

A Carbon-Based Biocompatible Drainage Article

Technical Field

5 The present disclosure relates to a biocompatible article applicable for alleviating fluid pressure in a bodily-fluid filled cavity by draining portion of the fluid out of the cavity. Particularly, the disclosed article is carbon-based. It can be useful for ophthalmologic surgery in reducing elevated intraocular pressure found in diseased eye conditions such as glaucoma, hyphema, hypopyon and the like.

Background

10 Galucoma is an ophthalmic disease with high intraocular pressure (IOP) associated with imbalance of liquid inflow and outflow of the eye. It is one of the major pathological causes of blindness. Typically, accumulation of the ocular fluid or aqueous humor in the eye results increased pressure onto the optic nerve. Having the optic nerve subjected to chronic or acute high intraocular pressure, more than 21 mmHg, progressively leads to appearance changes on the eye and may further advance in forming blind spots on the optic nerve. Without proper treatment to reduce the intraocular pressure, high fluid pressure within the eye can finally reach a point that irreversible optic neuropathy and vision loss.

20 The intraocular pressure can be regulated through medication or surgical intervention. Drugs such as carbonic anhydrase inhibitors, physostigmine, miotic agents, topical beta adrenergic antagonists and the like are commonly administrated to the patients suffering from glaucoma. These drugs either improve outflow of the aqueous humor through the trabecular meshwork or prohibit production of the fluid. On the other hand, surgical approach can be performed by way of canaloplasty, trabeculectomy, laser surgery or drainage implants to expedite outflow rate of the fluid thereby reducing the pressure. The therapeutic effect of the surgical approaches is short-term with recurrence of the symptoms after a given period in connection to blockage caused by generation of the scar tissues at the surgical spot. Among all the known solutions, implantation of a

drainage article or shunt directly into the diseased eye is considered the last resort to alleviate the IOP especially in circumstances where the patients fail to response other treatments.

- 5 Great effort has been devoted to develop improved drainage implant with fail-proof features to insure the implantation is always a viable option for glaucoma patient even the rest of the treatments showed unsatisfactory outcome. For example, international patent publication WO99/66871 discloses a silicon drainage implant fabricated with a stopper to discharge the aqueous humor when the IOP is greater than an optimal value
- 10 of the stopper thereby capable of regulating the fluid pressure in glaucoma affected eye. Peter Mitrev, in a United States patent application no. 6589203, discloses another glaucoma drainage implant having a drainage tube with one end connected to a deformable silicon episcleral plate being made foldable and rollable to be injected to the implant site without requiring extensive incision to be made. Having a smaller incision,
- 15 the inventor claims the disclosed implant critically reduces the likelihood of postoperative infection. Another United States patent application no. 6730056 describes an implant featuring improved biodegradable anchorage member to assist deposition of the implant into the incision site. Despite their capabilities in regulating IOP, these implants share some common drawbacks in attaining prolonged therapeutic effect.
- 20 Particularly, these devices can be easily obstructed by cellular particles in view of hydrophobic nature of the silicon material constructing the implants. Furthermore, the implant lacks substantial features to avoid fibrosis which progressively restricts the aqueous humor outflow.
- 25 Further attempts to prevent development of fibrosis-related flow resistance in the drainage implant are provided in United States patent publication no. 20120089073 and 20130150777. The former positions the inlet section of the implant appositionally to the intraocular surface in the vitreous body at the pars plana to reduce clogging. However, incision made onto the vitreous body may induce subsequent postoperative
- 30 endophthalmitis as shown in some studies. The latter employs a multiple valves system connecting to a fluid reservoir to synchronize the outflow of the aqueous humor thus

preventing fibrosis thereof. System facilitates the pressure control using a mechanism run by multiple components and failure in one component shall inevitably render the whole system inoperable. Considering the aforesaid shortcomings presented in the existing technologies, a drainage implant with good biocompatibility, chemical inertness against cellular proteins and simplified feature to overcome fibrosis-associated flow restriction is highly desired.

Summary

One of the objects of the present disclosure is to provide a micro-size drainage implant or micro-drainage implant for channeling accumulated bodily fluid out from an enclosed body cavity such as fluid-filled ocular chamber. By draining out the bodily fluid, the disclosed implant substantially decreases or regulates fluid pressure in the affected cavity.

Another object of the present disclosure is to offer a biocompatible drainage implant for reducing intraocular pressure. Particularly, the portion of the drainage implant in immediate contact with the bodily fluid or aqueous humor is carbon-based showing chemical and biological inertness towards cellular molecules such as proteins or dissolved minerals. Such chemical and biological inertness are highly desired to avoid inflammatory-induced fibrosis leading to restricted fluid flow after the implantation.

