A capsulotomy device comprises a cutting instrument that is disposed within an external sheath. During an operation, a surgeon inserts the capsulotomy device into the eye via an incision in the cornea, deploys the cutting instrument into a position suitable to make a desired incision in the lens capsule, and then actuates the capsulotomy device to cut the lens capsule. The cutting process may be automated, where the cutting instrument is guided along a cutting path to make the incision. The resulting incision in the lens capsule allows, for example, treatment of cataracts by removing affected portions of the lens and/or installing an intraocular lens in the lens capsule bag.
MICROSURGERY DEVICE FOR LENS CAPSULE SURGERY

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/876,910, filed December 22, 2006, which is incorporated by reference in its entirety.

BACKGROUND

[0002] This invention relates generally to medical treatment of an eye, and more specifically to procedures and devices for performing lens capsule surgery.

[0003] Lens cataract is the leading cause of blindness worldwide and surgical treatment by cataract removal is the treatment of choice. As a result, lens surgery is the most common of all surgical operations in medicine today, with about 1.8 million procedures performed in the United States in 2004. The number of cases of lens cataract surgery is expected to increase further as the general population ages and as the procedure becomes more common in other parts of the world.

[0004] Added to these strong demographic and socioeconomic factors is the arrival of another type of surgical lens replacement, involving the use of multifocal or accommodating intraocular lenses (IOLs) to provide better vision after cataract removal. An area of intense interest is the use of accommodating IOLs to treat presbyopia resulting from the age-related rigidity and lack of accommodative power by the lens resulting in poor vision at near distances. Refractive lens surgery treats presbyopia by substituting an aged, inflexible (and therefore non-accommodating) lens with a soft, flexible, and accommodating IOL.

[0005] Furthermore, the implantation of the newer multifocal or accommodating IOLs requires the creation of an opening in the lens capsule that is precisely centered, sized, and shaped for implant stability and for optimal IOL function. This required level of precision may not be possible with a surgeon controlling and guiding conventional hand-held cutting instruments and attempting to trace a precise circular route on the lens capsule.

[0006] Traditional intraocular lenses have one focal point, so patients receiving these lenses after cataract surgery will require eyeglasses or contact lenses to read or view objects at mid distances. Multifocal intraocular lenses allow the patient to see well at more than one distance, but to achieve its multifocal characteristics, more of the surface of this type of intraocular lens is used to provide optical correction. Therefore, the matching of the lens
capsule opening size to the peripheral margins of the IOL is typically much more critical than for traditional IOLs.

[0007] Industry trends also reveal a major focus by major IOL manufacturers on developing new complex accommodating IOLs. While current multifocal IOLs have more than one focal point, new accommodating IOLs will have an infinite number of focal points, mimicking the focusing ability of the actual lens itself. The use of accommodative IOL technology is therefore not only limited to patients requiring lens replacement after cataract removal, but is also of potential use in individuals with loss of lens refractive power resulting from age-onset presbyopia. Although cataract is a common disease, the rates of lens capsule surgery for cataract removal will be vastly dwarfed by the potential patient population for presbyopia lens refractive surgery, since every human is subject to this natural deterioration in lens function.

[0008] The new accommodating IOLs being developed require highly precise lens capsule openings. Since many of the accommodating IOL designs involve movement of the optic within the capsular bag, early experience with patients receiving these IOL implants has shown that proper capsulectomy sizing is a challenging aspect of their surgical use. Openings that are too large allow anterior vaulting of the IOL, while openings that are too small lead to overly aggressive fibrotic response and interfere with implant placement. Small lens openings may also dampen the accommodating movement of the IOL. Therefore, IOL centration and congruence between the diameter of lens capsule opening in relation to the haptic optic transition zone is important in many applications.

[0009] Lens surgery — for cataract removal or for any type of IOL implantation — requires opening of the lens capsule. The current standard for making an opening in the anterior face of the lens capsule (anterior capsulectomy) is the continuous curvilinear capsulectomy (CCC), also known as capsulorhexis. Capsulorhexis is typically performed by making a single puncture in the center of the anterior capsule using a bent needle or a cystotome. The lower part of the tear is then pulled towards the 6 o'clock position using forceps. The anterior capsule is then bent over on itself to create a shearing force to extend the tear. The tear is continued along its intended circular path by pulling on the capsule with the forceps. Forceps are repositioned periodically to maintain the shearing force vector in the desired direction. This procedure requires substantial experience and when the capsule tears in unintended directions the surgeon is often required to abandon the intended capsulorhexis and resort to various salvaging procedures. Capsulorhexis as currently performed is a manually directed procedure where the size of the opening is estimated and does not always
result in the opening of a pre-specified size, as needed for implantation of accommodating IOLs.

