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(54) Titre : CANULE DE KOURENKOV DESTINEE A UNE METHODE D'OPERATION DE KERATECTOMIE PHOTOREFRACTIVE INTRASTROMALE PAR LASER EXCIMERE

(54) Title: KOURENKOV'S CANNULA USED FOR A METHOD FOR AN OPERATION OF REFRACTORY-CORRELATING EXIMER-LASER INTRASTROMAL KERATECTOMY (REIK)

(57) Abrégé/Abstract:
The invention relates to medical instruments and can be used for an operation of refractory-correlating eximer-laser intrastromal keratectomy (REIK). The inventive cannula comprises a hollow body, a curved working part, side channels and a cavity connected to the hollow body. The side channels are used for instillating and/or irrigating the cornea flap while performing the refractory-correlating eximer-laser intrastromal keratectomy (REIK). Longitudinal axes of the side channels are placed across a plane of the working part bending and oriented angle-wise or angles-wise with respect to the longitudinal axis of the working part. The working part has a tapered end for facilitating its introduction and/or a separation of tissues. The body and/or the working part are embodied with equal cross-sections and/or with cross-sections whose shapes differ from each other.

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(71) Заявитель *(для всех указанных государств, кроме (US):* **ООО МЕДИЦИНСКИЙ НАУЧНО-ИССЛЕДОВАТЕЛЬСКИЙ ОФТАЛЬМОЛОГИЧЕСКИЙ ЦЕНТР «НОВЫЙ ВЗГЛЯД»** [RU/RU]; 121614 Москва, ул. Крылатские холмы, д. 30, к. 2 (RU) [**OOO MEDITSINSKY NAUCHNO-ISSLEDOVATELSKY OFTALMOLOGICHESKY TSENTR «NOVY VZGLYAD»**, Moscow (RU)].

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До истечения срока для изменения формулы изобретения и с повторной публикацией в случае получения изменений.

В отношении двухбуквенных кодов, кодов языков и других сокращений см. «Пояснения к кодам и сокращениям», публикуемые в начале каждого очередного выпуска Бюллетеня PCT.

(54) Title: KOURENKOV'S CANNULA USED FOR A METHOD FOR AN OPERATION OF REFRACTORY-CORRELATING EXIMER-LASER INTRASTROMAL KERATECTOMY (REIK)

(54) Название изобретения: КАНЮЛЯ КУРЕНКОВА ДЛЯ СПОСОБА ПРОВЕДЕНИЯ ОПЕРАЦИИ РЕФРАКЦИОННО-КОРРИГИРУЮЩЕЙ ЭКСИМЕРЛАЗЕРНОЙ ИНТРАСТРОМАЛЬНОЙ КЕРАТЭКТОМИИ (РЭИК)

(57) Abstract: The invention relates to medical instruments and can be used for an operation of refractory-correlating eximer-laser intrastromal keratectomy (REIK). The inventive cannula comprises a hollow body, a curved working part, side channels and a cavity connected to the hollow body. The side channels are used for instillating and/or irrigating the cornea flap while performing the refractory-correlating eximer-laser intrastromal keratectomy (REIK). Longitudinal axes of the side channels are placed across a plane of the working part bending and oriented angle-wise or angles-wise with respect to the longitudinal axis of the working part. The working part has a tapered end for facilitating its introduction and/or a separation of tissues. The body and/or the working part are embodied with equal cross-sections and/or with cross-sections whose shapes differ from each other.

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(57) Реферат: Изобретение относится к медицинским инструментам и может быть использовано при операции рефракционно-корригирующей эксимерлазерной интрастромальной кератэктомии (РЭИК). Канюля, содержащая полый корпус и изогнутую рабочую часть, имеющую боковые каналы и полость, сообщающуюся с полостью корпуса, причем боковые каналы выполнены для инстилляции и/или промывания подлоскутного пространства при проведении рефракционно-корригирующей эксимерлазерной интрастромальной кератэктомии (РЭИК), причем продольные оси боковых каналов расположены поперек плоскости изгиба рабочей части и ориентированны под углом или под углами к продольной оси рабочей части, при этом рабочая часть имеет сужающийся конец, для введения и/или разделения тканей, а корпус и/или рабочая часть выполнены с одинаковыми поперечными сечениями и/или с поперечными сечениями, не совпадающими по форме между собой.

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KURENKOV'S CANNULA FOR A METHOD FOR AN OPERATION OF REFRACTORY-CORRELATING EXIMER-LASER INTRASTROMAL KERATECTOMY (REIK)

This invention relates to the field of ophthalmology and allows performing a correction of vision using excimer laser.

The invention relates to medical instruments and it can be applied in all areas of surgery, especially during the operation of refraction-correcting excimer laser based intrastromal keratectomy, and other variants of intrastromal operations on the cornea.

Cannulas are designed for the performance of diagnostic and curative actions in natural superficial bodily cavities and fistulas. They are made mainly of metal, and - similar to medical needles - they are hollow.

