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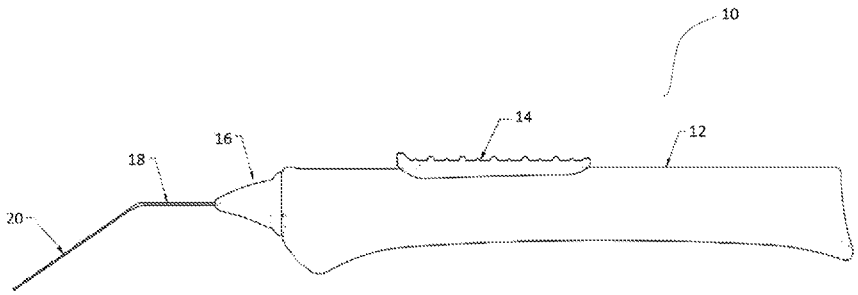

Figure 1

(57) **Abstract:** An ophthalmic surgical instrument comprising a handpiece, a grip, and a hollow shaft with an elongate rupturing device extending slidably from the hollow shaft. The elongate rupturing device is adapted to be inserted into tissue spaces within the eye. Embodiments of the invention are described wherein the elongate rupturing device may be a barbed catheter, or optical fibre, or adapted to deliver a payload into the eye, or any combination of the aforementioned. The ophthalmic surgical instrument is used in transluminal or circumferential trabeculotomy to rupture tissue within the eye to relieve intraocular pressure in patients suffering from glaucoma.

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OPHTHALMIC SURGICAL INSTRUMENT AND METHOD OF USE

FIELD OF THE INVENTION

[0001] The present invention relates broadly to improved methods and apparatus for the reduction of elevated pressure in the human eye. In particular, the present invention relates to an improved ophthalmic surgical instrument and a method of use of said instrument for performing trabeculotomy in patients suffering from glaucoma.

BACKGROUND TO THE INVENTION

[0002] Glaucoma encompasses a group of eye diseases characterised by pathological changes in the optic disc and damage to the optic nerve of the eye, which, if left untreated, leads to irreversible vision loss. The primary etiological factor in all forms of glaucoma is increased fluid pressure, or intraocular pressure, of the eye. Increased intraocular pressure is usually due to a resistance to the outflow of aqueous humour within the eye.

[0003] In most cases, the resistance to the outflow of aqueous humour occurs in the trabecular meshwork located adjacent to the canal of Schlemm, or more specifically, the juxtacanalicular meshwork. Trabecular meshwork tissue allows aqueous humour to enter the canal of Schlemm, interchangeably referred to as Schlemm's canal, which then drains into aqueous collector channels located in the posterior wall of the canal, eventually leading to aqueous veins. The intraocular pressure of the eye is determined through balance between the production of aqueous humour and its exit through the trabecular meshwork (the major route) or through uveoscleral outflow (the minor route).

[0004] Trabeculotomy is a commonly performed procedure to reduce resistance in the outflow pathway of the eye and therefore reduce intraocular pressure in individuals suffering from glaucoma. Transluminal trabeculotomy, also referred to as circumferential trabeculotomy, involves disrupting or removing part or all of the trabecular meshwork along the circumference of Schlemm's canal by tearing, excising, cutting, or other techniques.

[0005] Gonioscopy Assisted Transluminal Trabeculotomy ('GATT') is a minimally invasive glaucoma treatment procedure involving visualising the eye through a gonioscope, also

known as a gonioprism, and making one or more incisions in the cornea. These incisions, which are typically 1 mm in size, are made in the periphery of the cornea to access the anterior chamber of the eye. In some cases, an existing corneal incision from concurrent cataract surgery is utilised. After entering the eye, the procedure involves creating an incision or opening in the trabecular meshwork, cannulating Schlemm's canal between 30 and 360 degrees, and unroofing the canal. GATT works by restoring the trabeculocanalicular outflow pathway, allowing increased flow of aqueous humour from the anterior chamber directly into and around Schlemm's canal, ultimately exiting through the collector channels. This effectively works to reduce intraocular pressure.

[0006] There are two commonly practised techniques for ab interno transluminal trabeculotomy. The first approach involves inserting a catheter, suture, or other elongated device through a goniotomy. The device is then advanced through Schlemm's canal, intubating between 180 and up to 360 degrees before exiting the canal and re-entering the anterior chamber. Tension is then applied to the ends of the device to rupture the trabecular meshwork. This method allows for precise control over the extent of the transluminal trabeculotomy, enabling the rupture of a specific portion or the entire circumference of the trabecular meshwork. A shortcoming of this technique is that it requires the use of both hands and a surgical forceps, meaning that the gonioprism must be either handed off to or held in place by an assistant.

[0007] The other commonly practised technique involves inserting an elongated and flexible device, such as a catheter, suture, probe, or similar member, into Schlemm's canal. Once inside the canal, tension is applied to the device, or the device itself is used to exert a radial force, similar to a garrotte, within Schlemm's canal. The radial force ruptures the trabecular meshwork that lines the section of Schlemm's canal where the device is inserted. One advantage of this method is that is allows the surgeon to titrate the size or angle of tear of the goniotomy performed, catering the procedure to the clinical requirements of the patient. Further, if a handpiece-propelled device is used, the technique may be performed using only one hand. However, a shortcoming of the aforementioned method is that during the application of the radial force, a distal tip of the device may proximally shift within the canal, causing the device to partially exit the canal and reducing the size of the intended transluminal goniotomy. Furthermore, both methods do not present a simple way for the

surgeon to visualise the extent of the transluminal trabeculotomy, with the surgeon requiring additional assistance or relying on experience.

[0008] In order to overcome the aforementioned drawbacks of the above methods and the prior art, there exists a need for an ophthalmic surgical device that is simple to use and allows the surgeon themselves to visualise the extent of the transluminal trabeculotomy. Further, there exists a need to secure the device in place while tension is being applied to tear the juxtacanalicular meshwork.

[0009] It is an aspect of the present invention to overcome or ameliorate the problems of the prior art by providing an improved ophthalmic surgical instrument for use in transluminal trabeculotomy.

SUMMARY OF THE INVENTION

[0010] In a first aspect the invention comprises an ophthalmic surgical instrument comprising a handpiece held by a user having a proximal and a distal end; the handpiece comprising a hollow shaft extending from the distal end of the handpiece; a flexible elongate rupturing device extending from the hollow shaft, wherein the elongate rupturing device is adapted to be advanced through tissue spaces within an eye.

