US 20130281817A1

(19) **United States**

(12) **Patent Application Publication**

Schaller et al.

(10) **Pub. No.: US 2013/0281817 A1**

(43) **Pub. Date: Oct. 24, 2013**

(54) **DIRECT VISUALIZATION SYSTEM FOR GLAUCOMA TREATMENT**

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(21) Appl. No.: **13/865,927**

(22) Filed: **Apr. 18, 2013**

Related U.S. Application Data

(60) Provisional application No. 61/635,471, filed on Apr. 19, 2012.

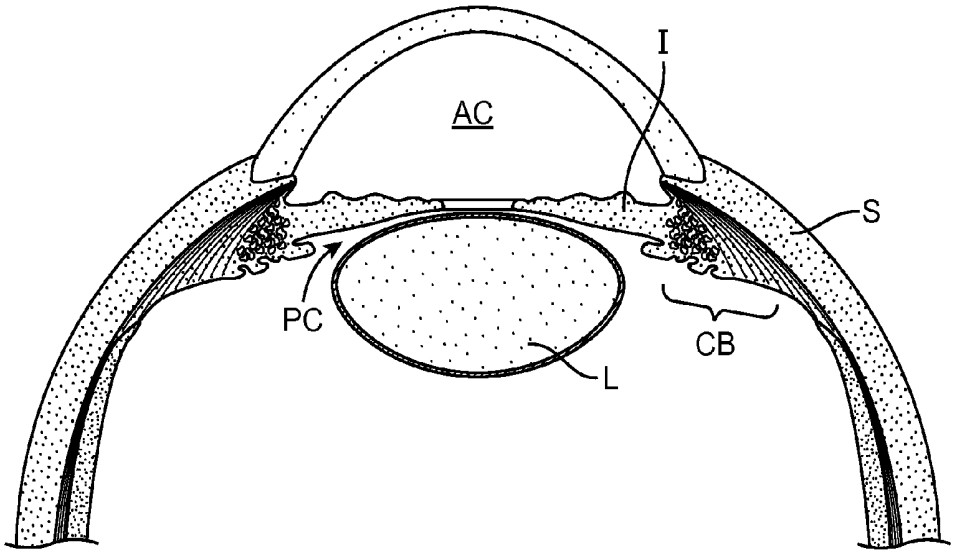
Publication Classification

(51) **Int. Cl.**
A61B 3/10 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 3/1005*** (2013.01)
USPC **600/398**; 600/558; 600/549; 600/425; 600/407; 600/473

(57) **ABSTRACT**

A direct visualization (DV) system and methods for measuring one or more anatomical features of the eye, including a depth of the iridocorneal angle of the eye. The DV system can include a wire extending distally from a handle with the wire having one or more indicators for measuring anatomical features of the eye. The DV system can be deployed into the eye and used with minimal trauma to ocular tissues. Furthermore, the DV system can be used independently or alongside other ocular instruments, such as instruments having indicators corresponding to the DV system for correctly implanting ocular implants without the use of a gonio lens.



