information.

US Patent 10,143,590 describes a method and apparatus for performing a laser-assisted posterior capsulotomy and for performing laser eye surgery on an eye having a penetrated cornea. A method for performing a posterior capsulotomy includes injecting fluid between the lens
5 posterior capsule and the anterior hyaloids membrane to separate the lens posterior capsule and the anterior hyaloids membrane. With the lens posterior capsule separated from the anterior hyaloids membrane, a posterior capsulotomy is performed on the lens posterior capsule by using a laser to incise the lens posterior capsule.

US Patent 10,849,789 describes an ophthalmic measurement and laser surgery system,
10 including: a laser source; a corneal topography subsystem; an axis determining subsystem; a ranging subsystem comprising an Optical Coherence Tomographer (OCT); and a refractive index determining subsystem. All of the subsystems are under the operative control of a controller. The controller is configured to: operate the corneal topography subsystem to obtain corneal surface information; operate the axis determining subsystem to identify one or more ophthalmic axes of
15 the eye; operate the OCT to sequentially scan the eye in a plurality of OCT scan patterns, the plurality of scan patterns configured to determine an axial length of the eye; operate the refractive index determining subsystem so to determine an index of refraction of one or more ophthalmic tissues, wherein at least one of the corneal surface information, ophthalmic axis information, and axial length is modified based on the determined index of refraction.

20 SUMMARY OF THE INVENTION

There is provided, in accordance with some embodiments of the present invention, a system, including a radiation source and a controller. The controller is configured to define a treatment zone on a capsule of an eye of a subject, and to form an opening in the capsule, subsequently to defining the treatment zone, by irradiating multiple target regions within the
25 treatment zone in an iterative process. The iterative process includes, during each one of multiple iterations of the process, acquiring an image of at least part of the capsule, based on the acquired image, designating one of the target regions, and causing the radiation source to irradiate the designated target region.

In some embodiments, the capsule is a posterior capsule.

30 In some embodiments, the controller is configured to define the treatment zone by:
based on at least one initial image of the eye, identifying an anterior-capsule opening in an anterior capsule of the eye, and

defining the treatment zone such that the treatment zone lies entirely behind the anterior-capsule opening.

5 In some embodiments, the controller is configured to define the treatment zone by:
based on at least one initial image of the eye, identifying an edge of an iris of the eye, and
defining the treatment zone such that the treatment zone lies entirely within the edge.

In some embodiments, the controller is configured to define the treatment zone by:
based on at least one initial image of the eye, identifying one or more features of a
prosthetic intraocular lens (IOL) in the eye,
10 in response to the features, calculating an estimated position of the IOL, and
defining the treatment zone in response to the estimated position.

In some embodiments, during at least one of the iterations, designating the target region
includes:
based on the acquired image, identifying tissue of the capsule at a last-designated one of
the target regions, and
15 in response to identifying the tissue, redesignating the last-designated one of the target
regions.

In some embodiments, during at least one of the iterations, designating the target region
includes:
based on the acquired image, identifying a portion of a perimeter of the opening that is
20 farther from a boundary of the treatment zone than are other portions of the perimeter, and
designating the target region at a predefined distance from the identified portion of the
perimeter.

In some embodiments, during at least one of the iterations, designating the target region
includes:
25 based on the image, identifying a fold within the treatment zone, and
in response to identifying the fold, designating the target region such that the target region
overlaps the fold.

In some embodiments, during at least one of the iterations, designating the target region
includes:
30 based on the acquired image, ascertaining that a perimeter of the opening is stable, and
in response to the ascertaining, designating the target region.

In some embodiments,

the controller is configured to form the opening subsequently to a designation of a sequence of tentative target regions, and

during at least one of the iterations, designating the target region includes:

5 based on the acquired image, ascertaining that a distance between a next one of the tentative target regions and a perimeter of the opening is greater than a predefined threshold distance, and

in response to ascertaining that the distance is greater than the predefined threshold distance, designating, as the target region, the next one of the tentative target regions.

10 In some embodiments, during at least one other one of the iterations, designating the target region includes:

based on the acquired image, ascertaining that the distance is not greater than the predefined threshold distance, and

15 in response to ascertaining that the distance is not greater than the predefined threshold distance, designating, as the target region, the tentative target region following the next one of the tentative target regions.

In some embodiments, during at least one other one of the iterations, designating the target region includes:

based on the acquired image, ascertaining that the distance is not greater than the predefined threshold distance, and

20 in response to ascertaining that the distance is not greater than the predefined threshold distance, designating the target region by applying an offset to a location of the next one of the tentative target regions.

In some embodiments, the controller is further configured to:

define a target boundary on the capsule, and

25 terminate the iterative process in response to ascertaining that the opening reaches a predefined threshold percentage of the target boundary.

