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(54) Title: SMALL GAUGE MECHANICAL TISSUE CUTTER/ASPIRATOR PROBE FOR GLAUCOMA SURGERY

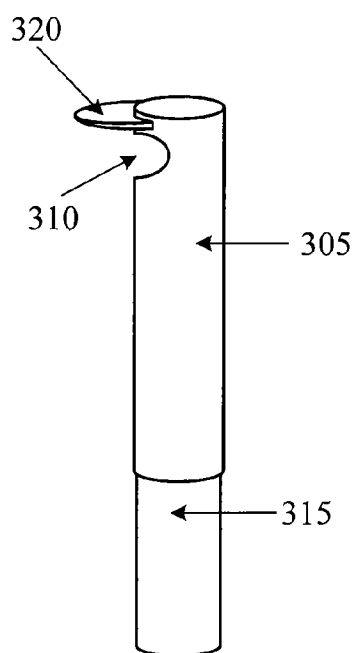


Fig. 3

(57) Abstract: A small gauge mechanical tissue cutter/aspirator probe useful for removing the trabecular meshwork of a human eye has a generally cylindrical outer cannula, an inner cannula that reciprocates in the outer cannula, a port located near or at the distal end of the outer cannula on a side or tip of the outer cannula, and a guide with a distal surface located on the distal end of the outer cannula. A distance between the distal surface of the guide and the port is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork.



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SMALL GAUGE MECHANICAL TISSUE CUTTER/ASPIRATOR PROBE FOR GLAUCOMA SURGERY

5 This application is a continuation-in-part of US 12/120,867 filed May 15,
2008.

BACKGROUND OF THE INVENTION

10 The present invention relates to glaucoma surgery and more particularly to a
method and device for performing glaucoma surgery using a small gauge mechanical
tissue cutter/aspirator probe with a retractable pick.

15 Glaucoma, a group of eye diseases affecting the retina and optic nerve, is one
of the leading causes of blindness worldwide. Glaucoma results when the intraocular
pressure (IOP) increases to pressures above normal for prolonged periods of time.
IOP can increase due to an imbalance of the production of aqueous humor and the
drainage of the aqueous humor. Left untreated, an elevated IOP causes irreversible
damage the optic nerve and retinal fibers resulting in a progressive, permanent loss of
vision.

20

25 The eye's ciliary body epithelium constantly produces aqueous humor, the
clear fluid that fills the anterior chamber of the eye (the space between the cornea and
iris). The aqueous humor flows out of the anterior chamber through the uveoscleral
pathways, a complex drainage system. The delicate balance between the production
and drainage of aqueous humor determines the eye's IOP.

30 Open angle (also called chronic open angle or primary open angle) is the most
common type of glaucoma. With this type, even though the anterior structures of the
eye appear normal, aqueous fluid builds within the anterior chamber, causing the IOP
to become elevated. Left untreated, this may result in permanent damage of the optic
nerve and retina. Eye drops are generally prescribed to lower the eye pressure. In
some cases, surgery is performed if the IOP cannot be adequately controlled with
medical therapy.

35 Only about 10% of the population suffers from acute angle closure glaucoma.
Acute angle closure occurs because of an abnormality of the structures in the front of
the eye. In most of these cases, the space between the iris and cornea is more narrow
than normal, leaving a smaller channel for the aqueous to pass through. If the flow of

aqueous becomes completely blocked, the IOP rises sharply, causing a sudden angle closure attack.

5 Secondary glaucoma occurs as a result of another disease or problem within the eye such as: inflammation, trauma, previous surgery, diabetes, tumor, and certain medications. For this type, both the glaucoma and the underlying problem must be treated.

10 Figure 1 is a diagram of the front portion of an eye that helps to explain the processes of glaucoma. In Figure 1, representations of the lens 110, cornea 120, iris 130, ciliary bodies 140, trabecular meshwork 150, and Schlemm's canal 160 are pictured. Anatomically, the anterior chamber of the eye includes the structures that cause glaucoma. Aqueous fluid is produced by the ciliary bodies 140 that lie beneath the iris 130 and adjacent to the lens 110 in the anterior chamber. This aqueous humor
15 washes over the lens 110 and iris 130 and flows to the drainage system located in the angle of the anterior chamber. The angle of the anterior chamber, which extends circumferentially around the eye, contains structures that allow the aqueous humor to drain. The first structure, and the one most commonly implicated in glaucoma, is the trabecular meshwork 150. The trabecular meshwork 150 extends circumferentially
20 around the anterior chamber in the angle. The trabecular meshwork 150 seems to act as a filter, limiting the outflow of aqueous humor and providing a back pressure producing the IOP. Schlemm's canal 160 is located beyond the trabecular meshwork 150. Schlemm's canal 160 has collector channels that allow aqueous humor to flow out of the anterior chamber. The two arrows in the anterior chamber of Figure 1 show
25 the flow of aqueous humor from the ciliary bodies 140, over the lens 110, over the iris 130, through the trabecular meshwork 150, and into Schlemm's canal 160 and its collector channels.

30 If the trabecular meshwork becomes malformed or malfunctions, the flow of aqueous humor out of the anterior chamber can be restricted resulting in an increased IOP. The trabecular meshwork may become clogged or inflamed resulting in a restriction on aqueous humor flow. The trabecular meshwork, thus, sometimes blocks the normal flow of aqueous humor into Schlemm's canal and its collector channels.