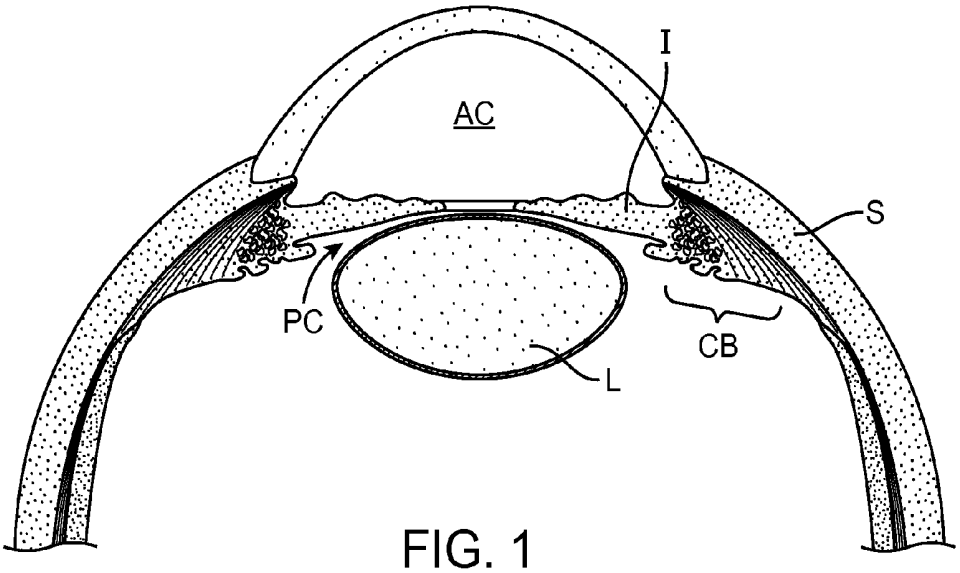


FIG. 1

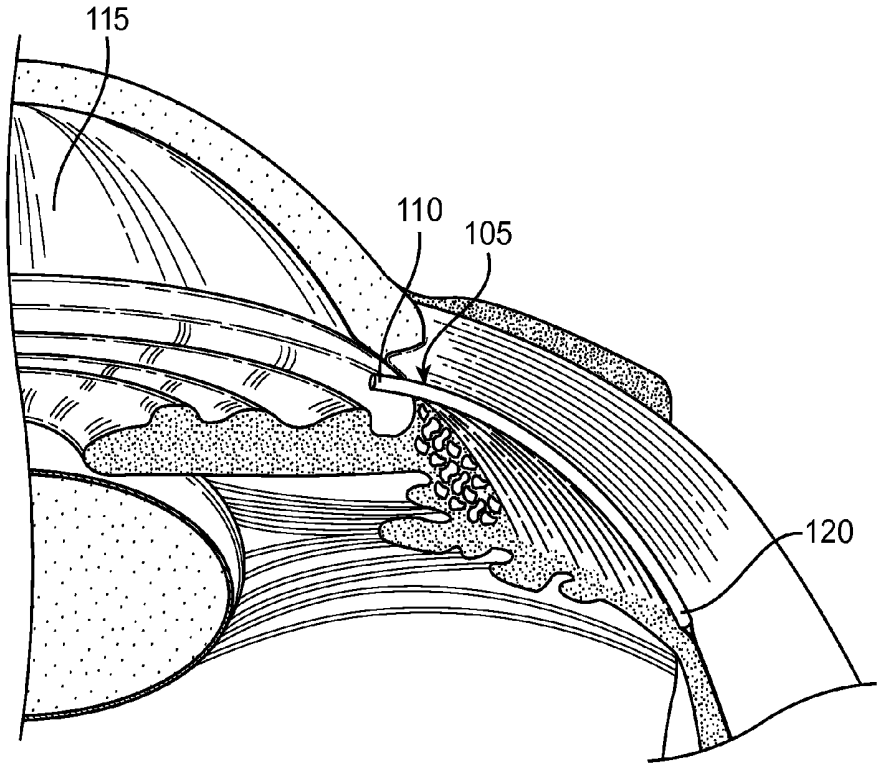


FIG. 2

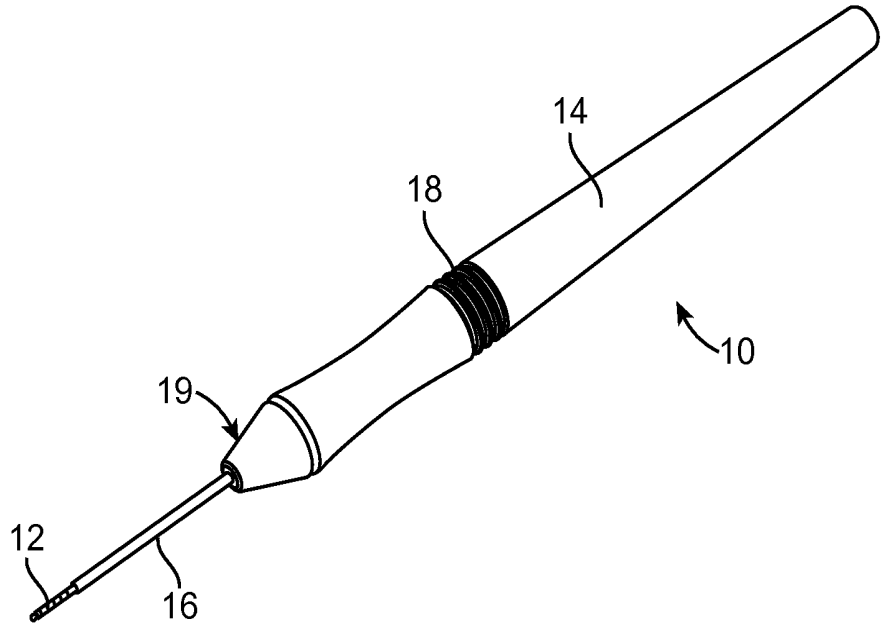


FIG. 3

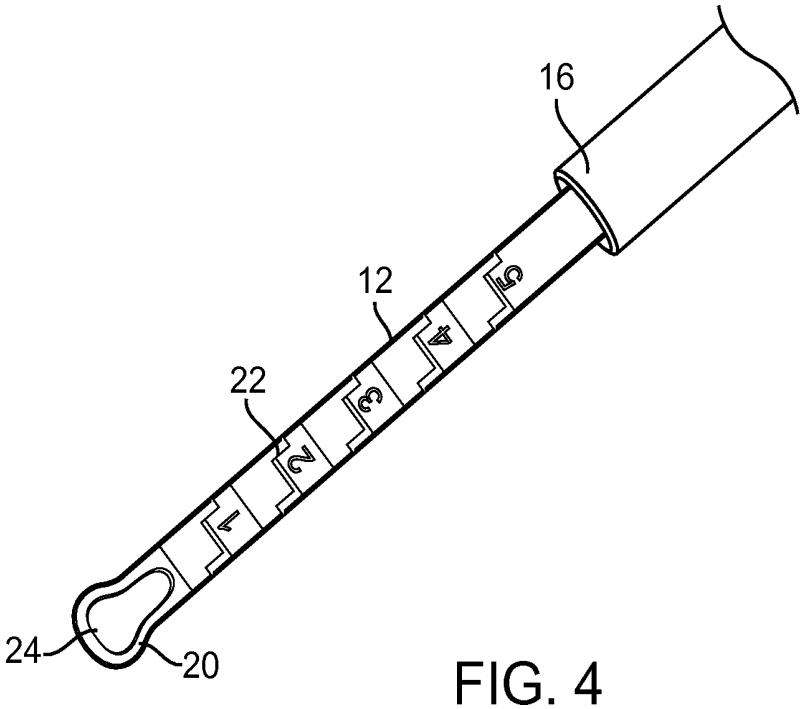


FIG. 4

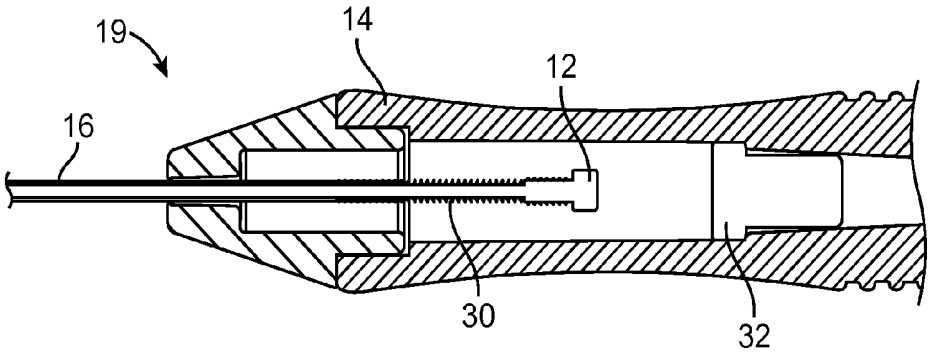


FIG. 5

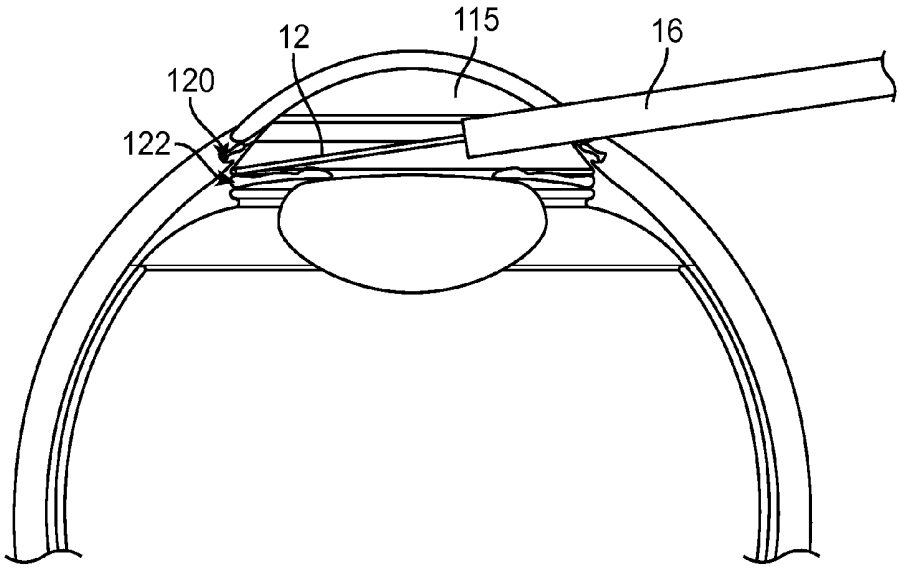


FIG. 6

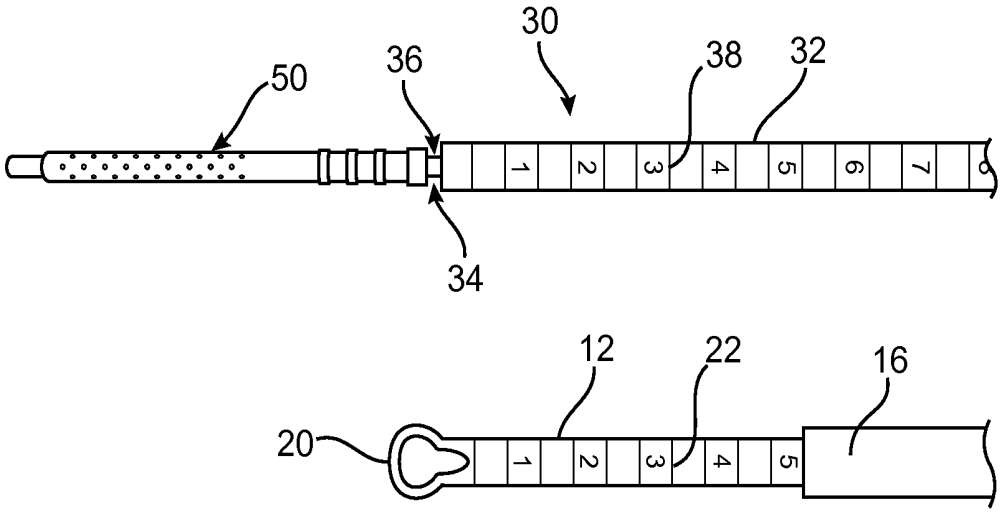


FIG. 7

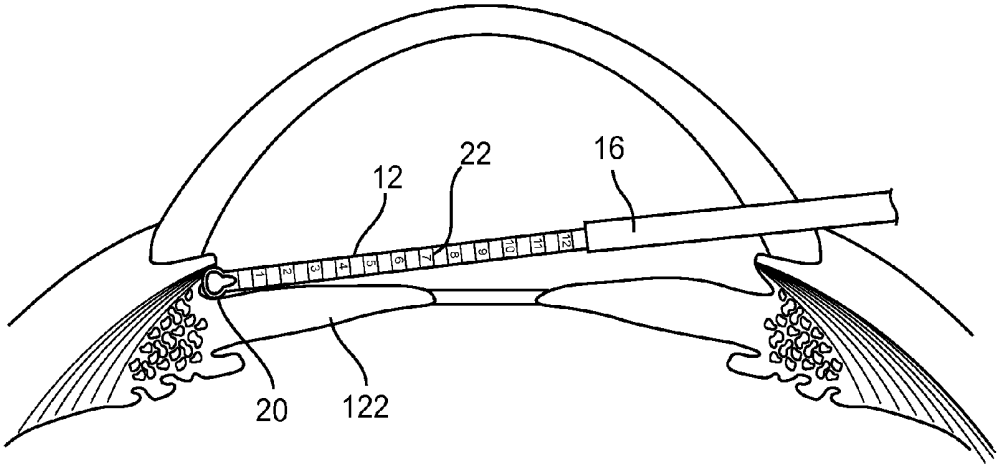


FIG. 8

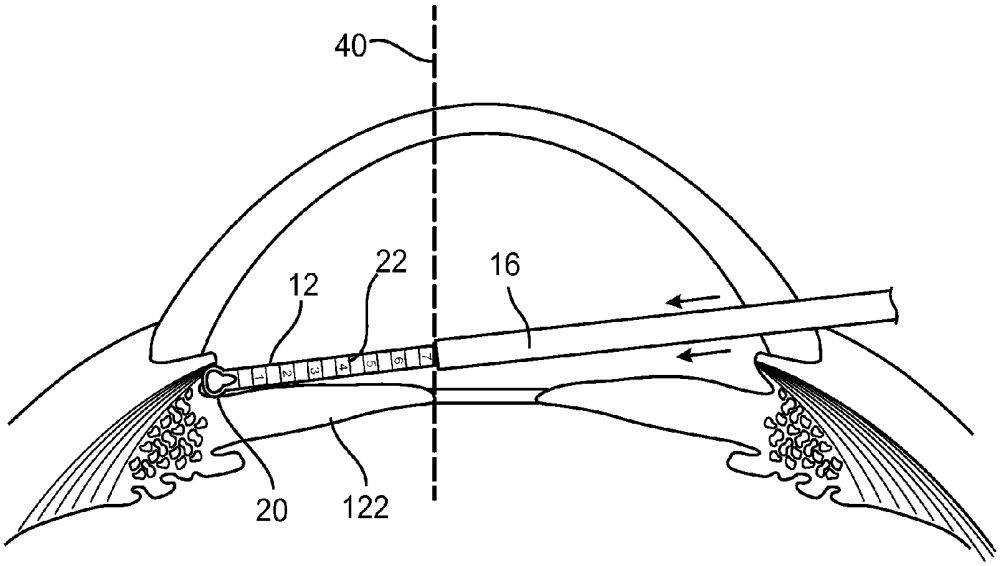


FIG. 9

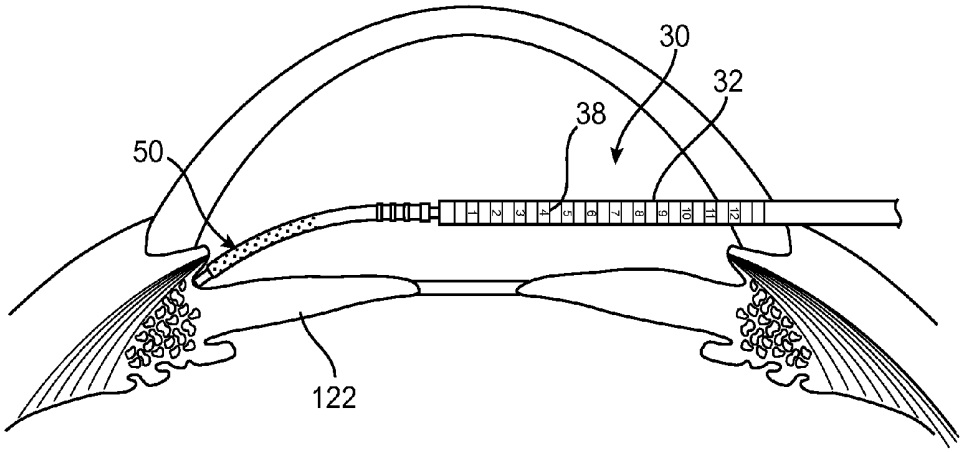


FIG. 10

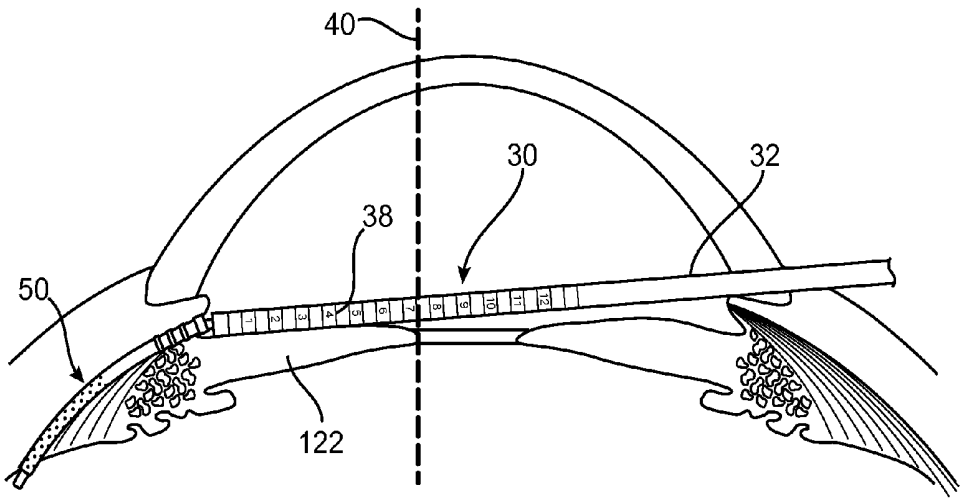


FIG. 11

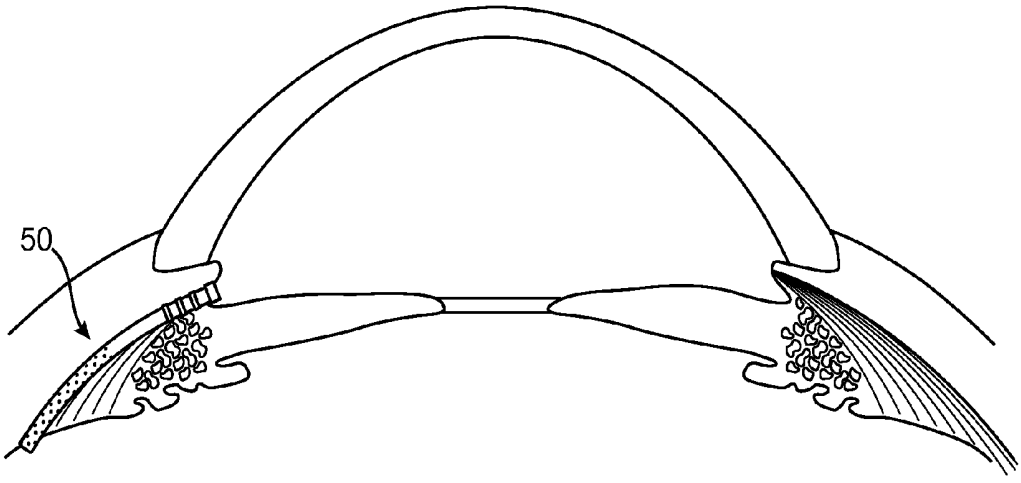


FIG. 12

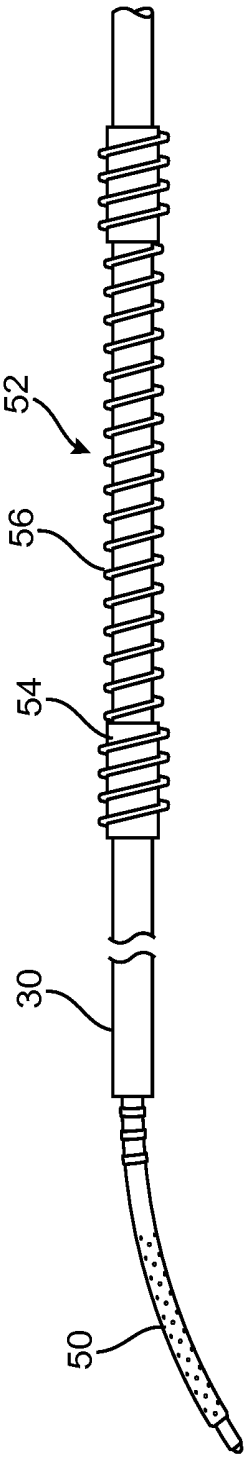


FIG. 13A

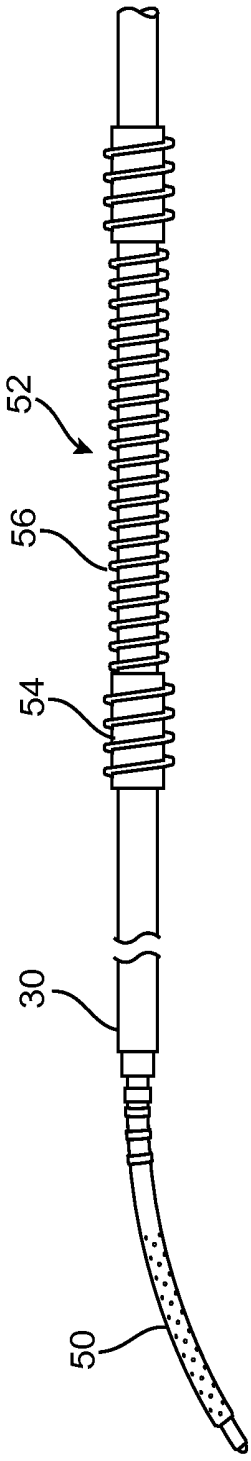


FIG. 13B

DIRECT VISUALIZATION SYSTEM FOR GLAUCOMA TREATMENT

REFERENCE TO PRIORITY DOCUMENT

[0001] This application claims priority benefit under 35 U.S.C. §119(e) of co-pending U.S. Provisional Patent Application Ser. No. 61/635,471, filed Apr. 19, 2012, and entitled "Direct Visualization System for Glaucoma Treatment." The priority of the filing date of Apr. 19, 2012 is hereby claimed, and the disclosure of the provisional patent application is hereby incorporated by reference in its entirety.

BACKGROUND

[0002] The mechanisms that cause glaucoma are not completely known. It is known that glaucoma results in abnormally high pressure in the eye, which leads to optic nerve damage. Over time, the increased pressure can cause damage to the optic nerve, which can lead to blindness. Treatment strategies have focused on keeping the intraocular pressure down in order to preserve as much vision as possible over the remainder of the patient's life.