In some embodiments, the controller is configured to define the target boundary by placing the target boundary at a predefined offset inward from a boundary of the treatment zone.

30 There is further provided, in accordance with some embodiments of the present invention, a method, including defining a treatment zone on a capsule of an eye of a subject and, subsequently to defining the treatment zone, forming an opening in the capsule by irradiating multiple target regions within the treatment zone in an iterative process. The iterative process includes, during each one of multiple iterations of the process, acquiring an image of at least part of the capsule,

based on the acquired image, designating one of the target regions, and causing a radiation source to irradiate the designated target region.

There is further provided, in accordance with some embodiments of the present invention, a computer software product including a tangible non-transitory computer-readable medium in which program instructions are stored. The instructions, when read by a controller, cause the controller to define a treatment zone on a capsule of an eye of a subject, and to form an opening in the capsule, subsequently to defining the treatment zone, by irradiating multiple target regions within the treatment zone in an iterative process. The iterative process includes, during each one of multiple iterations of the process, acquiring an image of at least part of the capsule, based on the acquired image, designating one of the target regions, and causing the radiation source to irradiate the designated target region.

The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of a system for performing a capsulotomy on a capsule of an eye of a patient, in accordance with some embodiments of the present invention;

Fig. 2 is a schematic illustration of a capsulotomy device, in accordance with some embodiments of the present invention;

Fig. 3 is a schematic illustration of a method for defining a treatment zone, in accordance with some embodiments of the present invention;

Fig. 4 is a schematic illustration of the formation of an opening in a capsule, in accordance with some embodiments of the present invention;

Figs. 5-6 are schematic illustrations of techniques for designating target regions, in accordance with some embodiments of the present invention;

Fig. 7 is a schematic illustration of a technique for designating target regions based on a predesignated sequence of tentative target regions, in accordance with some embodiments of the present invention; and

Fig. 8 is a flow diagram for an example iterative process for forming an opening in a capsule of an eye, in accordance with some embodiments of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

OVERVIEW

Conventional capsulotomy procedures require a specialist physician who has undergone extensive training. Unfortunately, however, such physicians may be in short supply.

5 To address this challenge, embodiments of the present invention provide an automated capsulotomy system, which allows even a physician who has undergone a lesser amount of training to perform the procedure. The system comprises a radiation source, a camera, a controller, and suitable optics. Based on images acquired by the camera, the controller controls the radiation source and optics so as to form an opening in the posterior capsule by irradiating the capsule.

10 Typically, the controller first defines a treatment zone, which includes at least some of the opacified portion of the posterior capsule. Next, the controller designates a first target region, typically at the center of the treatment zone, and then irradiates the first target region. After confirming, from an image of the capsule, that an opening was initialized at the first target region, the controller designates a second target region at a suitable distance from the perimeter of the opening, and then irradiates the second target region. After confirming, from another image of the capsule, that the opening was expanded, the controller designates and then irradiates a third target region. In this manner, the controller uses image processing to optimize the designation of the target regions, thus facilitating expanding the opening more efficiently, i.e., using fewer radiation beams. Upon ascertaining, from another image, that the opening has been sufficiently enlarged, 15 the controller terminates the procedure.

Typically, the controller is configured to identify, by image processing, any folds in the posterior capsule. In response to identifying a fold, a target region overlapping the fold may be designated. Advantageously, by targeting folds in the capsule, the opening may be expanded more efficiently.

25 In some embodiments, a sequence of tentative target regions is designated prior to any irradiation of the capsule. Subsequently, the controller iterates through the tentative target regions. For each tentative target region, based on the proximity of the tentative target region to the perimeter of the opening, the controller decides whether to irradiate the tentative target region, skip the tentative target region, or irradiate a new target region that is offset from the tentative target region. 30

In addition to performing an automated capsulotomy of a posterior capsule as described herein, the controller may form slit-shaped openings in the anterior capsule of the eye.

Alternatively or additionally, the controller may use any of the techniques described herein to form a larger opening in the anterior capsule.

SYSTEM DESCRIPTION

Reference is initially made to Fig. 1, which is a schematic illustration of a system 20, comprising a capsulotomy device 21, for performing a capsulotomy on a capsule of an eye 25 of a patient 22, in accordance with some embodiments of the present invention. Reference is further made to Fig. 2, which is a schematic illustration of capsulotomy device 21, in accordance with some embodiments of the present invention.