35 Surgical intervention is sometimes indicated for such a blockage. Numerous surgical procedures have been developed to either remove or bypass the trabecular meshwork. The trabecular meshwork can be surgically removed by cutting, ablation, or by means of a laser. Several stents or conduits are available that can be implanted

through the trabecular meshwork in order to restore a pathway for aqueous humor flow. Each of these surgical procedures, however, has drawbacks.

One approach that does not have the drawbacks of existing procedures involves using a small gauge mechanical tissue cutter/aspirator probe to remove trabecular meshwork tissue. A small gauge cutting device can be guided into Schlemm's canal and moved in a forward motion following the curvature of the trabecular meshwork. The motion causes the trabecular meshwork to be fed into the cutting port of the cutter, cutting and removing the trabecular meshwork blocking the outflow of the aqueous humor.

SUMMARY OF THE INVENTION

In one embodiment consistent with the principles of the present invention, the present invention is a small gauge mechanical tissue cutter/aspirator probe comprising a generally cylindrical first outer cannula, a port located near a distal end of the first outer cannula on a side of the first outer cannula, a second smaller gauge cannula located within first outer cannula connected to a diaphragm that reciprocates the second inner cannula within and along the axis of the first outer cannula, and a retractable pick. A distance between the distal end of the outer cannula and the port is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork in a human eye.

In another embodiment consistent with the principles of the present invention, the present invention is a small gauge mechanical tissue cutter/aspirator probe comprising a generally cylindrical first outer cannula with a smooth distal end, a port located near a distal end of the first outer cannula on a side of the first outer cannula, a second smaller gauge cannula located within first outer cannula connected to a diaphragm that reciprocates the second inner cannula within and along the axis of the first outer cannula, and a distance between the distal end of the first outer cannula and the port is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork in a human eye.

In another embodiment consistent with the principles of the present invention, the present invention is a method of cutting and removing trabecular meshwork from a human eye, the method comprising: providing a small gauge mechanical tissue cutter/aspirator probe with a generally cylindrical first outer cannula, a port located near a distal end of the first outer cannula on a side of the first outer cannula, such that

the location of the port on the first outer cannula facilitates the placement of the port at the trabecular meshwork of a human eye, a second smaller gauge cannula located within first outer cannula connected to a diaphragm that reciprocates the second inner cannula within and along the axis of the first outer cannula, such that the trabecular meshwork is cut without damaging the outer wall of Schlemm's canal; and aspirating the cut trabecular meshwork from the eye.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are intended to provide further explanation of the invention as claimed. The following description, as well as the practice of the invention, set forth and suggest additional advantages and purposes of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

Figure 1 is a diagram of the front portion of an eye.

Figures 2A and 2B are perspective views of a small gauge mechanical tissue cutter/aspirator probe (traditional vitrectomy probe).

Figure 3 is a perspective view of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figure 4 is a perspective view of a tapered small mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figures 5A and 5B are side cross section views of the distal end of an embodiment of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figures 6A-6C are side cross section views of the distal end of an embodiment of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

Figures 7 and 8 are top views of the distal end of various embodiments of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention.

- 5 Figures 9 and 10 are views of a small gauge mechanical tissue cutter/aspirator probe as used in glaucoma surgery.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

10

Reference is now made in detail to the exemplary embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers are used throughout the drawings to refer to the same or like parts.

15

- Figures 2A and 2B are perspective views of a traditional mechanical tissue cutter/aspirator probe (vitrectomy probe). In a typical mechanical tissue cutter/aspirator probe, an outer cannula 205 includes port 210. An inner cannula 215 reciprocates in cannula 205. One end of inner cannula 215 is configured so that it can cut tissue when as it enters port 210. As shown in Figures 2A and 2B, inner cannula 215 moves up and down in outer cannula 205 to produce a cutting action. Tissue enters port 210 when the mechanical tissue cutter/aspirator probe is in the position shown in Figure 2A. The tissue is cut as inner cannula 215 moves upward closing off port 210 as shown in Figure 2B. Cut tissue is aspirated through the inner cannula and away from the cutting location. Outer cannula 205 has a generally smooth top surface that can be abutted against eye structures without damaging them. As such, the cutting action, which is located on a side of outer cannula 205, allows the top surface of outer cannula 205 to remain smooth.

30

- Figure 3 is a perspective view of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. In the embodiment of Figure 3, an outer cannula 305 includes port 310. An inner cannula 315 reciprocates in outer cannula 305. One end of inner cannula 315 is configured so that it can cut tissue when as it enters port 310. Inner cannula 315 moves up and down in outer cannula 305 to produce a cutting action. Cut tissue can be aspirated through inner cannula 315 and removed from the cutting location. Outer cannula 305 has a generally smooth top surface that can be abutted against eye structures without damaging them. As such, the cutting action, which is located on a side of outer

cannula 305, allows the top surface of outer cannula 305 to remain smooth. A retractable pick 320 is located on a distal end of outer cannula 305.

