(11) **EP 3 017 770 A1**

(12)

EUROPEAN PATENT APPLICATION published in accordance with Art. 153(4) EPC

(43) Date of publication: 11.05.2016 Bulletin 2016/19

(21) Application number: 13889751.7

(22) Date of filing: 14.08.2013

(51) Int Cl.:

A61B 17/00^(2006.01)

A61B 8/12^(2006.01)

(86) International application number: PCT/CN2013/081433

(87) International publication number:WO 2015/007003 (22.01.2015 Gazette 2015/03)

(84) Designated Contracting States:

AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

Designated Extension States:

BA ME

(30) Priority: 19.07.2013 CN 201310306443

(71) Applicant: Lepu Medical Technology (Beijing) Co., Ltd. Beijing 102200 (CN)

(72) Inventors:

 HUANG, Jing Chongqing 400016 (CN) MA, Changsheng chongqing 400016 (CN)

 DONG, Saying Chongqing 400016 (CN)

 QIANG, Jun Chongqing 400016 (CN)

 WANG, Ting Chongqing 400016 (CN)

 XUE, Rui Chongqing 40006 (CN)

(74) Representative: Nordmeyer, Philipp Werner df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)

(54) SUBROUNDED ULTRASONIC ABLATION CATHETER

(57) An ultrasonic ablation catheter comprises a catheter body (1), an ultrasonic treatment energy converter set (2), an ultrasonic imaging energy converter set (3), a control handle (4) and an energy converter interface (5). The catheter body (1) is of a cylindrical structure; the ultrasonic treatment energy converter set (2) is disposed on the lateral surface of the far end of the catheter body (1), is of a sheet shape or an unclosed ring shape and can emit line-shaped or subrounded ultrasonic beams. The crossing distance between every two adjacent ultrasonic treatment energy converters (21) is more than or equal to 1 cm. Each ultrasonic imaging energy converter (31) is positioned between every two adjacent ultrasonic

treatment energy converters (21). The control handle (4) is disposed at the near end of the catheter body (1). The energy converter interface (5) comprises a first interface (51) and a second interface (52). After sympathetic nerve fibers are ablated by the ablation catheter, the nerve fibers can be cut into sections which are not continuous mutually and are completely separated in the middle; moreover, the coverage distance between the ultrasonic treatment energy converters (21) is long (more than or equal to 1 cm), so that mutual chemotaxis and self repair of the completely separated nerve fibers are avoided and stability of an effect of removing the sympathetic nerve fibers is improved.

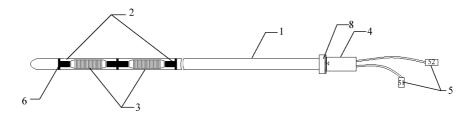


Fig. 1

40

45

50

Description

[0001] This application claims the benefit of priority to Chinese Patent Application No. 201310306443.9 titled "SUB-ROUNDED ULTRASOUNIC ABLATION CATHETER", filed with the Chinese State Intellectual Property Office on July 19, 2013, the entire disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present application relates to the technical field of medical devices, and particularly to a sub-rounded ultrasound ablation catheter.

BACKGROUND

[0003] In a catheter-based renal sympathetic denervation treatment, a radiofrequency catheter is used to enter a renal artery in a minimally invasive way and a spiral punctiform ablation is performed in the renal artery. Energy acts on sympathetic nerve fibers on a vascular adventitia and in an adipose tissue via a vascular intima, thereby decreasing a sympathetic tone of a kidney and a body and decreasing a blood-pressure. Currently, the catheter-based renal sympathetic denervation has become a very promising treatment method for a resistant hypertension. In addition, it is discovered from some new researches that decreasing the activities of sympathetic nerves of the kidney and the body not only can reduce the blood-pressure, but also can treat a cardiac failure, help prevent an arrhythmia and a sudden death from occurring, improve a blood glucose metabolism condition, and reduce an inflammation level of the body, etc.. The principle of the radiofrequency catheter performing a kidney sympathetic nerve ablation is to gradually transfer a large amount of heat energy produced by a radiofrequency energy in heat transfer form to the vascular adventitia or tissues around the adventitia via the vascular intima, causing degenerative necrosis of the sympathetic nerves on the vascular adventitia and in the tissues around the vascular adventitia, which may inevitably cause damages to a blood vessel endothelium in an ablation area, and it is found out that some patients have suffered a renal artery stenosis complication in long-term follow-up.

[0004] Ultrasound energy has a good directivity and a good tissue penetration. Compared with radiofrequency ablation, the energy consumed by ultrasound ablation is lower. When sound energy is being emitted, a wafer need not to contact with the tissues directly, and the ablation can be realized without breaking the intima, therefore the ultrasound energy used as an energy resource for a renal sympathetic denervation has a high efficiency and a better safety.

[0005] Research shows that after a nerve fiber is segmentally injured, a nerve at a far end can produce a neurotrophic and chemotaxis effect to a nerve at a near end, and a tube-like connection is regenerated between bro-

ken ends of the nerve. When an interval between the broken ends of the nerve is 5mm, it presents the strongest chemotaxis. In contrast, when the interval between the broken ends of the nerve is relatively large, dispersive ineurotrophy and chemotactic factor cannot reach the effective concentrations, and a research (Politis MJ, et al. Tropism in nerve regeneration in vivo. Attraction of regenerating axons by diffusible factors derived from cells in distal nerve stumps of transected peripheral nerves. Brain Res. 1982;253:1-12.) shows that the selfregeneration function is almost completely lost when the interval between the broken ends of the nerve is greater than 10mm. Therefore, when the ablation is being performed, if a short electrode or wafer is used, the sympathetic nerve fiber may be self-restored after operation, adversely affecting a therapeutic effect in the long-term; if an overlong ablation electrode or wafer is used, the released energy is greatly enhanced, which may increase a risk of the blood vessel being injured and an ablation complication.