[0003] Pursuant to such strategies, one or more implants can be delivered into the eye for shunting fluid out of the anterior chamber in order to regulate pressure in the eye. Accurate placement of an implant in the angle of the eye is critical for the targeted effect of reducing intraocular pressure (IOP). Placing an implant too distally into the eye, such as too distally into the supraciliary space, may leave no portion of the implant remaining in the anterior chamber. This may inhibit aqueous outflow, as the fluid will not have a direct communication with the flow target location if there is no opening to the anterior chamber.

[0004] Conversely if the implant is placed too proximally in the supraciliary space such that a significant portion of the implant remains in the anterior chamber, damage to the corneal endothelium may result from implants that protrude upwards and touch the cornea. Implants placed too proximally may also touch the iris resulting in increased amounts of pigment dispersion in the eye, which can increase outflow resistance and intraocular pressure by clogging the trabecular meshwork. Correct placement of the implant is desired for a safety and a successful surgical outcome.

[0005] Many surgical procedures in ophthalmology require visualization of the iridocorneal angle (sometimes referred to as "the angle") of the eye. Current techniques include endoscopy and gonioscopy, though both require clinicians to use at least two hands during surgery. This can be cumbersome for the surgeon. Surgical procedures that primarily involve the measurement of the depth of the angle, such as many minimally invasive glaucoma surgeries (MIGS), may benefit from a simplified method of placing implants in the angle of the eye particularly with respect to visualization of the iridocorneal angle.

[0006] Proper placement of ophthalmic implants in the angle of the eye can be critical to implant performance. Current visualization techniques may provide satisfactory angle visualization, although current techniques suffer from a multitude of issues. Gonioscopy requires the clinician to use an additional hand during surgery and the gonio lens must be placed directly on the cornea, increasing risk of infection and corneal damage. The surgical microscope used during gonioscopy may also require adjustment for proper angle visualization, which adds to surgery time. Endoscopy also requires the clinician to use an additional hand during surgery and a may involve a larger or second limbal incision for access to the anterior chamber, increasing the potential for surgical complications such as hypotony. Additionally, these techniques are not intuitive to many physicians and require significant training.

[0007] In view of the foregoing, there is a need for direct visualization (DV) systems which are configured and adapted for measuring a depth of the iridocorneal angle of the eye. In addition, there is a need for the DV systems to deploy into the eye and be used with minimal trauma to ocular tissues.

SUMMARY

[0008] There is a need for improved systems, devices and methods for the treatment of diseases, such as glaucoma.