[0010] Proper capsulectomy is critical as it provides the surgical opening for the remaining steps of the lens surgery. Complications in the form of unintentional capsule tears require modification of the surgical procedure and can be difficult to manage. The goals of CCC may include preserving the integrity of the capsular bag during phacoemulsification, preserving the integrity of the capsular bag for IOL implantation, and maintaining capsular integrity to confine haptics and prevent IOL subluxation. For implantation of IOLs, a standard currently used is for the diameter of the capsule opening to be 1.0 mm smaller than the diameter of the IOL to be implanted.

[0011] Given the drawback of existing manual treatment procedures for lens capsule surgery, improved surgery techniques and devices for performing them are needed.

SUMMARY

[0012] Embodiments of the invention provide microsurgery techniques and devices for performing lens capsule surgery. In various embodiments, an incision is made in the lens capsule of an eye using a device that includes a cutting instrument and a mechanism for moving the cutting instrument along a desired cutting path (e.g., a circle). This automated lens capsule surgery procedure may be useful in various applications, for example, for removing the lens during a cataract surgery and/or for implanting an intraocular lens. The microsurgical device removes many of the manual steps performed by surgeons in previous techniques, which in turn facilitates more precise cutting of the lens capsule. This enables surgical procedures that are relatively short in duration compared to previous surgical procedures, and it allows those procedures to be accomplished reliably with average surgical skill.

[0013] Embodiments of the invention include a method for performing microsurgery on an eye, e.g., for the treatment of medical conditions such as cataracts and/or for the implantation of an intraocular lens. Various devices and instruments may be used to perform procedures described herein. In one embodiment, a cutting instrument is disposed within an external sheath of a capsulectomy device. During an operation, a surgeon inserts the device into the eye via a incision in the cornea, places the cutting instrument in a position suitable for a desired incision in the lens capsule, and then uses the device to make the incision. The resulting incision in the lens capsule allows, for example, treatment of cataracts by removing affected portions of the lens and/or installing an intraocular lens in the lens capsule. The cutting process may be automated, where the device guides the cutting instrument along a
cutting path to make the incision. The device may also include various structural features to allow for proper alignment and positioning of the cutting instrument with respect to the tissue to be cut.

[0014] These techniques enable a surgeon to perform minimally invasive microsurgery on the lens capsule, which results in relatively low collateral damage to neighboring tissues as compared with previous treatment techniques. The techniques described herein also provide a high level of control of the positioning and orientation of the cutting instrument for precise location and sizing of the incision in the lens capsule.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIG. 1 is a cross sectional view of an eye, showing a cut in a lens capsule in accordance with an embodiment of the invention.

[0016] FIG. 2 is a perspective view of the eye of FIG. 1, showing an example cut in a lens capsule along a circular path.

[0017] FIGS. 3A and 3B are perspective and front views, respectively, of a cutting instrument, in accordance with one embodiment of the invention.

[0018] FIG. 4 is a perspective view of the cutting instrument of FIGS. 3A and 3B cutting through a surface of tissue.

[0019] FIG. 5 illustrates a knife, in accordance with another embodiment of the invention.

[0020] FIG. 6 illustrates the knife of FIG. 5 fixed temporarily to a block to facilitate assembly of the knife in the device, in accordance with an embodiment of the invention.

[0021] FIG. 7 illustrates a rectangular knife, in accordance with another embodiment of the invention.

[0022] FIGS. 8A and 8B illustrate a cutting instrument using the knife of FIG. 7, in accordance with an embodiment of the invention.

[0023] FIG. 9 illustrates a rectangular knife with rounded edges, in accordance with another embodiment of the invention.

[0024] FIG. 10 illustrates a knife with edges on two sides, in accordance with another embodiment of the invention.

[0025] FIG. 11 is a side view of a pivot arm and cutting instrument for a capsulotomy device, in accordance with an embodiment of the invention.

[0026] FIGS. 12A through 12C are cross sectional views of the pivot arm of FIG. 11, in accordance with different embodiments of the invention.
FIGS. 13A and 13B are bottom and side views, respectively, of a capsulectomy device for cutting a lens capsule, in accordance with an embodiment of the invention.

FIGS. 14 and 15 illustrate the insertion of the capsulectomy device into an eye, in accordance with an embodiment of the invention.

FIG. 16 is a cross sectional side view of an alternative embodiment of a capsulectomy device for cutting a lens capsule.

FIG. 17 is a perspective view of another embodiment of a capsulectomy device for cutting a lens capsule.