[0006] Besides, according to researches on the conventional technology, the inventor of the present application has found that: all the conventional catheters used in renal sympathetic denervation cannot identify the distribution condition in a periphery of the renal artery of the renal sympathetic nerves. A spiral ablation or a punctiform ablation is one kind of ablation based on "experience", which has a certain blindness in operation and cannot efficiently perform the ablation to the renal sympathetic nerve fiber, and brings unnecessary damages to tissues where no nerve is distributed. A circumferential ultrasound renal sympathetic denervation ablation is another kind of ablation. The circumferential ultrasound ablation may result in a complete sympathetic denervation effect, and it is known that a sympathetic nerve response is one of the important mechanisms for maintaining body homeostasis. Therefore, if the circumferential ultrasound ablation is employed, an excessive sympathetic denervation may occur, which may decrease a stress ability of the patient after the operation. The body of the patient cannot defense against a destructive stimulus from the outside, for example, the body cannot maintain recycling capacity, electrolyte level and the stability of blood pressure, which may dramatically decrease the stress ability of the body. In case of a blood loss or an electrolyte disturbance, etc., a mortality rate of the patient may even be increased, and, the circumferential ultrasound ablation may aggravate the damage to the intima of the renal arteries, thereby resulting in severe complications such as arterial stenosis, fibrosis and thrombosis after opera-

[0007] Therefore, the conventional catheter used in renal sympathetic denervation treatment is unable to meet the clinical demands, and a new ablation catheter is presently needed.

SUMMARY

[0008] In view of this, an ultrasound ablation catheter is provided in embodiments of the present application.

[0009] For achieving the above object, a technical solution according to an embodiment of the present application is described as follows.

[0010] An ultrasound ablation catheter includes a catheter body, an ultrasound treatment transducer assembly, an ultrasound imaging transducer assembly, a control handle, and a transducer interface, in which

the catheter body is of a cylindrical structure;

the ultrasound treatment transducer assembly is arranged on a lateral surface of a far end of the catheter body, and the ultrasound treatment transducer assembly includes at least two ultrasound treatment transducers, and a distance between two adjacent ultrasound treatment transducers is greater than or equal to 1cm;

the ultrasound imaging transducer assembly includes at least one ultrasound imaging transducer, and the ultrasound imaging transducer is arranged between two adjacent ultrasound treatment transducers;

the control handle is arranged at a near end of the catheter body.

the transducer interface includes a first interface connected to the ultrasound treatment transducer assembly and a second interface connected to the ultrasound imaging transducer.

[0011] Preferably, each of the ultrasound treatment transducers is a planar wafer or an unclosed circumferential wafer.

[0012] Preferably, a circumference angle of the unclosed circumferential wafer is greater than 0 degree and less than 360 degrees.

[0013] Preferably, the at least two ultrasound treatment transducers are in a same plane or a same curved surface, and acoustic beams emitted by each of the ultrasound treatment transducers are in parallel with or staggered with each other.

[0014] Preferably, gap portions without emitting acoustic beams of at least two unclosed circumferential transducers, are in parallel with or staggered with each other.
[0015] Preferably, in the case that each of the ultrasound treatment transducers is the planar wafer, long axes of the ultrasound treatment transducers are in a same straight line, and each of the ultrasound treatment transducers is in parallel with an axis of the catheter body.
[0016] In the case that each of the ultrasound treatment transducers is the unclosed circumferential wafer, an axis of the unclosed circumferential wafer coincides with the

axis of the catheter body.

[0017] Preferably, in the case that the circumference angle of the unclosed circumferential wafer is less than 360 degrees, the ultrasound ablation catheter may further include at least one independent ultrasound imaging transducer, which is of a strip shape, and the independent ultrasound imaging transducer is located at the gap portion of the unclosed circumferential wafer.

[0018] Preferably, each of the ultrasound treatment transducers is a piezo-electric wafer visible under X-ray, and a coating film visible under the X-ray is coated on a surface of the piezo-electric wafer.

[0019] Preferably, the ultrasound imaging transducer is arranged between two adjacent ultrasound treatment transducers, the ultrasound imaging transducer is a strip-shaped wafer with an arc-shaped surface or a circumferential wafer, and the acoustic beams emitted by each of the ultrasound treatment transducers are in an imaging area of adjacent ultrasound imaging transducer.

[0020] Preferably, in the case that each of the ultrasound treatment transducers is the planar wafer, the ultrasound imaging transducer is the strip-shaped wafer with the arc-shaped surface, and a long axis of the ultrasound imaging transducer coincides with a long axis of each of the ultrasound treatment transducers.

[0021] In the case that each of the ultrasound treatment transducers is the unclosed circumferential wafer, the ultrasound imaging transducer is the circumferential wafer, and an axis of the circumferential wafer of the ultrasound imaging transducer coincides with an axis of the unclosed circumferential wafer of each of the ultrasound treatment transducers.

[0022] Preferably, the control handle is configured to control the catheter body to unidirectionally rotate.

[0023] A spring piece and a wedge-shaped gear are provided in the control handle, and the catheter body is rotatably connected to the control handle via the wedge-shaped gear.

