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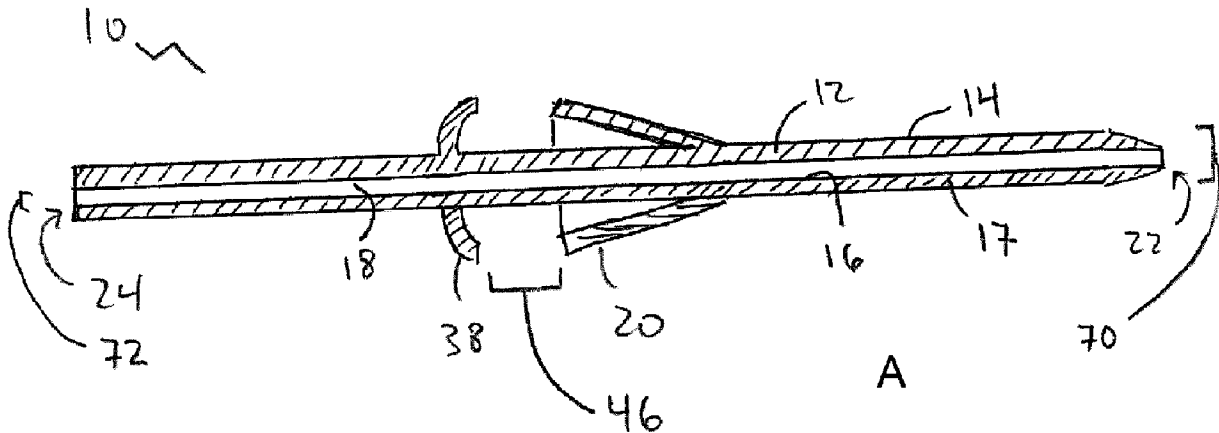
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(54) Titre : ANASTOMOSES GLAUCOMATEUSES ET METHODES D'UTILISATION CONNEXES

(54) Title: GLAUCOMA SHUNTS AND RELATED METHODS OF USE



(57) **Abrégé/Abstract:**

Glaucoma shunts comprising an elongate body with an outer surface and an inner surface, the elongate body comprising an inner wall that defines a lumen spanning a length of the elongate body are disclosed herein. Also disclosed are methods of decreasing intraocular pressure in an eye, the method comprising inserting at least a portion of a glaucoma shunt into an anterior chamber of the eye, and draining aqueous humour from the anterior chamber through the lumen.

ABSTRACT

Glaucoma shunts comprising an elongate body with an outer surface and an inner surface, the elongate body comprising an inner wall that defines a lumen spanning a length of the elongate body are disclosed herein. Also disclosed are methods of decreasing intraocular pressure in an eye, the method comprising inserting at least a portion of a glaucoma shunt into an anterior chamber of the eye, and draining aqueous humour from the anterior chamber through the lumen.

GLAUCOMA SHUNTS AND RELATED METHODS OF USE

FIELD OF INVENTION

[0001] The present invention relates to glaucoma shunts. More specifically, the present invention relates to minimally invasive glaucoma surgery shunts.

BACKGROUND OF THE INVENTION

[0002] Glaucoma is a medical term describing a group of progressive optic neuropathies characterized by degeneration of retinal ganglion cells and retinal nerve fibre layer and resulting in changes in the optic nerve head. Glaucoma is a leading cause of irreversible vision loss worldwide. With the ageing population, it is expected that the prevalence of glaucoma will continue to increase. Despite recent advances in imaging and visual field-testing techniques that allow the establishment of earlier diagnosis and treatment initiation, significant numbers of glaucoma patients are undiagnosed and present late in the course of their disease. This can lead to irreversible vision loss, reduced quality of life, and a higher socioeconomic burden.

[0003] Glaucoma may be categorized as primary or secondary glaucoma. Primary glaucoma is often defined as glaucoma that develops due to an unknown cause, while secondary glaucoma may develop from a known cause, such as injury, cataract, tumour or diabetes. Primary or secondary glaucoma may also be classified as open angle or angle-closure. It is estimated that 64.3 million people worldwide have glaucoma, of which three-quarters are open-angle. Glaucoma, both open-angle and angle-closure, is the second leading cause of irreversible blindness worldwide, with approximately 8.4 million people becoming blind from the disease.

[0004] Glaucoma may have a significant impact on patients' quality of life, such as the ability to walk, drive or read. The psychological burden may increase with decreasing vision, along with a growing fear of blindness, social withdrawal, and depression. Measurable loss in quality of life and functionality may be observed even in the early stages of the disease and the impact increases as visual field (VF) loss progresses.

[0005] Current treatment or prevention include prescription eye-drops, oral medications, laser treatment, surgery or a combination. There is a need in the art for a medical device that can treat or prevent glaucoma without the need for invasive surgery.