Retractable pick 320 is adapted to fit into Schlemm's canal so that mechanical
5 tissue cutter/aspirator probe cutting action can be used to cut and remove the
trabecular meshwork (through aspiration provided through port 310). Retractable
pick 320 is a short protrusion that extends outward from the distal tip of outer cannula
305 in the direction of port 310. In one embodiment of the present invention,
10 retractable pick 320 has a sharp end that can be used to pierce the trabecular
meshwork so that retractable pick 320 can be placed in Schlemm's canal. In another
embodiment of the present invention, retractable pick 320 is optional. While
retractable pick 320 facilitates entry into Schlemm's canal, once port 310 is located on
the trabecular meshwork, retractable pick 320 is largely unnecessary. As such,
15 retractable pick 320 is retracted into outer cannula 305. Cutting action is provided at
port 310 which is located along the trabecular meshwork (as best seen below). The
distance between port 310 and the distal end of outer cannula 320 determines the
location of port 310 in relation to the back wall of Schlemm's canal. This distance is
such that port 310 is located at the trabecular meshwork (preferably the distance from
20 the distal end of outer cannula 305 to the center of port 310 is equal to the distance
between the trabecular meshwork and the back wall of Schlemm's canal). Locating
port 310 at the trabecular meshwork ensures effective removal of it.

Figure 4 is a perspective view of a tapered small gauge mechanical tissue
cutter/aspirator probe according to the principles of the present invention. In this
25 embodiment, the distal end of outer cannula 305 is tapered. While taper 325 is
depicted, any type of taper can be employed. Due to the size of Schlemm's canal, it is
preferable to have the distal end of outer cannula measure about 0.25 to 0.36 mm
diameter (the approximate diameter of Schlemm's canal is about 0.3 mm). In one
embodiment, a 27 gauge cannula is used for outer cannula 305. In other
30 embodiments, a tapered 27 gauge or larger cannula is used. Such a cannula is tapered
in some fashion so that its distal end measures about 0.25 to 0.36 mm.

Figures 5A and 5B are side cross section views of the distal end of an
embodiment of a small gauge mechanical tissue cutter/aspirator probe according to
35 the principles of the present invention. Figure 5A shows retractable pick 520 in an
extended position. Figure 5B shows the retractable pick 520 in a retracted position.
In the embodiment of Figure 5A, retractable pick 520 is located at the distal end of
cannula 305. Retractable pick 520 may have a sharp tip 525 to pierce the trabecular

meshwork so that outer cannula 305 can be properly located for cutting. The distance (d) between the distal end of retractable pick 520 (or the distal end of cannula 305, if retractable pick 520 is not present) is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork. In this manner, as outer
5 cannula 305 is advanced into Schlemm's canal, the distal end of outer cannula 305 (or retractable pick 520 as the case may be) rests against the back wall of Schlemm's canal so that port 310 is located at the trabecular meshwork.

When retracted, retractable pick 520 is located inside of cannula 305. When
10 extended, retractable pick 520 protrudes through an opening on the outer surface of cannula 305. In one embodiment of the present invention, retractable pick 520 is located between inner cannula 315 and outer cannula 305. Retractable pick 520 travels in a passageway formed between inner cannula 315 and outer cannula 305. In another embodiment of the present invention, a sleeve (not shown) surrounds outer
15 cannula 305. In this case, retractable pick 520 is located between the sleeve (not shown) and the outer cannula 305. Retractable pick 520 travels in a passageway formed between the sleeve (not shown) and outer cannula 305.

Retractable pick 520 may be made of any resilient, durable substance. In one
20 embodiment of the present invention, retractable pick 520 is made of a nitinol wire with a sharpened (or beveled) distal tip. 525. In this case, the sharp tip 525, when extended, can be used to pierce or cut the trabecular meshwork. The sharp tip 525 is then retracted before the outer cannula is placed in Schlemm's canal.

Figures 6A, 6B, and 6C are side cross section views of the distal end of an
25 embodiment of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. Figures 6A and 6B show retractable pick 620 in an extended position. Figure 6C shows the retractable pick 620 in a retracted position. In the embodiment of Figure 6A, retractable pick 620 is located at the distal
30 end of cannula 305. Retractable pick 620 may have a sharp tip 625 to pierce the trabecular meshwork so that outer cannula 305 can be properly located for cutting. The distance (d) between the distal end of retractable pick 620 (or the distal end of cannula 305, if retractable pick 620 is not present) is approximately equal to the distance between the back wall of Schlemm's canal and the trabecular meshwork. In
35 this manner, as outer cannula 305 is advanced into Schlemm's canal, the distal end of outer cannula 305 (or retractable pick 620 as the case may be) rests against the back wall of Schlemm's canal so that port 310 is located at the trabecular meshwork.

In Figure 6B, retractable pick 620 has a curved profile when in an extended position. In this manner, retractable pick 620 can be oriented with respect to the distal end of cannula 305. In Figure 6A, retractable pick extends outward from the distal end of cannula 305. In Figure 6B, retractable pick extends at an angle from the distal
5 end of cannula 305.

When retracted, retractable pick 620 is located inside of cannula 305. When extended, retractable pick 620 protrudes through an opening on the distal end of cannula 305. In one embodiment of the present invention, retractable pick 620 is
10 located between inner cannula 315 and outer cannula 305. Retractable pick 620 travels in a passageway formed between inner cannula 315 and outer cannula 305. In another embodiment of the present invention, a sleeve (not shown) surrounds outer cannula 305. In this case, retractable pick 620 is located between the sleeve (not shown) and the outer cannula 305. Retractable pick 620 travels in a passageway
15 formed between the sleeve (not shown) and outer cannula 305.