[0024] The spring piece has one end fixed to the control handle and another end pressing against the wedge-shaped gear for preventing the wedge-shaped gear from reversely rotating.

[0025] Preferably, a dial for determining a rotation angle of the catheter body is provided on a circumferential surface of the control handle.

[0026] Preferably, the ultrasound ablation catheter further includes at least two developing markers visible under the X-ray.

[0027] The developing markers are configured to assist the operator in obtaining a position of the ultrasound ablation catheter entering a human body cavity and the rotation angle of the ultrasound ablation catheter.

[0028] At least two developing markers are separately located on the catheter body at positions at two ends of the ultrasound treatment transducers.

[0029] In the case that each of the ultrasound treatment transducers is the planar wafer, each of the developing markers is semi-annular, and two ends of each of the

semi-annular developing markers are fixed to two ends of the respective planar wafer.

[0030] In the case that each of the ultrasound treatment transducers is the unclosed circumferential wafer, each of the developing markers arranged on the catheter body is sheet-shaped. According to the above technical solutions, in the ultrasound ablation catheter according to the embodiments of the present application, the ultrasound treatment transducers and at least one ultrasound imaging transducer are provided at the portion at the far-end of the catheter body, the ultrasound imaging transducer is located between two adjacent ultrasound treatment transducers, and the distance between two adjacent ultrasound treatment transducers is set to be greater than or equal to 1cm, thus when the ablation treatment is being performed, the ultrasound treatment transducers laterally emit the non-focusing acoustic beams in parallel with or staggered with each other to the catheter body, and the rotation of the catheter body may allow the ultrasound treatment transducers to axially rotate (by an angle of zero degree to any degree) in the blood vessel and release heat. After ablation is performed to a sympathetic nerve fiber, the sympathetic nerve fiber may be cut off into sections disconnected to each other and have a middle section completely disconnected, and a reaching distance of each of the acoustic beams emitted by the ultrasound treatment transducers is relatively larger (≥ 1cm), which further lead the completely disconnected nerve fiber sections cannot perform the chemotaxis effect with each other and cannot be self-restored, thereby stabilizing an sympathetic denervation.

[0031] Besides, when the ablation catheter according to the present application is in use, the plate-shaped ultrasound treatment transducers arranged in the ablation catheter perform the sub-rounded (less than 360 degrees) rotation, or the unclosed circumferential treatment transducers emit sub-rounded (such as a three-fourths quadrant or two-thirds circumference) ultrasound acoustic beams, to generate an sub-rounded nerve ablation effect. When an effective renal-nerve ablation is reached, a part of sympathetic nerve tracts are controllably preserved to keep a basic sympathetic compensative capacity of the body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0032] For more clearly illustrating embodiments of the present application or the technical solution in the conventional technology, drawings referred to describe the embodiments or the conventional technology will be briefly described hereinafter. Apparently, the drawings in the following description are only several embodiments of the present application, and for the person skilled in the art other drawings may be obtained based on these drawings without any creative efforts.

Figure 1 is an overall top schematic view of an ultrasound ablation catheter according to an embodiment

of the present application;

Figure 2 is a schematic view showing a partial structure of an ultrasound ablation catheter according to an embodiment of the present application;

Figure 3 is a side schematic view of the structure in Figure 2; and

Figure 4 is schematic view showing a partial structure of another ultrasound ablation catheter according to an embodiment of the present application.

DETAILED DESCRIPTION

[0033] For those skilled in the art to better understand technical solutions of the present application, the technical solutions in the embodiments of the present application will be described clearly and completely hereinafter in conjunction with the drawings in the embodiments of the present application. Apparently, the described embodiments are only a part of the embodiments of the present application, rather than all embodiments. Based on the embodiments in the present application, all of other embodiments, made by the person skilled in the art without any creative efforts, fall into the scope of the present application.

[0034] Research shows that after a nerve fiber is segmentally injured, a nerve in a far end can produce a neurotrophic effect and a chemotaxis effect to a nerve in a near end, and a tube-like connection is regenerated between broken ends of the nerve, and when an interval between the broken ends of the nerve is 5mm, it presents the strongest chemotaxis. However, when the interval between the broken ends of the nerve is relatively large, dispersive ineurotrophy and chemotactic factor cannot reach the effective concentrations, and a research (Politis MJ, et al. Tropism in nerve regeneration in vivo. Attraction of regenerating axons by diffusible factors derived from cells in distal nerve stumps of transected peripheral nerves. Brain Res. 1982;253:1-12.) shows that the self-regeneration function is almost completely lost when the interval between the broken ends of the nerve is greater than 10mm. Therefore, when the ablation is being performed, if a short electrode or wafer is used, the sympathetic nerve fiber can be self-restored after operation, thus a therapeutic effect in the long-term is adversely affected; if an overlong ablation electrode or wafer is used, the released energy is greatly enhanced, increasing a risk of the blood vessel is injured and an ablation complication.

[0035] Therefore, considering the effective width and range of an ablation electrode, a new ultrasound ablation catheter is provided by the present application.

[0036] A first embodiment is described as follows.
[0037] Figure 1 is an overall top schematic view of an ultrasound ablation catheter according to an embodiment of the present application.

40

[0038] As shown in Figure 1, the ultrasound ablation catheter includes a catheter body 1, an ultrasound treatment transducer assembly 2, an ultrasound imaging transducer assembly 3, a control handle 4, and a transducer interface 5.