[0011] In an embodiment the elongate rupturing device comprises a plurality of rearwardly and outwardly extending barbs; wherein the barbs are adapted to engage surrounding tissue within the tissue spaces of the eye.

[0012] In an embodiment the barbs are unidirectional.

[0013] In an embodiment the barbs are bidirectional.

[0014] In an embodiment the elongate rupturing device comprises a central hollow tube adapted to deliver a payload to the eye.

[0015] In an embodiment the elongate rupturing device is an optical fibre, the optical fibre being slidably engaged with the hollow shaft and having an outer diameter between 50 µm and 350 µm.

[0016] In another aspect the invention comprises a method for performing trabeculotomy ab interno, the method comprising the steps of: making an incision in the trabecular meshwork of the eye to access the lumen of Schlemm's canal; placing a distal end of an elongate rupturing device through the incision and into Schlemm's canal; advancing the elongate rupturing device through Schlemm's canal between an angle of 0 and 360 degrees; applying tension to the optical fibre within the canal thereby rupturing the surrounding tissue thereby creating a trabeculotomy; and withdrawing the device through the incision.

[0017] In an embodiment the elongate rupturing device comprises barbs located along the device, and wherein prior to applying tension to the optical fibre, the elongate rupturing device is slightly retreated proximally or tangentially to engage the barbs with the surrounding tissue.

[0018] In an embodiment the elongate rupturing device is advanced along the full circumference of Schlemm's canal.

[0019] In an embodiment the elongate rupturing device is initially advanced 180 degrees, then repeating the procedure to then advance the remaining 180 degrees of the canal thereby creating a 360 degree trabeculotomy.

[0020] It should be noted that any one of the aspects mentioned above may include any of the features of any of the other aspects mentioned above and may include any of the features of any of the embodiments described below as appropriate.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] Preferred features, embodiments and variations of the invention may be discerned from the following Detailed Description which provides sufficient information for those skilled in the art to perform the invention. The Detailed Description is not to be regarded as limiting the scope of the preceding Summary of the Invention in any way. The Detailed Description will make reference to a number of drawings as follows.

[0022] Figure 1 is a side view of the ophthalmic surgical instrument;

[0023] Figure 2 is a close-up side view of the barbed elongate rupturing device;

[0024] Figure 3 is a close-up side view of the elongate rupturing device adapted to deliver a payload;

[0025] Figure 4 is a close-up side view of the elongate rupturing device adapted to transmit light;

[0026] Figure 5 illustrates several embodiments of the elongate rupturing device;

[0027] Figure 6 illustrates a cross-sectional view of the structure of an eye;

[0028] Figure 7 illustrates the creation of an incision in the trabecular meshwork of the eye;

[0029] Figure 8 illustrates the advancement of the optical fibre within Schlemm's canal in the eye; and

[0030] Figure 9 illustrates the completion of the trabeculotomy.

DETAILED DESCRIPTION OF THE INVENTION

[0031] The following detailed description of the invention refers to the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings and the following description to refer to the same and like parts. Dimensions of certain parts shown in the drawings may have been modified and/or exaggerated for the purposes of clarity or illustration.

[0032] Referring to Figure 1, the ophthalmic surgical instrument **10** comprises a handpiece **12** with a grip **14** adapted to be held with one hand. The handpiece **12** comprises a proximal and a distal end, wherein the distal end features a conical connector **16** from which a hollow shaft **18** extends. An elongate rupturing device **20** emerges from the hollow shaft, adapted to be advanced into tissue spaces for use in ophthalmic surgery and used to cannulate spaces within the eye such as, but not limited to, the canal of Schlemm, aqueous humour collector channels, aqueous veins, retinal veins, and the suprachoroidal space. It is to be understood that the term emerges is not limiting and could be interpreted as extending from as one of many other embodiments.

[0033] The elongate rupturing device **20** is made from a flexible material, which enables the device **20** to be advanced through and follow the curvature of desired tissue spaces without damaging the surrounding tissue structure. The distal end of the rupturing device **20** is appropriately shaped, for example with a curved distal end, for advancement along tissue spaces without rupturing the surrounding tissue.

[0034] In an embodiment the elongate rupturing device **20** comprises barbs **22** which allow the device **20** to be hooked to surrounding tissue during transluminal goniotomy, avoiding slippage of the device **20**. The barbs **22** may be structured to allow for retraction when the device is distally pushed and advanced along tissue spaces, while protruding when the device is retracted proximally. The angle of the barbs **22** allowing for different ease of hooking with the surrounding tissue; the barbs **22** more likely to latch onto surrounding tissue as their angle of protrusion approaches 90°.

[0035] Referring to Figure 2, the barbs **22** may be arranged in any manner allowing for the elongate rupturing device **20** to remain anchored as tension is applied to the device **20** or as the device is retracted proximally. Barbs **22** may extend partially or completely along the length and circumference of the device **20** and arranged in any suitable manner. Of importance is the presence of barbs **22** near the distal end of the device **20** to prevent any movement or slippage of the distal end of the device **20** when rupturing the surrounding tissue.

[0036] In an embodiment the barb orientation is unidirectional, but the invention also allows for bi-directional barbs **22** with varying sizes. This arrangement significantly enhances resistance to catheter migration. It accomplishes this by requiring the barbs, which oppose movement in a specific direction, to traverse a longer section of tissue before being withdrawn or displaced from it. The barbs may also be of varying shapes, widths and sizes, for example, the barbs located at the distal end of the device **20** may be longer or shorter than barbs located at a proximal end of the device **20.**

[0037] Furthermore, while the above description discloses the use of individual barbs **22**, it is to be understood that the barbs may be a single ring extending around the device **20** providing a wall that extends outwardly and proximally with an edge adapted to latch onto

tissue. Yet other types of anchoring devices may also be used.

[0038] In an embodiment the elongate rupturing device is a flexible hollow tube, such as a catheter. The flexible hollow tube features an inner hollow section **25** suitable for and delivering a solid or fluid payload into desired tissue spaces. Such payloads may be located within a payload storage unit **26** containing a hollow volume **28** adapted to hold the payload. The payload storage unit **26** may be located within the handpiece **12**, however, it is not limited to such a configuration and may very well be located external of the surgical instrument.