Capsulotomy device 21 comprises an optical unit 30 and a controller 44. Optical unit 30 comprises one or more beam-directing elements, comprising, for example, one or more galvo mirrors 50, which may be referred to collectively as a “galvo scanner,” and/or a beam combiner 56. Optical unit 30 further comprises a radiation source 48, which is configured to irradiate the capsule of eye 25 with one or more treatment beams 52 by emitting the treatment beams toward the beam-directing elements such that the beams are directed by the beam-directing elements toward the capsule. Typically, radiation source 48 is further configured to irradiate the capsule with a pair of aiming beams 53, which are configured to overlap one another only when the distance of the optical unit from the capsule and the positioning of the beam-directing elements provide a desired treatment spot size on the capsule. Thus, aiming beams 53 may be used to verify the spot size of each treatment beam prior to emitting the treatment beam, as further described below with reference to Fig. 8.

In some embodiments, optical unit 30 further comprises one or more other optics. For example, the optical unit may comprise a beam expander 70, which expands and then re-collimates treatment beams 52. In such embodiments, typically, optical unit 30 further comprises a focusing module (comprising, for example, an F-theta lens or another type of lens), configured to focus the treatment beams.

More specifically, before the emission of each treatment beam 52 from radiation source 48, or while the beam is being emitted, controller 44 aims the beam-directing elements at a target region of the capsule such that the beam is directed, by the beam-directing elements, toward the target region. For example, the beam may be deflected by galvo mirrors 50 through beam expander 70 toward beam combiner 56, and then deflected by the beam combiner through focusing module 72, such that the beam impinges on the target region with the desired spot size. (Since each treatment beam impinges on the capsule with a non-infinitesimal spot size, the present application generally describes each beam as impinging on a “region” of the capsule, rather than impinging at

a “point.”) The beam thus follows a path 92, which extends from the most downstream of the beam-directing elements – such as focusing module 72 – to the target region.

Typically, the radiation source comprises a laser, such as an Nd:YAG laser. (Examples of off-the-shelf products incorporating an Nd:YAG laser include Optimis II by Quantel Medical of Courmon-d’Auvergne, France, and Selecta Duet by Lumenis of Yokneam, Israel.) The laser may be modified to include an attenuator, an energy meter, and/or a mechanical shutter. Alternatively or additionally to a laser, the radiation source may comprise any other suitable emitter of radiation.

In some embodiments, the treatment beams include visible light. Alternatively or additionally, the treatment beams may include non-visible electromagnetic radiation, such as microwave radiation, infrared radiation, X-ray radiation, or gamma radiation. Typically, the wavelength of the treatment beams is between 400 and 1400 nm, e.g., 532 nm or 1064 nm.

Typically, the spatial profile of each treatment beam 52 on the capsule is approximately circular, e.g., with a spot size less than 22 μ m. Alternatively, the spatial profile of each treatment beam 52 may be elliptical, square, or of any other suitable shape. In general, the size and shape of the treatment beam spots are chosen so as to deliver sufficient energy for photodisruption of the capsule.

Typically, the aiming beams include visible light, e.g., with a wavelength of between 600 and 700 nm.

Optical unit 30 further comprises a camera 54, which is used by controller 44 to acquire images of the eye. As shown in Fig. 2, camera 54 is typically aligned, at least approximately, with path 92; for example, the angle between path 92 and a hypothetical line extending from eye 25 to the camera may be less than 15 degrees. In some embodiments, the camera is positioned behind beam combiner 56, such that the camera receives light via the beam combiner. In other embodiments, the camera is offset from the beam combiner.

At the start of the procedure, camera 54 acquires an initial image of the capsule, or at least a portion thereof. Based on the image, controller 44 defines a treatment zone on the capsule, as further described below with reference to Fig. 3. Subsequently, during the procedure, camera 54 acquires multiple images of the capsule, or at least a portion thereof, at a relatively high frequency. Controller 44 processes these images and, in response thereto, designates target regions within the treatment zone for irradiation, as further described below with reference to the subsequent figures.

In general, camera 54 may comprise one or more imaging sensors of any suitable type(s), such as a charge-coupled device (CCD) sensor, a complementary metal–oxide–semiconductor

(CMOS) sensor, an optical coherence tomography (OCT) sensor, and/or a hyperspectral image sensor. Using the sensors, the camera may acquire two-dimensional or three-dimensional images of any suitable type, such as monochrome images, color images (based, for example, on three color frames), multispectral images, hyperspectral images, optical coherence tomography (OCT) images, or images produced by fusing multiple images of different respective types.

Typically, optical unit 30 further comprises a light source 66, which is aligned, at least approximately, with path 92. For example, the angle between path 92 and a hypothetical line extending from the end of path 92 on eye 25 to light source 66 may be less than 20 degrees, such as less than 10 degrees. Light source 66 is configured to function as a fixation target 64 by transmitting visible fixation light 68, thus helping to stabilize the position of the eye. In particular, prior to the procedure, patient 22 is instructed to fixate eye 25 on light source 66. Subsequently, during the procedure, by virtue of light source 66 transmitting fixation light 68, eye 25 fixates on the light source, such that the eye's line-of-sight is approximately coincident with path 92 (due to the light source being approximately aligned with the path) and the eye is relatively stable. While the eye fixates on the light source, the radiation source irradiates the capsule of the eye with treatment beams 52.