Retractable pick 620 may be made of any resilient, durable substance. In one embodiment of the present invention, retractable pick 620 is made of a nitinol wire with a sharpened (or beveled) distal tip. 625. In this case, the sharp tip 625, when
20 extended, can be used to pierce or cut the trabecular meshwork. The sharp tip 625 is then retracted before the outer cannula is placed in Schlemm's canal. As is commonly known, a nitinol wire retains its shape so as to facilitate the retractable pick arrangement of Figure 6B.

Regardless of what type of pick is used (if any at all), the distance between the back wall of Schlemm's canal to the trabecular meshwork is about 0.3 mm. The approximate thickness of the trabecular meshwork is 0.1 mm. Accordingly, in one embodiment of the present invention, port 310 has an opening that is greater than 0.1 mm, and the distance from port 310 to the distal tip of cannula 305 is about 0.3 mm.
25 In other words, port 310 is located such that it can effectively cut and remove the trabecular meshwork.

Figures 7 and 8 are top views of the distal end of various embodiments of a small gauge mechanical tissue cutter/aspirator probe according to the principles of the present invention. Figures 7 and 8 depict two different embodiments of retractable
35 picks, such as retractable picks 320 or 520. In Figure 7, retractable pick 720 is generally egg shaped with a leading edge 705 and a trailing edge 710. Leading edge 705 extends outward from an outer cannula and is used to pierce the trabecular

meshwork. Trailing edge 710 is generally flush with the outer surface of the outer cannula. In the embodiment of Figure 7, leading edge is generally curved and may be sharp or blunt. If leading edge 705 is sharp, it is configured to pierce the trabecular meshwork so that the outer cannula can be advanced into Schlemm's canal and the cutting port can be aligned with the trabecular meshwork. In Figure 8, retractable pick 820 has a point at leading edge 805. Leading edge 805 extends outward from an outer cannula and is used to pierce the trabecular meshwork. Trailing edge 810 is generally flush with the outer surface of the outer cannula. In the embodiment of Figure 8, leading edge is pointed and may be sharp or blunt. If leading edge 805 is sharp, it is configured to pierce the trabecular meshwork so that the outer cannula can be advanced into Schlemm's canal and the cutting port can be aligned with the trabecular meshwork.

Figures 9 and 10 are views of a small gauge mechanical tissue cutter/aspirator probe as used in glaucoma surgery. In Figure 9, outer cannula 305 is inserted through a small incision in the cornea 120. The distal end of cannula 305 (the end that has port 310) is advanced through the angle to the trabecular meshwork 150. The retractable pick is extended so that an opening can be made in the trabecular meshwork. The retractable pick is then retracted so as to avoid damaging a wall of Schlemm's canal 160. The distal end of cannula 305 is then advanced through the opening in the trabecular meshwork 150 and into Schlemm's canal 160. In this position, port 310 is located at the trabecular meshwork 150 and is ready to be cut and removed from the eye.

Figure 10 is an exploded view of the location of the distal end of outer cannula 305 during the removal of the trabecular meshwork 150 (note that in this position, the retractable pick is in a retracted position). In this position, port 310 is located at the trabecular meshwork 150. Outer cannula 305 is then advanced in the direction of port 310 to cut and remove the trabecular meshwork 150. Outer cannula 305 is advanced through an arc in one direction, port 310 is then rotated 180 degrees, and outer cannula 305 is then advanced in an arc in the other direction. In this manner, the distal end of cannula 305 (and port 310) is moved in an arc around the circumference of the angle to remove a substantial portion of the trabecular meshwork through a single corneal incision. If desired, a second corneal incision opposite the first corneal incision can be made so that the outer cannula 305 can be swept through a second arc of the angle. In this manner, either through one or two corneal incisions, a significant portion of the trabecular meshwork can be cut and removed by the mechanical tissue cutter/aspirator probe.

From the above, it may be appreciated that the present invention provides a system and methods for performing glaucoma surgery with a small gauge mechanical tissue cutter/aspirator probe. The present invention provides a small gauge
5 mechanical tissue cutter/aspirator probe with an optional guide that can be advanced into Schlemm's canal to cut and aspirate the trabecular meshwork. Methods of using the probe are also disclosed. The present invention is illustrated herein by example, and various modifications may be made by a person of ordinary skill in the art.

10 Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:

1. A mechanical tissue cutter/aspirator probe comprising:
a generally cylindrical outer cannula, the outer cannula having a distal end that
5 defines a generally planar surface;
an inner cannula that reciprocates in the outer cannula;
a port located near a distal end of the outer cannula;
a retractable pick located on the distal end of the outer cannula;
wherein a distance between the generally planar surface of the distal end of the
10 outer cannula and the port is approximately equal to the distance between a back wall
of Schlemm's canal and a trabecular meshwork in a human eye.
2. The probe of claim 1 wherein the retractable pick further comprises a sharp
edge for piercing the trabecular meshwork.
15
3. The probe of claim 1 wherein the retractable pick is located between the inner
cannula and the outer cannula.
4. The probe of claim 1 wherein the retractable pick is located between the outer
20 cannula and a sleeve.
5. The probe of claim 1 wherein the outer cannula is tapered.
6. The probe of claim 1 wherein the outer cannula has a diameter between about
25 0.25 and 0.36 millimeters.
7. The probe of claim 1 wherein the distance between the generally planar
surface of the distal end of the outer cannula and the port is approximately 0.3
30 millimeters.
8. The probe of claim 1 wherein cut tissue is aspirated through the port.
9. The probe of claim 1 wherein the retractable pick is made of nitinol.

