

# **DRAINAGE DEVICE FOR CONTROLLING INTRAOCULAR PRESSURE IN GLAUCOMA**

## **DESCRIPTION**

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### **Technical Field**

15 The present invention generally relates to a surgical treatment for glaucoma and particularly to a stainless steel device allowing the drainage of aqueous humor to the intrascleral and episcleral space, creating to that end two virtual spaces communicating the anterior chamber with the intrascleral and episcleral space. This drainage allows controlling pressure within the eye and preventing blindness, pain and other illnesses associated with glaucoma.

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### **Background of the Invention**

25 Glaucoma is, after diabetes, the second leading cause of blindness in the world. Vision loss as a result of glaucoma involves both central and peripheral vision and has a major impact on the ability of people to live independent lives.

30 Glaucoma is an optic neuropathy (a disorder of the optic nerve) caused by an elevated intraocular pressure. The high pressure inside the eye compresses the outlet of the optic nerve (papilla) causing changes in its appearance and in the visual function (increase of the optic cup and alterations to the visual field). If the pressure remains increased over a sufficient period of time, a complete and irreversible vision loss takes place.

35 The intraocular pressure is maintained by a balance between the production and the outflow of aqueous humor. Aqueous humor is a fluid produced by the ciliary body in the posterior chamber of the eye at a rate of approximately 3 to 5 microliters per minute. The fluid produced then passes through the pupillary opening of the iris into the anterior chamber of the eye. Once in the anterior  
40 chamber, the fluid leaves the eye through two different routes: the "uveoscleral" route responsible for 10% of the outflow, in which the fluid is filtered between muscle fibers of the ciliary body, and the "canalicular" route responsible for 90% of the outflow, in which the fluid drains through the junction between the cornea and the iris (iridocorneal angle) through a filter called Trabecula which is  
45 composed by collagen bundles arranged in a three-dimensional structure similar to a sieve. From that point the aqueous humor goes to the so-called Schlemm's canal and then to the episcleral veins.

- As the eye is a closed area, the production and outflow of aqueous humor necessarily have to be equal. This causes a pressure inside the eye that is determined by the amount of fluid produced and the capacity of outflow thereof.
- 10 In normal conditions, the intraocular pressure is between 10 and 21 mm Hg.
- If aqueous humor production increases with respect to outflow resistance, the intraocular pressure will increase to force the outflow. If the outflow resistance increases, the intraocular pressure will increase to force the outflow even with a
- 15 normal aqueous humor production. Both scenarios will increase intraocular pressure and may cause glaucoma, being much more frequent the increase in the outflow resistance.
- Aqueous humor outflow resistance may be increased by several factors. Thus, in
- 20 the so-called "primary open angle glaucoma" (responsible for 85% of glaucoma), the abnormal resistance is produced along the outer aspect of the trabecular meshwork and the inner wall of the Schlemm's canal. In "angle-closure glaucoma", the resistance increases due to mechanical blocking of the angle and in "secondary glaucoma" due to various reasons such as inflammatory waste
- 25 deposits, vascularization of the area, pigment blocking, etc.
- Regardless of the factor that produces it, increased intraocular pressure compresses the outlet of the optic nerve and interferes in its vascularization, causing the death of nerve cells that carry visual stimuli to the brain, producing
- 30 alterations in the visual field and, in advanced cases, total and irreversible blindness.
- The only therapeutic approach currently available for glaucoma is to reduce intraocular pressure. The clinical treatment of glaucoma is done step by step, the
- 35 first step being the medical treatment either by oral means or with drops.
- The drugs work by reducing aqueous humor production or by facilitating its outflow. Currently available medicinal products can have many side effects, some serious, including congestive heart failure, respiratory distress, hypertension,
- 40 depression, kidney stones, aplastic anemia, sexual dysfunction and death. Compliance with medication is also a major problem with more than half of glaucoma patients being estimated as not following their dosing schedules correctly.
- 45 While drugs work, they will be the treatment of choice, but often they are not sufficient to maintain a safe intraocular pressure and surgery is needed. The most frequently performed surgeries are trabeculoplasty and trabeculectomy.