FIGS. 18A and 18B are perspective and side views, respectively, of another embodiment of a capsulectomy device for cutting a lens capsule.

FIG. 19 is a perspective view of an embodiment of a capsulectomy device for cutting a lens capsule that includes a suspension.

FIGS. 20A and 20B are perspective and bottom views of the suspension shown in FIG. 19.

FIG. 21A and 21B are top and side views of a capsulectomy device including a knife tip for making an incision in the cornea, in accordance with an embodiment of the invention.

The figures depict various embodiments of the present invention for purposes of illustration only. One skilled in the art will readily recognize from the following discussion that alternative embodiments of the structures and methods illustrated herein may be employed without departing from the principles of the invention described herein.

DETAILED DESCRIPTION

Embodiments of the invention are described herein in the context of a lens capsule surgery in which a portion of the anterior surface of a lens capsule is cut. This technique may be used for performing a medical treatment for cataracts in which all or a portion of a lens located within the lens capsule is removed from the eye. The procedure may also be used to create an access hole in the lens capsule through which to implant an artificial lens (e.g., an intraocular lens, or IOL) within the lens capsule. Moreover, the techniques and devices described herein may be useful tools for performing other medical procedures (such as corneal surgeries), which may or may not currently exist.

FIG. 1 shows a cross sectional view of an eye 1, such as a human eye, which includes a cornea 2 and a lens 3. The outer membrane of the lens is called the lens capsule. During a lens capsule surgery to remove and/or replace the lens 3, as described herein, the lens capsule is cut by a knife 4 or some other appropriate cutting instrument. Typically, the
path 5 of the cut made is roughly a circle, which corresponds to the shape of the lens 3. In addition, the edge of the cut is preferably smooth, not ragged or torn. Embodiments of the invention include a microfabricated knife 4 mounted on a mechanism that moves and guides the knife 4 along the desired cutting path 5. The mechanism may also maintain the knife 4 in an appropriate orientation for the desired cut. To form a circular path 5, for example, the knife 4 may rotate once while it revolves around the lens capsule, thereby maintaining the knife's cutting edge in the same direction as the cut is being made along the path 5.

[0038] FIG. 2 is a top perspective view of the eye 1, cornea 2, and lens 3. In this view, the knife 4 is shown in eight locations as it would travel along the circular path 5 during the cutting operation. The knife 4 is thus guided along a path 5 to achieve the desired cut through the lens capsule as needed for the operation. In one embodiment, during the cutting operation, the knife 4 just penetrates through the thickness of the lens capsule to cut it completely, but the knife 4 does not cut significantly past the lens capsule into the lens material. (The lens itself may be removed in a subsequent operation anyway, in which case it is not critical to avoid cutting it).

[0039] A variety of cutting instruments may be used to make the incision through the lens capsule. In one embodiment, any of the precise micro-incisions described herein can be made by a MEMS (microelectromechanical systems) microknife whose cutting edge has a radius of curvature on the order of nanometers. MEMS fabrication techniques can produce devices on the order of 100-200 microns in size and have micron scale features that are designed for various ophthalmic tissues of interest. Various methods for forming microsurgical cutting instruments that can be used with embodiments of the invention, including instruments having self-sharpening cutting edges, are disclosed in International Application No. PCT/US07/61701, filed February 6, 2007, and U.S. Provisional Application No. 60/837,401, filed August 11, 2007, each of which is incorporated by reference in its entirety.

[0040] Such ultra-sharp cutting edges create minimal tissue tearing, distortion, and other tissue trauma, which activate an undesirable wound healing response. Due to the small size of these surgical devices, minimally invasive procedures can be used for their introduction into the eye, minimizing any inflammatory responses while maintaining the ability to target specific tissue layers for removal.

[0041] The microknife may be mounted in a variety of ways on different types of structures, as desired for the design of the device. For example, FIG. 3A shows a perspective view of a knife 4 mounted on a support block 6. FIG. 3B shows a front view of the knife 4 and support block 6, e.g., looking from a direction in which the structure makes a cut. The
knife 4 is mounted to the support block 6 so that its edge extends a predetermined distance 7 past the edge of the support block 6. This distance 7 is the maximum depth of the cut, as the support block 6 acts as a cutting guide when the structure is drawn over tissue. FIG. 4 illustrates how the structure shown in FIGS. 3A and 3B can be used to make a cut through tissue.