10. A mechanical tissue cutter/aspirator probe comprising:
a generally cylindrical outer cannula with a generally smooth distal end;
an inner cannula that reciprocates in the outer cannula;
a port located near a distal end of the outer cannula on a side or end of the
5 outer cannula;
wherein a distance between the distal end of the outer cannula and the port is
approximately equal to the distance between a back wall of Schlemm's canal and a
trabecular meshwork in a human eye.
- 10 11. The probe of claim 10 wherein the distal end of the outer cannula is
configured to rest against the outer wall of Schlemm's canal.
12. The probe of claim 10 wherein the outer cannula is tapered.
- 15 13. The probe of claim 10 wherein the distal end of the outer cannula has a
diameter between about 0.25 and 0.36 millimeters.
14. The probe of claim 10 wherein the distance between the distal end of the outer
cannula and the port is approximately 0.3 millimeters.
- 20 15. The probe of claim 10 wherein cut tissue is aspirated through the port.

16. A method of cutting and removing trabecular meshwork from a human eye, the method comprising:
- providing a mechanical tissue cutter/aspirator probe with a generally cylindrical outer cannula, an inner cannula that reciprocates within the outer cannula,
- 5 and a port located near a distal end of the outer cannula on a side of the outer cannula, such that the location of the port on the outer cannula facilitates the placement of the port at the trabecular meshwork of a human eye;
- actuating the inner cannula so that the trabecular meshwork is cut without damaging the outer wall of Schlemm's canal; and
- 10 aspirating the cut trabecular meshwork from the eye.
17. The method of claim 16 wherein aspirating the cut trabecular meshwork from the eye further comprises aspirating the cut trabecular meshwork through the port and through the inner cannula.
- 15
18. The method of claim 16 wherein the mechanical tissue cutter/aspirator probe is provided with a retractable pick located on the distal end of the outer cannula.
19. The method of claim 18 further comprising:
- 20 extending the retractable pick so that an opening can be formed in the trabecular meshwork;
- retracting the retractable pick; and
- inserting the distal end of the outer cannula in Schlemm's canal.

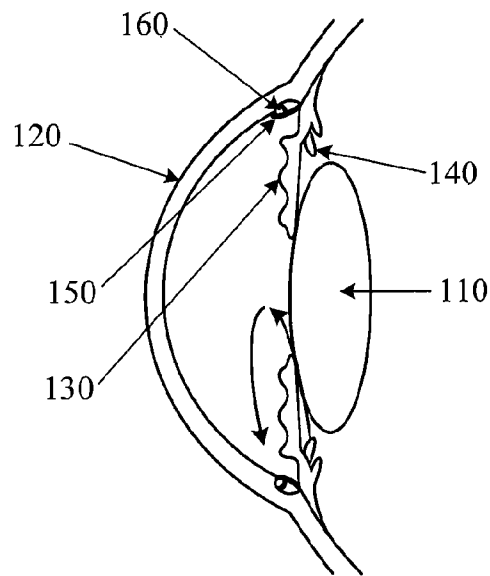


Fig. 1

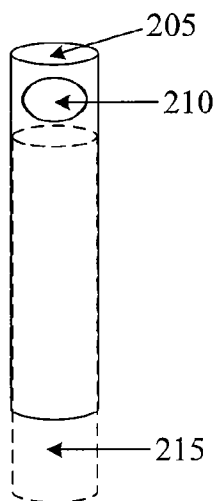


Fig. 2A
(Prior Art)

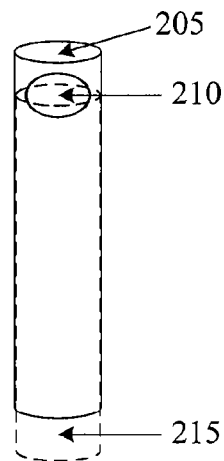


Fig. 2B
(Prior Art)