In laser trabeculoplasty, thermal energy from a laser is applied to a number of noncontiguous spots in the trabecular meshwork. It is believed that the laser energy somehow stimulates the metabolism of the trabecular cells and changes the extracellular material of the trabecular meshwork. In approximately 80% of patients, aqueous outflow is increased and the pressure decreases. However, the effect often is not long lasting and 50% of patients develop hypertension again in five years. In addition, laser trabeculoplasty is not an effective treatment for primary open angle glaucoma in patients of less than fifty years old nor is it effective for angle-closure glaucoma and many secondary glaucomas.

If laser trabeculoplasty does not reduce the pressure to the desired level, filtering surgery is then performed.

The most commonly performed filtering procedure is trabeculectomy. In a trabeculectomy an incision is made in the conjunctiva, which is the transparent tissue that covers the sclera. The conjunctival tissue is lifted and a scleral flap of approximately 4x4 mm is made with a depth of 50% of the scleral thickness and is lamellar dissected up to 1 mm into the cornea. The anterior chamber is entered beneath the scleral flap and a section of the deep sclera and trabecular meshwork is excised. The scleral flap is loosely sewn back into place and conjunctival incision is closed well. Postoperatively, the aqueous humor passes through the hole beneath the scleral flap and goes to the subconjunctival space where it forms a blister from where it passes to the blood vessels of the conjunctiva or goes through the conjunctiva to the surface.

Trabeculectomy is associated with many problems, among them, the fibroblasts that are present in the episclera proliferate, migrate and can scar the scleral flap, failures in healing may occur, particularly in children and young adults. Of the eyes that have had an initially successful trabeculectomy, 80% will stop filtering in a period of 3 to 5 years after surgery. To minimize fibrosis, surgeons are now applying antifibrotic agents such as mitomycin C (MMC) and 5-fluorouracil (5-FU) to the scleral flap at the time of surgery. The use of these agents has increased the success rate of trabeculectomy, but also has increased its complications.

When trabeculectomy does not successfully lower the eye pressure, the next surgical step is often an aqueous shunt valve. This device consists of a silicone tube that is attached at one end to a plastic (polypropylene or other synthetic) plate with a valve shape that is sewn to the ocular equator or an element found thereafter and the other end of the silicone tube is introduced into the anterior chamber through a hole made in the corneal limbus. The outer portion of the tube is covered with sclera or pericardium from donor, it is all covered with the conjunctiva and the incision is closed. The current technology of these aqueous shunt valves presents many problems, including poor healing, valve failure, hypotony and infection.

10 In the year 1999, the company Optonol Ltds. patented a tubular filtering device not valved for controlling intraocular pressure in glaucoma (Patent 5968058). This device was a small stainless steel tube that, once placed in the corneal limbus, allowed the flow of aqueous humor through the tube from the anterior chamber to an intrascleral space and from there to the subconjunctival space. Since 2002, the company Alcon sells this device under the name of Ex-Press.

15 The implantation of these devices allows performing less invasive surgeries compared to trabeculectomy as it allows the aqueous humor outflow without the need of extracting a segment of the trabecula or performing an iridectomy.

20 Several studies have reported the effectiveness of these devices for significantly reducing intraocular pressure, but they also report complications, the most common ones being a flat chamber and bleeding in anterior chamber, which is believed may be related with the anchorage system.

25 All the surgical techniques to reduce intraocular pressure seek to create a new drainage pathway for aqueous humor that replaces the obstructed normal path with the smallest possible amount of complications.