Further object of the present disclosure is to provide a drainage implant for reducing intraocular pressure produced from an activated graphitized fiber structure, having a matrix formed by a plurality of bundled carbonized and graphitized microfibrils. This configuration adopted by the disclosed activated graphitized fiber favors the attachment of the fibroblasts at the periphery of the microfibrils and control progress of the potential fibrosis in a much arranged manner, thus, minimizing the negative impact on the fluid outflow.

Still, another object of the present disclosure is to offer micro-drainage implant featuring high specific surface area and sorption capacity for the fluid draining. The

high specific surface area and sorption capacity reinforce capillary effect brought forth by the micro structures of the drainage.

At least one of the preceding objects is met, in whole or in part, by the present disclosure in accordance with one or more embodiment of the present invention, in which one of the embodiments involves an implantable article for reducing fluid pressure of a bodily fluid-filled cavity by draining portion of the bodily fluid comprising one or more micro-sized activated graphitized fiber, having a first end insertable into the cavity and a second end extending away from where the first end is in direct contact with the bodily fluid, being configured to drain the bodily fluid from the first end to the second end at a flowing rate which is correspondingly varied to a pressure difference present in between the first and second ends, wherein the activated graphitized fiber is fabricated from a pre-treated viscose fiber by way of carbonization and graphitization under heat treatment with further activation in the presence of oxygen or carbon dioxide gas flow of 10 to 100 liter per hour.

In several embodiments, the viscose fibers are pre-treated to have the surface coated with catalytic additives. Preferably, the catalytic additives and the viscose fiber have a ratio of 1-2: 4-20 by weight.

In an embodiment, the fibers are rayon fibers having the preferred carbon content and cellulose arrangement to finally provide the disclosed drainage article after being subjected to aforementioned stringent heat treatments.

Further embodiment of the present disclosure includes an implantable article for reducing fluid pressure of a bodily fluid-filled cavity by draining of portion of the bodily fluid comprising a micro-sized activated graphitized fiber, having a first end insertable into the cavity and a second end extending away from where the first end is in direct contact with the bodily fluid, being configured to drain the bodily fluid from the first end to the second end at a flowing rate which is correspondingly varied to a pressure difference present in between the first and second ends, wherein the activated

graphitized fiber is derived from rayon fibers and characterized by having a sorption capacity of 350 to 420 cm³/g and specific surface area of 1900 to 2100 m²/g.

Brief Description Of The Drawings

5 Figure 1 is an electron micrograph showing the cross-sectional image of the produced carbon fibers in micro-size; and

Figure 2 is an enlarged view of the carbon fibers shown in the figure 1.

10 Figure 3 is a schematic view of drainage implant for reducing intraocular pressure.

Figure 4 is a variation of the shape of drainage implant for reducing intraocular pressure.

15 Detailed Description

It is to be understood that the present invention may be embodied in other specific forms and is not limited to the sole embodiment described herein. However modification and equivalents of the disclosed concepts such as those which readily occur to one skilled in the art are intended to be included within the scope of the claims
20 which are appended thereto.

The term "catalytic additives" described herein throughout the specification may refer to organic or inorganic chemical entities react directly or indirectly with the viscose fibers to facilitate formation of the disclosed activated graphitized fiber in the sequential
25 carbonizing and graphitizing steps. Portion of these chemical entities may not essentially carry catalytic effect towards the chemical reactions occurred in the stabilizing step.

It is important to note that the graphitization of the mentioned in the present disclosure
30 may refer to a reaction with controlled condition capable of prompting formation of the graphite though the produced drainage article may not be completely graphitic in terms

of crystallographic configuration at the molecular level. The graphitized fibers acquired in one embodiment may only contain partial formed graphite showing the desired graphitic properties. Apart from that, presence of the graphite or graphitic properties significantly enhances mechanical integrity of the produced drainage article. Having the mechanical properties improved the produced drainage article is less vulnerable to the external forces arisen during the implantation procedures maneuvering. This mechanically enhanced structure renders the drainage articles more readily employed as a drainage implant.

Further, the carbonizing step is conducted at a chemically inert environment by having the reaction performed under argon or nitrogen gas curtain. The stabilized fibers are preferably thermally decomposed in a non-oxidizing environment and contact with oxygen shall be avoided.

According to preferred embodiment of the present disclosure, the disclosed implantable article for reducing fluid pressure of a bodily fluid-filled cavity by draining portion of the bodily fluid comprises one or more micro-sized activated graphitized fiber, having a first end insertable into the cavity and a second end extending away from where the first end is in direct contact with the bodily fluid, being configured to drain the bodily fluid from the first end to the second end at a flowing rate which is correspondingly varied to a pressure difference present in between the first and second ends, wherein the activated graphitized fiber is fabricated from a pre-treated viscose fiber by way of carbonization and graphitization under heat treatment with further activation in the presence of oxygen or carbon dioxide gas flow of 10 to 100 liter per hour. One at least ordinary skilled in the art shall appreciate the fact that the insertion or communication of the activated graphitized fiber with the eyeball can be established using any known medical procedures known in the field. Moreover, the present disclosure may have more than one activated graphitized fiber implanted onto the subject. Several embodiments of the disclosed implantable article may preferably bundle multiple activated graphitized fibers to form capsule-like drainage vessel to channel the aqueous humor.