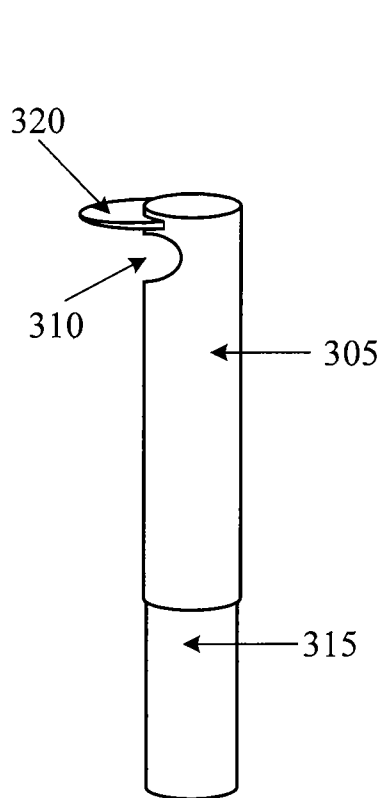


Fig. 3

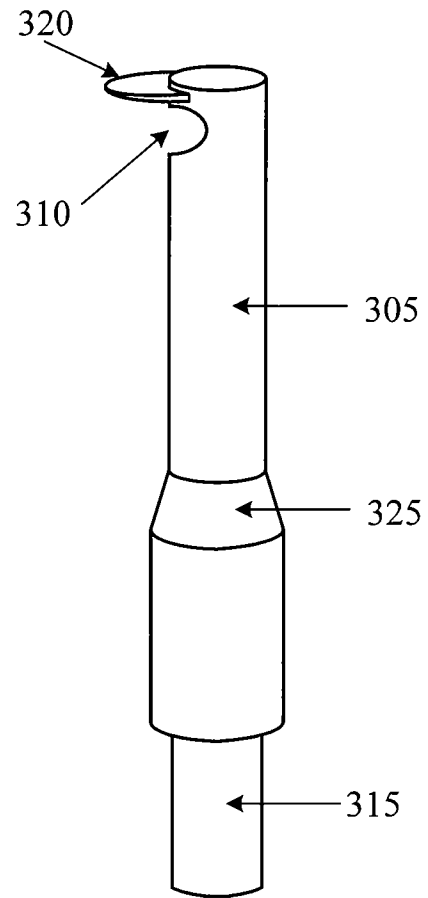


Fig. 4

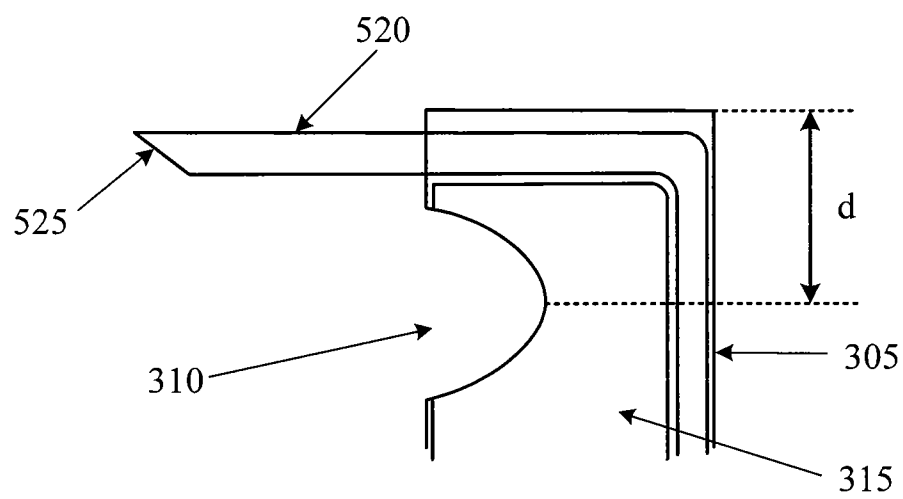


Fig. 5A

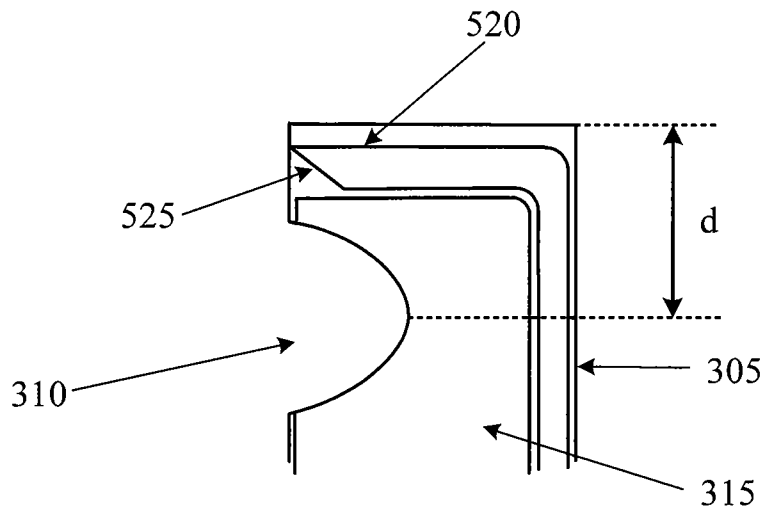


Fig. 5B

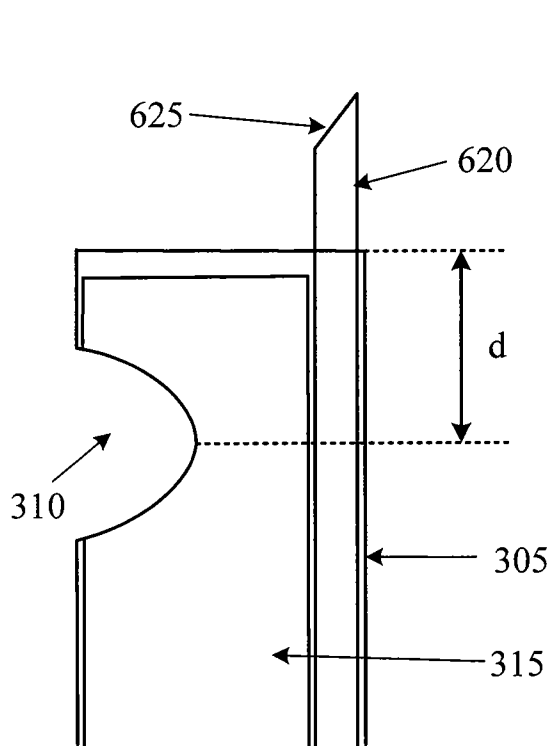


Fig. 6A

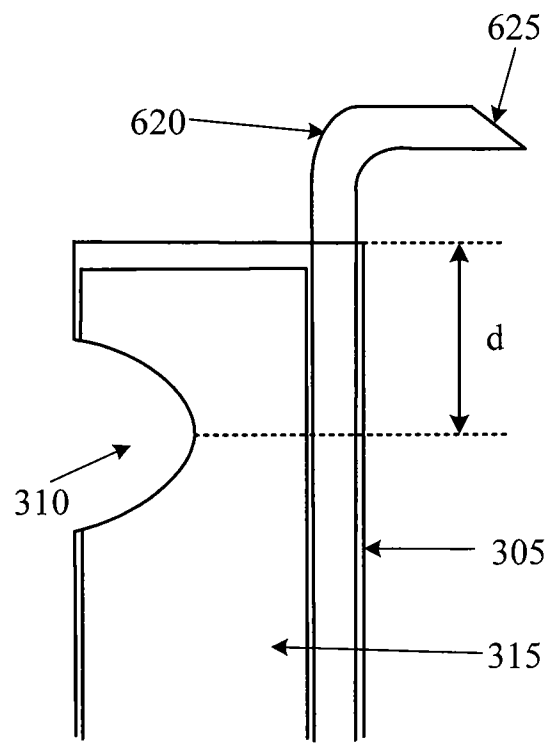


Fig. 6B

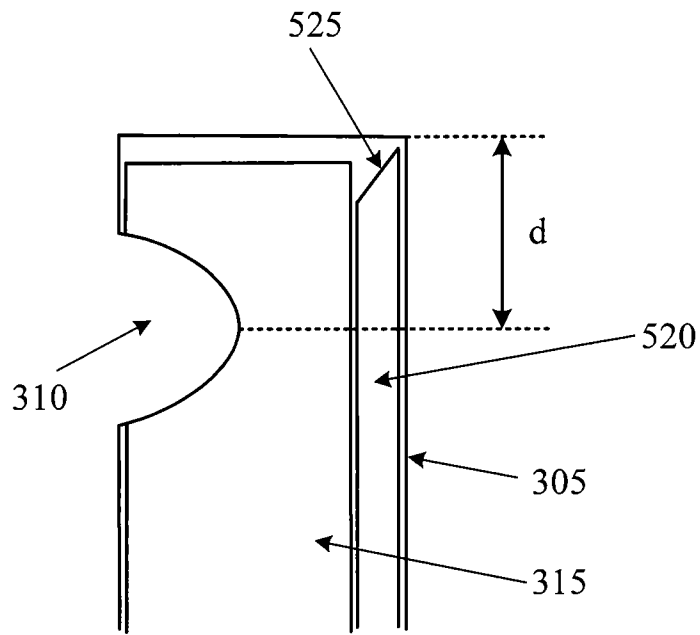


Fig. 6C

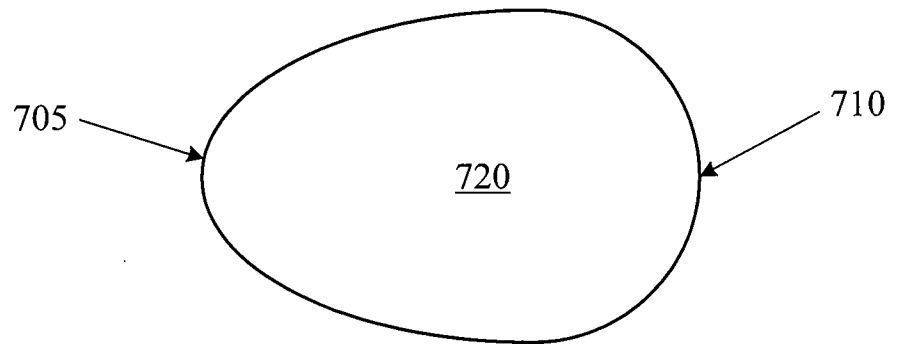


Fig. 7

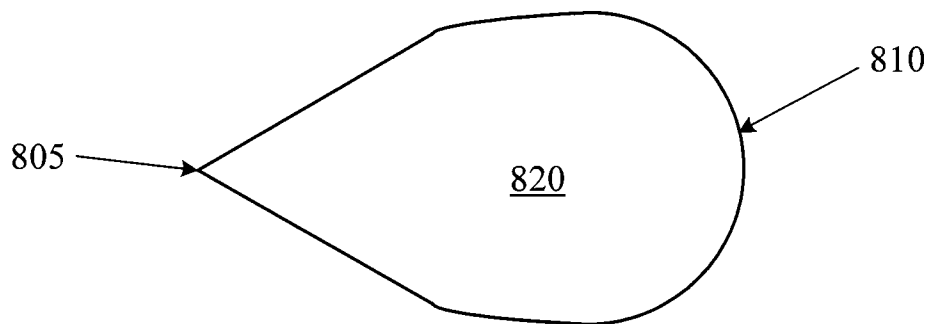


Fig. 8

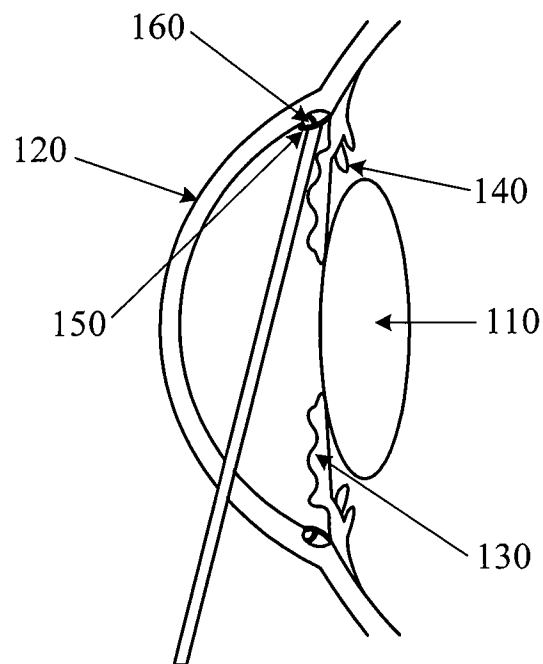


Fig. 9

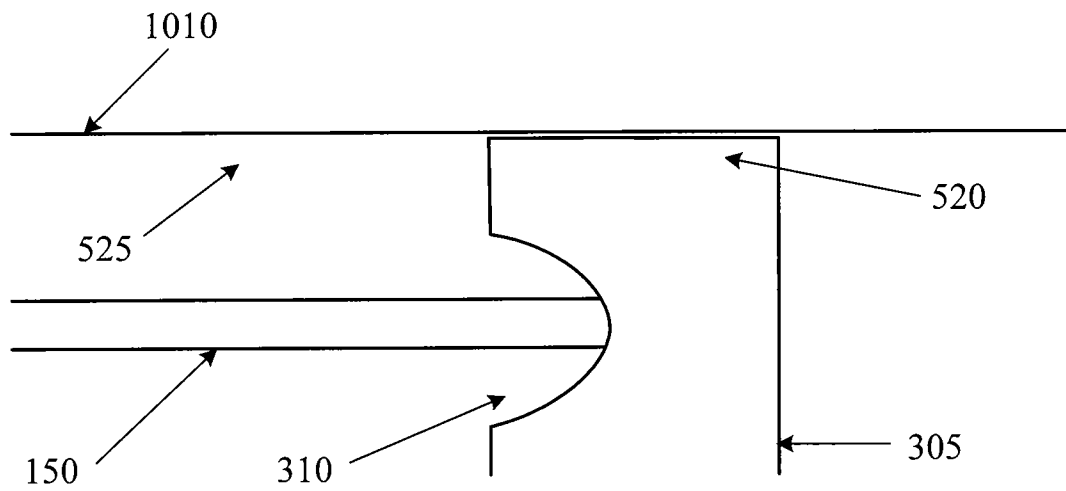


Fig. 10

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/043420

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F9/007 A61B17/32 A61B17/34
 ADD. A61B17/30 A61M1/00

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)

A61F A61B

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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| X | US 5 527 332 A (CLEMENT THOMAS P [US]) 18 June 1996 (1996-06-18) | 10,11,15 |
| Y | | 12-14 |
| A | abstract; figures 2,3 column 7, line 17 - line 19 column 6, line 11 - line 16 ----- | 1 |