[0009] In a first embodiment, disclosed herein is a device for measuring anatomical features of an eye. The device can include a handle and a wire including a contact tip at a distal end of the wire. In addition, the wire can extend out of the handle and can be configured to be inserted ab-internally and positioned against ocular tissue in the eye. The wire can include at least one indicator for assisting in measuring at least one anatomical feature of the eye.

[0010] Also described herein are methods of measuring anatomical features of an eye and implanting an ocular implant. In an embodiment, disclosed is a method including forming an incision in the cornea of the eye into an anterior chamber of the eye. The method can also include introducing through the incision a distal end of a device for measuring at least one anatomical feature of the eye. The device can comprise a handle with a wire extending out of a distal end of the handle. In addition, a distal end of the wire can be configured to be pressed against ocular tissue in the eye. The wire can include at least one indicator for measuring at least one anatomical feature of the eye. The method can also include passing the distal end of the wire through the incision and across the anterior chamber of the eye and positioning the distal end of the wire against ocular tissue below the scleral spur and above the iris. The method can also include measuring at least one anatomical feature of the eye by identifying one or more indicators along a length of the wire relative to one or more anatomical features.

[0011] Other features and advantages should be apparent from the following description of various embodiments, which illustrate, by way of example, the principles of the described subject matter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] These and other aspects will now be described in detail with reference to the following drawings.

[0013] FIG. **1** shows an example cross-sectional view of a portion of the human eye.

[0014] FIG. **2** shows and an example partial cross-sectional view of the eye showing a part of the anterior and posterior chambers of the eye and an ocular implant implanted in the eye.

[0015] FIG. **3** shows a perspective view of an embodiment of a direct visualization (DV) system.

[0016] FIG. **4** shows an enlarged view of a distal end of the DV system including a part of a DV wire **12** and stopper tube **16**.

[0017] FIG. **5** shows a cross-sectional view of a portion of the DV system shown in FIG. **3**.

[0018] FIG. **6** shows the distal end of the DV system shown in FIG. **3** inserted into an eye.

[0019] FIG. **7** shows the DV wire of the DV system aligned alongside an implant delivery applier showing the corresponding indicators.

[0020] FIG. **8** shows the DV wire inserted into the eye for measuring anatomical features of the eye.

[0021] FIG. **9** shows the distal end of the DV wire abutting the base of the angle of the eye and the stopper tube in an advanced position along the DV wire.

[0022] FIG. **10** shows the implant delivery applier implanting an ocular implant through the same incision the DV system used in FIGS. **8** and **9**.

[0023] FIG. **11** shows the indicators on the implant delivery applier being used to determine the proper insertion depth of the implant.

[0024] FIG. **12** shows the implant in its implanted state and providing fluid communication between the anterior chamber and the suprachoroidal or supraciliary space.

[0025] FIG. **13**A shows an embodiment of the implant delivery applier having a feedback mechanism.

[0026] FIG. **13**B shows the feedback mechanism of the implant delivery applier shown in FIG. **13**A in a retracted state.

[0027] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0028] Disclosed is a direct visualization (DV) system configured and adapted for measuring a depth of the iridocorneal angle of the eye. The system is configured to be deployed into the eye and used with minimal trauma to ocular tissues. The system includes a direct visualization (DV) wire with indicators, such as numbers or patterns that indicate or represent known distances. In use, the DV wire can be placed directly against the base of the iridocorneal angle allowing for depth measurements. The system can further include a spring connected to the DV wire. In addition, the spring can have a very low spring constant. The spring can allow the DV wire to abut against the tissues in the eye with low contact force. Such a system may be used independently or alongside other ocular instruments, such as instruments having indicators corresponding to the DV system for correctly implanting ocular implants without the use of a gonio lens.

[0029] The disclosed system provides reduced or minimal risk of damaging ocular tissue and has several advantageous qualities over current visualization techniques. The disclosed system requires only one limbal incision, which may be on the scale of 1.0-2.5 mm. For cases where the DV system is used alongside another tool with matching calibrated depth measuring features, the same limbal incision may be used for both the DV system and the additional tool. Once inside the anterior chamber the DV system can interact solely with the aqueous humor and tissues comprising the angle of the eye.

[0030] FIG. **1** is a cross-sectional view of a portion of the human eye. The eye is generally spherical and is covered on the outside by the sclera S. The retina lines the inside posterior half of the eye. The retina registers the light and sends signals to the brain via the optic nerve. The bulk of the eye is filled and supported by the vitreous body, a clear, jelly-like substance. The elastic lens L is located near the front of the eye. The lens L provides adjustment of focus and is suspended within a capsular bag from the ciliary body CB, which contains the muscles that change the focal length of the lens. A volume in front of the lens L is divided into two by the iris I, which controls the aperture of the lens and the amount of light striking the retina. The pupil is a hole in the center of the iris I through which light passes. The volume between the iris I and the lens L is the posterior chamber PC. The volume between the iris I and the cornea is the anterior chamber AC. Both chambers are filled with a clear liquid known as aqueous humor.

[0031] The ciliary body CB continuously forms aqueous humor in the posterior chamber PC by secretion from the blood vessels. The aqueous humor flows around the lens L and iris I into the anterior chamber and exits the eye through the trabecular meshwork, a sieve-like structure situated at the corner of the iris I and the wall of the eye (the corner is known as the iridocorneal angle). Some of the aqueous humor can filter through the trabecular meshwork near the iris root into Schlemm's canal, a small channel that drains into the ocular veins. A smaller portion rejoins the venous circulation after passing through the ciliary body and eventually through the sclera (the uveoscleral route).

[0032] FIG. **2** is a cross-sectional, perspective view of a portion of the eye showing the anterior and posterior chambers of the eye. A schematic representation of an embodiment of an implant **105** is shown positioned inside the eye such that a proximal end **110** is located in the anterior chamber **115** and a distal end **120** communicates with and/or is located in or near the suprachoroidal space. It should be appreciated that FIG. **1** and other figures herein are schematic and are not necessarily to scale with respect to size and relative positions of actual eye tissue. Prior to insertion and implantation of an implant, such as the implant shown in FIG. **2**, it can be beneficial to first measure the angle of the eye. For example, measuring the angle of the eye can assist in determining the proper size and shape of the implant for implantation, as well as the proper placement of the implant in the eye. At least one benefit of the DV system embodiments disclosed herein includes the ability to assist in determining the proper size and shape of implant as well as properly placing an implant in the eye.

[0033] FIG. **3** shows a perspective view of an embodiment of a DV system **10** which can be comprised of a hand-held tool having a DV wire **12** that is movably coupled to an elongated handle **14**. At least a portion of the DV wire **12** can be slidably and axially-positioned in a stopper tube **16** affixed to a distal end **19** of the handle **14**. Both the stopper tube **16** and the DV wire **12** can extend outward from the distal end **19** of the handle **14**. The handle **14** can be sized and shaped to be held in a single hand of a user. In addition, the handle **14** can be configured such that the DV system **10** can be operated single handedly. Furthermore, the handle **14** can have one or more gripping features **18**, such as ridges and cutouts, for improved ergonomics and ease of holding.

[0034] The DV wire **12** can be coupled to a spring **30** inside the handle **14** which can allow the DV wire **12** to move inward and outward along a longitudinal axis of the DV system **10** and relative to the handle **14** and stopper tube **16**. The spring **30** can provide a spring force that can assist in allowing the DV wire **12** to retract proximally into the handle **14** upon an applied force against the distal end of the DV wire **12**. The spring constant of the spring **30** can be relatively low such that the DV wire **12** moves relatively easily when a force is applied. In one aspect, the spring constant can be sufficiently low such that the DV wire **12** will yield and ocular tissue is not damaged when the distal tip of the DV wire **12** is pressed

against ocular tissue. In addition, a handle plug **32** (as shown in FIG. **5**) inside the handle **14** can provide a hard stop for the DV wire **12** which can limit the distance that the DV wire **12** can retract into the stopper tube **16** and handle **14**.