In ophthalmology, cylindrical or flattened cannulas are used to rinse the lacrimal duct, suck off the lens' mass, and also to introduce air and perfusing fluid into the anterior chamber of the eye.

The current technology knows a puncture needle comprising a cannula, an auxiliary pipe and the working part curved on the radius, where the convex surface of the working part comprises several apertures and the bevel of the end of the working part is directed towards the side of the convex surface. The puncture needle includes an arresting device between the auxiliary tube and the working part (see patent [registered in the Russian Federation] RF No. 543395 cl. A 61 B 17/34, published 25.1.77).

The technical solution closest to the present invention is a cannula designed for the performance of operation of laser-based intrastromal keratomileusis. This cannula used

for perfusing the eye cornea comprises a source of perfusing solution, a tube, which is moved manually and which is of sufficient length to penetrate into the zone under the patch of the upper part of the cornea, created by a surgical intervention. The end of the tube has the form of a flattened head, the top of which comprises an aperture for delivering the perfusing fluid, and another two apertures - one on the upper side, the other one on the lower side - to deliver the fluid in two more directions. The aforementioned upper and lower aperture are arranged at an angle of 90° from the axis intersecting the upper aperture and they lie in one line; in another variant they can be shifted up or down (patent USA No. 5755700, cl. 604-257, published 26.5.1998).

The disadvantage of the known cannula consists in irregular supply and distribution of the perfusing fluid under the surface, which results in leaving parts of tissue previously subjected to the effect of the excimer laser beam, and also organic particles from the conjunctiva content.

The technical result of the present cannula design is a uniform distribution of the perfusing fluid under the surface and the complete cleaning of the zone under the patch, as well as the formation of a flow of perfusing fluid in one direction which reduces the possibility of mixing with conjunctiva fluid and contaminating it with organic particles.

The described result is achieved in V. Kurenkov's cannula. The cannula comprising a hollow body and a bent working part, having lateral channels and hollow space connected with the hollow space of the body, where the lateral channels are designed to instil and/or perfuse the zone under the patch during the performance of refraction-

correcting excimer laser based intrastromal keratectomy including the performance of anaesthesia by instillation, clean-up of the conjunctiva cavity, establishment of a vacuum ring, performance of a cut to create a patch on a stem, opening the patch, performance of laser kerato-ablation, instillation of medical preparations, and repositioning of the patch, where anaesthesia is performed by means of a vasoconstrictor, the vacuum ring is placed in such a manner that its longitudinal axis passes the centre of the pupil, after which the vacuum ring is shifted vertically down by 0.5 - 1 mm. Before the creation of a patch, the conjunctiva cavity is instilled with a mixture of solutions of 0.4 - 0.6% methyl cellulose and 0.17 - 0.19% sodium hyaluronate. The base of the patch is selected at "12 o'clock", and the lower end of the patch must not be further than 2 mm from the limbus; before opening the patch it is to be folded in half with inner surface inside. After the performance of laser kerato-ablation, the stromal bed is perfused with preparations improving its regeneration, and after the repositioning a solution of antibiotics and non-steroid preparations is instilled. Then the patch is manually spread in transpalpebral sense. The lateral axes of the lateral channels of the cannula run across the curve of its working part and are oriented longitudinally at an angle or angles to the longitudinal axis of the working part, where the working part comprises a narrow end to penetrate and/or separate tissue and the body and/or the working part are designed with the same cross-section and/or with cross-sections differing in their form.

The cannula comprises a curve of the working part forming an angle of 130° - 150°.

The cannula comprises lateral channels with their longitudinal axes running at an angle of 30° - 50° to the longitudinal axis of the working part.

The lateral channels of the cannula have a formed cross-section or formed cross-sections in the shape of a circle and/or an oval and/or a polygon.

The cannula is made of metal.

The cannula is used in the operation of refraction-correcting excimer laser based intrastromal keratectomy.

Figure 1 shows a general view of V. Kurenkov's cannula.

Figure 2 shows V. Kurenkov's cannula, in which the apertures closer to the end are designed at an angle of 90°.

Figure 3 shows V. Kurenkov's cannula, in which the working part is designed with a radial curve.

Figure 4 shows the location of V. Kurenkov's cannula during the perfusing of the zone under the patch.

V. Kurenkov's cannula comprises a solid body 1 and a curved working part 2. The working part comprises lateral channels 3 and hollow space 4, which is connected with the hollow space of body 1. The longitudinal axes of lateral channels 3 run across the hollow space of the working part's curve, and they are oriented at an angle or angles to the longitudinal axis of working part 2. The working part has a narrow end for penetrating and/or separating tissues. Body 1 and/or working part 2 are designed having the same cross-section or having cross-sections of different forms. As indicated, the cannula is used for the operation of refraction-correcting excimer laser based intrastromal keratectomy and for other variants of intrastromal operations on the cornea.