| X | US 4 530 359 A (HELFGOTT MAXWELL A [US] ET AL) 23 July 1985 (1985-07-23) claim 18; figures 6,7 | 1-4,8 |
| Y | column 3, line 63 - column 3, line 14 column 6, line 37 - line 42 column 11, line 48 - line 58 column 12, line 37 - line 43 ----- -/-- | 5-7,9 |

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

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O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

14 July 2009

Date of mailing of the international search report

27/07/2009

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Authorized officer

Kajzar, Anna

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/043420

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| Y | US 5 733 297 A (WANG CARL C T [US]) 31 March 1998 (1998-03-31) column 2, line 21 - line 26; figure 3 ----- | 7,14 |
| Y | WO 03/045290 A (ISCIENCE CORP [US]; CONSTON STANLEY R [US]; YAMAMOTO RONALD K [US]) 5 June 2003 (2003-06-05) page 12, line 25 - line 28 ----- | 9 |
| Y | WO 2007/121485 A (CASCADE OPHTHALMICS [US]; PARDO GEOFFREY [US]; CONNORS KEVIN S [US]; C) 25 October 2007 (2007-10-25) paragraph [0142] ----- | 6,13 |
| Y | EP 0 537 116 A (CAPONI MAURO [IT]) 14 April 1993 (1993-04-14) figure 1 ----- | 5,12 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/043420

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 16-19
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2009/043420

| Patent document cited in search report | | Publication date | Patent family member(s) | | Publication date |
|---|---|---------------------|----------------------------|---------------|---------------------|
| US 5527332 | A | 18-06-1996 | NONE | | |
| US 4530359 | A | 23-07-1985 | CA | 1233718 A1 | 08-03-1988 |
| US 5733297 | A | 31-03-1998 | NONE | | |
| WO 03045290 | A | 05-06-2003 | AU | 2002365403 A1 | 10-06-2003 |
| | | | CA | 2466835 A1 | 05-06-2003 |
| | | | EP | 1455698 A1 | 15-09-2004 |
| | | | JP | 2005521435 T | 21-07-2005 |
| | | | US | 2006149194 A1 | 06-07-2006 |
| WO 2007121485 | A | 25-10-2007 | AU | 2007237905 A1 | 25-10-2007 |
| | | | CA | 2649721 A1 | 25-10-2007 |
| | | | EP | 2012654 A2 | 14-01-2009 |
| | | | US | 2008027304 A1 | 31-01-2008 |
| EP 0537116 | A | 14-04-1993 | IT | 1249714 B | 09-03-1995 |