[0042] FIG. 5 illustrates an alternative embodiment of a knife 4, which may be etched from single crystal silicon. In this embodiment, atomically sharp cutting edges 8 and point 9 allow for precise cutting and penetration of tissue. The knife 4 comprises a thin breakaway beam 10 that connects the knife 4 to a handle member 11. FIG. 6 illustrates how the knife 4 of FIG. 5 is connected to a handle block 12 (e.g., by gluing or otherwise fixing the handle member 11 of the knife 4 to the handle block 12). The handle block 12 is preferably large enough to facilitate the controlled handling of the knife 4. This makes the assembly of the knife to a support block 6 easier, e.g., when the knife 4 is glued or otherwise fixed to a support block 6. After the knife 4 has been fixed to a support block 6, the handle block 12 can be pulled away by breaking the breakaway beam 10, leaving just the knife 4 fixed to the support block 6.

[0043] FIG. 7 illustrates an embodiment of a rectangular knife 13, which may be etched from silicon. FIG. 8A shows a perspective view of the rectangular knife 13 mounted on a supporting block 14. The angles at which the knife 13 is mounted to the support block 6 may be selected based at least in part on the desired cutting force. A shallow angle of attack of the cutting edge 15 (i.e., where the cutting edge 15 of the knife 13 is closer to parallel with the surface being cut) reduces the force needed to cut through the tissue. FIG. 8B shows an end view of the knife 13 and block 14 in the direction that a cut may be made.

[0044] FIG. 9 illustrates another embodiment of a cutting instrument that can be used with embodiments of the device. In this embodiment, the cutting instrument comprises a rectangular knife 16 with rounded corners, which geometry may be useful in some applications. FIG. 10 illustrates another embodiment of a cutting instrument that comprises a knife with both sides of the cutting edge beveled and attached to a support block. It can thus be appreciated that any number of configurations can be used for the cutting instrument to achieve the desired surgical device. In certain embodiments used for lens capsule surgery, any microfabricated knife design that is small enough to fit in the space between the lens and cornea might be used. In typical embodiments, although not meant to be limiting, the width of the knife may range from about 5 microns to about 1000 microns; the thickness may range from about 5 microns to about 50 microns; and the length may range from about 100 microns to about 1000 microns.
As described herein, an automated cutting instrument can be used to guide a knife 4 to make the desired incision in the lens capsule, while the device itself is small enough to fit under the cornea 2 and over the lens. In one embodiment, this is achieved by attaching the knife 4 to a pivot arm 17. Moving the pivot arm 17 brings the knife 4 into a cutting position with respect to the lens capsule, and rotating the pivot arm 17 moves the knife 4 to result in a circular cut through the lens capsule. Embodiments of such a device are described herein.

FIG. 11 illustrates an embodiment of the pivot arm 17 with a knife 4 mounted to the pivot arm 17 by a support block 6. In one embodiment, the pivot arm 17 comprises a hollow rounded shaft 22 that is configured to be mounted in the device (e.g., as shown in FIGS. 13A and 13B). In particular, the pivot arm 17 is configured to enable deflecting the knife 4 downward (direction A in FIG. 11) as well as rotating the knife 4 in a circular path about an axis pointing upward (direction B in FIG. 11). Deflecting the knife 4 into a lens capsule causes the knife to be deployed into a cutting position, while rotating the knife 4 in the deployed state causes the knife to make a circular incision in the lens capsule.

The deflection of the knife 4 via the pivot arm 17 may be accomplished by pivoting the pivot arm 17 about an axis or by changing the shape of the pivot arm 17. In one embodiment, the shape of the pivot arm 17 is controlled by its internal pressure. Fluid can be made to enter or leave the arm through port 21, where the pivot arm 17 is otherwise sealed. As shown, the internal pressure of the pivot arm 17 is sufficiently low so that the arm 17 is in its relaxed position (e.g., for storage inside an external sheath). When the pressure in the pivot arm 17 is increased, the pivot arm 17 bends downward (in direction A) to the deployed position to push the knife 4 into the lens capsule membrane. This bending motion may be accomplished by constructing the pivot arm 17 of a relatively rigid bottom surface 18 that does not stretch significantly under tension and a relatively flexible sides and upper surface 19 that do stretch under tension. The tension in the pivot arm 17 is caused by the internal pressure in the arm 17, which can be increased by increasing the pressure at port 21. The combination of stretching deformation of the sides and upper surface 19 and very little stretching on the bottom surface 18 causes the pivot arm 17 to bend downward as internal pressure is increased.

FIGS. 12A through 12C illustrate embodiments of the pivot arm 17 configured to deflect in response to an increased internal pressure. For example, FIG. 12A shows a transverse cross section through an embodiment of the pivot arm 17 having sides and a top surface 70 made from a low stiffness material (such as silicone rubber) and a bottom surface 72 made from a high stiffness material (such as stainless steel). FIG. 12B shows another embodiment of the pivot arm 17, where a rigid bottom member 73 is molded into a flexible
top member 71. FIG. 12C shows another embodiment of the pivot arm 17, which comprises a rigid bottom member 74 fully enclosed within a flexible tubing 75. It can be appreciated that many alternative embodiments are possible, depending on the design goals and requirements.