[0039] Payloads may comprise a fluid and/or solid object such as a stent or drug. Examples of fluid payloads include, but are not limited to, viscoelastic fluids, saline solutions, and aqueous solutions. Solid payloads include, but are not limited to, microsurgical instruments such as forceps, instruments for penetrating tissue, instruments for cutting tissue, stents, light guides, and wires.

[0040] In an embodiment the elongate rupturing device **20** may comprise a light source (not illustrated) for illuminating the distal end of the device. The light source may be coupled to the device, directing light through said device and providing illumination. The light source may also be coupled to a light guide to illuminate the distal end of the catheter, wherein a light guide refers to optical elements capable of transmitting electromagnetic radiation through the guide. Such light guides may include, but are not limited to, mirrors arranged to direct light from a source to a destination, a flexible optical fibre, and a bundle of optical fibres.

[0041] The elongate rupturing device **20** may comprise a connector located at the proximal end of the handpiece. The connector may facilitate, without limitation, an illumination source, or an external payload to be coupled to the device **20**. The illumination source coupled to the device may be used to illuminate its distal end.

[0042] In an embodiment, the elongate rupturing device **20** is slidably engaged with the handpiece **12**, allowing for extension or retraction of the rupturing device **20** to a desired length.

[0043] In these embodiments, the elongate rupturing device **20** may be manufactured

from a variety of suitable materials to allow for insertion into the body and for delivering fluid payloads. Such materials are well known in the art, such as but not limited to polymers such as polyimides, polyamides, polyolefins, polyvinylchlorides, fluoropolymers, polysulfones, polyurethanes and compositions thereof.

[0044] In an embodiment, the elongate rupturing device **20** is a flexible optical fibre adapted to mechanically rupture tissue. Such an optical fibre may be approximately 200 µm in length. Illuminated rupturing devices allow the surgeon to visualise the location of the rupturing device **20** as it is inserted and advanced along desired tissue spaces, allowing for increased accuracy in the location of tearing. The optical fibre as the elongate rupturing device **20** may be distally illuminated **21** or may be longitudinally illuminated **23** along the length of the device, dependent on its material.

[0045] In the embodiment where the rupturing device **20** is an optical fibre, the optical fibre may be made from material appropriate for simultaneously transmitting light and rupturing tissue. These materials may include, but not are not limited to silica, doped silica including germanium-doped or phosphorus-doped silica, plastic including polymethyl methacrylate or polycarbonate, glass including fluoride glass, chalcogenide glass or heavy-metal oxide glass, and polymer optical fibres made from perfluorinated polymers or polyethylene.

[0046] The use of an optical fibre as a rupturing tool offers an additional advantage of reduced production costs for the surgical apparatus. Unlike existing prior art devices that include catheters or similar devices that typically consist of a hollow tube for delivering a payload, the optical fibre of the invention does not require such components for payload delivery. This design simplicity results in a more cost-effective manufacturing process through the elimination of the hollow tube and payload delivery mechanism. The instrument may include connections for coupling light from light source. The mechanism of directing light through an optical fibre is well known in the art.

[0047] Several embodiments of the elongate rupturing device **20** are demonstrated in Figure 5, demonstrating various barb **22** arrangements, embodiments with and without an internal hollow tube **25**, and demonstrating a distal illumination **21** of the device. However, it

should be noted that the elongate rupturing device **20** is not limited to such embodiments, and various improvements and alternative configurations may be possible depending on the user's requirements.

[0048] Detailed methods for performing transluminal trabeculotomy ab interno utilising the invention is described as follows. The described method allows for the alleviation of intraocular pressure for the treatment of glaucoma. In embodiments of the invention, the lumen of Schlemm's canal is accessed from the anterior chamber without the need or requirement for dissection of the sclera or conjunctiva. This is possible because the inner wall of Schlemm's canal, the trabecular meshwork, is directly adjacent to the anterior chamber.

[0049] Referring to Figure **6,** a cross-sectional representation of the eye is provided. The lens **32**, iris **34**, cornea **36**, location of the trabecular meshwork **28**, and the canal of Schlemm **40** are visible.

[0050] A microsurgical instrument is used to create a goniotomy, or incision, of Schlemm's canal. The incision is made from within the anterior chamber with the aid of a gonioprism or other imaging device to visualise the anterior chamber angle. As shown in Figure **7**, an incision **42** is made in the trabecular meshwork **38** using a cutting instrument (not shown) from within the anterior chamber. The rupturing device **20** may then be used to cannulate the goniotomy opening, i.e., the device is inserted into the goniotomy opening and advanced along Schlemm's canal **30.** The device may be advanced within the canal to a desired angle, typically between 0 and 360 degrees.

[0051] In an embodiment the device **20** may be advanced through the canal by hand, the user applying a force to the handpiece **12** to facilitate advancement along the canal. Alternatively, a gripping instrument **44** may be used to aid in positioning and advancing the device **20** through the canal. The gripping instrument **44** may be but is not limited to a surgical forceps or an ocular micro forceps.

[0052] The device **20** is advanced through Schlemm's canal to desired angle between 0 and 360 degrees, before retracting (pulling) the instrument **10** slightly proximally or tangentially allowing the barbs to engage with the surrounding tissue. Traction or tension may then be applied to the device **20**, to pull the device into the anterior chamber, thereby

rupturing the trabecular meshwork, exposing Schlemm's canal to alleviate intraocular pressure. The device may then be further advanced along Schlemm's canal and retrieved using the gripping instrument **44.**

[0053] In an embodiment of the invention, an incision is made through the cornea **36** for insertion of the elongate rupturing device **20**.

[0054] In an embodiment of the invention, the elongate rupturing device **20** is advanced within Schlemm's canal until the distal end of the optical fibre is near the initial goniotomy incision, i.e., 360 degrees. The gripping instrument **44** may then be used to retrieve the distal end of the end of the device **20** as illustrated in Figure **8**. Traction or tension may then be applied to the device **20** to pull the device into the anterior chamber, thereby rupturing the trabecular meshwork, exposing Schlemm's canal, and creating a 360 degree trabeculotomy **46** ab interno as shown in Figure **9**.

[0055] In cases where Schlemm's canal is scarred or malformed, it is not always possible to advance the device **20** around the complete circumference of the canal. In this situation, the trabeculotomy procedure utilising the surgical apparatus is performed on a portion of Schlemm's canal as a partial trabeculotomy. The device **20** is partially advanced through Schlemm's canal 30 degrees or more. The distal end of the device **20** may then be retrieved through the trabecular meshwork via a goniotomy. Applying tension to one or both ends of the optical fibre then forms a partial trabeculotomy between the goniotomy and the distal end of the device.