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SUMMARY OF THE INVENTION

[0006] It is an object of the present invention to provide a shunt for minimally invasive glaucoma surgery which addresses the limitations of the prior art.

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[0007] According to one aspect of the present invention, there is provided a glaucoma shunt comprising: an elongate body with an outer surface and an inner surface, the elongate body comprising an inner wall that defines a lumen spanning a length of the elongate body.

[0008] In one embodiment, the shunt further comprises an umbrella connected to and extending from the glaucoma shunt such that the umbrella abuts an inner wall of an eye when positioned in the eye.

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[0009] In another embodiment, the shunt further comprises one or more anchors laterally extending away from the elongate body and spaced from the umbrella. The one or more anchors abut an outer surface of an eye when positioned in the eye.

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[0010] In yet another embodiment, at least a portion of the inner surface comprises poly(methylmethacrylate). In another embodiment, at least a portion of the umbrella comprises silicone. In another embodiment, at least a portion of the outer surface comprises acrylic. In another embodiment, at least a portion of the one or more anchors comprises silicone.

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[0011] In yet another embodiment, the glaucoma shunt decreases intraocular pressure by drainage of aqueous humour via the lumen. Embodiments of the glaucoma shunt may be used to treat glaucoma, for example primary open angle glaucoma or secondary open angle glaucoma.

[0012] According to another aspect of the present invention, there is provided a glaucoma shunt comprising: an elongate body with an outer surface and an inner

surface, the elongate body comprising an inner wall that defines a lumen spanning a length of the elongate body, wherein at least a portion of the inner surface comprises poly(methylmethacrylate), and at least a portion of the outer surface comprises acrylic.

5 [0013] In another embodiment, the glaucoma shunt further comprises an umbrella connected to and extending from the glaucoma shunt such that the umbrella abuts an inner wall of an eye when positioned in the eye, and at least a portion of the umbrella comprises silicone.

10 [0014] In yet another embodiment, the glaucoma shunt further comprises one or more anchors laterally extending away from the elongate body and spaced from the umbrella and at least a portion of the one or more anchors comprises silicone.

15 [0015] According to another aspect of the present invention, there is provided a method of decreasing intraocular pressure in an eye, the method comprising: inserting at least a portion of a glaucoma shunt into an anterior chamber of the eye, the glaucoma shunt comprising: an elongate body with an outer surface and an inner surface, the elongate body comprising an inner wall that defines a lumen spanning a length of the elongate body; and draining aqueous humour from the anterior chamber through the lumen.

20 [0016] In another embodiment of the present invention, the shunt further comprises an umbrella connected to and extending from the glaucoma shunt such that the umbrella abuts an inner wall of an eye when positioned in the eye. In another embodiment, the glaucoma shunt further comprises one or more anchors laterally extending away from the elongate body and spaced from the umbrella.

25 [0017] In yet another embodiment of the present invention, the method further comprising abutting at least a portion of the umbrella to the eye. In a further embodiment, abutting comprises abutting against a cornea of the eye. In another embodiment, abutting comprises abutting a portion of the umbrella against an inner surface of a cornea of the eye and abutting a portion of the anchor against an outer surface of the cornea.

[0018] In a further embodiment of the present invention, inserting comprises inserting the umbrella of the glaucoma shunt into the anterior chamber of the eye. In another embodiment, inserting comprises inserting the portion of the glaucoma shunt into the eye with the aid of a slit lamp. In yet another embodiment, inserting
5 comprises inserting the glaucoma shunt under a conjunctiva of the eye. In some embodiments, inserting comprises inserting the glaucoma shunt under a Tenon's capsule of the eye.

[0019] In an embodiment of the present invention, the umbrella prevents movement of the glaucoma shunt while draining. In another embodiment, the one or more
10 anchors prevent movement of the glaucoma shunt while draining.

[0020] According to another aspect of the invention, a use of a glaucoma shunt for decreasing intraocular pressure in an eye, the use comprising: insertion of at least a portion of the glaucoma shunt into an anterior chamber of the eye, the glaucoma shunt comprising: an elongate body with an outer surface and an inner surface, the elongate
15 body comprising an inner wall that defines a lumen spanning a length of the elongate body; and drainage of the aqueous humour from the eye through the lumen.

[0021] In an embodiment of the present invention, the shunt further comprises an umbrella connected to and extending from the glaucoma shunt such that the umbrella abuts an inner wall of an eye when positioned in the eye. In some embodiments, the
20 use further comprising abutment of at least a portion of the umbrella to the eye. The shunt further comprises one or more anchors laterally extending away from the elongate body and spaced from the umbrella.

[0022] In some embodiments, the glaucoma shunt is abutted against a cornea of the eye. In further embodiments, a portion of the umbrella is for abutment against an
25 inner surface of a cornea of the eye and a portion of the anchor is for abutment against an outer surface of the cornea.