[0039] Both of the ultrasound treatment transducer assembly 2 and the ultrasound imaging transducer assembly 3 are arranged on a lateral surface of a far end of the catheter body 1, and the control handle 4 is arranged at a position at a near end of the catheter body 1. The transducer interface 5 includes a first interface 51 connected to the ultrasound treatment transducer assembly 2 and a second interface 52 connected to the ultrasound imaging transducer assembly 3. The transducer interface 5 is provided for powering the ultrasound treatment transducer assembly 2 and receiving imaging data from the ultrasound imaging transducer assembly 3.

[0040] It should be noted that, "far end", "near end" and other position relationships in the present application all refer to a relative position relationship between the ablation catheter and an operator of the ablation catheter, in which "far end" refers to a position away from the operator, and "near end" refers to a position near the operator.

[0041] As shown in Figure 1, the catheter body 1 is of a cylindrical structure. A groove is provided on the lateral surface of a far end of the catheter body 1 for accommodating the ultrasound treatment transducer assembly 2 and the ultrasound imaging transducer assembly 3. Moreover, the catheter body 1 may be of a hollow structure for accommodating a cable between the ultrasound treatment transducer assembly 2 and the ultrasound imaging transducer assembly and the transducer interface 7. The catheter body 1 is provided for supporting the whole ultrasound ablation catheter, such that the arranged ultrasound treatment transducer assembly 2 and the ultrasound imaging transducer assembly 3 may be sent into a human body cavity. In addition, a diameter of the catheter body 1 may have multiple options according to clinical requirements.

[0042] Figure 2 is a schematic view showing a partial structure of an ultrasound ablation catheter according to the embodiment of the present application.

[0043] Figure 3 is a side schematic view of the structure in Figure 2.

[0044] The ultrasound treatment transducer assembly 2 includes at least two ultrasound treatment transducers 21, which are located at a same plane or a same curved surface, and acoustic beams emitted by the ultrasound treatment transducers 2 are in parallel with each other or staggered with each other, thus the emitted acoustic beams does not focus. The ultrasound treatment transducers 21 are provided for emitting an adjustable ultrasound acoustic beam, so as to ablate nerve fibers on tunica adventitia of artery.

[0045] As shown in Figure 2 and Figure 3, each of the ultrasound treatment transducers 21 is a planar wafer, and the at least two ultrasound treatment transducers 21

are in a same plane. Further, long axes of the at least two ultrasound treatment transducers 21 are in a same straight line, and each of the at least two ultrasound treatment transducers 21 is in parallel with an axial direction of the catheter body 1.

[0046] In the case that each of the ultrasound treatment transducers 21 is the planar wafer, when the ablation is being performed, the control handle 4is controlled to rotate the catheter body 1 and the at least two ultrasound treatment transducers 21 are further rotated unidirectionally, thereby performing a sub-rounded ablation to nerves in a controllable angle.

[0047] The ultrasound treatment transducer assembly 2 includes at least two ultrasound treatment transducers 21. In this embodiment according to the present application, the number of the ultrasound treatment transducers 21 is three as shown in Figures 2 and 3, and a distance between two adjacent ultrasound treatment transducers 21 is greater than or equal to 1cm.

[0048] The distance between two adjacent ultrasound treatment transducers 21 is set to be greater than or equal to 1cm. Thus, when the ultrasound ablation catheter is used to perform an ablation treatment, after the two adjacent ultrasound treatment transducers 21 perform the sub-rounded ablation, a distance between two adjacent ablation points that formed is greater than or equal to 1cm. The reason for this is that the self-regeneration function is almost completely lost when the interval between the broken ends of the nerve is greater than 10mm, which may further avoid the sympathetic nerve fiber being self-restored after the operation and adversely affect a long-term treatment effect.

[0049] In the embodiment of the present application, each of the ultrasound treatment transducers 21 may be formed by a piezo-electric wafer which is visible under X-ray and a coating film visible under the X-ray, such as gold, platinum, etc., is coated on a surface of the piezo-electric wafer.

[0050] As shown in Figure 2 and Figure 3, in the embodiment of the present application, the ultrasound imaging transducer assembly 3 includes at least one ultrasound imaging transducer 31, which is arranged between two adjacent ultrasound treatment transducers 21. That is to say, the number of the ultrasound imaging transducer 31 is one less than the number of the ultrasound treatment transducers 21. At least one ultrasound imaging transducer 31 is in a same plane or a same curved surface, and each of the ultrasound treatment transducers 21 is in an imaging area of adjacent ultrasound imaging transducer 31. The ultrasound imaging transducer 31 is to provide a convex-array-form high-frequency ultrasound images of tissues at a periphery of an artery, display a distribution condition of the nerve fiber and monitor a difference between images before and after the ablation, and eliminate an interference of tissues at a periphery of a target area to the images by connecting an ultrasound subtraction image analysis system, thereby accurately evaluating an instant effect of the ablation.

45

20

25

30

40

45

[0051] As shown in Figure 2 and Figure 3, in the case that each of the ultrasound treatment transducers 21 is the planar wafer, the ultrasound imaging transducer 31 may be a strip-shaped wafer with an arc-shaped surface, and a long axis of each of the at least one ultrasound imaging transducer 31 coincides with the long axis of each of the ultrasound treatment transducers 21, that is, the ultrasound imaging transducer 31 and the ultrasound treatment transducers 21 are in a same straight line.

[0052] In addition, as shown in Figure 4, in the case that each of the ultrasound treatment transducers 21 is an unclosed circumferential wafer, the ultrasound imaging transducer 31 may be an circumferential wafer, and an axis of the circumferential wafer of the ultrasound imaging transducer 31 coincides with an axis of the unclosed circumferential wafer of each of the ultrasound treatment transducers 21, that is, the ultrasound imaging transducer 31 and the ultrasound treatment transducers 21 are in a same straight line.