[0056] In certain embodiments of the invention, the trabeculotomy may continue to be applied to the untreated portion of Schlemm's canal by cannulating the remaining portion of the canal and repeating the partial trabeculotomy procedure. For example, the entire canal could be treated by two 180 degree procedures, three 120 degree procedures, or other desired combinations. In highly compromised or diseased eyes, only a portion of Schlemm's canal may be cannulated and a partial trabeculotomy performed using the technique described.

[0057] The device **20** that is used to cannulate Schlemm's canal comprises may be flexible, and is of a suitable size, shape, and thickness to enter and cannulate the

circumference of the canal. Schlemm's canal has a meridional diameter typically ranging from 200 to 250 µm, although it has been observed to be as large as 350 to 500 µm. The reported length of the canal is approximately 36 mm, although there may be some variation depending on factors such as the size of the eye or existing disease conditions. For cannulating Schlemm's canal, the device **20** is approximately between 50 µm and 350 µm in diameter, and has a length of at least 36 mm. To facilitate advancement of the optical fibre in the canal, its distal tip may be rounded, and the device may have a lubricious coating on at least the distal end. Such coatings may be hydrophilic or hydrophobic in nature, and are common knowledge in the art. A hydrophilic coating may be applied to aid in intubation of the device within the eye, whereas hydrophobic coatings may aid in retention of the device within structures of the eye. The device may be straight, or also incorporate a curve at the distal end. The curve may be greater than or approximate the curvature of Schlemm's canal. In certain embodiments of the invention, the curved tip has a radius ranging from 2 to 4 mm. In addition, the device may have markings along the length of the device or at the tip to help visualisation of the device within the canal.

[0058] The device **20** may transmit light from a light source, emitting light to allow the location of the device **20** to be visualised through the trabecular meshwork from within the eye as well as through the sclera and conjunctiva from outside the eye to provide guidance for advancement within the canal.

[0059] An advantage of the presently described ab interno approach is that it does not require a conjunctival or scleral incision. As such, no scleral dissection is required and there is no risk of causing a pulmonary bleb on the surface of the eye. This approach also spares the entire conjunctiva and sclera, which is ideal in the event that traditional glaucoma surgery or other eye surgery is needed in the future. Post-operatively, the recovery time is at least on par with patients who have undergone a 360 degree trabeculotomy ab externo.

[0060] In an embodiment of the invention, a lid speculum is placed in the eye and a gonioprism (or other anterior chamber angle imaging device) is placed onto the eye. The surgical microscope is tilted so that the anterior chamber angle at the goniotomy site can be appreciated. In accordance with the embodiment of the invention, the ciliary body structures, the trabecular meshwork, as well as the scleral spur in the anterior chamber angle are

identified.

[0061] In an embodiment of the invention, a tangential paracentesis incision is made in the cornea, through which an intraocular composition is injected in order to constrict the pupil and facilitate access to the trabecular meshwork from the anterior chamber. In certain embodiments of the invention, the composition that is used comprises acetylcholine. Examples of such compositions include Miochol-E®and Miostat®.

[0062] In accordance with an embodiment of the invention, a surgical viscoelastic such as a solution of sodium hyaluronate is injected into the anterior chamber of the eye to maintain or enlarge the chamber dimensions. The composition may include, but are not limited to Healon®, a non-pyrogenic solution of a highly purified high molecular weight fraction of sodium hyaluronate extracted from animal tissue dissolved in a physiological buffer. Following the viscoelastic injection, a clear corneal incision of approximately 1-3 mm in width is made approximately 3 clock hours away from the paracentesis using a microsurgical blade. A different microsurgical blade is inserted into the corneal incision and used to form a goniotomy by incising the trabecular meshwork in the region directly across the eye from the corneal incision to create direct access to the lumen of Schlemm's canal.

[0063] The device **20** is inserted into the paracentesis and the gonioprism is placed on the eye to visualise the distal end of the device approaching the angle structures in the incised region of the canal. Surgical forceps are then inserted into the eye through the clear corneal incision. These are used to grasp the device and direct the distal part of the device into the incision of Schlemm's canal. The gonioprism (or other device used to image the anterior chamber angle) is placed in or on the eye and allows visualisation of this procedure. The device is threaded into Schlemm's canal through the incision created by the microsurgical blade.

[0064] The positioning of the device **20** is confirmed through an external view of the eye. The transillumination of the light of the device **20** in Schlemm's canal can be visualised internally or externally.

[0065] Following cannulation of Schlemm's canal, the surgical forceps may be placed back into the eye with a gonioprism on the eye for visualisation and the optical fibre advanced

around the canal. The distal end of the device is retrieved with the surgical forceps and removed from the eye through the clear corneal incision, creating a 180 degree trabeculotomy in the inferior quadrant. The 360 degree trabeculotomy may then completed by grasping and applying tension to the proximal end of the optical fibre to finish the trabeculotomy 180 degrees superiorly. The device is then removed from the eye through the paracentesis.

[0066] In accordance with an embodiment of the invention, an endoscopic camera may be used to visualise the surgical procedure within the anterior chamber to facilitate proper placement and use of the instruments within the anterior chamber. Upon completing the trabeculotomy, blood reflux is typically noted from the canal. Surgical viscoelastic may be injected into the eye to reform the chamber and maintain adequate pressure with the additional goal of blocking the flow of blood. A single suture such as an interrupted 10-0 nylon suture is placed through the clear corneal incision if needed. Prior to tying the suture, the previously injected surgical viscoelastic is irrigated out of the anterior chamber, as is blood that has refluxed into the anterior chamber. The suture is then tied off and the eye pressurised by injection of balanced salt solution to a pressure of at least 10-15 mmHg by palpation.

[0067] The reader will now appreciate the present invention which provides an ophthalmic surgical instrument and a method of use of said instrument in treating glaucoma.

[0068] While the invention has been described with reference to specific embodiments, the description is illustrative of the invention and is not to be construed as limiting the invention. Various modifications and applications may occur to those who are skilled in the art, without departing from the true spirit and scope of the invention as described by the appended claims.