### **Brief Description of the Present Invention**

30 **Figure 1** shows a **three-dimensional view** of the device object of the present invention which has been divided into three parts: "A", "B" and "C". Part "A" will be arranged in the anterior chamber between the cornea and the iris and will have a double triangle shape, which allows introducing and removing it with ease while at the same time keeping it fixed in its position. Part "B" will puncture the eye in the corneal limbus, being arranged between the cornea and the sclera, and part "C" will be arranged outside the eye covered by a scleral flap, on the episclera or both.

40 **Figure 2** shows a **side view** of the device object of the present invention which has been divided into three parts: "A", "B" and "C". Part "A" will be arranged in the anterior chamber between the cornea and the iris and will have a double triangle shape, which allows introducing and removing it with ease while at the same time keeping it fixed in its position. Part "B" will puncture the eye in the corneal limbus and part "C" will be arranged outside the eye covered by a scleral flap, on the episclera or both.

**Figure 3** shows a **top view** of the device object of the present invention which has been divided into three parts: "A", "B" and "C". Part "A" will be arranged in the anterior chamber between the cornea and the iris, part "B" will puncture the eye

in the corneal limbus and part "C" (which can have variable measurements) will be arranged outside the eye.

10 **Figure 4** shows a **front view** of the device object of the present invention which has been divided into three parts: "A", "B" and "C". Part "A" will be arranged in the anterior chamber between the cornea and the iris, part "B" will puncture the eye in the corneal limbus and part "C" (which can have variable measurements) will be arranged outside the eye.

15 **Figure 5** is an illustration showing a sagittal section diagram of the human eye depicting therein the anatomical details of the iridocorneal angle which is the area on which the present invention will influence. The following can be seen therein: 1. Cornea, 2. Sclera, 3. Iris, 4. Corneal limbus, 5. Trabecula, 6. Schlemm's canal 7. Crystalline lens.

20 The indication 8. Flap shows the area of the eye where the flap or scleral flap will be made. Part "C" of the device will be arranged between the scleral flap and the sclera, creating two virtual spaces, one towards the flap and another towards the sclera. Aqueous humor will flow through these virtual spaces and be diffused into the interscleral space and subconjunctival space.

25 **Figure 6** is an illustration showing the device object of the present invention in its working position and in which: Part "A" will be arranged in the anterior chamber. Part "B" will puncture the eye and create a virtual space upwardly between the cornea and the upper surface of the device and create a virtual space downwardly between the sclera and the lower surface of the device. Part "C" will be arranged outside the eye between the scleral flap and the sclera, similarly creating two virtual spaces, one towards the flap and another towards the sclera. Aqueous humor will flow through these virtual spaces and be diffused into the interscleral space and subconjunctival space.

35 **Figure 7** is an illustration similar to that of Figure 6 but in which: Part "C" is longer and, in addition to being arranged between the scleral flap and the sclera, it comes out the flap to the episcleral space, creating a virtual corridor that leads to the ocular equator, increasing the area of diffusion of the aqueous humor. This can be beneficial in cases of neovascular glaucoma.

#### **Detailed Description of the Present Invention**

45 The present invention provides a device for permanent insertion into the scleral angle of the eye to reduce intraocular pressure and control glaucoma.

Since the device is a long-term implant, it must be manufactured with a material that is harmless to the tissues and fluids with which it will be in contact. The

device must not be absorbed, corroded or structurally compromised while it is being arranged in place. In addition, it is equally important that the eye tissues and the aqueous humor are not negatively affected by the presence of the implanted device.

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The device may be made of stainless steel or other biocompatible materials that do not adhere to the eye tissues which may include but are not limited to, among others, silicone or similar polymers, polytetrafluoroethylene, polypropylene or other thin wall polymers. Metals and alloys known in the art for making implants can also be used. It is important that the material used does not adhere to the eye tissues in order to create one or more virtual spaces from the anterior chamber to the exterior of the eye, be it an intrascleral space, an episcleral space or both. The space is virtual, not real, which creates a one-direction path through which the aqueous humor will flow with higher or lower speed depending on the pressure gradient between the interior and the exterior of the eye. Since the drainage path is a virtual path, it minimizes the possibility of the chamber being flat or of germs penetrating through the device, furthermore the anchorage system is less aggressive, thus reducing the possibility of bleeding.