In some embodiments, light source 66 comprises a light emitter, such as a light emitting diode (LED). In other embodiments, the light source comprises a reflector configured to reflect light emitted from a light emitter.

Typically, the wavelength of fixation light 68, which may be higher or lower than that of the treatment beams, is between 350 and 850 nm. For example, fixation light 68 may be orange or red, with a wavelength of 600-750 nm.

Typically, the optical unit comprises an optical bench, and at least some of the aforementioned components belonging to the optical unit, such as the radiation source, the galvo mirrors, and the beam combiner, are coupled to the optical bench. Typically, the optical unit further comprises a front face 33, through which the treatment beams and the fixation light pass. For example, optical unit 30 may comprise an encasement 31, which at least partially encases the optical bench and comprises front face 33. (Encasement 31 may be made of a plastic, a metal, and/or any other suitable material.) Alternatively, front face 33 may be attached to, or may be an integral part of, the optical bench.

In some embodiments, front face 33 is shaped to define an opening 58, through which the treatment beams and fixation light pass. In other embodiments, the front face comprises an exit window in lieu of opening 58, such that fixation light 68 and treatment beams 52 pass through the

exit window. The exit window may be made of a plastic, a glass, or any other suitable material that is generally transparent to the treatment beams, aiming beams, fixation light 68, and any light used for imaging the eye, such as light from the illumination sources 60 described below.

Optical unit 30 is mounted onto an XYZ stage unit 32, which is controlled by a control
5 mechanism 36, such as a joystick. Using control mechanism 36, the user of system 20 may position the optical unit (e.g., by adjusting the distance of the optical unit from the eye) prior to treating the eye. In some embodiments, XYZ stage unit 32 comprises locking elements configured to inhibit motion of the stage unit following the positioning of the stage unit.

In some embodiments, XYZ stage unit 32 comprises one or more motors 34, and control
10 mechanism 36 is connected to interface circuitry 46. As the user manipulates the control mechanism, interface circuitry 46 translates this activity into appropriate electronic signals, and outputs these signals to controller 44. In response to the signals, the controller controls motors 34.

In other embodiments, XYZ stage unit 32 is controlled manually by manipulating the
15 control mechanism. In such embodiments, the XYZ stage unit may comprise a set of gears instead of motors 34.

System 20 further comprises a headrest 24, comprising a forehead rest 26 and a chinrest
28. During the capsulotomy, patient 22 presses his forehead against forehead rest 26 while resting his chin on chinrest 28. In some embodiments, headrest 24 further comprises an immobilization strap 27, configured to secure the patient's head from behind and thus keep the patient's head
20 pressed against the headrest.

In some embodiments, system 20 further comprises a contact lens, configured to focus the treatment beams and/or stabilize eye 25 while contacting the eye.

In some embodiments, as shown in Fig. 1, headrest 24 and XYZ stage unit 32 are both
mounted onto a surface 38, such as the top surface of a tray or table. In other embodiments, the
25 XYZ stage unit is mounted onto surface 38, and the headrest is attached to the XYZ stage unit.

System 20 further comprises a monitor 42, configured to display the images of the eye
acquired by the camera. Monitor 42 may be attached to optical unit 30 or disposed at any other suitable location, such as on surface 38 next to device 21. In some embodiments, monitor 42
comprises a touch screen, such that the user may input commands and/or information to the system
30 via the touch screen. Alternatively or additionally, system 20 may comprise any other suitable input devices, such as a keyboard or a mouse, which may be used by the user.

In some embodiments, monitor 42 is connected directly to controller 44 over a wired or

wireless communication interface. In other embodiments, monitor 42 is connected to controller 44 via an external processor, such as a processor belonging to a standard desktop computer.

In some embodiments, as shown in Fig. 2, controller 44 is disposed within XYZ stage unit 32. In other embodiments, controller 44 is disposed externally to the XYZ stage unit. Alternatively or additionally, the controller may cooperatively perform at least some of the functionality described herein with another, external processor.

In some embodiments, system 20 is also configured to perform trabeculoplasty procedures, e.g., as described in International Patent Application Publication WO/2020/008323, whose disclosure is incorporated herein by reference. Thus, using system 20, a trabeculoplasty procedure may be performed on patient 22 before or after a capsulotomy procedure is performed on the patient; for example, both procedures may be performed during a single sitting of patient 22.