[0053] As shown in Figure 1, the control handle 4 is located at a near end of the catheter body 1, and the control handle 4 is provided for unidirectionally rotating the catheter body 1, and then the sub-rounded ablation is performed by the ultrasound treatment transducers 21 arranged in the catheter body 1 in a controllable angle. [0054] In the embodiment of the present application, a spring piece and a wedge-shaped gear are mounted in the control handle 4, and the catheter body 1 is rotatably connected to the control handle via the wedge-shaped gear. In addition, the spring piece has one end fixed to the control handle 4 and another end pressing against the wedge-shaped gear for preventing the wedge-shaped gear from reversely rotating.

[0055] For conveniently controlling a rotation angle of the control handle 4, a dial 8 for determining a rotation angle of the catheter body may be provided on a surface of the control handle 4, as shown in Figure 1.

[0056] For more conveniently and accurately controlling the rotation angle of the control handle 4, a stepping motor may be installed in the control handle 4, which may allow the wedge-shaped gear to rotate in a pre-set direction by a fixed angle when the stepping motor is connected to a pulse signal source.

[0057] Moreover, in order to conveniently determine a position of the ablation catheter entering a human body cavity and to control the rotation angle of the ablation catheter when an ablation operation is being performed. The ablation catheter may be provided with at least two developing markers 6, as shown in Figures 1 to 3.

[0058] The at least two developing markers 6 are made of a material visible under the X-ray, the at least two developing markers 6 are separately located at the catheter body 1 and at two ends of the ultrasound treatment transducers 21.

[0059] For helping the operator easily obtain the position of the ultrasound ablation catheter in the human body and the rotation angle thereof, in the embodiment, in the case that each of the ultrasound treatment transducers

21 is the planar wafer, each of the developing markers 6 is semi-annular, and each of the semi-annular developing markers 6 has two ends fixed to two ends of the respective planar wafer, thus when the catheter body 1 is rotating, the operator may determine the positions of the ultrasound treatment transducers 21 according to the shapes of the developing markers 6.

[0060] According to the above technical solutions, in the ablation catheter according to the embodiment of the present application, the ultrasound treatment transducers and at least one ultrasound imaging transducer are provided at the portion at the far-end of the catheter body, the ultrasound imaging transducer is located between two adjacent ultrasound treatment transducers, and the distance between two adjacent ultrasound treatment transducers is set to be greater than or equal to 1cm. Thus when the ablation treatment is being performed, the ultrasound treatment transducers laterally emit the acoustic beams in parallel with or staggered with each other to the catheter body 1 which are not focused. Rotating the catheter body 1 may allow the ultrasound treatment transducers to axially rotate (by an angle of zero degree to any degree) in the blood vessel and release energy. After the ablation is performed to sympathetic nerve fiber, the sympathetic nerve fiber may be cut off into sections disconnected to each other and having a middle section completely disconnected, and a reaching distance (≥ 1cm) of each of the acoustic beams emitted by the ultrasound treatment transducers 21 may further lead the completely disconnected nerve fiber sections cannot perform the chemotaxis effect on each other and be self-restored, thereby stabilizing the sympathetic denervation effect.

[0061] When the ablation catheter according to the embodiment of the present application is in use, the plate-shaped ultrasound treatment transducers arranged in the ablation catheter perform sub-rounded (less than 360 degrees) rotation, or the unclosed circumferential treatment transducers emit sub-rounded (such as a three-fourths quadrant or two-thirds circumference) ultrasound acoustic beams, to produce an sub-rounded renal-nerve ablation effect, and while an effective renal-nerve ablation is performed, a part of sympathetic nerve tracts are controllably preserved to keep a basic sympathetic compensative capacity of the body.

[0062] A second embodiment of the present application is described as follows.

[0063] In the above embodiment, in the case that the ultrasound treatment transducer 21 is the planar wafer, when the ablation is being performed, the control handle 4 is provided for controlling the rotation of the catheter body 1, and the ultrasound treatment transducer 21 is further moved circumferentially, thereby performing a circumferential ablation to the nerves. Therefore, during the operation, an operator is required to monitor the ablation area in real time and rotate the catheter body 1 slowly, which may increase the operating difficulty to the operator and proposes high requirements to the operator. An

improper operating which may adversely affect the ablation effect may even occur.

[0064] For addressing the issue that the catheter body 1 is required to be rotated to perform the sub-rounded ablation, in other embodiment of the present application, each of the ultrasound treatment transducers 21 is an unclosed circumferential wafer, as shown in Figure 4. A circumference angle of the unclosed circumferential wafer of each of the ultrasound treatment transducers 21 is greater than 0 degree and less than 360 degrees, and at least two ultrasound treatment transducers 21 are in a same curved plane. Besides, an axis of each of the unclosed circumferential wafers coincides with an axis of the catheter body 1, gaps of the unclosed circumferential wafers are coaxially or uncoaxially in parallel with each other, which makes all of the ultrasound treatment transducers 21 emit acoustic beams in parallel with each other or staggered to cover a distribution range of the renal sympathetic nerves.

[0065] In this embodiment, the unclosed circumferential wafer is employed, thus when the ablation is being performed, the catheter body 1 is not required to be rotated to perform the sub-rounded ablation to the nerves, thereby allowing the ablation operation to be simply and conveniently operated.