In the absence of the stabilized cellulose structure, the viscose fibers are likely to be suffered from large void or hollow formations, sometimes may even lead to rupture of the fiber, upon heating directly under the high temperature of the carbonizing or graphitizing processes. Creation of the uncontrolled voids or ruptured activated graphitized fibers adversely affects the performance of the produced article in draining out the bodily fluid. More specifically, the bodily fluid siphoned out from the cavity preferably by way of capillary effect, in connection to the longitudinal canals extending in the matrix of the fiber, is disrupted. The viscose fibers can be stabilized by way of oxidation, cross-linking, polymerization, degradation and/or cyclization relying on the temperature of the treatment, duration, temperature increment rate, types of gasses present in the heat treatment and/or pretreatment performed onto the viscose fibers. More preferably, the rayon fibers for producing the activated graphitized fiber are subjected to pretreatment including chemical modification of at least portion of the microfibrils or impregnating of chemical additives onto the surface of the viscose fibers. Particularly, the viscose fibers are pre-treated to have the surface coated with catalytic additives selected from the group consisting ammonium chloride, sodium phosphate, ammonium phosphate and any combination derived thereof, optionally, in combination of ammonium carbamate or ammonium orthoborate. The ammonium phosphate, sodium phosphate, ammonium chloride and the like salts are flame resistant salts. Presence of these flame retardant salts on the viscose fibers insures the reactions occurred without substantially incineration of the viscose fibers. In the more preferred embodiments, the rayon fibers are thermally decomposed to a more heat-stable intermediate structure prior to being graphitized at the later stage of the disclosed process. Furthermore, the catalytic additives and the viscose fiber are in ratio of 1-2: 4-20 by weight. Typically, the viscose fibers may be soaked into a solution containing the dissolved catalytic additives for a preferred period to let the dissolved catalytic additives gradually seeping into the matrix of the viscose fibers using the solution as a transferring medium. Once the soaking is finished, the viscose fibers impregnated or coated with the catalytic additives are further subjected to a drying process to get rid of the solution preferably under reduced air pressure with or without low temperature heating.

Other pretreatment may involve removal of the contaminants or pollutants adhered on the viscose fibers by washing. Preferably, the washing is performed before impregnation of the catalytic additives if these chemical entities are employed. Organic solution such as acetone, acetonitrile or the like can be used in the washing step to dissolve thus removing the contaminants.

Preferably, the viscose fibers employed in the present disclosure are rayon fibers containing the preferred amount of the carbon content and cellulose molecules with the desired crystalline arrangement to produce the drainage article. Specifically, the viscose fibers have cellulosic matrix composed of almost equal amount of crystalline and amorphous molecules. The crystalline molecules are dispersed in the amorphous molecules randomly and almost 50% of the crystalline molecules oriented in a position perpendicular to the axis of the viscose fibers. The like molecular arrangement generally shows higher reactivity including interaction with oxygen and inclines to create rough or uneven surfaces in the heat treatment of activating or carbonizing step. The created rough or uneven surfaces lead to increased specific porous surface area on the activated graphitized fibers. The viscose fibers employed in the present disclosure to derive at least part of the implantable article are rayon fibers containing the preferred amount of the carbon content and cellulose molecules with the desired crystalline arrangement to produce the drainage article. Typically, the rayon type viscose fibers possess 44% of weight percentage as carbon content from which the disclosed activated graphitized fiber acquires 35 to 40% by weight percentage of the carbon content preserved through the carbonization and graphitization processes. It was found by the inventors of the present disclosure that viscose fibers processed through the described conditions show carbon preservation as high as 35 to 40%.