[0035] In some embodiments the stopper tube **16** can extend straight out of and along the same longitudinal axis as the handle **14**. However, in some embodiments the stopper tube **16** can be curved or extend in a variety of other configurations. For example, the stopper tube **16** may be curved which can provide easier access to particular anatomical parts of the eye, such as the base of the iridocorneal angle. The distal end of the stopper tube **16** can have rounded edges which can assist in preventing damage to ocular tissue during use. In addition, the stopper tube **16** can be manufactured out of a variety of materials, such as stainless steel, titanium, plastics, or other equivalent materials, including any number of medical grade materials.

[0036] FIG. **4** shows an enlarged view of the DV wire **12** and distal region of the stopper tube **16**. The DV wire **12** can have a distal contact tip **20** that can be configured to be pressed against ocular tissue. The contact tip **20** may be rounded or blunt to eliminate or reduce tissue damage by the contact tip **20** when pressed against ocular tissue. In addition, one or more indicators or marks **22** can be positioned along a length of the DV wire **12**. In some embodiments, one or more indicators **22** can be positioned along a length of either the DV wire **12** or stopper tube **16**. The indicators **22** can assist a user in acquiring measurements of one or more anatomical features of the eye. For example, the distal end of the DV wire **12** can be placed against the base of the angle of the eye such that the user can then determine the depth of the angle.

[0037] The indicators **22** can be arranged along the DV wire **12** such that they correspond to a standard form of measurement, i.e., millimeters, fractions of an inch, etc. In such an embodiment, a user can use the DV wire **12** to make specific measurements, including measurements of particular anatomical features of the eye. In some embodiments, the indicators **22** do not correlate with a standard form of measurement and are simply reference points along the DV wire **12**. In either embodiment, a user can position the DV wire **12** in the eye and use any of the indicators **22** as reference points relative to various anatomical features in the eye. As will be discussed in greater detail below, the referenced indicators **22** can assist the user in subsequent procedures, including determining an appropriately sized implant for the eye as well as assisting in correctly inserting the implant into the eye.

[0038] The DV wire **12** can be manufactured out of a variety of materials, such as stainless steel, titanium, plastics, or other equivalent materials, including any number of medical grade materials. In addition, the DV wire **12** can be at least partially tubular or hollow in order to allow one or more components, such as the measuring features discussed below, to be contained within the DV wire **12**, including within the contact tip **20**.

[0039] The contact tip **20** can be configured to provide sufficient surface area so as to not be traumatic to ocular tissues and/or create accidental cyclodialysis. The indicators **22** can be visible to the physician through the cornea when the DV wire **12** is extended from the stopper tube **16**. In addition, the indicators **22** can be visible through the cornea so that a gonio lens is not needed in order to determine the depth of the iridocorneal angle. Furthermore, the DV system **10** can perform sufficient measurements such that a gonio lens is not necessary to perform a procedure. By relieving the need for a gonio lens to conduct a procedure, both procedure time and efficiency can be improved.

[0040] The DV wire **12** can be stamped, chemically etched, or marked with any number of patterning techniques in order to provide indicators **22** that can be seen by a user while inserted in the eye. The indicators **22** may exhibit any combination of numbering and or patterning features, with varying degrees of darkness, contrast, size, shape and color.

[0041] In some embodiments, the contact tip **20** can include a loop **24** which can provide additional damping when the contact tip **20** is in contact with ocular tissue. In addition, the contact tip **20** can be made out of a material that allows the loop **24** to deform, such as a soft or flexible material, in order to provide a damping effect. The loop **24** can be made out of the same or different material than the rest of the DV wire **12**, or the loop **24** can be coated with a material, such as a flexible or soft material.

[0042] In some embodiments, deformation of the contact tip **20** or loop **24** can assist in providing a visual cue to the user that the distal end of the DV wire **12**, such as the contact tip **20** or loop **24**, is in contact with tissue. For example, the contact tip **20** can include one or more features having a spiral cut or any number of a variety of looped patterns which can allow for visually identifiable movements at low forces. Furthermore, deformation of the loop **24** can act as a deformable element which can provide visual cues to the user, such as when the loop **24** is in contact with tissue.

[0043] The cross section of the DV wire **12** can be rectangular, although the shape may vary. For example, the DV wire **12** can have a circular, elliptical or any one or more of a variety of cross sections along the length of the DV wire **12**. In addition, the edges of the DV wire **12** can be smooth and free of sharp edges to avoid damage to tissue. The proximal end of the DV wire **12** can have ridges for holding the spring **30** in place as well as a hard stop to prevent the spring **30** from sliding off the proximal end.

[0044] FIG. **5** shows a cross-sectional view of a part of the DV system **10**, including the distal end **19** of the handle **14**. The DV wire **12** of the DV system **10** can be coupled to a spring **30** at a proximal region which can bias the DV wire **12** toward a distally outward direction relative to the handle **14**. In addition, the spring **30** can resist movement of the DV wire **12** in a proximal direction (i.e., into the handle **14**) and urge the DV wire in a distal direction (i.e., out of the handle **14**).

[0045] The spring **30** can be a low force spring (i.e., a spring constant in the range of 0.001 to 0.100 Newtons). The spring **30** may be made of Nitinol, stainless steel, titanium, plastics, or other equivalent materials, and may exhibit strain induced deformation. Additionally, the spring **30** may be at least one of a tension spring, compression spring, torsion spring, leaf spring, Belleville washer, constant force spring, or urethane spring. The spring **30** may be an ultra-low force spring (i.e., less than 0.001 Newtons) for greater sensitivity, or a higher force spring (i.e., greater than 0.100 Newtons) for overcoming frictional viscous forces of aqueous fluids.

[0046] One or more features may be added or removed from the DV system **10** based on its intended use (i.e., disposable, re-usable, etc.). For example, one or more holes through the handle **14** and handle plug **32** may be included in the system in order to allow for sterilization and re-use of the DV system **10**. Other features can be implemented for special or improved use of the DV system **10**.

[0047] FIG. **6** shows an example of a part of the distal region of the DV system **10** inserted in an eye. The DV system **10** can be inserted into the anterior chamber **115** of the eye via a corneal or limbal incision such that the DV wire **12** can pass across the anterior chamber **15** (pursuant to an ab-interno approach) toward the base of the angle, such as below the scleral spur **120** and above the iris **122**. The distal end of the DV wire **12**, such as the contact tip **20**, can be pressed against ocular tissue, as shown by way of example in FIG. **6**.

[0048] The DV wire **12** can apply a force against ocular tissue while the handle **14** and stopper tube **16** continue to advance in the direction of the eye. The spring **30** can allow the proximal end of the DV wire **20** to travel towards the handle plug **32** while the handle **14** and stopper tube **16** continue to travel in the direction of the eye. In some embodiments, the DV wire **20** can continue to retract into the handle **14** until the proximal end of the DV wire **20** abuts the handle plug **32**. Retraction of the DV wire **20** into the stopper tube **16** and handle **14** can indicate to the user that the contact tip **20** of the DV wire **12** is properly positioned, such as the distal end of the DV wire **12** is positioned against the base of the angle. This can assist in at least minimizing damage to the ocular tissue by preventing the user from applying more force than is necessary when attempting to properly position the DV wire **12** in the eye.