LIST OF COMPONENTS

[0069] The drawings include the following integers:

10 ophthalmic surgical instrument

12 handpiece

14 grip

16 connector

18 hollow shaft

20 elongate rupturing device

21 distal illumination

22 barbs

23 longitudinal illumination

25 hollow tube

26 payload storage

28 payload storage chamber

32 lens

34 iris

36 cornea

38 trabecular meshwork

40 canal of Schlemm

42 incision

44 gripping instrument

46 trabeculotomy

[0070] Further advantages and improvements may very well be made to the present invention without deviating from its scope. Although the invention has been shown and described in what is conceived to be the most practical and preferred embodiment, it is recognized that departures may be made therefrom within the scope of the invention, which is not to be limited to the details disclosed herein but is to be accorded the full scope of the claims so as to embrace any and all equivalent devices and apparatus. Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of the common general knowledge in this field.

[0071] In the present specification and claims (if any), the word "comprising" and its

derivatives including "comprises" and "comprise" include each of the stated integers but does not exclude the inclusion of one or more further integers.

CLAIMS

1. An ophthalmic surgical instrument comprising:

a handpiece held by a user having a proximal and a distal end;

the handpiece comprising a hollow shaft extending from the distal end of the handpiece;

a flexible elongate rupturing device extending from the hollow shaft, wherein the elongate rupturing device is adapted to be advanced through tissue spaces within an eye.

2. The ophthalmic surgical instrument of claim 1, wherein the elongate rupturing device comprises a plurality of rearwardly and outwardly extending barbs, wherein the barbs are adapted to engage surrounding tissue within the tissue spaces of the eye.

3. The ophthalmic surgical instrument of claim 2, wherein the barbs are unidirectional.

4. The ophthalmic surgical instrument of claim 2, wherein the barbs are bidirectional.

5. The ophthalmic surgical instrument as in any of the previous claims, wherein the elongate rupturing device comprises a central hollow tube adapted to deliver a payload to the eye.

6. The ophthalmic surgical instrument of claim 5, wherein a proximal end of the rupturing device further comprises a connector, said connector able to be connected with an illumination source, providing visualisation of the location of the position of the flexible elongate rupturing device within the eye.

7. The ophthalmic surgical instrument as in any of the previous claims, wherein the elongate rupturing device comprises entirely or in part an optical fibre.

8. An ophthalmic surgical instrument comprising:

a handpiece held by a user having a proximal and a distal end;

the handpiece comprising a hollow shaft extending from the distal end of the handpiece;

a flexible elongate rupturing device comprised of an optical fibre with an outer diameter of between 50µm and 350 µm slidably extending from the hollow shaft;

wherein the elongate rupturing device is adapted to be advanced through tissue spaces within an eye.

9. The ophthalmic surgical instrument of claim 8, wherein a proximal end of the rupturing device further comprises a connector, said connector able to be connected with an illumination source, providing visualisation of the location of the position of the flexible elongate rupturing device within the eye.

10. The ophthalmic surgical instrument of claims 8 or 9, wherein the elongate rupturing device comprises a plurality of rearwardly and outwardly extending barbs, wherein the barbs are adapted to engage surrounding tissue within the tissue spaces of the eye.

11. The ophthalmic surgical instrument of claim 8, wherein the barbs are unidirectional.

12. The ophthalmic surgical instrument of claim 8, wherein the barbs are bidirectional.

13. The ophthalmic surgical device as in any of the previous claims, wherein the elongate rupturing device further comprises a hydrophilic coating to aid in intubation of structures of the eye.

14. The ophthalmic surgical device as in any of the previous claims, wherein the elongate rupturing device further comprises a hydrophobic coating to aid in retention of said elongate rupturing device within structures of the eye as tension is applied.

15. A method for performing trabeculotomy ab interno, the method comprising the

steps of:

making an incision in the trabecular meshwork of the eye to access the lumen of Schlemm's canal;

placing a distal end of a flexible elongate rupturing device through the incision and into Schlemm's canal;

advancing the elongate rupturing device through Schlemm's canal between an angle of 0 and 360 degrees; and

applying tension to the flexible elongate rupturing device within the canal thereby rupturing the surrounding tissue thereby creating a trabeculotomy; and

withdrawing the device through the incision.

16. The method of claim 15, wherein the elongate rupturing device comprises barbs located along the device, and wherein prior to applying tension to the elongate rupturing device, the elongate rupturing device is slightly retreated proximally or tangentially to engage the barbs with the surrounding tissue.

17. The method of claim 16, wherein the elongate rupturing device is advanced along the full circumference of Schlemm's canal.

18. The method of claim 17, wherein the elongate rupturing device is initially advanced 180 degrees, then repeating the procedure to then advance the remaining 180 degrees of the canal thereby creating a 360 degree trabeculotomy.