More particularly, the stabilizing and carbonizing processes in the present disclosure causes the viscose fibers to undergo thermal decomposition and destruction with the formation of a plurality of capillary-like pore structures within the matrix of the carbonized fibers. Existence of these capillary-like pore structures greatly boosts the specific surface area of the carbonized fibers and also the derived activated graphitized

fibers. The derived carbonized fiber or the activated graphitized fiber preferably has specific surface area of 1900 to 2100 m²/g. The significantly increased surface area attributes to the capillary mechanism or effect found in disclosed article for channeling out the excessive intraocular fluid. More specifically, the drainage article has a plurality of capillary structures or longitudinally extending grooves with averaged diameter below 50 Angstrom distributed within the matrix of the derived activated graphitized fibers. According to one preferred embodiment, the one or more of the capillary structures are interconnected to form a network of draining canals within the matrix of the carbonized fibers or the derived activated graphitized fibers. Interconnectivity of the capillary structures imparts greater resistance to the disclosed drainage structure in acting against blockage of the fluid flow. The aqueous humor can be drained out from the eye through the interconnected network of draining canals even one or more route is found blocked. The flexibility of adapting different draining routes regardless of blockage of part of the network, thus, prolongs the service life of the implanted drainage article substantially. In connection to the aforesaid feature, some embodiments of the present disclosure have the first end and the second end of the activated graphitized fiber connected through an interconnected network of porous canals defined within the activated graphitized fiber. More specifically, in these embodiments, the activated graphitized fiber internally defines one or more interconnected network of porous canals.

Most of these capillary structures are originated from enclosed pinholes distributed in the matrix of the viscose fibers. The enclosed pinholes are changed into capillary structures or through grooves in the thermal decomposition or pyrolysis process. Firstly, the enclosed pinholes may be changed into the “open” pinholes which finally advance into the, preferably interconnected, capillary structures or the extending grooves. It is important to be noted that the rayon type viscose fibers inherently possessing the “closed” pinholes is the key factor to realize the at least partial interconnected capillary structures in the finally produced drainage article. These structures improve the wettability of the article surface and the flow of aqueous humor. Interconnected network of porous canals provides the drainage of humor by the capillary effect. Moreover, this effect affect the rate of drainage depending from pressure difference on the ends of

article, so the higher the pressure inside of eyeball the greater the rate of drainage. Thus, this system provides the optimal outflow of aqueous humor and substitutes the complex and unreliable valves system.

5 Further, the carbonized fibers are preferably graphitized in the presence of a tension force equal to 0.01 N per Tex applied onto it. The tension force can be generated through holding the carbonized fibers to suspended load or the like. The tension force assists in orienting the carbonized fibers to a more preferred configuration for the graphitization. In one aspect, the tension force straightens the potentially cuddled
10 carbonized fibers to expose all the available surface area for graphitization. It is more preferred that the carbon residues in the carbonized fibers proceed to aromatization of the carbon structures. More specifically, the carbon atoms in the carbonized fibers self-manifest to form C6 ring structure and orient into a graphite-like plane. The C6 ring structure can be considered both chemically and biologically stable molecules. It is less
15 probable to instigate cellular reaction once implanted.

Pursuant to preferred embodiments, to further activate the graphitized fibers via a surface treatment. Particularly, the graphitized fibers are activated in the presence of oxygen or carbon dioxide gas flow at a rate of 10 to 100 liter per hour to produce the
20 drainage article having a sorption capacity of 350 to 420 cm³/g. Without proper surface treatment, the sorption capacity of the graphitized fibers is far from satisfactory as shown in the examples below. Preferably, the surface treatment is conducted at a temperature of 800 to 1200⁰C. More preferably, the oxygen flows through the graphitized fibers at a rate of 50 to 80 liter per hour while the carbon dioxide flows at a
25 rate of 10 to 30 liter per hour.

Apart from that, the activated graphitized fiber is impregnated by 30 to 70% glucose solution to become fully functional. The impregnation can be conducted through submerging the activated graphitized fiber into the glucose solution for a predetermined
30 duration. The glucose solution changes the activated graphitized fiber from roving into the torsion condition.

In other embodiments, the micro-sized activated graphitized fiber can function as a standalone drainage article without the concurrent use of the valve assembly. Or, more preferably, the micro-sized activated graphitized fiber can coupled with other tools to carry out the drainage function to treat diseased condition besides galucoma. The implantable article, of such embodiment, for reducing fluid pressure of a bodily fluid-filled cavity by draining of portion of the bodily fluid comprising a micro-sized activated graphitized fiber having a first end insertable into the cavity and a second end extending away from where the first end is in direct contact with the bodily fluid to flow the bodily fluid from the first end to the second end of the activated graphitized fiber, with the flow being permitted to pass therethrough when the fluid pressure in the cavity exceeds a predetermined threshold, wherein the activated graphitized fiber is derived from rayon fibers and characterized by having a sorption capacity of 350 to 420 cm³/g and specific surface area of 1900 to 2100 m²/g.