In such embodiments, the treatment wavelength used for trabeculoplasty procedures (e.g., 532 nm) may be the same as that used for capsulotomy procedures. Alternatively, radiation source 48 may comprise a wavelength converter, configured to convert the wavelength of the treatment beams from a first wavelength used for capsulotomy procedures (e.g., 1064 nm) to a second wavelength used for trabeculoplasty procedures (e.g., 532 nm), or vice versa. Typically, the radiation source further comprises a switch, configured to switch the treatment beams between a first optical path, which includes the wavelength converter, and a second optical path, which does not include the wavelength converter.

Alternatively or additionally, in such embodiments, optical unit 30 may further comprise one or more illumination sources 60 comprising, for example, one or more LEDs, such as white-light or infrared LEDs. For example, the optical unit may comprise a ring of LEDs surrounding opening 58. In such embodiments, controller 44 may cause illumination sources 60 to intermittently flash light at the eye during a trabeculoplasty procedure, as described in International Patent Application Publication WO/2020/008323, whose disclosure is incorporated herein by reference. This flashing may facilitate the imaging performed by the camera, and, by virtue of the brightness of the flashing, may further help constrict the pupil of the eye. (For ease of illustration, the electrical connection between controller 44 and illumination sources 60 is not shown explicitly in Fig. 2.) In some embodiments, illumination sources 60 are coupled to front face 33, as shown in Fig. 2.

As shown in Fig. 1, in some embodiments – particularly those in which a trabeculoplasty, which generally requires that the entire limbus be visible, is performed - the optical unit is directed obliquely upward toward the eye while the eye gazes obliquely downward toward the optical unit,

such that path 92 is oblique. For example, the path may be oriented at an angle θ of between five and twenty degrees with respect to the horizontal. Advantageously, this orientation reduces occlusion of the patient's eye by the patient's upper eyelid and associated anatomy.

In some embodiments, as shown in Fig. 1, the oblique orientation of path 92 is achieved by virtue of the optical unit being mounted on a wedge 40, which is mounted on the XYZ stage unit. In other words, the optical unit is mounted onto the XYZ stage unit via wedge 40. (Wedge 40 is omitted from Fig. 2.)

In some embodiments, at least some of the functionality of controller 44, as described herein, is implemented in hardware, e.g., using one or more fixed-function or general-purpose integrated circuits, Application-Specific Integrated Circuits (ASICs), and/or Field-Programmable Gate Arrays (FPGAs). Alternatively or additionally, controller 44 may perform at least some of the functionality described herein by executing software and/or firmware code. For example, controller 44 may be embodied as a programmed processor comprising, for example, a central processing unit (CPU) and/or a Graphics Processing Unit (GPU). Program code, including software programs, and/or data may be loaded for execution and processing by the CPU and/or GPU. The program code and/or data may be downloaded to the controller in electronic form, over a network, for example. Alternatively or additionally, the program code and/or data may be provided and/or stored on non-transitory tangible media, such as magnetic, optical, or electronic memory. Such program code and/or data, when provided to the controller, produce a machine or special-purpose computer, configured to perform the tasks described herein.

In some embodiments, the controller comprises a system on module (SOM), such as the DART-MX8M by Variscite of Lod, Israel.

DEFINING THE TREATMENT ZONE

Reference is now made to Fig. 3, which is a schematic illustration of a method for defining a treatment zone, in accordance with some embodiments of the present invention.

Fig. 3 shows eye 25 at the start of the capsulotomy procedure. In particular, Fig. 3 shows the anterior capsule 76 of the eye lying within the edge 78 of the iris 74 of the eye. An opening 84 has been formed in anterior capsule 76, so as to allow the natural lens of the eye to be removed (e.g., via phacoemulsification) and a prosthetic intraocular lens (IOL) 80 to be inserted. Behind IOL 80 lies an opacified posterior capsule 86 of the eye, on which the capsulotomy procedure is to be performed.

Typically, IOL 80 includes an elliptical optic 89 connected to curved filaments, or “haptics,” that anchor the IOL in place. For example, optic 89 may be circular, having a diameter of between 6 and 14 mm. Although IOL 80 is generally transparent, in some cases, as shown in Fig. 3, one or more features of IOL 80 (in particular, optic 89 of the IOL) may be visible behind opening 84. For example, in some cases, optic 89 includes a Fresnel lens including multiple lens zones, and concentric circles 82, which demarcate the lens zones, are visible.

At the start of the capsulotomy procedure, controller 44 (Fig. 2) defines a treatment zone 88, demarcated in the present figures by a boundary 90, on posterior capsule 86. Typically, treatment zone 88 is elliptical, e.g., circular.