19. The method of claims 15-17, wherein the elongate rupturing device comprises entirely or in part an optical fibre.

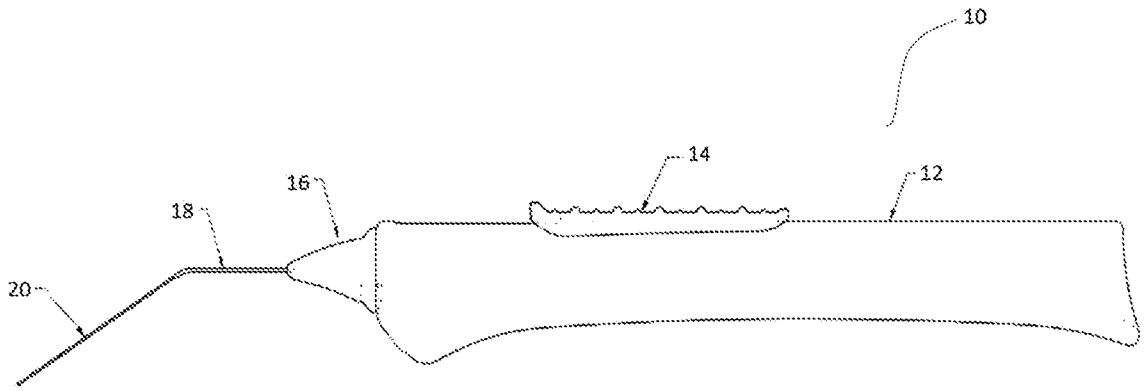

Figure 1

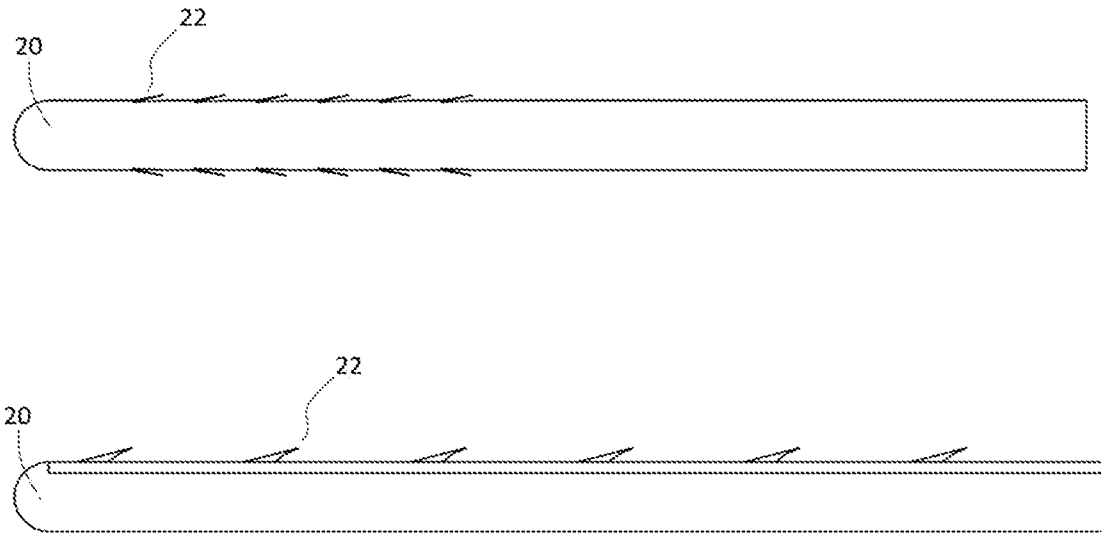

Figure 2

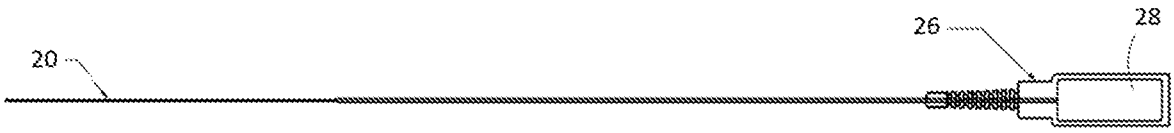

Figure 3

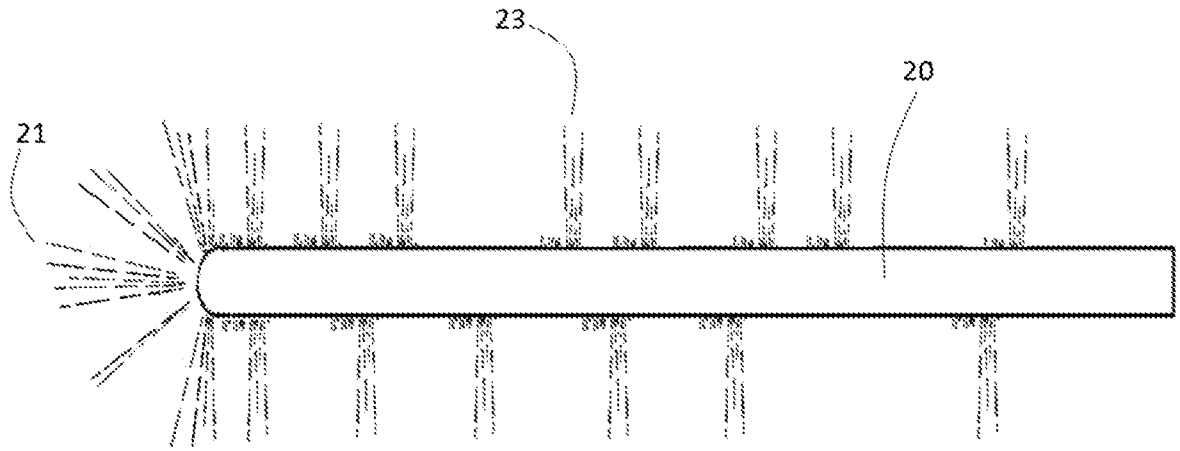

Figure 4

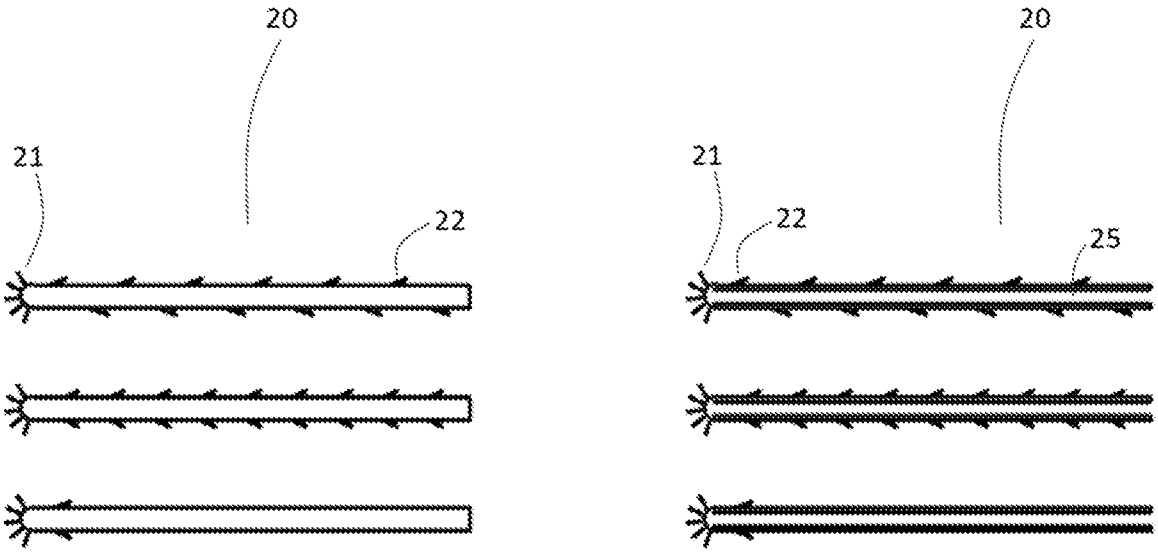

Figure 5

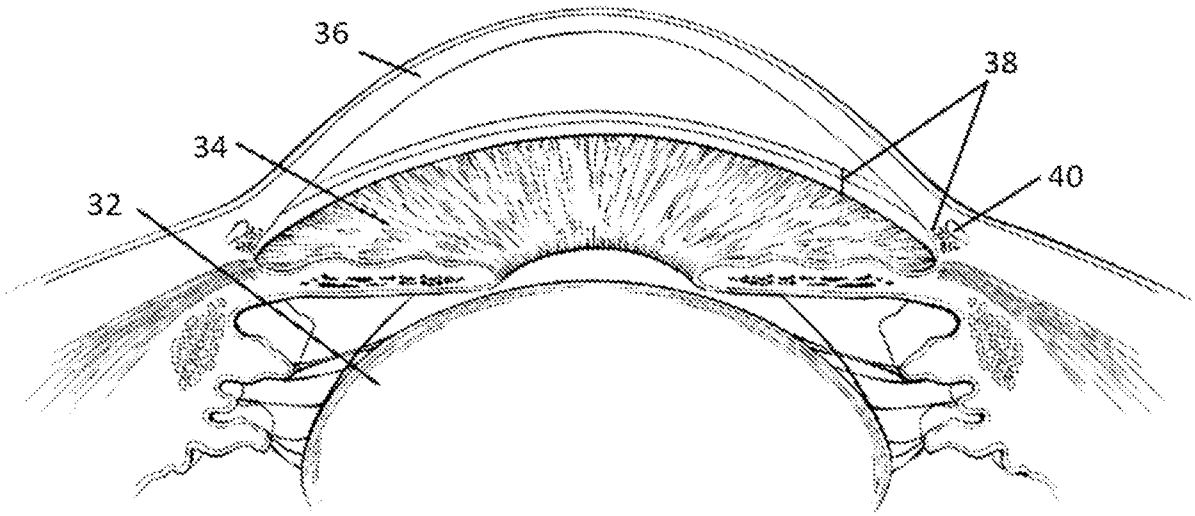

Figure 6

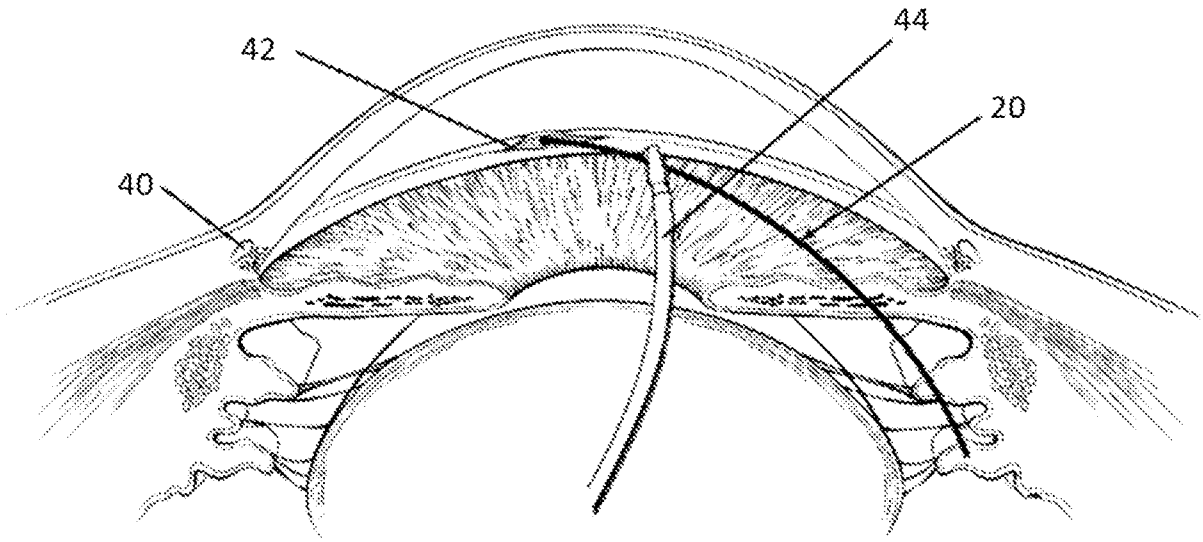

Figure 7

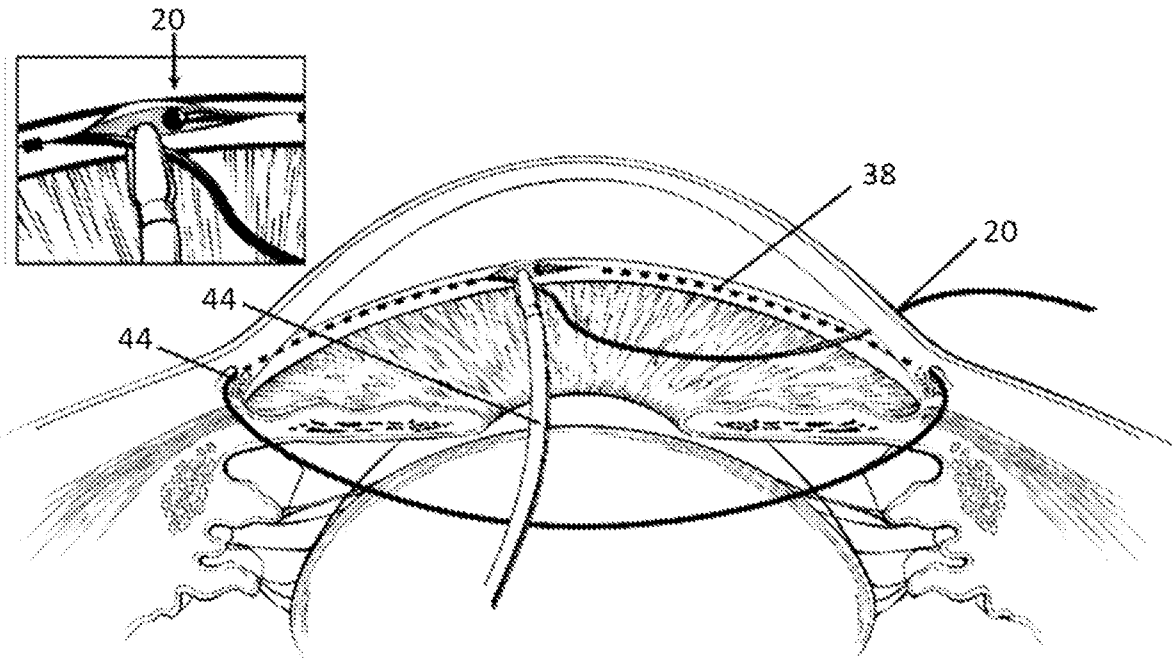

Figure 8

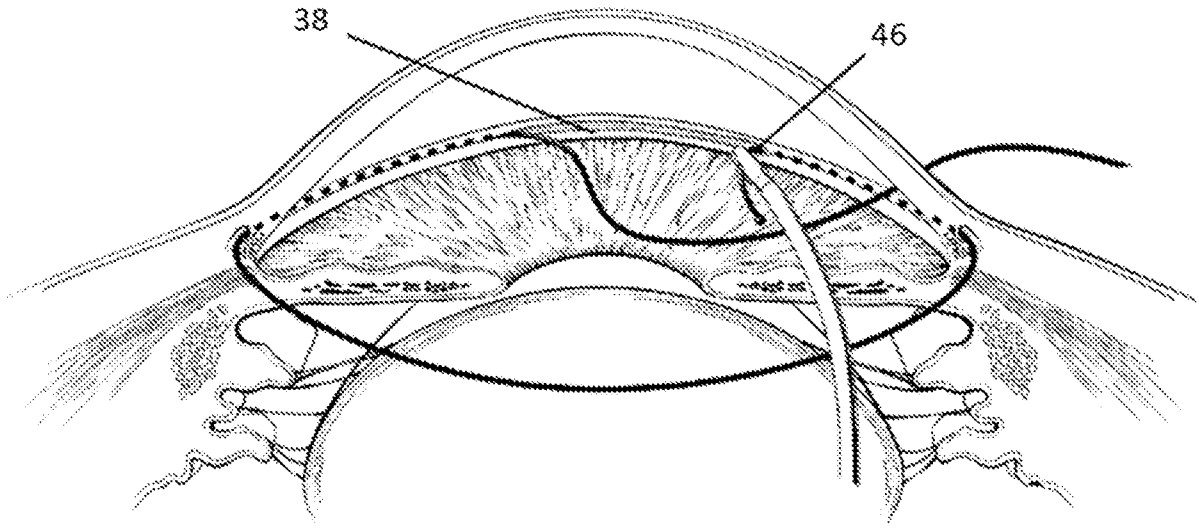

Figure 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2023/051147

A. CLASSIFICATION OF SUBJECT MATTER

A61F 9/007 (2006.01) A61B 1/00 (2006.01) A61B 17/22 (2006.01) A61B 17/34 (2006.01) A61M 25/00 (2006.01)

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)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Databases: PATENW, Google Images, Google AND IPC & CPC Marks A61F9/00781, A61F9/008, A61B17/3421, A61M2025/0042 , A61M25/0054, A61M25/008 & Keywords FLEX+, SLID+, STEER+, MANOUV+, +CATHETER, +CANNULA , BARB?, TEETH, PROTRUSION?, PROJECTION and like terms and inventor/applicant name search. Applicant(s)/Inventor(s) name searched in internal databases provided by IP Australia.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 January 2024	19 January 2024
Name and mailing address of the ISA/AU	**Authorised officer**
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustralia.gov.au	Kalpana Narayan AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61 2 6285 0731

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2023/051147**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 20210128356 A1 (MORENO et al.) 06 May 2021 see figs. 1-3, 11, 21-25, 30; paras. [0061], [0065-0067], [0071-0072], [0078], [0087], [0093-0097], [0100], [0108], [0126], [0128], [0138],	1-19
X	WO 2013115861 A2 (INNOVATIVE GLAUCOMA SOUUTIONS, LLC) 08 August 2013 see figs. 2-4; paras. [00019-00020], [00022], [00025]	15, 19