[0023] In some embodiments, the umbrella of the glaucoma shunt is for insertion into the anterior chamber of the eye. In further embodiments, the portion of the glaucoma shunt is for insertion into the eye with the aid of a slit lamp. In yet another
30 embodiment, the glaucoma shunt is for insertion under a conjunctiva of the eye. In an

embodiment, the glaucoma shunt is for insertion under a Tenon's capsule of the eye. In some embodiments, the umbrella prevents movement of the glaucoma shunt after insertion. In one embodiment, the one or more anchors prevent movement of the glaucoma shunt after insertion.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] These and other features of the invention will become more apparent from the following description in which reference is made to the appended drawings wherein:

[0025] **FIGURE 1A** shows a side elevation view of an embodiment of the glaucoma shunt in the deployed configuration;

[0026] **FIGURE 1B** shows a side elevation view of the glaucoma shunt of Fig. 1A in the collapsed configuration;

[0027] **FIGURE 2** shows a front end view of the glaucoma shunt of Fig. 1A;

[0028] **FIGURE 2A** shows a cross-sectional view taken along the 2A-2A cross-section line in Fig. 2;

[0029] **FIGURE 3** shows a cross-sectional view of an eye and the glaucoma shunt of Fig. 1A; and

[0030] **FIGURE 4** shows a side elevation view of the glaucoma shunt of Fig. 1A with an embodiment of an injector.

DETAILED DESCRIPTION

[0031] One or more illustrative embodiments have been described by way of example. Described herein are glaucoma shunts and methods of treatment of glaucoma. All references to embodiments, examples, aspects, formulas, compounds, compositions, apparatuses, kits and the like are intended to be illustrative and non-limiting.

[0032] In one embodiment there is provided a glaucoma shunt 10 for decreasing intraocular pressure in an eye. Shunt 10 comprises an elongate body 12 with an outer surface 14 and an inner surface 16. Shunt 10 comprises an inner wall 17 that defines lumen 18. The lumen 18 spans a length of elongate body 12. Shunt 10 may comprise umbrella 20 mounted on and extending from shunt 10. The umbrella 20 abuts an inner wall of the eye when positioned in the eye. Glaucoma shunt 10 may be used to treat or prevent primary open angle glaucoma or secondary open angle glaucoma.

[0033] Inner membrane wall 34 refers to an inward facing surface of a part of the eye, such as a surface facing the anterior chamber. In some embodiments, the inner membrane wall 34 refers to the inner wall of the cornea, sclera, or both. Outer membrane surface 36 refers to an outer surface of a part of the eye, such as an outward facing surface (i.e. away from the anterior chamber) of the cornea, sclera, or both. In some cases, the outer surface refers to parts of the conjunctiva or Tenon's capsule.

[0034] Referring to Figs. 1 and 2, elongate body 12 comprises a head 22 and an opposed tail 24. Head 22 may define a suitably pointed shape with one or more slanted surfaces 26. A portion of head 22 may comprise a biocompatible material, such as poly(methylmethacrylate) (PMMA). Lumen 18 may extend through the elongate body 12 from head 22 to tail 24. Lumen 18 may be defined by inner surface 16. Lumen 18 may be free of any valves or obstructions to allow passive drainage of fluid, such as aqueous humour, from the eye.

[0035] Referring to Figs. 1A, 1B and 2A, umbrella 20 can move between deployed and collapsed configurations. Umbrella 20 may be mounted on, or be integrated with, elongate body 12. Umbrella 20 may extend in a direction substantially away from head 22 and toward tail 24. Umbrella 20 has a suitable shape, such as a frustoconical shape and others. Movement of the glaucoma shunt 10 may be prevented by umbrella 20 when positioned in the eye. In example of a collapsed configuration of umbrella 20 is depicted in Fig. 1B and an example of a deployed configuration of umbrella 20 is depicted in Fig. 1A. In the deployed configuration, width 44A of the umbrella 20 may be greater than width 44B of the umbrella in the collapsed configuration. The collapsed configuration may be used during insertion into the eye of the patient. The

umbrella 20 may then be deployed when it reaches anterior chamber 30. Deployed umbrella 20 may then engage the inner membrane wall 34 and prevent movement of the umbrella, relative to the eye. In some cases, umbrella 20 may transition between the collapsed and deployed configurations by mechanical means, such as a lever or switch. In other cases, umbrella 20 may transition between the configurations by a passive mechanism, such as elasticity of the umbrella, or free movement. Umbrella 20 may be stored in a collapsed configuration in an injector.