V. Kurenkov's cannula shown in Figure 2 comprises apertures closer to the cannula's end and designed at an angle of 90°. A cannula of such a design can usually be used for operations with patches of a smaller size.

The cannula version whose working part comprises a radial curve (Figure 3) allows a most comfortable perfusing of the zone under the patch.

The cannula is used for the operation of refraction-correcting excimer laser based intrastromal keratectomy.

For refraction surgery the ophthalmology currently uses lasers working with a mixture of argon-fluorine with a radiation wave of 193 nanometers, of which the most promising is the Nidek - 5000 2c laser. One of its advantages is the use of low-density energy, which allows reducing the traumatizing of the cornea, and lowering the acoustic shock. Besides that, the temperature in the zone of ablation does practically not rise. The system of beam delivery rules out the formation of any central islet, which often represents a complication when broad-profile lasers are used.

The indicated method is characterized by the following stages.

At the first stage, in order to obtain a maximum of predictable refraction result and to reduce any inaccuracy, it is necessary to change the conditions of the anaesthesia of the cornea, and in doing so, to exclude or significantly reduce damaging and toxic effects of the anaesthetic on the epithelium, and also reduce its diffusion into the stroma. The reduction of diffusion results in reducing the effect of the anaesthetic on the hydration of the tissue. The change of constant conditions in hydration has an influence on the working accuracy of the excimer laser, since a saturation

with water of the cornea tissue hinders the programmed removal of the tissue during one single scanning with the laser beam. However, the complex of aforementioned conditions worsens the quality of the cut being made with a micro-keratome (consisting in irregular surface of the cut) due to a less consistent nature of the stroma. The toxic properties of the anaesthetic cause a maceration of the epithelium, which affects the ensuing adaptation of the patch due to impairment of the sliding properties of the cornea surface.

In order to prevent or significantly reduce the indicated detrimental conditions, we recommend to reduce the number of instillation of the anaesthetic and replace it with vasoconstrictor, and - as a result - also shorten the time up to the start of the laser effect, thus preventing an increased hydration during the operation. On the other hand, the length of the effect of the dripping form of anaesthetic in conjunction with vasoconstrictor must not exceed 2 - 3 minutes until the start of the procedure, which is contingent upon the time it takes the anaesthetic to permeate the cornea. As opposed to the known method, the present method includes an instillation of the anaesthetic 2 - 3 minutes before the start of the laser beam, and thus also shortens the duration of the entire operation. In addition, the application of vasoconstrictor allows avoiding the stage of drying up the stromal bed.

In the second stage, the conjunctiva cavity is perfused and cleaned and any impurities and detritus are mechanically removed. The clean-up is performed by means of perfusing the conjunctiva surface with a balanced isotonic solution in mixture with an antibiotic using an injection needle - i.e., under pressure - in combination with a fluid-distributing

cannula, which reduces the risk of infection in the zone under the patch after the operation. [It is to be noted that] in the described method, we propose not only an isotonic solution as proposed in the known method, but rather a mixture of isotonic solution with a solution of antibiotic.

The third stage represents the establishment of a vacuum ring. The vacuum ring is placed on the cornea around the centre of the pupil and not the centre of the cornea, with a subsequent vertical shift to the bottom. By means of an applanation tonometer we then confirm the achievement of an optimal pressure in the eye. The lower edge of the patch must not be located further than 2 mm from the limbus since in the process of physiological blinking - and taking into account the standard position of the lower eyelid - this reduces the risk of subsequent shifting of the patch after its repositioning. With the described position of the vacuum ring we have observed a better fixation of the cornea patch to the stroma in later stages of the post-operation period.

The fourth stage of the operation includes microscopic intrastromal section with a lubricant. The section is performed exclusively with a lubricant, i.e., a substance with sliding properties in the form of a mixture of a 0.4 - 0.6% solution of methyl cellulose and a 0.17 - 0.19% solution of sodium hyaluronate. The selected concentrations allow developing a maximum effect in sliding the patch. In lower concentrations the solution becomes thin, in higher concentrations it becomes dense and does not provide the right effect of sliding. The use of the described lubricant significantly reduces friction during the cutting-out of the cornea patch and, therefore, it also reduces any damage to the epithelial surface of the patch.

The fifth stage of the operation includes the separation and lifting of the patch while avoiding contact of the inner surface of the patch with air. A spatula is introduced under the base of the patch in the location "at 12 o'clock", and in a movement parallel to the limbus and to the top in the plane of the cornea the patch is being lifted in the direction towards "12 o'clock" spot. In doing so, the inner surface of the patch must not come in contact with air. The patch is positioned on the "12 o'clock" spot after being folded in half with the inner surface inside. During the sliding of the patch on the created intrastromal surface the fluid is distributed in a very thin film over the whole area, since the quantity of the fluid present in the section is optimal to form a fluid layer on the surface of the stromal bed, which becomes a natural mask smoothening the surface of the section. The surface created in this manner and levelled out by the fluid is optimal for the performance of kerato-ablation.