To improve anchorage of the disclosed article, the inventors of the present disclosure preferably shape the activated graphitized fiber into a substantially U-shaped or inverted U-shaped construct as depicted in Figure 4. In several embodiments, the articles may inherently carried one or more curved arcs on the body of the article with one or more curved arcs interposed in between the first and second ends. Presence of one or more arcs on the body of the activated graphitized fiber improves anchorage of the implanted article onto the cellular structure where it disposed. The arc literally hooks the entire implanted article onto the surrounding cellular structure that its removal can only be achieved via an externally applied force. According to the most preferred embodiments, the like feature should enable the implanted article remained substantially unaffected by the eye movement, particularly random eye movement in the sleeping phases. The drainage efficiency of the article is free from substantial negative impact in connection to the arc formation as well.

The following example is intended to further illustrate the invention, without any intent for the invention to be limited to the specific embodiments described therein.

Example 1

The inventors of the present disclosure researched different raw materials such as hydrocellulose, PAN-fiber, comprehensive set of nonwoven fibrous materials for production of carbon polyfilament thread. The only one type of carbon fiber made up of hydrocellulose was chosen from the variety of materials. The results of series researches done proved that the most perspective materials for getting the carbon polyfilament thread are the fibers of hydrocellulose. The hydrocellulose fibers show the best adhesion to polymeric carbon matrix besides keeping longer stable characteristics under the action of bioactivity and climatic decomposition than the rest of the alternative materials.

The surface of the original viscose fibers is heterogeneous. During the process of filament formation the generated deposits were placed perpendicular to the axis of the fibers formed. Also the rough and uneven surface of the filament section was arisen as the result of the spun-bond orientation. After transformation of the filaments into the carbon fiber through the carbonization and graphitization processes at temperatures above 2000°C the intrinsic features of the structure on the surface of the original fiber were preserved. The transverse irregularities were slightly increased while heating during the carbonization process. It is linked to the fact that the “thin” structure of the viscose fibers produced employing the cord technology is microcrystalline and characterized by the alteration of crystalline and amorphous structures. The simplified structure of viscose fibers can be considered as a net of the crystalline elements dispersed in the amorphous environment. So the crystalline and amorphous elements appear on the surface of the viscose fiber with equal probability and at the same time this elements oriented randomly around the fiber axis. Thus the probability of the presence of crystalline structural elements oriented athwart to the axis of fiber is about 50%. Such structural arrangement of the crystalline and amorphous elements renders the higher interaction reactivity of viscose fibers, including reaction with oxygen. As a result the fiber etching effect appears during the carbonization process which helps to increase the thin relief of the carbonized fiber. The rough relief of the carbonized fibers surface is preserved during the next high temperature heat treatment and leads to increasing of the specific absorption surface of the viscose based carbon fibers. Apart

from surface roughness the viscose fibers naturally have pinholes with diameter up to 10 Å. Most of these pinholes are closed and represent the chambers by itself and during the process of the pyrolysis the side gaseous products create significant pressure inside of them. As a result inside of this chambers the excessive pressure creates the conditions then the sequences and speed of the pyrolysis reactions flow are significantly differ from the reaction in the open pinhole system. In this case the predominant deposition and condensation of the volatile products in the form of the carbon formations might occur instead of their evacuation through the open canals from reaction zone. Thus, during the process of pyrolysis of the fibers, it is needed to provide the conditions to open the closed pinholes so the open pinholes prevailed in the graphitized viscose fiber. The developed specific surface of the disclosed viscose carbon fibers and the natural open porosity which eventually form the interconnected capillaries found in the fibers increases the wettability of the carbon fibers and capability of the liquids transferring by capillary absorption effect.

In order to produce the carbon fiber, the viscose thread was processed by thermal treatment step by step. Preferably, the process involves the cellulose material treatment with (10–19) % aqueous mixture of catalyst until the content of catalyst on the fiber reached 5–20% by weight. The initial thermal treatment - activation in the air or inert environment in conjunction with the constant increase of the temperature aims to stabilize the fiber. The next step was carbonization of the fiber in an inert environment under argon curtain with the constant rate of broaching through the furnace. The impact of the temperature of the acquisition and activation towards the carbon fiber are listed in the table 1 below. The increase of the temperature of acquisition lowered the specific surface are and sorption capacity of the acquired carbon in line with increase of the strength of the fibers.

Table 1

Fiber feature	Acquisition temperature, °C	Features			
		Sspe, m ² /g	Vsorp, cm ³ /g	σp, Mpa	G, Gpa
Original	1200	0,5	0,7	-	-
Activated		1713,0	529	-	-

Original	1400	0,6	0,76	172	18,1
Activated		1635,0	512	98	13,6
Original	1700	3,6	1,07	553	34
Activated		372	123	418	30,2
Original	2000	8,99	2,1	616	37,0
Activated		14,24	4,4	334	27,4

It is an object of the present invention to develop a method for preparing of the biocompatible, durable carbon drainage with high functional properties improving on liquid draining from the eyeball via the surgical treatment of glaucoma. Carbon fiber based on rayon filament is found to be the most suitable material. Various desired carbon fibers can be fabricated under heat treatment at a temperature from 1000 to 3000°C depending on the application and the necessary density, chemical purity, the sorption capacity, strength and other characteristics. Preferably, the number of filaments in each carbon fiber (a bundle) was about 100-1200 units, the diameter was 7-9 microns length, the density is 1.4 cm³/g, carbon content is at least 99.93% and the tearing tow strength is 300 MPa.