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**Figure 1** shows a three-dimensional view of the device object of the present invention which has been divided into three parts: "A", "B" and "C". This device will be made of stainless steel or another biocompatible material that does not adhere to the eye tissues, the device will have a uniform or variable thickness. Part "A" will be arranged in the anterior chamber between the cornea and the iris and will have a double triangle shape, which allows introducing and removing it with ease while at the same time keeping it fixed in its position. Part "B" will puncture the eye in the corneal limbus, being arranged between the cornea and the sclera, and part "C" will be arranged outside the eye covered by a scleral flap, on the episclera or both.

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**Figure 2** shows a side view of the device object of the present invention. The device will have a uniform or variable thickness and will measure between 0.02 and 0.3 mm. The device is a one-piece device, but it has been divided into three parts for description purposes: "A", "B" and "C". Part "A" will be arranged inside the eye in the anterior chamber between the cornea and the iris. Part "B" will puncture the corneal limbus forming two virtual spaces through which it will drain the aqueous humor and part "C" will be arranged outside the eye, in the interscleral space, episcleral space or both. The parts forming the device of the invention are:

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#### **Part "A":**

**Figure 2** shows a side view of a filtering device in which part "A", which will be arranged in the anterior chamber between the cornea and the iris (see Figure 6),

can be seen. This part "A" will have a double triangle shape with an upper base "b" having measurements between 0.3 and 1.0 mm, height "h" between 0.3 and 0.9 mm and a rounded lower vertex "v" to facilitate its insertion. This allows a less traumatic anchorage in addition to facilitating its introduction or removal.

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**Figure 3** shows a top view of the device in which part "A" can be seen. This part has a rectangular shape in which it is continued with part "B" on the proximal side and becomes a triangle on the distal side. The rectangular part will have a width between 0.5 and 4 mm equal to that of part B and a length between 0.3 and 1.2 mm. The triangular distal part will have a base of the same width as the rectangular part and a height between 0.3 and 0.8 mm. The edges will be sharp to facilitate insertion.

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#### **Part "B":**

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**Figure 2** shows a side view of the filtering device in which part "B" can be seen. This part will puncture the corneal limbus, forming a virtual space upwardly between the cornea and the upper surface of the device and another virtual space downwardly between the sclera and the lower surface of the device. The aqueous humor will drain through these virtual spaces from the anterior chamber to an intrascleral or episcleral space. The sheet forming part "B" of the device will have a thickness between 0.02 and 0.3 mm.

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**Figure 3** shows a top view of the device in which part "B" can be seen, the upper surface of which will be in contact with the cornea and form with it a virtual space through which the aqueous humor will flow. The lower surface will be in contact with the sclera and form another virtual space. The surfaces of this sheet can be smooth, rough, wavy, grooved or with another finish. Part "B" of the device will have a length between 0.3 and 1.2 mm with a width equal to that of part "A", this width will measure between 0.5 and 4 mm.

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#### **Part "C"**

**Figure 2** shows a side view of the filtering device in which part "C" can be seen. This part will have a length between 0.5 and 15 mm and a thickness between 0.02 and 0.3 mm, it will be thin, malleable and will be curved to approximately the eye curvature.

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**Figure 3** shows a top view of the device in which part "C", being in the form of a rectangular sheet with rounded edges and wider than part "B", can be seen. It will measure between 0.7 and 5 mm in width and will have a length between 0.5 and 15 mm. This sheet can be smooth, rough, wavy, grooved or with another finish, it will be arranged outside the eye and covered by a scleral flap, arranged in the episcleral space or both.

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10 **Figure 5** is an illustration showing the area of the eye where the flap or scleral flap will be made to create the interscleral virtual space. This flap will be similar to that obtained for a trabeculectomy surgery and will have a length of approximately 4 mm, a width of 4 mm and a depth of about 50% the scleral thickness.