For example, based on at least one initial image of the eye acquired by camera 54 (Fig. 2), the controller may identify opening 84 in anterior capsule 76, e.g., by applying any suitable pattern-matching and/or edge-detection techniques to the initial image. Subsequently, the controller may define the treatment zone such that the treatment zone lies entirely behind the opening. For example, the controller may offset boundary 90 a predefined distance (e.g., 0.1-1 mm) inward from the perimeter of opening 84. As an extra safety precaution, the controller may further identify edge 78 of iris 74 based on the initial image, and verify that the treatment zone lies entirely within edge 78.

Alternatively, based on the initial image of the eye, the controller may identify one or more features of IOL 80, e.g., by applying any suitable pattern-matching and/or edge-detection techniques to the initial image. In response to the features, the controller may calculate an estimated position of the IOL, and then define the treatment zone in response to the estimated position. In particular, the controller may define the position and size of the treatment zone such that, even if the entire treatment zone were to be opened, the IOL would not fall through the opening. As an extra safety precaution, the controller may further verify that the treatment zone lies entirely within edge 78, and/or verify that the treatment zone lies entirely behind opening 84.

For example, prior to the procedure, a user may input, to the controller, relevant features of the IOL, such as the dimensions of, and/or number of lens zones belonging to, optic 89. Subsequently, based on the input and in response to identifying one or more circles 82, the controller may calculate the position of the center of the optic. In response thereto, the controller may center the treatment zone at the center of the optic, and/or offset boundary 90 a predefined distance (e.g., 0.5-1 mm) inward from the perimeter of the optic, e.g., per guidelines specified in the relevant medical literature.

Alternatively, the controller may define the treatment zone by offsetting boundary 90 a predefined distance (e.g., up to 1 mm) inward from edge 78, without necessarily identifying opening 84 or any features of IOL 80.

Typically, subsequently to defining the treatment zone, the controller overlays boundary 90, which demarcates the treatment zone, on the initial image of the eye, and displays the image with the overlaid boundary on monitor 42 (Fig. 1). The user may then adjust the treatment zone, e.g., by using a mouse to drag one or more points on boundary 90, prior to approving the treatment zone.

In other embodiments, the controller defines the treatment zone in response to input from the user, without necessarily performing any of the image processing described above. For example, the user may input the desired center and radius of the treatment zone, and/or drag points on boundary 90 as described above.

FORMING THE OPENING

Subsequently to defining treatment zone 88, the controller forms an opening in capsule 86 by irradiating multiple target regions 94 within the treatment zone in an iterative process. During each iteration of the process, the controller acquires an image of at least part of the capsule, designates one of the target regions 94 based on the acquired image, and causes radiation source 48 (Fig. 2) to irradiate the designated target region. For example, Fig. 3 shows an initial target region at the center of treatment zone 88, which the controller may designate and then irradiate during the first iteration of the process.

For further details, reference is now made to Fig. 4, which is a schematic illustration of the formation of an opening 96 in capsule 86, in accordance with some embodiments of the present invention.

Section A of Fig. 4 shows an image 98 of the eye following the initialization of opening 96, which is performed by irradiating the first designated target region 94 shown in Fig. 3. Based on the image, the controller designates a second target region 94, e.g., as further described below with reference to Fig. 5.

Section B of Fig. 4 shows another image 98 following the irradiation of the second target region, which expands opening 96. Based on the image, the controller designates a third target region 94.

Section C of Fig. 4 shows another image 98 following a number of further iterations in which target regions 94 are irradiated. Based on such an image, the controller may decide to refrain from designating any further target regions, thus terminating the iterative process.

For example, the controller may define a target boundary 91 for the opening, e.g., by placing target boundary 91 at a predefined offset (e.g., 0.01–1 mm) inward from boundary 90 of the treatment zone. Subsequently, the controller may terminate the process in response to ascertaining that the opening reaches a predefined threshold percentage (e.g., 90%-100%) of target boundary 91. (In such embodiments, prior to the first treatment beam, target boundary 91 may be overlaid on the initial image of the eye and the user may then adjust the target boundary, as described above for boundary 90 with reference to Fig. 3.) Alternatively (e.g., if the pupil of the eye is relatively small), the controller may terminate the process in response to ascertaining that the opening reaches a predefined threshold percentage (e.g., 90%-100%) of boundary 90 of the treatment zone.

Reference is now made to Fig. 5, which is a schematic illustration of a technique for designating target regions 94, in accordance with some embodiments of the present invention.

Fig. 5 shows the scenario generally shown in Sections A-B of Fig. 4, in which opening 96 is being formed. In this scenario, in some cases, the controller designates the next target region by performing the following technique.

First, based on image 98, the controller identifies a portion of the perimeter of the opening that is farther from boundary 90 than are other portions of the perimeter.

For example, for multiple points 104a along the perimeter, the controller may calculate the shortest distance d_{0a} between point 104a and boundary 90, i.e., the length of the shortest line between point 104a and boundary 90. Subsequently, the controller may identify the point 104a for which d_{0a} is a maximum.