During the activation the increase of the specific surface of carbon fiber and sorption capacity occurs due to the result of the tearing away of the weakly connected with the main grid low numbered groups of atoms, as the result the pinholes open in the fiber leaving firm frame. In other words, the changes are happening at the surface of the fiber at the nano-level.

The electron-microscopic study of carbon fiber structure showed that the porosity arisen inside the matrix of the fibers, during the thermal treatment, which the pinholes of capillary structure were oriented along the carbon thread. As shown in figure 1 and 2, the assessment on the shape and size of the pinholes was conducted on the microscopic photos of the face section of the carbon fiber. The pinholes were the oval form with an axis about 0.12 micrometer or smaller.

The efficiency of the yielded carbon fibers as the drainage material mainly depends on its specific surface area and sorption capacity. Particularly, the carbon fibers activated in

the environment with constant oxygen flow showed sorption capacity at 398 sm^3/g and specific surface area of 1960 m^2/g . When the same activation was conducted in the environment under constant carbon dioxide flow, the sorption capacity became 415 sm^3/g with the specific surface is 2009 m^2/g .

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Example 2

The carbon thread or activated graphitized fiber, produced from pyrolysis of hydrate-cellulose, with increased sorption capacity and specific surface area were used for studying its drainage properties in 3 sets of experiments under laboratory conditions.

- 10 We got sure by the results of the experiments about the efficiency of the long conductivity of the thread of protein liquid. The study showed association in between the rate of liquid outflow and the level of pressure inside the eye. The higher of the liquid pressure inside the eye the greater the rate of the liquid outflow through the drainage. The studied drainage article would work more efficient at a higher level of
- 15 intraocular pressure. For the in vitro study of the mechanical characteristics of the carbon drainage it is being subjected to the impact of different medications in order to decrease the disband and fragility of the thread. The experiments also proved that it was more comfortable to use the produced carbon thread after soaking the threads around 1 minute in an aqueous mixture with ~40% glucose. The fibers become mechanically
- 20 stronger and less friable leading to easier implantation of the drainage article.

- Thus, as the result of the research done was invented the micro-drainage made up of carbon fiber with a maximum sorption capacity: the carbon micro-drainage is represented by the thread up to 25-30 mm long, it has the diameter of 100-150
- 25 micrometer made up of carbon fiber of hydrate-cellulose, it is previously experienced the heat treatment at 1000°C and activated in the flow of CO_2 at 900°C, the thread mellowed within 1 min in 40% of mixture of the glucose before being used.

- Three experimental groups were formed in the in vivo experiments in order to study the
- 30 association between the level of intraocular pressure decrease and the size of the carbon micro-drainage. The diameters of thread used were 150 micrometer (15 eyes)- the first

group, 450 micrometer (20 eyes) – the second group and 600 micrometer (15 eyes) the third group. The operated rabbits were observed for 15 months.

The techniques of performing the operation included minimal surgery intervention (microinvasive): the intrascleral cut made by the lanceolate knife on the anterior chamber of the eye (without forming the deep sclera pocket), fixing of the drainage to sclera by single stitch with the its simultaneous introduction to the anterior chamber of the eye by using the special spatula. The operation lasted no more than 5-7 minute. It aimed to lower the possibility of postsurgical complications. During the experiments some minor shortcomings in 3 cases were observed due to uneven cut of the drainage fiber tip 1 rabbit had thread with diameter of 400 micrometer and 2 rabbits with thread of 600 micrometer.

It was found that the clinical manifestations significantly corresponded to the size of the implanted micro-drainage during the observation of the experimental groups. The bigger the diameter of the thread the better the outflow but there was some disadvantages as well. The cosmetic defects and minor complications were more noticed in the groups implanted with the threads of larger diameter, along with the faster decrease of the intraocular pressure. The group implanted with the threads having diameter of 150 micrometer showed highest compliance to the hypertensive effect with full absence of the observed complications.

The formation of filtration pillows were noticed in the early post-surgery period, also there was the some small swelling of the conjunctiva in the surgery zone, the iris was not affected, optical environment was transparent, the small front cavity was noticed in two eyes which recovered on its own on the second week. The experimental eyes of the rabbits remained absolutely calm during the farther observation. The iris, cornea and moisture of the anterior chamber of the eye were not affected; obfuscation of the crystalline lens and vitreous body was not noted during the whole period of the observation. The inflammatory and hemorrhagic complexities were not found.