[0036] Referring to Fig. 1, shunt 10 may comprise one or more anchors 38 extending away from, and substantially perpendicular to, the elongate body 12. Anchors 38 may be spaced from the umbrella 20 by width 46. For example, anchors 38 may be spaced from umbrella 20 such that a part of the eye, such as the width of cornea 32, may pass between anchors 38 and umbrella 20. In some cases, width 46 is sized to accommodate the diameter of the cornea 32 or the sclera 48 (Fig. 3). One or more anchors 38 may abut an outer membrane surface 36 of eye 28 in use. Movement of the glaucoma shunt 10 may be prevented by one or more anchors 38 in use. The shunt 10 may be locked in place relative to the eye by umbrella 20 and/or one or more anchors 38.

[0037] Referring to Figs. 1 and 3, in one embodiment there is described a method of decreasing intraocular pressure in an eye 28, the method comprising inserting at least a portion of glaucoma shunt 10 into an anterior chamber 30 of eye 28, abutting at least a portion of the umbrella 20 to an interior surface of eye 28. In some embodiments, the umbrella 20 and anchor 38 may act to “lock” the shunt in position relative to the eye. Shunt 10 may act to drain the aqueous humour from the anterior chamber 30 via the lumen 18. Draining the aqueous humour may act to lower the intraocular pressure. The aqueous humour may drain into an appropriate subconjunctival area, such as a bleb 50 between the sclera and the Tenon’s capsule or conjunctiva. The shunt 10 may be used to treat glaucoma, such as primary open angle or secondary open angle glaucoma by decreasing the intraocular pressure.

[0038] Referring to Figs. 1 and 3, at least part of shunt 10 is inserted into the eye 28 in use. Shunt 10 may be inserted through the cornea 32 into the anterior chamber 30. The anterior chamber may comprise aqueous humour which may be drained through

lumen 18 by passive means, such as diffusion. In certain embodiments, the shunt 10 may be inserted under the conjunctiva 40. In further embodiments, the shunt 10 may be inserted under the Tenon's capsule 42 and conjunctiva 40. Shunt 10 may be inserted such that the umbrella 20 is within the anterior chamber 30 of the eye.

5 [0039] Referring to Figs. 3 and 4, insertion of shunt 10 may occur without the need for surgery. Shunt 10 may be inserted via an insertion device 52, such as the embodiment shown in Fig. 4. Insertion device 52 comprises body 56, actuator 58, and an adjustable head 54. Body 56 may be shaped as a grip or handle to accommodate a user's hand. A user of device 52 may position the head 54 using one or more hinges
10 or joints, such as accordion hinge 54A. Hinge 54A may permit a right or left-handed user to operate the device. Other types of hinges known in the art may be used, such as living hinges and others.

[0040] Actuator 58 may be provided as a slider 59. Slider 59 may be connected to pads 60 such that when the slider is moved along an axis 62, the pads move in a
15 direction along head 54 substantially towards distal end 54B, such as direction 64. Pads 60 may rest against anchor 38 and may act to grip the outer surface of shunt 10 to hold it in place relative to the device 52. One or more pads 60 may be connected to a needle 62. Needle 62 may be hollow, with the shunt 10 within the needle 62, and have a suitable shape with one or more sloped edges. In some cases, needle 62 is
20 shaped to correspond with distal end 54B of head 54.

[0041] Actuator 58 may be provided as a push button (not pictured). The button may be connected to pads 60 such that when the button is depressed between a first and second position, the pads move in a direction along head 54 substantially towards
25 distal end 54B, such as direction 64. When the button is released from the second position to the first position, the pads may move in a direction substantially towards hinge 54A, such as direction 66. The first and second positions may be reversed such that depressing the button moves the pads in direction 66.

[0042] The adjustable head 54 may be inserted into the eye, such as subconjunctival or under the Tenon's capsule. A user then operates the actuator 58, such as slider 59
30 or a button, which is connected to operate one or more pads 60. When the head 54 is in position (i.e. under the conjunctiva but before breaching the outer wall of the eye)

the user may operate the actuator 58. The actuator 58 may move pads 60 and needle 62 through the outer wall of the eye (such as the cornea and/or sclera). When the actuator 58 has moved from a first position, such as a rear 55 of the device in cases of a slider 59, to a second position, such as indentation 56A, the pads 60 may disengage from the shunt 10. Once the pads 60 have disengaged, the actuator 58 may be moved back from the second position to the first position, thereby causing the pads 60 and needle 62 to move in a direction away from the eye, such as direction 66. The device 52 may be removed, leaving the shunt 10 in the eye.

[0043] Insertion of glaucoma shunt 10 may occur with the aid of a slit lamp or surgical microscope. In some cases, shunt 10 is inserted ab externo or ab interno.

[0044] Referring to Fig. 3, shunt 10 may abut against cornea 32, such as in the anterior chamber, of eye 28. Umbrella 20 may abut against an inner membrane surface 34 of cornea 32 after insertion. Anchor 38 may abut against an outer membrane surface 36 of cornea 32, such as under tenon's capsule at the limbus external to cornea. Contacting or abutting the inner membrane surface 34 and/or outer membrane surface 36 may decrease movement of shunt 10 relative to eye 28.