The present method lacks the phase of drying out the surface in any way after lifting the patch, which is used in the known operation procedure (with a scalpel, sponge, micro-sponge). The present method forbids any [mechanical] contact with the surface, since it would alter its smooth nature, which may lead to a lower quality of the kerato-ablation.

The sixth stage includes a specialized photo-kerato-ablation by means of excimer laser. The proposed operation allows only the use of excimer laser with a rotation-scanning system of delivery of the laser beam through a slot. A certain beam frequency and scanning area and special nomograms (computer programs for the laser operation) are used.

This type of laser prevents the fluid on the surface from boiling and avoids collection of excessive quantity of fluid in the central zone as well as the formation of a central islet. The speed of motion, angle of rotation and the laser beam impulse frequency rule out an excessive heating of the surface and, therefore, any singeing of tissue, and also contribute to a smoother and more levelled surface as opposed to the known method.

The seventh stage of the operation includes the handling of ablated surface.

The handling comprises wetting and two phases of mechanical clean-up. After the completion of the ablation, the stromal surface is wetted with a balanced solution of a medication preparation which facilitates the process of the cornea regeneration; a solution of carnosin is especially advantageously used since the pH value of carnosin corresponds with the pH value of the cornea tissue. Subsequently any residue of tissue debris is mechanically removed from the ablated surface with a cornea scraper. The movements must occur only vertically in the direction from "12 o'clock" to "6 o'clock" without any movements in the opposite direction. In case of any movements of the scraper from the bottom to the top or at any angle in relation to the stem of the patch, the fluid will develop micro-molds on the surface of the stroma, which will negatively affect the refraction results after the operation.

The mechanical removal of micro-particles must be completed by perfusing the surface of the stromal section with a solution of anti-oxidants, e.g., carnosin, under pressure by means of an injection needle through a

distributing cannula. In this process, the fluid forms a continuous film on the cornea surface.

The eighth stage includes the repositioning of the patch without contact with air. The folded patch in the position of "12 o'clock" is unfolded by uniformly spreading it down over the entire surface. First, the inner surfaces slide in relation to each other and then the free edge moves to the position of "6 o'clock". During the sliding of the patch on the stromal surface the fluid layer transits onto the surface of the cornea patch, which prevents air and any micro-particles borne by atmospheric air from getting underneath the patch, and it allows an optimal repositioning of the patch in the bed. This method minimizes the occurrence of introducing any impurities under the patch, which simplifies and shortens the process of perfusing the zone underneath the patch and, as a consequence, the trauma factor is minimized.

The ninth stage is the perfusing of the zone underneath the patch. A cannula is introduced under the base of the patch at "12 o'clock". The cornea part of the cannula is located parallel to the patch stem, the end of the cannula must not reach the edge of the patch in order not to lift it. When the solution is supplied, the fluid moves in one direction through a channel along the cannula body.

The tenth stage includes instillation of medical preparations.

We recommend that immediately after the completion of the procedure of perfusing an anti-bacterial preparation together with a non-steroid anti-inflammatory substance be instilled and the bluffarostat [sic] be immediately removed. This should exclude any mutual diffusion between the medical prepartion and the capillary layer of the fluid underneath

the patch including any osmotic processes. This allows maintaining a thin homogeneous film, which directly influences a smooth adaptation of the patch and the best sharpness of the vision functions. On the contrary, any inhomogeneous film hinders an optimal adaptation for a number of reasons, e.g., a relative disturbance of the spheric surface due to a diversity of substances in the layer, after this situation becomes fixed by the process of epithelialization, the pair of the patch sulcus blocks micro-excursion; similarly different times of disappearance of the capillary layer underneath the patch results in the loss of lines during normal refraction.

The eleventh stage of the operation relates to trans-palpebral adaptation of the patch. After the eyelid holding device is removed, the upper and lower eyelids are held with fingers. Afterwards, by pressing the finger against the upper eyelid while holding the lower eyelid, the upper eyelid is forced to move over the patch from the position of "12 o'clock" to the position of "6 o'clock". After completing this movement, the upper eyelid is released and its return occurs automatically. Then the patient is requested to blink while the lower eyelid is being held fixed. Subsequently the lower eyelid is released and the eye is observed for about 1 - 2 minutes. In this manner, i.e., by ensuring a uniform distribution of pressure over the surface of the patch, and by pressing out excessive fluid from underneath it, a maximum uniform distribution of the fluid underneath the patch is achieved. The proposed cannula may also be used for the introduction into a tissue. Unlike other known methods of [substance] introduction, this method avoids the use of instruments and sponges, which eliminates the influence of

various damaging factors and reduce to the very minimum the possibility of incorrect adaptation.

An example:

Patient K. turned to our clinic and complained about his weakened vision. An ensuing examination discovered myopia of - 5.0 D in his right eye. The patient was offered the operation of refraction-correcting excimer laser based intrastromal keratectomy, to which he agreed.