Alternatively, for multiple angles, the controller may calculate the distance d_{0b} between (i) the point 104b at which a line 102 radiating from the center 100 of the treatment zone at the angle intersects the perimeter of opening 96, and (ii) the point at which line 102 intersects boundary 90. Subsequently, the controller may identify the point 104b for which d_{0b} is a maximum.

Next, the controller designates target region 94 at a predefined distance d_1 from the identified portion of the perimeter. For example, subsequently to identifying a point 104a as described above, the controller may designate a target region 94a lying on the shortest line between

the identified point and boundary 90 at a distance of $d1$ from the identified point 104a. Similarly, subsequently to identifying a point 104b as described above, the controller may designate a target region 94b lying on the line 102 joining the identified point to boundary 90, at a distance $d1$ from the identified point 104b.

5 Reference is now made to Fig. 6, which is a schematic illustration of another technique for designating target region 94, in accordance with some embodiments of the present invention.

 In some cases, at least one fold 106 in the tissue of the capsule lies within the treatment zone. In such cases, the controller may identify fold 106, e.g., by applying an edge-detection algorithm, a line-detection algorithm, or any other suitable image-processing algorithm to image
10 98. Subsequently, in response to identifying the fold, the controller may designate target region 94 such that the target region overlaps the fold.

 For example, for each of the identified folds, the controller may calculate two distances: (i) the distance $d2$ between the center of the fold and the nearest point on the perimeter of the opening, and (ii) the distance $d3$ between the center of the fold and the nearest point on boundary
15 90. The controller may then identify a set of “targetable” folds for which $d2$ is within a predefined range of distances (e.g., 0.2-2 mm, such as 0.5-1 mm). Subsequently, the controller may select the targetable fold for which $d3$ is a maximum, and then place target region 94 at the center of the selected fold. Alternatively, if there are no targetable folds, the controller may instead use the technique of Fig. 5 to designate the target region.

20 Reference is now made to Fig. 7, which is a schematic illustration of a technique for designating target regions based on a predesignated sequence of tentative target regions, in accordance with some embodiments of the present invention.

 In some embodiments, prior to irradiating the capsule (and subsequently to the definition of the treatment zone), a sequence of tentative target regions 130 is designated. For example, the
25 controller may display an image of the capsule to the user, and the user may then manually designate the sequence by clicking a mouse over each portion of the image at which a tentative target region 130 is desired. Alternatively, the controller may designate the sequence and display the sequence to the user, and the user may then approve the sequence after shifting, adding, or deleting any number of tentative target regions 130.

30 Typically, the sequence generally follows a geometric pattern. For example, the tentative target regions may be arranged in a spiral 132, which spirals outward from the center of the treatment zone, or in multiple crossed lines that define an asterisk. Parts of the sequence may

deviate from the pattern slightly, e.g., so as to allow one or more tentative target regions 130 to overlap folds 106 (Fig. 6).

In such embodiments, when forming opening 96, the controller iterates through the sequence of tentative target regions 130. For each of the tentative target regions, the controller
5 either (i) designates the tentative target region as the next target region 94, i.e., approves the tentative target region for irradiation, as illustrated in the top-right inset portion of Fig. 7, (ii) designates the next target region by applying an offset (typically away from the perimeter of opening 96) to the location of the tentative target region, as illustrated in the middle-right inset portion of Fig. 7, or (iii) designates the following tentative target region as the next target region,
10 as illustrated in the bottom-right inset portion of Fig. 7.

In particular, for each tentative target region, the controller ascertains whether the distance d_2 between the tentative target region and the perimeter of opening 96 is greater than a predefined threshold distance (e.g., 0.2-0.9 mm). If d_2 is greater than the predefined threshold distance, the tentative target region is designated as the target region 94. Otherwise, the controller either applies
15 the offset or designates the following tentative target region.

Notwithstanding the examples shown in Figs. 4-7, it is noted that opening 96 need not necessarily be initialized at the center of the treatment zone. For example, when sweeping across the capsule in a cross or asterisk pattern, the first target region in each line of the cross or asterisk may be designated near the edge of the treatment zone.

20

EXAMPLE ITERATIVE PROCESS

Reference is now made to Fig. 8, which is a flow diagram for an example iterative process 108 for forming an opening in a capsule of an eye, in accordance with some embodiments of the present invention. Iterative process 108 may be performed by the controller subsequently to defining the treatment zone, e.g., as described above with reference to Fig. 3.