[0066] In addition, in other embodiment of the present application, in the case that each of the ultrasound treatment transducers 21 is the unclosed circumferential wafer, and the circumference angle of each of the unclosed circumferential wafers is less than 360 degrees, the ultrasound ablation catheter may include multiple independent ultrasound imaging transducers 7.

[0067] Each of the independent ultrasound imaging transducers 7 is located at the gap of the unclosed circumferential wafer of one ultrasound ablation catheter. Each of the independent ultrasound imaging transducers 7 may be of a planar structure, or may form a complete annular shape with the unclosed circumferential wafer.

[0068] The independent ultrasound imaging transducers 7 are provided for rotating the catheter body 1 after using the ultrasound imaging transducer 31 to find the ablation area, and the independent ultrasound imaging transducers 7 are used to scan the ablation area to know an overall distribution position of the nerves, etc..

[0069] Moreover, in the case that each of the ultrasound treatment transducers 21 is the unclosed circumferential wafer, each of the developing markers 6 arranged on the catheter body 1 may be sheet-shaped. The sheet-shaped developing markers 6 may be located at the gap of the unclosed circumferential wafer, and a long axis of each of the developing markers 6 coincides with a long axis of each of the unclosed circumferential wafers of the ultrasound treatment transducers 21.

[0070] The ultrasound ablation catheter provided by the present application is described in details hereinabove, the principle and the embodiments of the present application are illustrated herein by specific examples, and the above description of examples is only intended

to help the understanding of the method and the spirit of the present application. Besides, for the person skilled in the art, a few of modifications in embodiments and the application scope may be made to the present application according to the spirits of the present application, and the embodiments in this specification should not be interpreted as a limitation to the present application.

[0071] The above embodiments are described in a progressive manner. Each of the embodiments is mainly focused on describing its differences from other embodiments, and references may be made among these embodiments with respect to the same or similar portions among these embodiment.

[0072] It should be noted that, relation description in the present application such as "greater than", "exceed", "higher than", "less than", "lower than" can be interpreted as "greater than or not equal to" or "less than or not equal to"; and can also be interpreted as "greater than or equal to" or "less than or equal to" or "less than or equal to", however should not necessarily be required or implied to be one restrictive or intrinsic condition.

[0073] In addition, terms indicating the relationships such as "first" and "second" herein are only used to distinguish an entity or an operation from another entity or operation, and are not intended to demand or indicate that there is any actual relationship or order between the entities or operations. And in the present application, the terms "include", "including" or any other variations thereof are intended to cover a non-exclusive inclusion, such that a process, method, article, or apparatus that comprises a list of elements does not include only those elements but may include other elements not expressly listed or inherent to such process, method, article, or apparatus. Without more constraints, an element proceeded by "comprises a..." does not preclude the existence of additional identical elements in the process, method, article, or apparatus that comprises the element.

[0074] It should be noted that, the described embodiments are only a part of the embodiments of the present application, making the person skilled in the art to understand or implement the present application, rather than all embodiments, and the general principle defined herein may be applied to other embodiments without departing from the spirit or scope of the present application. Therefore, based on the embodiments in the present application, many kinds of apparent modifications and polishes may be made by the person skilled in the art without departing from the principles of the present application and without any creative efforts, and all other embodiments obtained from these modifications and polishes can be applied in the technical solutions of the present application, which may not affect the implementations of the present application, and all fall into the scope of the present application. Therefore, the present application is not limited to the embodiments illustrated herein, but should be defined by the broadest scope consistent with the principle and novel features disclosed herein.

20

25

30

35

40

45

50

55

Claims

An ultrasound ablation catheter, comprising a catheter body, an ultrasound treatment transducer assembly, an ultrasound imaging transducer assembly, a control handle, and a transducer interface, wherein

the catheter body is of a cylindrical structure; the ultrasound treatment transducer assembly is arranged on a lateral surface of a far end of the catheter body, the ultrasound treatment transducer assembly comprises at least two ultrasound treatment transducers, and a distance between two adjacent ultrasound treatment transducers is greater than or equal to 1cm;

the ultrasound imaging transducer assembly comprises at least one ultrasound imaging transducer, and the ultrasound imaging transducer is arranged between two adjacent ultrasound treatment transducers;

the control handle is arranged at a near end of the catheter body; and

the transducer interface comprises a first interface connected to the ultrasound treatment transducer assembly and a second interface connected to the ultrasound imaging transducer.

- The ultrasound ablation catheter according to claim 1, wherein each of the ultrasound treatment transducers is a planar wafer or an unclosed circumferential wafer.
- 3. The ultrasound ablation catheter according to claim 2, wherein a circumference angle of the unclosed circumferential wafer is greater than 0 degree and less than 360 degrees.
- 4. The ultrasound ablation catheter according to claim 3, wherein at least two ultrasound treatment transducers are in a same plane or a same curved surface, and acoustic beams emitted by each of the ultrasound treatment transducers are in parallel with or staggered with each other; and gap portions without transmitting acoustic beams of at least two unclosed circumferential transducers is configured to be in parallel with or staggered with each other.
- 5. The ultrasound ablation catheter according to claim 4, wherein in the case that the ultrasound treatment transducer is the planar wafer, long axes of the ultrasound treatment transducers are in a same straight line, and each of the ultrasound treatment transducers is in parallel with an axis of the catheter body; and in the case that each of the ultrasound treatment transducers is the unclosed circumferential wafer, an axis of each of the unclosed circumferential wa-

fers coincides with the axis of the catheter body.