15 **Figure 6** is an illustration showing the device object of the present invention in its working position and in which part "A" will be arranged in the anterior chamber. Part "B" will puncture the eye and create a virtual space upwardly between the cornea and the upper surface of the device and create a virtual space downwardly between the sclera and the lower surface of the device. Part "C" will be arranged outside the eye between the scleral flap and the sclera, similarly creating two virtual spaces, one towards the flap and another towards the sclera.  
20 Aqueous humor will flow through these virtual spaces and be diffused into the interscleral space and subconjunctival space.

25 **Figure 7** is an illustration similar to that of **Figure 6** but in which part "C" is longer and, in addition to being arranged between the scleral flap and the sclera, it comes out the flap towards the episcleral space, creating a virtual corridor that leads to the ocular equator, increasing the area of diffusion of the aqueous humor. This can be very beneficial in cases of neovascular glaucoma.

30 The surgical procedure needed to insert the device can include all or some of the following steps: **1.** an incision is made in the conjunctiva that may be limbus or fornix based, **2.** a scleral flap of approximately 4 x 4 mm with a thickness of approximately 50% the scleral thickness is delimited and a dissection parallel to the sclera is made until entering 1 mm into the corneal tissue, **3.** paracentesis is performed parallel to the limbus with a blade of 15°, **4.** the device is inserted into the paracentesis, **5.** the flap is closed with 2 loose stitches, **6.** the conjunctiva is closed.  
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## Claims

1. A filtering device for continuous use in the eye to alleviate excessive intraocular pressure facilitating the drainage of aqueous humor from the anterior chamber to an intrascleral or episcleral space through one or more virtual spaces. The device is a one-piece device but has three well defined parts: Part "A" is located in the anterior chamber. Part "B" puncturing the corneal limbus and establishing two virtual spaces through which it drains the aqueous humor and Part "C" which will be outside the eye in an intrascleral or episcleral space, forming virtual spaces through which the aqueous humor is diffused out of the eye.
2. The filtering device according to claim 1, the part "A" of which, in a side view, is characterized by having a double triangle shape with a base "b" that will measure between 0.3 and 1.0 mm and a height "h" that will measure between 0.3 and 0.9 mm.
3. The filtering device according to claim 1, the part "A" of which, in a top view, is characterized by having a rectangular shape with a width between 0.5 and 4 mm and a length between 0.3 and 1.0 mm. The distal side of this rectangle is continued with a triangle with a height that will measure between 0.3 and 0.8 mm, the triangle will have sharp edges to facilitate its insertion.
4. The filtering device according to claim 1, the part "B" of which, in a side view, is characterized by being a sheet which will have a thickness between 0.02 mm and 0.3 mm.
5. The filtering device according to claim 1, the part "B" of which, in a top view, is characterized by being a sheet having a rectangular shape with a width between 0.5 and 4 mm and a length between 0.3 and 1.0 mm. The upper surface of this sheet will be in contact with the cornea and the lower surface with the sclera.
6. The filtering device according to claim 1, the part "B" of which is characterized by having a surface that can be flat, curved, smooth, rough, wavy, grooved or with another finish.
7. The filtering device according to claim 1, the part "C" of which, in a side view, is characterized by being a sheet which will have a thickness between 0.02 mm and 0.3 mm.
8. The filtering device according to claim 1, the part "C" of which, in a top view, is characterized by having a rectangular shape with rounded corners, with a width between 0.7 and 5 mm and a length between 0.5 and 15 mm.

- 9.** The filtering device according to claim 1, the part “C” of which is characterized by having a surface that can be flat, curved, smooth, rough, wavy, grooved or with another finish.
- 10    **10.** Any filtering device inspired by claim 1, the main feature of which is to create one or more virtual spaces for draining aqueous humor from the anterior chamber of the eye to the intrascleral or epiescleral space.