Each iteration of process 108 begins with an imaging step 110, at which the controller,
25 using camera 54 (Fig. 2), acquires an image of at least part of the capsule. Subsequently to imaging step 110, the controller, at a location-identifying step 112, identifies the location of boundary 90 (Fig. 3) of the treatment zone in the field of view (FOV) of the camera, by repeating whichever image processing was used previously to define the treatment zone. (The location of the treatment-
30 zone boundary in the FOV may change throughout the procedure, due to movement of the eye.) For example, if the treatment zone was defined by placing boundary 90 at a predefined distance from the perimeter of opening 84 (Fig. 3), the controller may identify the perimeter of opening 84

in the latest acquired image, and then identify the location of the treatment-zone boundary at the predefined distance therefrom. For embodiments in which target boundary 91 (Fig. 4) is defined, the controller may also identify the location of boundary 91 in the FOV of the camera.

Subsequently, at a checking step 114, the controller checks whether at least one target
5 region was already irradiated (i.e., whether at least one iteration was already performed). If not, the controller performs a target-designating step 124, described below. Otherwise, the controller checks, at another checking step 116, whether the last-designated (and irradiated) target region was opened. In other words, based on the acquired image, the controller checks whether tissue of the capsule is present at the last-designated target region.

Typically, checking step 116 comprises two sub-steps. In the first sub-step, the controller
10 identifies the location of the last target region based on the location of boundary 90. For example, based on the location of boundary 90, the controller may calculate any shift in the location of the center of the treatment zone, and then apply the same shift to the location of the last target region. Thus, for example, assuming that (i) the last target region was centered at (x_0, y_0) with the center
15 of the treatment zone being at $(0, 0)$, and (ii) the center of the treatment zone is now at (dx, dy) , the controller may identify $(x_0 + dx, y_0 + dy)$ as the new location of the last target region. Subsequently, in the second sub-step, the controller computes the change in pixel value between the last target region in the current image and the last target region in the last image, and compares this change to a predefined threshold.

If the last target region was not opened (i.e., if the controller identifies capsular tissue at
20 the last target region), the controller, at a target-redesignating step 126, redesignates the last target region. In some embodiments, the controller may also increase, by a predefined increment, the energy with which the target region is subsequently irradiated. (In such embodiments, typically, the energy may be increased multiple times by the predefined increment up to a predefined
25 maximum energy, after which, if the target region is still not opened, process 108 is aborted.)

Alternatively, if the last target region was opened, the controller, at a perimeter-identifying
step 118, identifies the perimeter of opening 96 (Fig. 4), e.g., using any suitable edge-detection algorithm. Subsequently, at a size-checking step 120, the controller checks whether the opening is
large enough, e.g., by checking whether the opening reaches target boundary 91 as described above
30 with reference to Fig. 4. If yes, process 108 ends. Otherwise, the controller proceeds to a stability-checking step 122.

At stability-checking step 122, the controller checks the stability of the perimeter of the opening by comparing the current location of the perimeter relative to the treatment-zone

boundary, and shape of the perimeter, to the last location and shape. In response to ascertaining that the perimeter is stable, the controller proceeds to target-designating step 124. Alternatively, in response to ascertaining that the perimeter is not stable – i.e., that the opening is still expanding as a result of previous irradiation - the controller refrains from designating a new target region, and returns to imaging step 110.

At target-designating step 124, the controller designates a new target region. For example, the controller may first check for any targetable folds, as described above with reference to Fig. 6. If a targetable fold is found, the controller may target the fold, as further described above with reference to Fig. 6. Otherwise, the controller may designate a target region as described above with reference to Fig. 5 or Fig. 7.

Subsequently to performing target-designating step 124 or target-redesignating step 126, the controller, at an aiming step 128, aims aiming beams 53 (Fig. 2) at the designated target region. Subsequently, the controller acquires another image of the capsule at imaging step 110. The controller then checks, at a checking step 134, whether the aiming beams overlap one another at the designated target region. If not, the controller, at a distance-adjusting step 136, adjusts the distance of optical unit 30 from the eye, e.g., by communicating appropriate control signals to motors 34 (Fig. 2). Alternatively or additionally, the controller may adjust the position of at least one optic in the optical unit, such as galvo mirrors 50 or focusing module 72 (Fig. 2). The controller then acquires another image of the capsule, and repeats checking step 134. In this manner, the distance of the optical unit from the eye, and/or the position of the optic, may be iteratively adjusted by the controller. Alternatively, the distance of the optical unit from the eye may be manually adjusted by the user.

Upon the controller (or the user) ascertaining that the aiming beams overlap one another, the controller causes radiation source 48 (Fig. 2) to irradiate the designated target region, at an irradiating step 138. The controller then begins another iteration of process 108.

In some embodiments, the aiming beams are shaped to define different respective portions of a predefined composite pattern, such that the predefined composite pattern is formed on the capsule only when the aiming beams overlap one another. Examples of such patterns are described, for example, in International Patent Application Publication WO/2020/008323, whose disclosure is incorporated herein by reference.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described

hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.