6. The ultrasound ablation catheter according to claim 5, wherein in the case that the circumference angle of each of the unclosed circumferential wafers is less than 360 degrees, the ultrasound ablation catheter further may comprise:

at least one independent ultrasound imaging transducer, which is of a strip shape, and the independent ultrasound imaging transducer is located at the gap portion of the unclosed circumferential wafer.

- 7. The ultrasound ablation catheter according to claim 6, wherein each of the ultrasound treatment transducers is a piezo-electric wafer visible under X-ray, and a coating film visible under the X-ray is coated on a surface of the piezo-electric wafer.
 - 8. The ultrasound ablation catheter according to claim 7, wherein the ultrasound imaging transducer is arranged between two adjacent ultrasound treatment transducers, the ultrasound imaging transducer is a strip-shaped wafer with an arc-shaped surface or a circumferential wafer, and the acoustic beams emitted by each of the ultrasound treatment transducers are in an imaging area of adjacent ultrasound imaging transducer.
 - 9. The ultrasound ablation catheter according to claim 8, wherein, in the case that the ultrasound treatment transducer is the planar wafer, the ultrasound imaging transducer is the strip-shaped wafer with the arc-shaped surface, and a long axis of the ultrasound imaging transducer coincides with a long axis of each of the ultrasound treatment transducers; and in the case that each of the ultrasound treatment transducers is the unclosed circumferential wafer, the ultrasound imaging transducer is the circumferential wafer, and the circumferential wafer of the ultrasound imaging transducer has an axis coinciding with an axis of the unclosed circumferential wafer of
 - 10. The ultrasound ablation catheter according to claim 9, wherein the control handle is configured to control the catheter body to unidirectionally rotate; a spring piece and a wedge-shaped gear are provided in the control handle, and the catheter body is rotatably connected to the control handle via the wedge-shaped gear; and the spring piece has one end fixed to the control handle and another end pressing against the wedge-shaped gear for preventing the wedge-shaped gear from reversely rotating.

each of the ultrasound treatment transducers.

11. The ultrasound ablation catheter according to claim 10, wherein a dial for determining a rotation angle of the catheter body is provided on a circumferential surface of the control handle.

12. The ultrasound ablation catheter according to claim 11, further comprising at least two developing markers visible under the X-ray, wherein the developing markers are configured to assist the operator in obtaining a position of the ultrasound ablation catheter entering a human body cavity and the rotation angle of the ultrasound ablation catheter; at least two developing markers are separately located at the catheter body at positions at two ends of the ultrasound treatment transducers; in the case that each of the ultrasound treatment

transducers is the planar wafer, each of the developing markers is semi-annular, and two ends of each of the semi-annular developing markers are fixed to two ends of the respective planar wafer; and in the case that each of the ultrasound treatment transducers is the unclosed circumferential wafer, each of the developing markers arranged on the catheter body is sheet-shaped.