The ultrasonic microscopy and gonioscopy on the front incision of the eye were conducted by selecting 5 rabbits out of each group one time per quarter of the year. The implanted drainage was found at the anterior chamber of the eye in all the cases. In one case the drainage entered the anterior chamber of the eye very shortly less than 1mm.

- 5 The contact between the end of drainage end and the thread and the cornea were found in two cases. Endothelial microscopy was made in order analyze the impact of the carbon micro-drainage implanted on the corneal endothelial cells (1 time per quarter of the year during the whole period of observation – 15 months. After the endothelial microscopy, there were no significant decrease of the quantity of the endothelial cells
10 and the changes of their quality composition in both experimental and control eyes.

- The relatively minor aftereffects arose after the surgery, there were small anterior chamber of the eye on the first week in two eyes of the rabbits from the third group, the contact between the cornea and iris of one of the rabbits from the second group and two
15 rabbits of the third group suffered from the same problem; too long and, probably, badly fixed outer drainage end occurred in the second group – 2 cases, in the third group – one case. No aftereffects were found in the first group, minor adverse outcome were found in the second group for 3 cases and 6 cases (39,8%) in third group. The inventors haven't registered any case of serious complications, like hypotension, eyeball
20 subatrophy, detachment of the choroid and retina, hyphema, hemophthalmus or endophthalmitis.

- The hypotensive effect after the surgery was assessed by the tonometry and tomography of all the 50 experimental bodies and comparison of the 50 control eyes within the
25 whole period of the observations (15 months). The tonometry was done in all the rabbits before the surgery, on the 3th, 7th, 15th day and then each 2 weeks.

Table 2

Group	The diameter of thread	Period				
		before the surgery	on the third post-surgery	a week later	after 6 months left	after 15 months left

		day				
		The intraocular pressure, mm Hg			The difference of the intraocular pressure against control group, %	
1	150 μ m	20,5 $\pm$ 0,5	13,4 $\pm$ 0,7	13,8 $\pm$ 0,24	24,7	20,1
2	450 μ m	20,5 $\pm$ 0,5	12,8 $\pm$ 0,4	12,8 $\pm$ 0,22	27,5	23.2
3	600 μ m	20,5 $\pm$ 0,5	11,2 $\pm$ 0,5	11,1 $\pm$ 0,7	33,2	25.5

The results of the tonographic studies, as in table 2, show the reliable decrease of true intraocular pressure of 23,3% on average ($p < 0,001$) and significant increase of the coefficient the flow easiness in three times. It is necessary to mention that the tonographic and true intraocular pressure was significantly lower in the main groups compared to the control group within the whole period of the observation. Comparing the values of the intraocular pressure among the tested groups related to different periods of observation, the pressure was found significantly lower in the third group than in the second group as well as in the first group. There was stabilization noticed in the dynamics of the decrease of the intraocular pressure after 6 months, the hypotensive affect progressed significantly slower than the earlier periods of the implantation.

The reliability and efficiency of the implanted carbon thread through live tissues of the eye within different time periods was tested by the experiment where blue dye was deposited into the anterior chamber of the eye being operated and tracked the time of the blue dye appearance under the conjunctiva in the implanted drainage area. The appearance of the dye under the conjunctiva in the field of drainage was within 15-65 sec. The wider the drainage and the shorter the time period of implantation the higher was the liquid drainage rate. The time period of the liquid drainage in the third group was 20s less than in the first group on average.

The histological studies showed that, by the end of the observation, the zone of the wounded area in which the thread fixed showed no formation of scar tissue and the carbon thread was sighted. The carbon drainage made up of grouped thread strands of

carbon microfibrils. The thin interlayer of conjunctive tissue made up of the 2-3 layers of fibroblasts formed at the periphery of the thread in 3 months after the surgery performed. The “capsule” kept the integrity of the implanted thread and limited the aseptic inflammation aimed on the partial absorption of the carbon fragments. It was noticed the existence of the macrophages and single multinucleated giant cells surrounding the carbon particles by the end of the observation. There was absolute absence of inflammatory response of the surrounding tissues around the carbon thread.

The hypotensive effect in 12-15 months after the surgery intervention performed was 23.2% compare to the control group on average. The simplicity and convenience of equipment for surgery performed using the biocompatible drainage material (according to data of histology) provides the minimal risk of possible aftereffects after the surgery performed in the long term as observed. It is noticed the presence of the dependency of the hypotensive effect and the clinical experimental complications from the size of the diameter of the drainage. The hypotensive effect is higher in the third group on 6,5% than in the first group and it is higher on 3,4% than in the second group, however, the complications were noticed in four times more often than in the first group and in 2,5 time more often than in the second one. Thereby, the optimal result was noticed in the first group (with the diameter of the thread is 150 micrometer). The Hypotensive result was 20,1% in 15 months. There were no complications noticed. The use of the micro-drainage of the present disclosure made up of the material which is biocompatible shows excellent sorption or drainage functions for removal of bodily fluid. The activated graphitized fiber, composed of polyfilaments, has a diameter of around 150 micrometer. The experiments of clinical intervention with the disclosed carbon drainage revealed good clinical and hypotensive efficiency along with the minimal traumatization on the eye tissues.