After positioning the patient on the operation table, an instillation of a 0.5%-solution of proparacain was performed. After an exposure of 10 - 20 seconds the feeling of pinching receded, and blufforostat [sic] was installed. A second instillation of a 1%-solution of proparacain was performed at the eye's positions maximum up, maximum down and straight, after which two drops of adrenaline hydrochloride at a ratio of 1:1000 were instilled. After an exposure of up to 60 seconds, the conjunctival cavity was cleaned with a mixture of isotonic solution with a solution of cipromed [sic] for 10 - 15 seconds. Subsequently a vacuum ring was immediately placed on the cornea around the centre of the pupil, with a subsequent vertical shift to the bottom, while also taking into account that, after the section, the lower edge of the patch should be no more than 1.5 mm from the limbus. The vacuum system was connected, the internal eye pressure was verified with an applanation tonometer. A few drops of a mixture of 0.5%-solution of methyl cellulose and 0.18%-solution of sodium hyalurate were instilled. Afterwards, the previously assembled head of the micro-keratome and the motor are installed on the holding pin of the vacuum ring. Then the patch is created. After terminating the hermetization the vacuum system is removed. However, the patient's eye had to

remain in the same axis with the laser beam system. This was achieved by the patient focussing his eyes on a visible laser mark. After removing the system, the condition of the cornea was visually evaluated and a spatula was introduced underneath the base or stem of the patch in the spot "at 12 o'clock". By moving the spatula up in the plane of the cornea in the direction to "12 o'clock" the patch was pulled up and folded in half so that the inner surface remained inside. The visors of the excimer laser are established and centralized in the vision's axis and, finally, the ablation starts according to a nomogram prepared for this patient and put into the laser's computer before the operation. After the completion of the ablation the surface of the cornea was wetted with a solution of carnasin. Subsequently any residue of tissue debris was mechanically removed from the ablated surface with a spatula. The movements occurred only vertically in the direction from "12 o'clock" to "6 o'clock" without any movements in the opposite direction. After that, the surface was perfused by means of a distributing cannula, and a fluid layer was formed. After that, the spatula was applied to the location of the patch fold and moved the patch down to position "6 o'clock" in such a manner that the lower edge of the patch was sliding on the stromal surface, and the fluid remained on the epithelial surface. After this procedure the patch was fully spread. In the next phase a cannula was introduced underneath the patch in such a manner that a slot-like aperture forms at the spot the cannula was introduced and the opposite side remains connected with the stroma. Then a solution is applied so that it moves mainly to the side of the slot-like aperture, and the opposite side becomes an indicator of the pressure of the fluid that

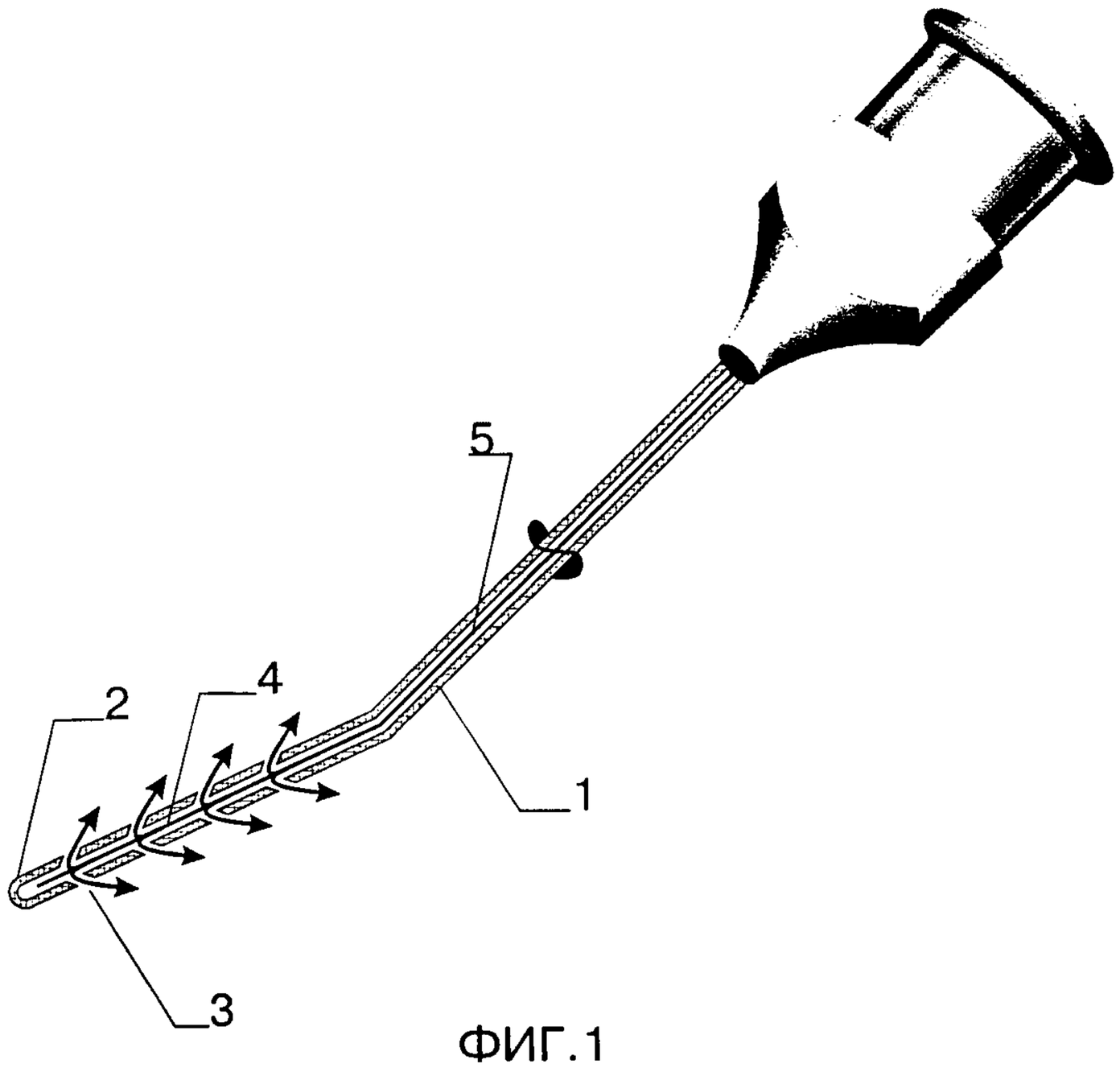
circulates underneath the patch. The opposite side opens only when the pressure becomes excessive and thus sends a signal to lower the pressure. The cannula moved in the direction from "12 o'clock" to "6 o'clock". The procedure of perfusing was verified by means of a microscope. Afterwards a solution of cipromid [sic] and diclof [sic] was instilled, after which the eyelid holding device was removed. Eyelids were now manually fixed in open position. While the lower eyelid was fixed, the upper lid was mildly pressed and moved to close the eye. Subsequently the upper eyelid was released and it returned to its open position on its own. While holding the lower eyelid, the patient was requested to blink. Then the position of the patch was visually evaluated. After that the patient was requested to blink without his lower eyelid being held. Then the patient was lifted and removed from the operation table. The patient was monitored for 2 hours. On the whole, the patient was monitored for a whole year, and no change in refraction was observed.