[0049] Once the surgeon becomes aware that the DV wire **20** is properly positioned, the surgeon can then take appropriate measurements, such as of the iridocorneal angle of the eye. Measurements can be made by, for example, referencing the indicators **22** along the DV wire **12** relative to one or more anatomical features of the eye. After measurements have been taken, the surgeon can then retract the distal end of the DV system **10** from the eye. Any number of procedures can follow the removal of the DV system **10**, including the insertion of an ocular implant.

[0050] FIG. **7** shows the distal end of the DV system **20**, including the DV wire **12**, aligned alongside a distal end of an implant delivery applier **30**. The implant delivery applier **30** can have an elongated body **32** with an adaption feature **34** at a distal end **36** of the elongated body **32**. The adaptation feature **34** can be configured to adapt one or more ocular implants **50** to the distal end **36** of the implant delivery applier **30**, as shown in FIG. **7**. The body **32** of the implant delivery applier **30** can include indicators or marks **38** which correspond with the indicators **22** along the DV wire **12**, as also shown in FIG. **7**. The corresponding indicators along the implant delivery applier **30** and DV wire **12** can allow measurements and positioning of the DV wire **12** relative to anatomical features of the eye to be easily replicated with the implant delivery applier **30**, as will be discussed in greater detail below.

[0051] FIGS. **8-11** show an example method of use of the implant delivery applier **30** and DV wire **12** of the DV system **10** having corresponding marks **38** and **22**, respectively, for properly inserting an implant in the eye. The method shown can be used, for example, to at least acquire one or more measurements of the eye, determine a properly sized implant and implant the properly sized implant into the eye. Furthermore, this method can be completed without the use of a gonio lens which can improve the time and efficiency of the procedure.

[0052] As shown in FIG. **8**, a user can first insert the distal end of the DV wire **12** through a corneal or limbal incision along the eye and advance the distal end of the DV wire **12** across the anterior chamber of the eye (pursuant to an ab-interno approach). Viscoelastic substances or balanced saline solutions may be used to maintain the anterior chamber of the eye and open a space comprising a part of the angle of the eye. The incision can be approximately 0.08 mm to 2.0 mm in length and can be either created by the DV wire **12** or a separate instrument. Additionally, the incision can be approximately 1.2 mm to 1.7 mm in length.

[0053] The user can advance the DV system **10** and position the distal end of the DV wire **12** against ocular tissue, such as between the scleral spur **120** and iris **122** in order to measure the depth of the iridocorneal angle. The spring loaded feature of the DV wire **12** can assist the user in determining when the distal end, such as the loop **24** or contact tip **20**, of the DV wire **12** is in contact with ocular tissue. For example, the user can continue to advance the DV system **10** into the eye until the user begins to observe the stopper tube **16** travel over the DV wire **12**. Movement of the stopper tube **16** relative to the DV wire **12** can alert the user that the distal end of the DV wire **12** is positioned against ocular tissue within the eye.

[0054] Once the user has determined that the distal end of the DV wire **12** is positioned against the base of the angle of the eye, such as between the scleral spur **120** and iris **122**, the user can take measurements of the eye using the DV wire **12**. For example, the user can use the indicators **22** along the DV wire **12** to take measurements of certain anatomical features of the eye, including the depth of the angle of the eye. As shown in FIG. **9**, the user can view the DV wire **12** along a generally vertical line of sight **40** in order to observe which indicator **22** is aligned with one or more anatomical features of the eye when the distal end of the DV wire **12** is positioned against the base of the angle. For example, the user can view the DV wire **12** along the vertical line of sight **40** and observe which indicator **22** is aligned with, for example, the inner edge of the iris **122**. Any number of anatomical features can be measured using the indicators **22** along the DV wire **12** without departing from the scope of this disclosure.

[0055] In addition, the user can advance a feature of the DV system **10**, such as the stopper tube **16**, in order to assist the user in determining which indicator **22** is aligned with certain anatomical features of the eye. FIG. **9** shows an example of the stopper tube **16** being used to assist the user in determining which indicator **22** or part of the DV wire **12** aligns with the inner edge of the iris **122** when the distal end of the DV wire **12** is placed against the base of the iridocorneal angle in order to measure the depth of the angle. The stopper tube **16** can be advanced across the DV wire **12** by simply continuing to advance the DV system **10** after the distal end of the DV wire **12** is positioned against ocular tissue within the angle of the eye, as discussed above.

[0056] Once the user has obtained appropriate measurements, the user can remove the DV wire **12** from the eye. The implant **50** coupled to the implant delivery applier **30** can then be inserted into the eye. The same incision that was used to insert the DV wire **12** can be used to insert the implant delivery applier **30** and implant **50**. In addition, the implant **50** can be advanced across the eye along the same or similar trajectory such that the distal end of the implant **50** contacts generally the same area of ocular tissue between the scleral spur **120** and iris **122** that the distal end of the DV wire **12** had previously contacted while taking measurements.

[0057] As shown in FIGS. **10** and **11**, the implant delivery applier **30** can be advanced in order to allow the implant **50** to be inserted into the suprachoroidal or supraciliary space. The

user can continue to advance the implant **50** into the suprachoroidal or supraciliary space until one or more indicator **38** along the implant delivery applier **30** aligns with one or more anatomical features of the eye. In particular, the user can advance the implant delivery applier **30** until the same indicator **38** along the implant delivery applier **30** is aligned with the iris **122** as was along the DV wire **12** when the distal end of the DV wire **12** was in contact with the base of the angle (see, for example, FIGS. **9** and **11**).

[0058] As shown in FIG. **11**, the user can advance the implant delivery applier **30** until the user observes a particular anatomical feature of the eye align with an indicator **38** along the implant delivery applier **30** which corresponds to an indicator **22** along the DV wire **12** which had previously been aligned with the same particular anatomical feature, such as when the distal end of the DV wire **12** was in contact with the base of the angle. When this corresponding indicator **38** on the implant delivery applier **30** is aligned with the particular anatomical feature of the eye, the user can determine that the implant **50** is properly positioned in the eye for permanent implantation. For example, proper positioning in the eye for permanent implantation includes positioning the implant so that it can provide fluid communication between the anterior chamber and the suprachoroidal or supraciliary space without discomfort or irritation to the eye. Therefore, once the user has aligned the appropriate indicator **38** along the implant delivery applier **30** with the particular anatomical feature, the user can then release the implant **50** from the implant delivery applier **30** and remove the implant delivery applier **30** from the eye. As shown in FIG. **12**, the implant **50** can then remain in the implanted position permanently or for a desired length of time.

[0059] The DV wire can be aligned with the implant delivery applier such that the distal end of the DV wire aligns with a position along the length of the head of the implant **50** when the implant **50** is coupled to the implant delivery applier **30**. The alignment of the distal end of the DV wire **12** relative to the head of the implant **50** coupled to the implant delivery applier **30** can vary depending on the desired placement of the head relative to the anterior chamber of the eye when the implant **50** is in its permanently implanted position. For example, and shown by way of example in FIG. **12**, it may be beneficial to have at least a portion of the head of the implant **50** extend into the anterior chamber of the eye. This can assist in ensuring that the implant **50** provides a fluid pathway between the anterior chamber and supraciliary or suprachoroidal space.