[0045] Portions of shunt 10 may comprise biocompatible material. Examples of suitable material are poly(methylmethacrylate) (PMMA), silicone, acrylic, hydrophobic acrylate, hydrophobic acrylate, COLLAMER™ and others. In some cases, at least a portion of the inner surface 16 comprises PMMA. Inner surface 16 may be comprised entirely of PMMA. A portion of the first end 22, such as the tip of the shunt and slanted surfaces 26, may comprise PMMA. All or at least a portion of the umbrella 20 may comprise silicone. All or at least a portion of the outer surface 14 may comprise acrylic. All or at least a portion of the one or more anchors 38 may comprise silicone.

[0046] Shunt 10 may be a microshunt. Shunt 10 may have a suitable length, such as 8 mm. Shunt 10 has an outer diameter 70, such as 135-195 μm , for example 165 μm . Shunt 10 has a suitable inner diameter 72, such as 20-80 μm , for example 50 μm . Shunt 10 may have a suitable width or spacing 46 between the umbrella 20 and anchor 38 to accommodate a part of the eye, such as the cornea or sclera. Spacing 46

may be a suitable width, such as 0.3-0.8 mm, for example 0.5 mm. The actual size of the shunt will be determined based on the application.

[0047] Shunt 10 may be used in combination with other suitable treatments. Some examples include cataract surgery, prescription eye-drops, oral medication, laser treatment, trabeculectomy, other shunts, surgery and others. Shunt 10 may be used in combination with metabolites such as MMC (mitomycin C), 5-FU (5-fluorouracil), Anti-Vascular Endothelial Growth Factor (AntiVEGF) treatments such as Avastin/Lucentis/Eylea, and others.

[0048] In the event of conflicting information and statements between any reference referred to or incorporated herein and the present disclosure, the present disclosure will act as the guiding authority.

[0049] The present invention has been described with regard to one or more embodiments. However, it will be apparent to persons skilled in the art that a number of variations and modifications can be made without departing from the scope of the invention as defined in the claims.

WHAT IS CLAIMED IS:

1. A glaucoma shunt comprising:

an elongate body with an outer surface and an inner surface, the elongate body comprising an inner wall that defines a lumen spanning a length of the elongate body.

2. The glaucoma shunt of claim 1, further comprising an umbrella connected to and extending from the glaucoma shunt such that the umbrella abuts an inner wall of an eye when positioned in the eye.

3. The glaucoma shunt of any one of claims 1-2, further comprising one or more anchors laterally extending away from the elongate body and spaced from the umbrella.

4. The glaucoma shunt of claim 3, wherein the one or more anchors abut an outer surface of an eye when positioned in the eye.

5. The glaucoma shunt of any one of claims 1-4, wherein at least a portion of the inner surface comprises poly(methylmethacrylate).

6. The glaucoma shunt of any one of claims 1-5, wherein at least a portion of the umbrella comprises silicone.

7. The glaucoma shunt of any one of claims 1-6, wherein at least a portion of the outer surface comprises acrylic.

8. The glaucoma shunt of any one of claims 2-7, wherein at least a portion of the one or more anchors comprises silicone.

9. The glaucoma shunt of any one of claims 1-8, wherein the glaucoma shunt decreases intraocular pressure by drainage of aqueous humour via the lumen.

10. The glaucoma shunt of claim 9, for treating primary open angle glaucoma.

11. The glaucoma shunt of claim 9, for treating secondary open angle glaucoma.

12. A glaucoma shunt comprising:

an elongate body with an outer surface and an inner surface, the elongate body comprising an inner wall that defines a lumen spanning a length of the elongate body,

wherein at least a portion of the inner surface comprises poly(methylmethacrylate), and at least a portion of the outer surface comprises acrylic.

13. The glaucoma shunt of claim 12, further comprising an umbrella connected to and extending from the glaucoma shunt such that the umbrella abuts an inner wall of an eye when positioned in the eye, and at least a portion of the umbrella comprises silicone.

14. The glaucoma shunt of any one of claims 12-13, further comprising one or more anchors laterally extending away from the elongate body and spaced from the umbrella and at least a portion of the one or more anchors comprises silicone.

15. A method of decreasing intraocular pressure in an eye, the method comprising:

inserting at least a portion of a glaucoma shunt into an anterior chamber of the eye, the glaucoma shunt comprising:

an elongate body with an outer surface and an inner surface, the elongate body comprising an inner wall that defines a lumen spanning a length of the elongate body; and

draining aqueous humour from the anterior chamber through the lumen.

16. The method of claim 15, wherein the glaucoma shunt further comprises an umbrella connected to and extending from the glaucoma shunt such that the umbrella abuts an inner wall of an eye when positioned in the eye.