[0049] FIGS. 13A and 13B are bottom and side views, respectively, of a capsulotomy device for cutting a lens capsule. The device comprises an external sheath 28, which in one embodiment has an oblique distal opening. The oblique distal opening may serve several functions. In one embodiment, the external sheath 28 is rigid, and the oblique opening provides a sharp point for piercing the cornea of an eye to provide access to the lens capsule. In addition, the oblique distal opening results in a shape that avoids touching the lens with the external sheath 28 when entering from a transverse angle (see, e.g., FIGS. 14 and 15), and it may provide a necessary clearance to allow a full rotation of the pivot arm 17.

[0050] The device further comprises a sealed tube 25 that is filled with fluid 30 that transmits fluid pressure through orifice 21 to the tubular arm 17. This action controls the deflection of the pivot arm 17, as explained above. The device may include a seal 26 to prevent fluid from leaking out of the system.

[0051] The shaft 22 of the pivot arm 17 is bonded to a ratchet wheel 23, so that the pivot arm 17 rotates around the wheel’s axis when the wheel 23 turns. Turning the ratchet wheel 23 thus causes the knife 4 to move around in a circular path over the lens capsule. To turn the ratchet wheel 23, the device includes a rod 24 that can be moved back and forth (e.g., by a solenoid) to press on individual teeth of the ratchet wheel 23. Accordingly, each cycle of the rod 24 pushes the teeth and rotates the ratchet wheel 23 a certain amount. The device may further include a pawl 29 biased against the teeth of the ratchet wheel 23 to prevent the ratchet wheel 23 from rotating in the wrong direction.

[0052] FIG. 16 is an alternative embodiment of the capsulotomy device, which uses solenoids to control the deflection and rotation of the pivot arm 17. In this embodiment, the external sheath 28 is bonded to the base of the sealed tube 25. A first solenoid 50 moves the rod 24 back and forth to rotate the ratchet wheel 23. A second solenoid 51 attached to a rod 52 is controllable to push the rod 52 against diaphragm 53. This pushing action tends to increase the hydrostatic pressure of the fluid 30 inside the sealed tube 25. A housing 60 mounts to a micromanipulator or positioning stages appropriate for the controlled motions.

[0053] As mentioned, FIGS. 14 and 15 illustrate the entry of the capsulotomy device into an eye to cut a portion from the lens capsule. In operation, once the cornea has been penetrated by the external sheath 28, the external sheath 28 is held steady with respect to the cornea without further motion. The pivot arm 17 is stowed within the external sheath 28 and
in its undeployed (e.g., low pressure) state. At this point, sealed tube 25 is slid forward with respect to the external sheath 28 so that the knife mechanism that it carries is moved out of the external sheath 28. The device is positioned so that the shaft 22 of the pivot arm 17 is located substantially over the center of the lens 3. A surgeon may align the position and orientation (such as the tilt angle) of the pivot arm 17 so that a circular path created by a rotation of the pivot arm 17 is aligned above and concentric with the lens. The alignment of the device may be performed manually by the surgeon and/or automatically by a computer vision system that controls the positioning of the device.

[0054] When the device is in place over the lens, the pivot arm 17 carrying the knife 4 is deployed into a cutting position. As described above, in one embodiment the hydrostatic pressure of fluid 30 is increased (e.g., by a solenoid plunger pushing on a membrane) until the pivot arm 17 is deflected sufficiently to push the knife 4 into the lens capsule. Because the support block 6 prevents the knife 4 from cutting into the tissue past a predetermined depth, the pivot arm 17 may be deflected using a force beyond that required to cause the full deployment of the knife 4 into the tissue. This additional force causes the knife 4 to be biased against the lens capsule, which provides a slight tolerance for minor misalignments when the knife 4 is rotated around the lens capsule.

[0055] When deployed, the knife can then be moved in a circular motion to cause a precise incision in the lens capsule. In the embodiment shown, this rotation can be achieved by moving the rod 24 back and forth repeatedly. This action causes the rod 24 to press against the teeth of the ratchet wheel 23 successively, which makes the wheel 23 rotate. The pivot arm 17, connected to the wheel 23, likewise swings around in a circular motion, which causes the knife 4 to make a circular incision into the lens capsule. By positioning the shaft 22 of the pivot arm 17 correctly over the lens, the height of the knife 4 can remain constant as it moves through the cutting path. In one embodiment, however, the height of the knife 4 may be adjusted if needed by adjusting the fluid pressure that controls deflection of the pivot arm 17.