X	iTrack, Canaloplasty for Glaucoma (Ab-interno Surgical Technique), YouTube, Nova Eye Medical [retrieved from the internet on 2 January 2023] <URL: https://youtube/sMp2Jv07Kgs?t=177 > published on 26 Aug 2021 see whole document	1, 5-9, 15, 19
X	WO 2016159999 A1 (SIGHT SCIENCES, INC.) 06 October 2016 see figs. 2,10A, 18C, 22C; paras. [091], [0104], [0121], [0205-0206],	1-13, 18
X	WO 03/045290 A1 (ISCIENCE CORPORATION) 05 June 2003 see whole document	1-15, 19
A	US 10369050 B2 (CAMRAS VISION INC.) 06 August 2019 see whole document	
A	US 20120095434 A1 (FUNG et al.) 19 April 2012 see whole document	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2023/051147

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.:
because they relate to subject matter not required to be searched by this Authority, namely:
the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including

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:

See Supplemental Box for Details

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying 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 report covers 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.

Supplemental Box

Continuation of: **Box III**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1-14 are directed to an opthalmic surgical instrument. The feature of of the instrument comprising a handpiece comprising a hollow shaft, a flexible elongate rupturing device extending from the hollow shaft is specific to this group of claims.

- Claims 15-19 are directed to a method for performing trabeculotomy ab interno. The feature of the method steps of: making an incision in the trabecular meshwork of the eye to access the lumen of Schlemm's canal; placing a distal end of a flexible elongate rupturing device through the incision and into Schlemm's canal; advancing the elongate rupturing device through Schlemm's canal between an angle of 0 and 360 degrees; and applying tension to the flexible elongate rupturing device within the canal thereby rupturing the surrounding tissue thereby creating a trabeculotomy; and withdrawing the device through the incision is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. The only feature common to all of the claimed inventions and which provides a technical relationship among them is **a flexible elongate rupturing device that is placed through tissue spaces with in the eye.**

However this feature does not make a contribution over the prior art because it is disclosed in:

D1-D6 (see Box V for details).

Therefore in the light of this document this common feature cannot be a special technical feature. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied *a posteriori*.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2023/051147**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
US 20210128356 A1	06 May 2021	US 2021128356 A1	06 May 2021
		US 11564835 B2	31 Jan 2023
		AU 2018353126 A1	07 May 2020
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		JP 7370990 B2	30 Oct 2023
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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2023/051147**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
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INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2023/051147**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
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		WO 2016033270 A1	03 Mar 2016
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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2023/051147**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
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		US 2011282250 A1	17 Nov 2011
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		WO 2011130456 A1	20 Oct 2011

End of Annex

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.