17. The method of claim 16, further comprising abutting at least a portion of the umbrella to the eye.

18. The method of any one of claims 15-17, wherein the shunt further comprises one or more anchors laterally extending away from the elongate body and spaced from the umbrella.

19. The method of any one of claim 17-18, wherein abutting comprises abutting against a cornea of the eye.

20. The method of claim 19, wherein abutting comprises abutting a portion of the umbrella against an inner surface of a cornea of the eye and abutting a portion of the anchor against an outer surface of the cornea.

21. The method of any one of claim 15-20, wherein inserting comprises inserting the umbrella of the glaucoma shunt into the anterior chamber of the eye.

22. The method of any one of claim 15-21, wherein inserting comprises inserting the portion of the glaucoma shunt into the eye with the aid of a slit lamp.

23. The method of any one of claim 15-22, wherein inserting comprises inserting the glaucoma shunt under a conjunctiva of the eye.

24. The method of claim 23, wherein inserting comprises inserting the glaucoma shunt under a Tenon's capsule of the eye.

25. The method of any one of claim 16-24, wherein the umbrella prevents movement of the glaucoma shunt while draining.

26. The method of claim 25, wherein the one or more anchors prevent movement of the glaucoma shunt while draining.

27. A use of a glaucoma shunt for decreasing intraocular pressure in an eye, the use comprising:

insertion of at least a portion of the glaucoma shunt into an anterior chamber of the eye, the glaucoma shunt comprising:

an elongate body with an outer surface and an inner surface, the elongate body comprising an inner wall that defines a lumen spanning a length of the elongate body; and

drainage of the aqueous humour from the eye through the lumen.

- 5 28. The use of claim 27, wherein the shunt further comprises an umbrella connected to and extending from the glaucoma shunt such that the umbrella abuts an inner wall of an eye when positioned in the eye.
29. The use of claim 28, further comprising abutment of at least a portion of the umbrella to the eye.
- 10 30. The use of any one of claims 28-29, wherein the shunt further comprises one or more anchors laterally extending away from the elongate body and spaced from the umbrella.
31. The use of any one of claims 28-30, wherein the glaucoma shunt is abutted against a cornea of the eye.
- 15 32. The use of claim 31, wherein a portion of the umbrella is for abutment against an inner surface of a cornea of the eye and a portion of the anchor is for abutment against an outer surface of the cornea.
33. The use of any one of claim 28-32, wherein the umbrella of the glaucoma shunt is for insertion into the anterior chamber of the eye.
- 20 34. The use of any one of claim 28-33, wherein the portion of the glaucoma shunt is for insertion into the eye with the aid of a slit lamp.
35. The use of any one of claim 28-34, wherein the glaucoma shunt is for insertion under a conjunctiva of the eye.
36. The use of claim 34, wherein the glaucoma shunt is for insertion under a
25 Tenon's capsule of the eye.
37. The use of any one of claim 28-34, wherein the umbrella prevents movement of the glaucoma shunt after insertion.

38. The use of claim 37, wherein the one or more anchors prevent movement of the glaucoma shunt after insertion.

39. The use of any one of claim 28-38, for treating primary open angle glaucoma.

40. The use of any one of claim 28-38, for treating secondary open angle glaucoma.

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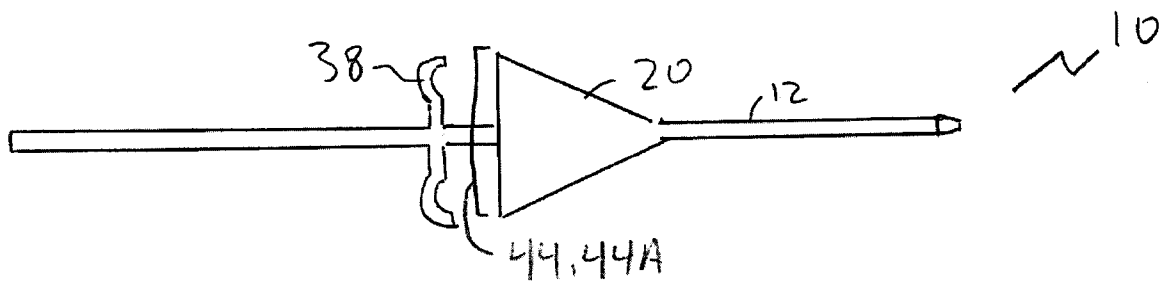