[0056] Once the lens capsule membrane has been cut along the desired circular path, that piece of capsule membrane can be removed. One technique is to grip that tissue with microtweezers, peel it off of the lens, and withdraw it through the existing incision in the cornea. In another embodiment, the capsulectomy device includes a gripping mechanism (such as tweezers that can be actuated from the proximate end of the capsulectomy device) to grip and remove the released piece of lens capsule membrane.

[0057] FIG. 17 illustrates an embodiment of the capsulectomy device that can be inserted at any angle, such as at angles other than horizontal (or, parallel to the plane of the lens). For
example, if the device does not enter the cornea horizontally, a surgeon may have to control an additional parameter (e.g., tilt of the cutting instrument). In this embodiment, the device further comprises a gimbal 104 that couples a ratchet wheel 103 and a pivot arm 106 to the tube 101. The gimbal 104 allows the pivot arm 106 to be rotated with respect to the tube 101, which allows an operator to make the shaft 110 of the pivot arm 106 perpendicular to the plane of the lens even when the device is inserted into the eye at an angle to the lens. This embodiment of the device thus enables the device to be adjusted before the cutting occurs so that the circular cutting path to be made by the knife 4 is aligned with the lens capsule to be cut.

[0058] To enable adjustment of the tilt angle of the cutting path, the shaft 110 is attached to a tilt adjustment bar 105 above the gimbal 104. The tilt adjustment can then be achieved by pushing or pulling the tilt adjustment bar 105, which causes the pivot arm 106 to tilt about the axis of the gimbal 104. As with the embodiments described above, the device can be actuated by moving a bar 102 back and forth (e.g., by a solenoid) to cause a ratchet wheel 103 to rotate, which in turn rotates the pivot arm 106 and knife 4 about the shaft 110 to make the desired incision. In one embodiment, the tube 101 can also be translated and rotated along its longitudinal axis, with respect to the external sheath 100, which further assists in positioning the knife 4.

[0059] FIGS. 18A and 18B show an embodiment of a capsulotomy device for which the knife 4 is mounted directly on a rotating shaft 200. In this embodiment, the surgeon moves the knife 4 around a desired cutting path while the device facilitates proper alignment of the knife 4 during the cutting operation. The device includes a gimbal 202, as described above, allowing rotation of the cutting instrument to occur about the axis of the gimbal 202 as well as about the longitudinal axis of the support tube 204. These motions may be used to set the orientation of the knife 4 with respect to the lens when the device is placed inside an eye. For example, the location of the knife 4 may be controlled by sliding the support tube 204 in or out within the external sheath 206 and by adjusting the pitch and yaw of the external sheath 206. The tilt angle of the knife 4 can be adjusted by moving the rod 208 to tilt the rotating shaft 200 about the axis of the gimbal 202. The ratchet wheel 212 can be turned in one direction by moving the bar 210 back and forth, as needed, to orient the angular direction of the knife 4. In operation, a surgeon would guide the knife 4 in a path (e.g., a circular) over the lens capsule, and the capsulotomy device would orient and position the knife 4 properly as it is moved along the cutting path. Each of the adjustments may be performed manually by the surgeon, or automatically by a computer vision system coupled to control one or more motorized stages.
In one embodiment, the capsulectomy device further comprises a passive suspension to help align the knife 4 to the tissue surface being cut and to allow for a small amount of excess force or deflection applied on the knife 4 during the cutting step. FIG. 19 show an embodiment of the device that includes a suspension 300 inserted into an eye, and FIGS. 20A and 20B further illustrate an embodiment of the suspension 300 mounted on a rotatable shaft 301.

In this embodiment, the location of the knife 4 is controlled by sliding a support tube 302 within an external sheath 303, and also by adjusting the pitch and yaw of the external sheath 303 to move the knife along the desired circular cutting path. In use, as the knife 4 is moved towards the lens capsule to be cut, one of the three contact balls 305 on the suspension 300 will contact the lens capsule. The bending stiffness of the suspension 300 is relatively low to avoid transferring an unacceptable amount of pressure to the lens capsule. When the suspension 300 is pressed against the lens, the contact force between the ball and the lens will rotate the platform 307 of the suspension 300 so that all three contact balls 305 are in contact with the lens capsule. Since the knife 4 is mounted perpendicular to the platform 307, the knife 4 will be appropriately tilted to address the lens capsule (e.g., perpendicular to the surface of the lens capsule).