The proposed V. Kurenkov's cannula allows performing the cleaning process of the zone underneath the patch more efficiently, since the entire zone is being washed at the same time, the flow of the fluid is organized in one direction, it does not create zones where particles of tissue (being present after the action of the excimer laser) may remain.

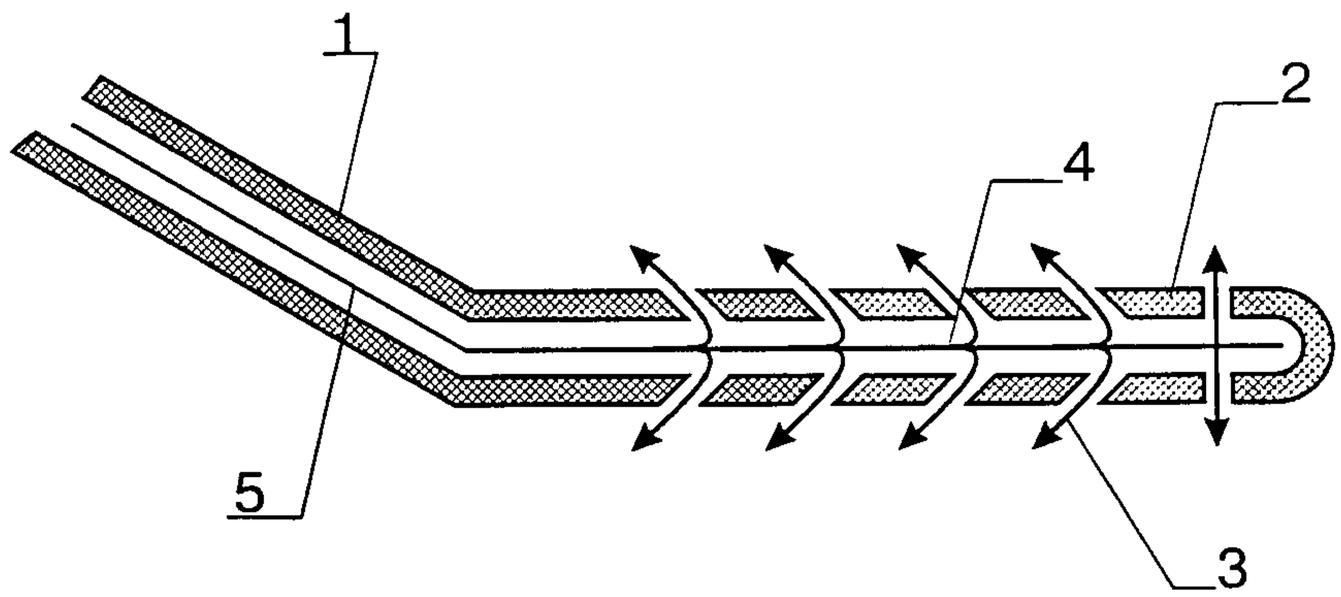
Definition of Invention

A cannula comprising a hollow body and a curved working part with lateral channels and hollow space connected with the hollow space of the body, characterized in that the lateral channels are designed for instillation and/or perfusing of the zone underneath the patch during the operation of refraction-correcting excimer laser based intrastromal keratectomy, including the performance of anaesthesia by instillation, clean-up of the conjunctiva cavity, establishment of a vacuum ring, execution of a section resulting in a patch on a stem, removal of the patch, performance of laser-based kerato- ablation, instillation of pharmaceutical preparations and repositioning of the patch, where the anaesthesia is performed by means of vasoconstrictor. The vacuum ring is positioned in such a manner that its longitudinal axis