FIG. 1 A

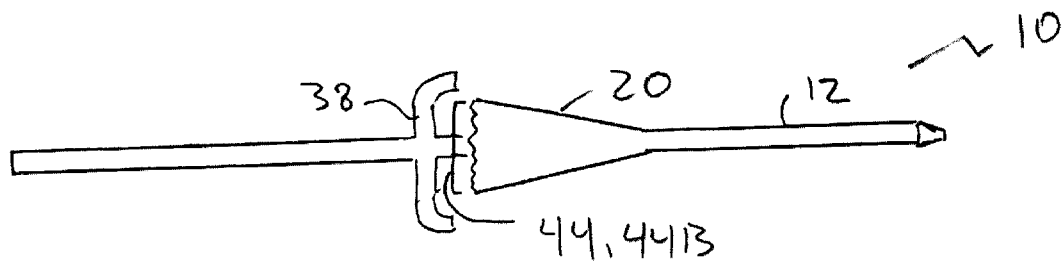


FIG. 1 B

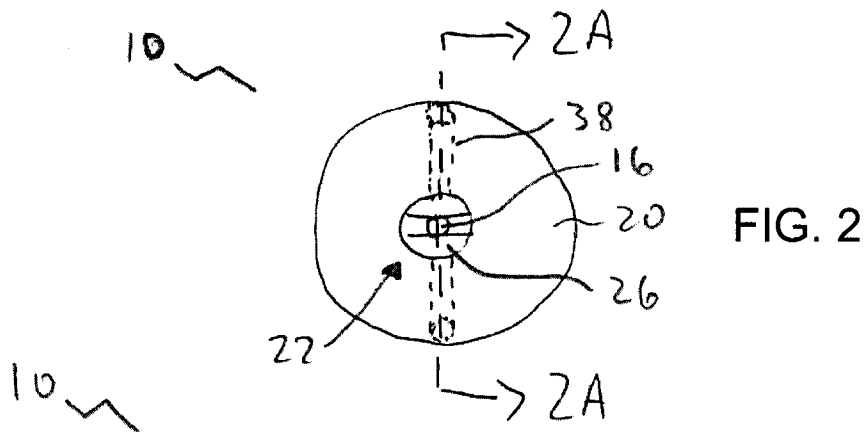


FIG. 2