In this way, the suspension 300 helps to align the orientation of the knife 4 as well as provide for some amount of tolerance in the force applied to the knife 4 during the cutting operation. The suspension 300 is relatively stiff to in-plane forces, so no significant deflection should occur due to shear forces during cutting. However, the suspension has very low stiffness for pitch and roll moments and for normal forces, so the three contact balls 305 can stay in contact with the surface of the lens capsule during cutting, and the knife 4 can be maintained approximately perpendicular to the surface at the point of cutting.

As the knife 4 is moved around the cutting path, it is rotated by the ratchet wheel 23 being driven by the rod 24. The suspension 300 is attached to the rotatable shaft 301 so it rotates with the shaft. The knife 4 and support block 6 are attached to the suspension 300, so they also rotate with the shaft. Although described for the cutting operation shown in FIG. 19 (i.e., where a surgeon guides the knife 4 along a cutting path), the suspension 300 can be used in any other embodiments of the capsulectomy device described herein (such as where the device automatically guides the knife 4 in a circular cutting path).

FIGS. 21A and 21B illustrate another embodiment in which the capsulectomy device comprises a knife tip 410, which may be used to make a slit incision in the cornea to allow the capsulectomy device to be passed through the cornea. As illustrated, the knife tip 410 is attached to the external sheath 400, within which the inner tubing 405 and the other
associated parts of the capsulectomy device (not shown here) are slidably and rotatably disposed. The knife tip 410, in one embodiment, is spear shaped, or otherwise shaped like existing or known knives used for making corneal incisions. The contours of the knife tip 410 and the external sheath 400 blend smoothly so the cornea tissue does not snag or tear. [0065] In use, a surgeon advances the capsulectomy device toward an eye and then makes an incision into the cornea using the knife tip 410. To make the incision in the cornea, the surgeon simply pushes the knife tip 410 through the cornea. The incision in the cornea may be about 3 mm wide, where the external sheath 400 is less than 3 mm in diameter. With the incision in the cornea made, the surgeon inserts the capsulectomy device into the eye and slides the inner tubing 405 to deploy the cutting element into a cutting position next to the lens capsule. The surgeon then makes an incision in the lens capsule according to any of the methods described herein. Once the incision in the lens capsule is made, the surgeon withdraws the capsulectomy device from the eye. Beneficially, since the incision in the cornea was made with the knife tip 410, upon removal of the capsulectomy device the cornea reseals without the need for sutures. [0066] Embodiments of the invention have been described herein in the context of lens capsule surgery. However, it will be appreciated that certain of the techniques and devices described may be used to achieve the same cuts or other microsurgical effects for treatment of other medical conditions. Although the dimensions of the device have been chosen in order to provide optimal use within the eye and for lens capsule surgery, the fundamental device design will have utility for other types of microsurgery in the eye or elsewhere in the body. The device also includes other non-medical uses, where access to small spaces must be combined with precisely controlled cutting, sampling, or other modifications of the accessed structures. [0067] The foregoing description of the embodiments of the invention has been presented for the purpose of illustration; it is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Persons skilled in the relevant art can appreciate that many modifications and variations are possible in light of the above disclosure. The language used in the specification has been principally selected for readability and instructional purposes, and it may not have been selected to delineate or circumscribe the inventive subject matter. It is therefore intended that the scope of the invention be limited not by this detailed description, but rather by any claims that issue on an application based hereon. Accordingly, the disclosure of the embodiments of the invention is intended to be illustrative, but not limiting, of the scope of the invention, which is set forth in the following claims.
What is claimed is:

1. A method for performing microsurgery on an eye, the method comprising:
   - moving a capsulectomy device to a position proximate to a lens capsule of the eye, the capsulectomy device comprising an external sheath and a cutting instrument mounted therein;
   - deploying the cutting instrument from the external sheath into a cutting position on the lens capsule;
   - moving the cutting instrument in a path over a surface of the lens capsule to create an incision in the lens capsule; and
   - removing the capsulectomy device from the eye.

2. The method of claim 1, wherein the cutting instrument comprises a microknife.

3. The method of claim 2, wherein the microknife comprises a cutting edge with a radius of curvature that is less than 50 Angstroms.

4. The method of claim 2, wherein the microknife comprises a cutting edge that is self-sharpening.

5. The method of claim 2, wherein the microknife comprises a body that comprises single-crystal silicon and a cutting edge that comprises a film of silicon nitride.

6. The method of claim 1, wherein moving the capsulectomy device to the position proximate to the lens capsule of the eye comprises:
   - making an incision into a cornea of the eye; and
   - feeding the capsulectomy device through the incision in the cornea.

7. The method of claim 6, wherein the incision in the cornea is made using a knife tip attached to the external sheath of the capsulectomy device.