All the invented and mentioned above positive features of the carbon thread or micro-sized activated graphitized fiber aim to offer efficient and safe implantable drainage alternative for surgical treatment of glaucoma and other drainage surgeries.

Aspects of particular embodiments of the present disclosure address at least one aspect, problem, limitation, and/or disadvantage associated with existing drainage implant for reducing intraocular pressure. While features, aspects, and/or advantages associated with certain embodiments have been described in the disclosure, other embodiments
5 may also exhibit such features, aspects, and/or advantages, and not all embodiments need necessarily exhibit such features, aspects, and/or advantages to fall within the scope of the disclosure. It will be appreciated by a person of ordinary skill in the art that several of the above-disclosed structures, components, or alternatives thereof, can be desirably combined into alternative structures, components, and/or applications. In
10 addition, various modifications, alterations, and/or improvements may be made to various embodiments that are disclosed by a person of ordinary skill in the art within the scope of the present disclosure, which is limited only by the following claims.

Claim

1. An implantable article for reducing fluid pressure of a bodily fluid-filled cavity by draining portion of the bodily fluid comprising

one or more micro-sized activated graphitized fiber, having a first end insertable
 5 into the cavity and a second end extending away from where the first end is in direct contact with the bodily fluid, being configured to drain the bodily fluid from the first end to the second end at a flowing rate which is correspondingly varied to a pressure difference present in between the first and second ends,

wherein the activated graphitized fiber is fabricated from a pre-treated viscose
 10 fiber by way of carbonization and graphitization under heat treatment with further activation in the presence of oxygen or carbon dioxide gas flow of 10 to 100 liter per hour.

2. The article of claim 1, wherein the viscose fiber is pre-treated with catalytic
 15 additives selected from the group consisting of ammonium chloride, sodium phosphate, ammonium phosphate and any combination derived thereof, optionally, in combination of ammonium carbamate or ammonium orthoborate coated onto the surface.

3. The article of claim 2, wherein the catalytic additives and the viscose fiber have
 20 a ratio of 1-2: 4-20 by weight.

4. The article of claim 1 or 2, wherein the activated graphitized fiber is impregnated by 30 to 70% glucose solution.

5. The article of claim 1 or 2, wherein the activated graphitized fiber has a sorption
 25 capacity of 350 to 420 cm³/g.

6. The article of claim 1 or 2, wherein the activated graphitized fiber has specific
 surface area of 1900 to 2100 m²/g.

7. The article of claim 1 or 2, wherein the graphitized fiber is subjected to a tension
 30 force equal to 0.01 N per Tex in the graphitization.

8. The article of claim 1 or 2, wherein the activated graphitized fiber has a plurality of capillary structures or longitudinally extending grooves with averaged diameter below 50 Angstrom distributed within the matrix of the activated graphitized fibers.

5 9. The article of claim 1 or 2, wherein the viscose fibers are rayon fibers.

10. The article of claim 1 or 2, wherein the activated graphitized fiber has a diameter not greater than 150 micrometer.

10 11. The article of claim 1 or 2, wherein the first end and the second end of the activated graphitized fiber are connected through an interconnected network of porous canals defined within the activated graphitized fiber.

12. The article of claim 1 or 2, wherein the activated graphitized fiber internally
15 defines one or more interconnected network of porous canals.

13. An implantable article for reducing fluid pressure of a bodily fluid-filled cavity by draining of portion of the bodily fluid comprising

a micro-sized activated graphitized fiber, having a first end insertable into the
20 cavity and a second end extending away from where the first end is in direct contact with the bodily fluid, being configured to drain the bodily fluid from the first end to the second end of the activated graphitized fiber at a flowing rate which is correspondingly varied to a pressure difference present in between the first and second ends,

wherein the optimal flow is provided by dependence of the rate of fluid transfer
25 by the article surface interconnected network of porous canals from the pressure difference on the ends of article and the activated graphitized fiber is derived from rayon fibers and characterized by having a sorption capacity of 350 to 420 cm³/g and specific surface area of 1900 to 2100 m²/g.

30 14. The article of claim 13, wherein the activated graphitized fiber internally defines one or more interconnected network of porous canals.

15. The article of claim 13, wherein the viscose fibers are rayon fibers.