passes through the centre of the pupil, after which the vacuum ring is vertically shifted to the bottom by 0.5 - 1.0 mm. Before creating the patch, the conjunctiva cavity is instilled with a mixture of solutions of 0.4 - 0.6% methyl cellulose and 0.17 - 0.19% sodium hyaluronate. The base of the patch is selected in the position of "12 o'clock", and the lower end of the patch must not be further than 2 mm from the limbus; before opening the patch it is to be folded in half with inner surface inside. After the performance of laser kerato-ablation, the stromal bed is perfused with preparations improving its regeneration, and after the repositioning a solution of antibiotics and non-steroid preparations is instilled. Then the patch is manually spread in transpalpebral sense. The lateral axes of

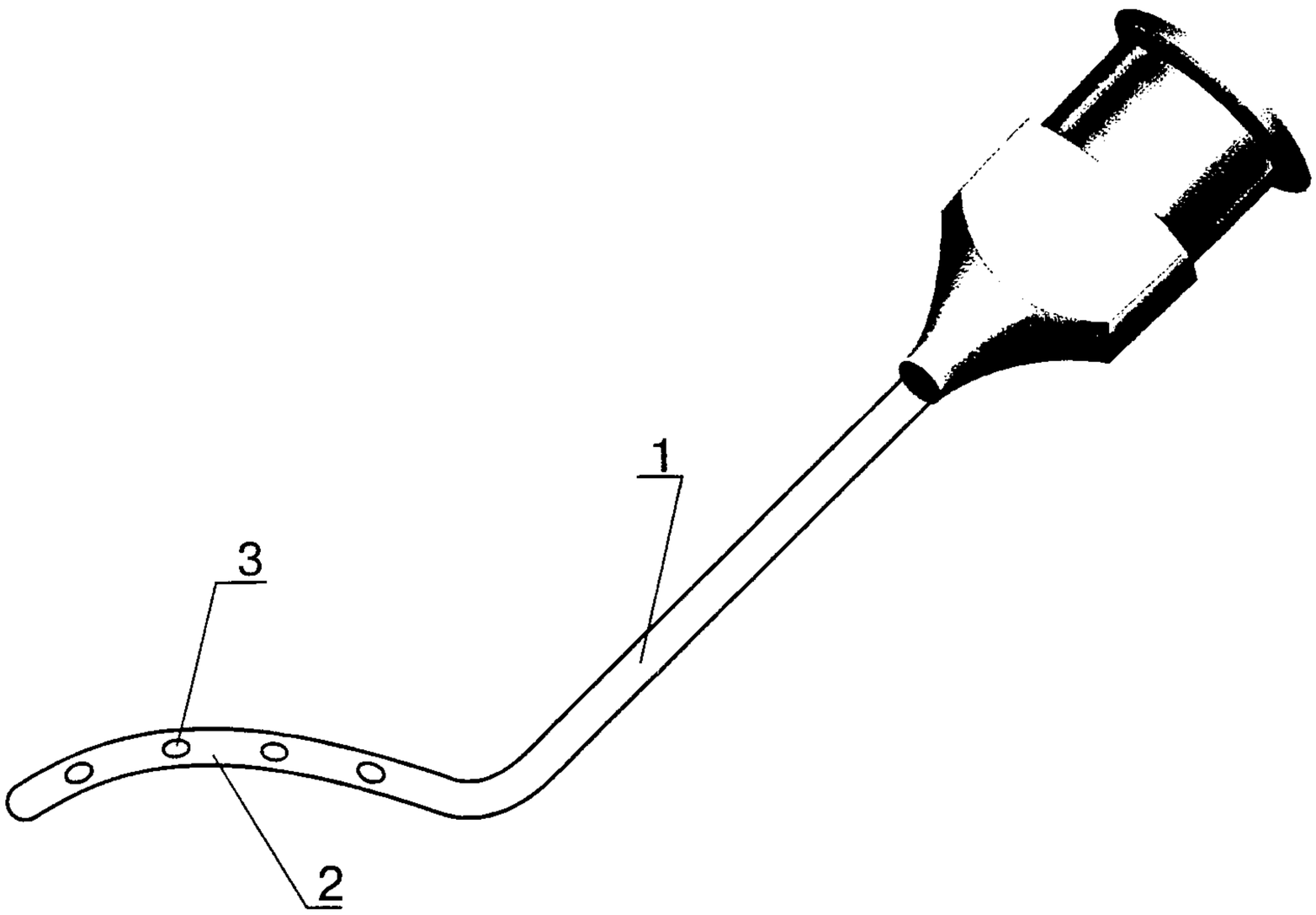
the lateral channels of the cannula run across the curve of its working part and are oriented longitudinally at an angle or angles to the longitudinal axis of the working part, where the working part comprises a narrow end to penetrate and/or separate tissue and the body and/or the working part are designed with the same cross-section and/or with cross-sections differing in their forms.