[0060] FIGS. **13**A-**13**B shows an embodiment of a feedback mechanism **52** coupled to or comprising the implant delivery applier **30**. The feedback mechanism **52** can include a sheath **54** coupled to a spring **56** at a proximal end of sheath **52**. In such an embodiment, the spring loaded sheath **54** can be used to indicate depth or acknowledge when a certain landmark has been reached. For example, the sheath **54** can be positioned such that the distal end of the sheath **54** extends a distance over the implant **50** attached to the distal end of the implant delivery applier **30**. Upon implantation of the implant **50** within the eye, the sheath **54** can be pushed in the proximal direction, or retracted, when the implant **54** has been implanted to a preferred depth within the eye. Retraction of the sheath **54** can indicate to a user that the sheath **54** has hit a hard stop, such as ocular tissue, and the implant **50** has been properly implanted. The implant **50** can then be released for permanent implantation once proper implant positioning has been determined.

[0061] In addition, the feedback mechanism **52** can assist the user in positioning the implant **50** such that the proximal end of the implant **50** is in direct communication with the anterior chamber of the eye in an implanted state. This can ensure that the implant **50** can provide a fluid path from the anterior chamber of the eye to another part of the eye, such as to the suprachoroidal or supraciliary space, and improve fluid flow within the eye.

[0062] Furthermore, the DV system **10** can be used for a variety of surgical procedures. For example, the DV system can be used to accurately locate and take measurements relating to a variety of anatomical structures, such as the trabecular meshwork and the Schlemm's Canal. The various measurements taken with the DV system **10** can be used for accurately positioning implants into one or more anatomical structures, including at least the trabecular meshwork and Schlemm's Canal.

[0063] Furthermore, in some embodiments, the distal end of the DV system **10**, such as the distal end of the DV wire **12**, can include non-contact measuring features for determining one or more of a measurement or a distance within the eye. For example, the distal end of the DV wire **12** can include one or more measuring features which can include ultrasound, infrared, optical coherence tomography, or the like. In some embodiments, the measuring features can assist in measuring the relative distance of an anatomical feature of the eye relative to a part of the DV wire **12**, such as the distal end. Additionally, the DV wire **12** can include various other features which can assist in providing information to a user, such as pressure and temperature sensors.

[0064] In some embodiments, the handle can include a display which can indicate to a user one or more parameters measured by the DV system **10**, such as by a measuring feature of the DV system **10**. Information displayed on the display can include, for example, at least one or more of a distance measured between the distal end of the DV wire **12** and an anatomical feature, a measurement of an anatomical feature, a pressure exerted by the distal end of the DV wire **12** against tissue, pressure within the eye or temperature.

[0065] Although embodiments of various methods and devices are described herein in detail with reference to certain versions, it should be appreciated that other versions, embodiments, methods of use, and combinations thereof are also possible. Therefore the spirit and scope of the appended claims should not be limited to the description of the embodiments contained herein.

1. A device for measuring anatomical features of an eye, comprising:

a handle;

a wire including a contact tip at a distal end of the wire, wherein the wire extends out of the handle and is configured to be inserted ab-internally and positioned against ocular tissue in the eye, the wire including at least one indicator for assisting in measuring at least one anatomical feature of the eye.

2. The device of claim **1**, further comprising a spring coupled to a proximal end of the wire which biases the wire toward a distally outward direction relative to the handle.

3. The device of claim **2**, wherein the spring is made out of at least one of a Nitinol, stainless steel, titanium, or plastics.

4. The device of claim **2**, wherein the spring has a spring force which is less than 0.001 Newtons.

5. The device of claim **2**, wherein the spring has a spring force which is greater than 0.100 Newtons.

6. The device of claim **1**, wherein the contact tip is configured to be pressed against ocular tissue without damaging the ocular tissue.

7. The device of claim **1**, wherein the contact tip includes at least one of a rounded or blunt configuration.

8. The device of claim **1**, wherein contact tip includes one or more of a loop, spring, spiral cut or looped patterned element which deforms when placed in contact with tissue.

9. The device of claim **1**, wherein the wire is made out of at least one of a stainless steel, titanium, plastics, or other equivalent materials, including any number of medical grade materials.

10. The device of claim **1**, further comprising a stopper tube affixed to a distal end of the handle with at least a portion of the wire positioned within the stopper tube.

11. The device of claim **10**, wherein the stopper tube has at least one of a straight or curved configuration.

12. The device of claim **1**, wherein the handle is sized and shaped to be held and operated in a single hand of a user.

13. The device of claim **1**, wherein the at least one indicator extends along the wire.

14. The device of claim **11**, wherein the stopper tube includes at least one indicator along a length of the stopper tube.

15. The device of claim **1**, wherein the wire includes at least one measuring feature including one or more of a pressure sensor, temperature sensor, ultrasound, infrared or optical coherence tomography.

16. The device of claim **1**, wherein the device includes a display which displays at least one measurement taken by the at least one measuring feature.

17. A method of measuring anatomical features of an eye and implanting an ocular implant, comprising:

forming an incision in the cornea of the eye into an anterior chamber of the eye;

introducing through the incision a distal end of a device for measuring at least one anatomical feature of the eye, the device comprising a handle with a wire extending out of a distal end of the handle and a distal end of the wire configured to be pressed against ocular tissue in the eye, the wire including at least one indicator for measuring at least one anatomical feature of the eye;

passing the distal end of the wire through the incision and across the anterior chamber of the eye;

positioning the distal end of the wire against ocular tissue below the scleral spur and above the iris; and

measuring at least one anatomical feature of the eye by identifying one or more indicators along a length of the wire relative to one or more anatomical features.

18. The method of claim **17**, further comprising withdrawing the ocular measuring device from the eye.

19. The method of claim **18**, further comprising determining a properly sized implant and coupling the implant to a distal end of an implant delivery applier.

20. The method of claim **19**, further comprising inserting the ocular implant coupled to the implant insertion device through the incision, advancing the implant across the anterior chamber of the eye and implanting the implant into the eye such that the implant forms a fluid communication between an anterior chamber of the eye and a suprachoroidal or supraciliary space.

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专利名称(译)	用于青光眼治疗的直接可视化系统		
公开(公告)号	US20130281817A1	公开(公告)日	2013-10-24
申请号	US13/865927	申请日	2013-04-18
[标]申请(专利权)人(译)	创森德医疗设备公司		
申请(专利权)人(译)	TRANSCEND MEDICAL，INC.		
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IPC分类号	A61B3/10		
CPC分类号	A61B3/1005 A61B90/06 A61B2090/061 A61B2090/3735 A61F9/0017 A61F9/00781 A61F2009/00891		
优先权	61/635471 2012-04-19 US		
其他公开文献	US10085633		
外部链接	Espacenet USPTO		

摘要(译)

一种直接可视化（DV）系统和用于测量眼睛的一个或多个解剖特征的方法，包括眼睛的虹膜角膜角度的深度。 DV系统可包括从手柄向远侧延伸的线，线具有一个或多个用于测量眼睛的解剖特征的指示器。 DV系统可以部署到眼睛中，并且对眼组织的创伤最小。此外，DV系统可以独立使用或与其他眼科器械一起使用，例如具有对应于DV系统的指示器的仪器，用于在不使用角膜镜的情况下正确植入眼植入物。