8. The method of claim 1, wherein deploying the cutting instrument into the cutting position comprises:
   - moving the cutting instrument through a distal lumen of the external sheath; and
   - deflecting the cutting instrument towards the surface of the lens capsule.

9. The method of claim 1, wherein the cutting instrument is coupled to the capsulectomy device by a pivot arm filled with a fluid, and deploying the cutting instrument
into the cutting position comprises changing a pressure of the fluid within the pivot arm to cause the pivot arm to deflect toward the lens capsule.

10. The method of claim 1, wherein moving the cutting instrument in the path over the surface of the lens capsule comprises:
    rotating the cutting instrument around an axis substantially perpendicular to the surface of the lens capsule while the cutting instrument is deployed.

11. The method of claim 1, wherein the cutting instrument is coupled to a ratchet wheel with a plurality of teeth, and rotating the cutting instrument comprises repeatedly pressing against the teeth in a substantially linear motion using an actuating rod within the capsulectomy device.

12. The method of claim 11, wherein the actuating rod is driven by a solenoid.

13. The method of claim 1, wherein moving the capsulectomy device to a position proximate to the lens capsule of the eye comprises forming an incision through a side of a cornea of the eye by piercing the cornea with the external sheath.

14. The method of claim 1, further comprising:
    before deploying the cutting instrument, aligning the cutting instrument with the lens capsule by translating and tilting the cutting instrument so that the path cut by the cutting instrument is substantially centered over the lens capsule.

15. The method of claim 1, wherein the cutting instrument is coupled to the capsulectomy device by a compliant suspension while the cutting instrument is moved over the surface of the lens capsule.

16. The method of claim 1, further comprising:
    removing a portion of the lens capsule using the cutting instrument.

17. A capsulectomy device comprising:
    an external sheath;
    a pivot arm mounted within the external sheath;
    a cutting instrument attached to a distal end of the pivot arm;
    a deployment actuator configured to deflect the distal end of the pivot arm into a deployed cutting position; and
a cutting actuator configured to rotate the distal end of the pivot arm about a center axis to form a circular cutting path over a surface.

18. The capsulectomy device of claim 17, wherein the cutting instrument comprises a microknife.

19. The capsulectomy device of claim 18, wherein the microknife comprises a cutting edge with a radius of curvature that is less than 50 Angstroms.

20. The capsulectomy device of claim 18, wherein the microknife comprises a cutting edge that is self-sharpening.

21. The capsulectomy device of claim 18, wherein the microknife comprises a body that comprises single-crystal silicon and a cutting edge that comprises a film of silicon nitride.

22. The capsulectomy device of claim 17, wherein the cutting instrument is mounted to a support block so that the cutting instrument extends from the support block by a predefined maximum cutting depth.

23. The capsulectomy device of claim 17, wherein the pivot arm is filled with a fluid, and the pivot arm is configured to deflect when a pressure of the fluid within the pivot arm is changed.

24. The capsulectomy device of claim 17, wherein the cutting actuator comprises a ratchet wheel with a plurality of teeth, and an actuating rod configured to rotate the ratchet wheel by repeatedly pressing against the teeth in a substantially linear motion

25. The capsulectomy device of claim 24, wherein the actuating rod is coupled to a solenoid for driving the actuating rod.

26. The capsulectomy device of claim 24, wherein the pivot arm is coupled to the external sheath by a gimbal for allowing tilting alignment of the pivot arm with respect to the external sheath.

27. The capsulectomy device of claim 24, further comprising:
   a compliant suspension coupled between the cutting instrument and the external sheath.

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28. The capsulectomy device of claim 24, further comprising:
   a knife tip coupled to a distal end of the external sheath and shaped to make an
   incision in a cornea.

29. A device for performing microsurgery on an eye, the device comprising:
   an external sheath including a microknife that is deployable into a cutting
   position;
   a means for deploying the microknife into the cutting position for a lens capsule
   of the eye; and
   a means for moving the microknife in a cutting path along a surface of the lens
   capsule to cause cutting of an incision in the lens capsule.

30. A device for performing microsurgery on an eye, the device comprising:
   an external sheath having a distal opening;
   a microknife; and
   a means for actuating the microknife to make a circular cut from a distal end of
   the external sheath, the means for actuating the microknife coupled to the
   microknife and mounted within the external sheath.
A CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 9/00 (2008.04)
USPC - 606/166

According to International Patent Classification (IPC) or to both national classification and IPC

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 9/00 (2008 04)
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
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C DOCUMENTS CONSIDERED TO BE RELEVANT

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Date of the actual completion of the international search
25 April 2008

Date of mailing of the international search report
16 MAY 2008

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