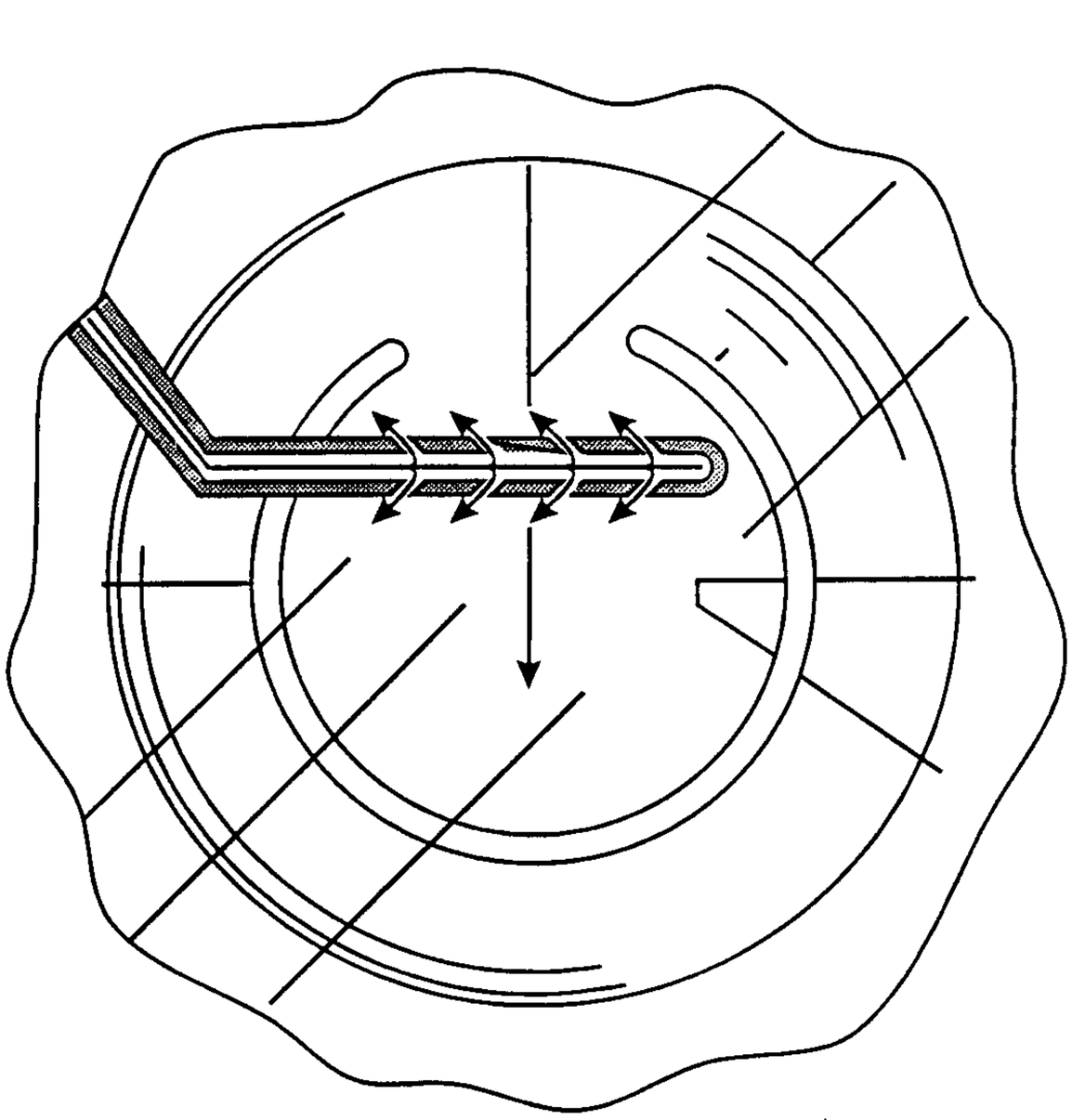
ФИГ.1



ФИГ.2



ФИГ.3



ФИГ.4