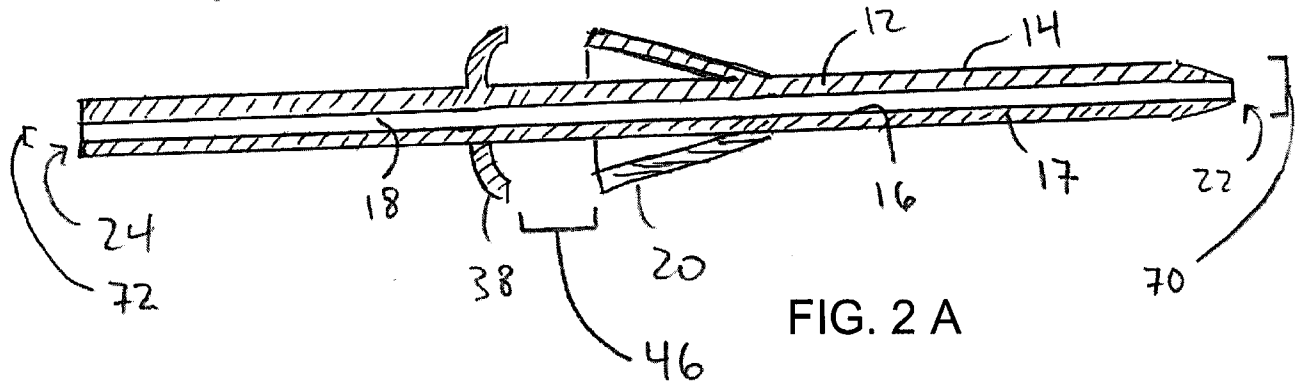


FIG. 2 A

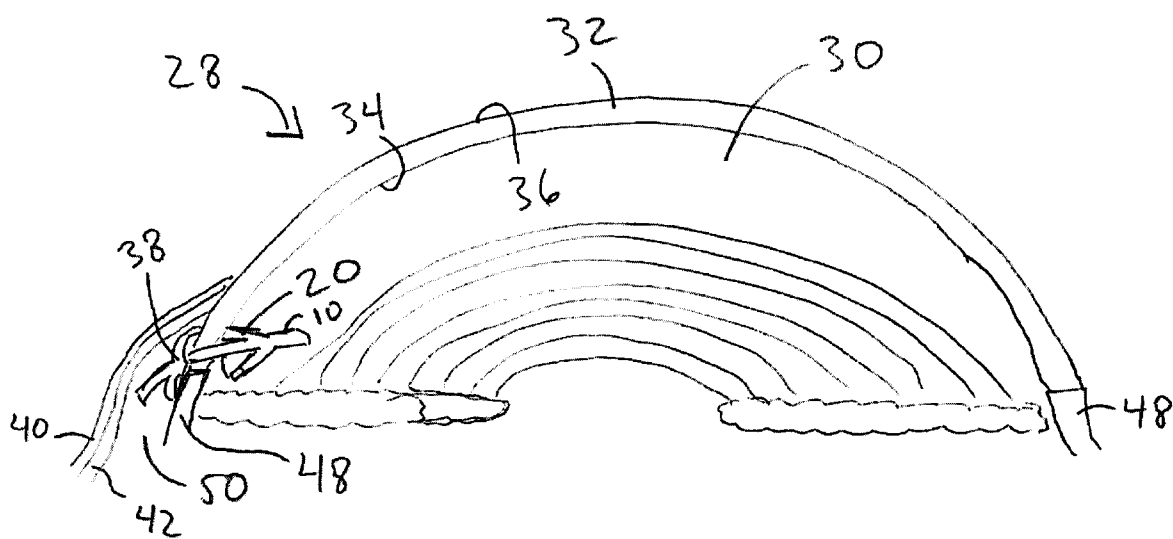


FIG. 3

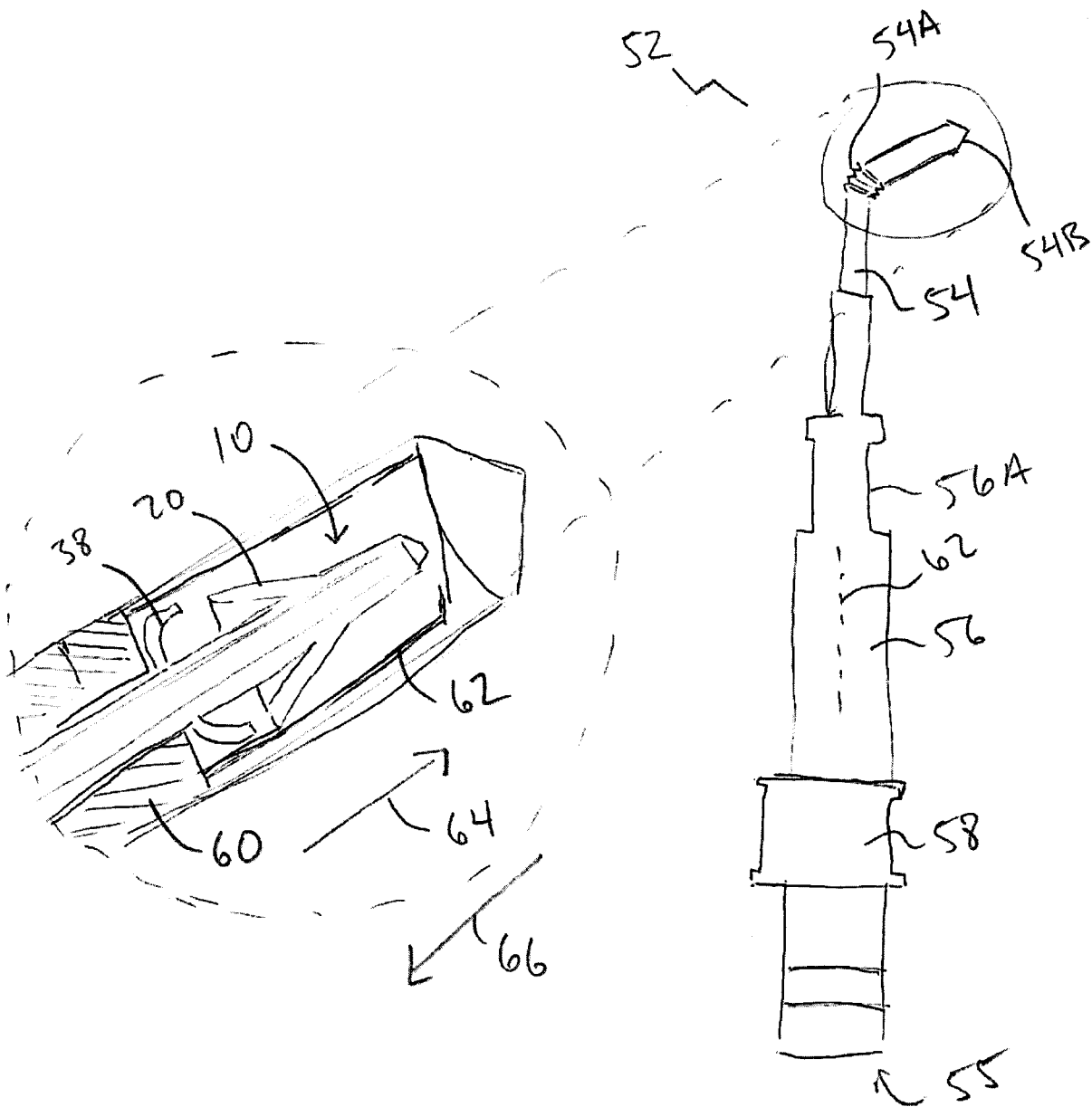


FIG. 4