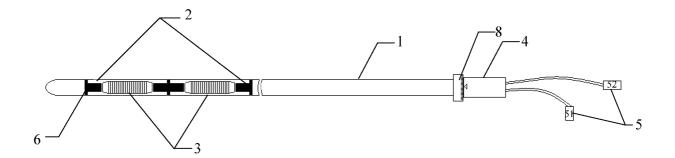


Fig. 1

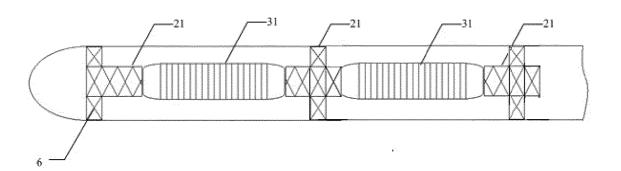


Fig. 2

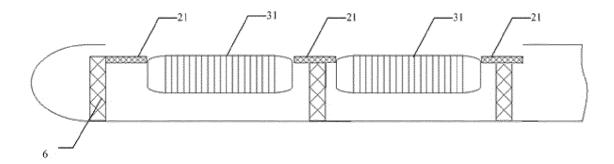


Fig. 3

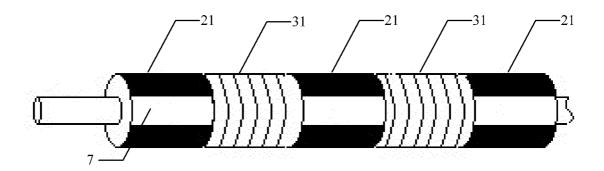


Fig. 4

INTERNATIONAL SEARCH REPORT

International application No. PCT/CN2013/081433

5	A. CLASS	A. CLASSIFICATION OF SUBJECT MATTER								
	A61B 17/00 (2006.01) i; A61B 8/12 (2006.01) i According to International Patent Classification (IPC) or to both national classification and IPC									
10	B. FIELDS SEARCHED									
	Minimum documentation searched (classification system followed by classification symbols)									
		A61B 17; A61B 8								
15	Documentat	Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched								
	Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)									
20	CNABS, VEN: transduc+, annulus, ablat+, electrod+, catheter?, treat+, therap+, hifu, focused, ultrasound, electrod+, image, mapultras+, plate, crystal, lepu									
20	C. DOCUI	C. DOCUMENTS CONSIDERED TO BE RELEVANT								
	Category*	Citation of document, with indication, where a	ppropriate, of the relevant passages	Relevant to claim No.						
25	Е	CN 203354582 U (LEPU (BEIJING) MEDICAL EQU (25.12.2013) claims 1-12	1-12							
	Y	US 2004015065 A1 (SCIMED LIFE SYSTEMS INC description, paragraphs [0032]-[0039], [0054] and [00	1, 2							
	Y	CN 102068308 A (HUANG, Jing) 25 May 2011 (25.0 figures 2 and 3	1, 2							
30	A	CN 101073501 A (MA, Changsheng et al.) 21 Novem document	1-12							
	A	US 6206831 B1 (SCIMED LIFE SYSTEMS INC.) 27 document	MED LIFE SYSTEMS INC.) 27 March 2001 (27.03.2001) the whole							
35	□ Furth	☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.								
	"A" docur	ial categories of cited documents: nent defining the general state of the art which is not lered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention							
40	"E" earlier application or patent but published on or after the international filing date "I" document which more throughout son priority claim(s) or		"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone							
45	 "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means 		"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art							
		nent published prior to the international filing date terms than the priority date claimed	"&"document member of the same pater	nt family						
50	Date of the actual completion of the international search		Date of mailing of the international search report							
	Name and ma	17 April 2014 iling address of the ISA	28 April 2014							
	State Intelle	ctual Property Office of the P. R. China heng Road, Jimengiao	Authorized officer WANG, Jinjing							
55	Haidian Dis	trict, Beijing 100088, China (86-10) 62019451	Telephone No. (86-10) 62085625							

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No. PCT/CN2013/081433

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim
A	US 2012065506 A1 (SMITH SCOTT) 15 March 2012 (15.03.2012) the whole document	1-12
A	CN 1186420 A (IMAR PHARMACEUTICAL CORP.) 01 July 1998 (01.07.1998) the whole document	1-12

Form PCT/ISA/210 (continuation of second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No. PCT/CN2013/081433

Patent Documents referred in the Report	Publication Date	Patent Family	Publication Date
CN 203354582 U	25 December 2013	None	-
US 2004015065 A1	22 January 2004	US 2007156048 A1	05 July 2007
		US 7364546 B2	29 April 2008
		US 7194294 B2	20 March 2007
CN 102068308 A	25 May 2011	CN 102068308 B	08 August 2012
CN 101073501 A	21 November 2007	CN 100448407 C	07 January 2009
US 6206831 B1	27 March 2001	US 2003153907 A1	14 August 2003
		CA 2358428 A1	13 July 2000
		EP 1139894 A1	10 October 2001
		US 6824515 B2	30 November 2004
		JP 2002534152 A	15 October 2002
		US 2001000791 A1	03 May 2001
		WO 0040166 A1	13 July 2000
		US 6508765 B2	21 January 2003
US 2012065506 A1	15 March 2012	WO 2012033974 A3	07 June 2012
		WO 2012033974 A2	15 March 2012
		EP 2613704 A2	17 July 2013
		CN 103220984 A	24 July 2013
CN 1186420 A	01 July 1998	AU 711788 B2	21 October 1999
		US 5558092 A	24 September 1996
		EP 0836420 A4	08 December 1999
		JP 2007289693 A	08 November 2007
		CA 2220756 A1	12 December 1996
		EP 0836420 A1	22 April 1998
		AU 5875696 A	24 December 1996
		JPH 11506636 A	15 June 1999
		WO 9639079 A1	12 December 1996

Form PCT/ISA/210 (patent family annex) (July 2009)

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

• CN 201310306443 [0001]

Non-patent literature cited in the description

 POLITIS MJ et al. Tropism in nerve regeneration in vivo. Attraction of regenerating axons by diffusible factors derived from cells in distal nerve stumps of transected peripheral nerves. *Brain Res.*, 1982, vol. 253, 1-12 [0005] [0034]



专利名称(译)	接地超声消融导管				
公开(公告)号	EP3017770A4	公开(公告)日	2017-03-29		
申请号	EP2013889751	申请日	2013-08-14		
[标]申请(专利权)人(译)	乐普(北京)医疗器械股份有限公司				
申请(专利权)人(译)	乐普医疗科技(北京)有限公司.				
当前申请(专利权)人(译)	乐普医疗科技(北京)有限公司				
[标]发明人	HUANG JING MA CHANGSHENG DONG SAYING QIANG JUN WANG TING XUE RUI				
发明人	HUANG, JING MA, CHANGSHENG DONG, SAYING QIANG, JUN WANG, TING XUE, RUI				
IPC分类号	A61B17/00 A61B8/12 A61B8/00 A61B90/00 A61N7/00				
CPC分类号	A61B8/12 A61B8/445 A61B2090/378 A61B2090/3784 A61N7/022 A61N2007/0021 A61N2007/003 A61N2007/0043 A61N2007/0078				
优先权	201310306443.9 2013-07-19 CN				
其他公开文献	EP3017770A1 EP3017770B1				
外部链接	Espacenet				

摘要(译)

超声消融导管包括导管主体(1),超声治疗能量转换器组(2),超声成像能量转换器组(3),控制手柄(4)和能量转换器接口(5)。导管主体(1)是圆柱形结构;超声治疗能量转换器组(2)设置在导管主体(1)的远端的侧表面上,具有片状或未闭合的环形形状,并且可以发射线形或子接地的超声波束。每两个相邻的超声治疗能量转换器(21)之间的交叉距离大于或等于1cm。每个超声成像能量转换器(31)位于每两个之间相邻的超声波处理能量转换器(21)。控制手柄(4)设置在导管主体(1)的近端。能量转换器接口(5)包括第一接口(51)和第二接口(52)。在通过消融导管消融交感神经纤维之后,可以将神经纤维切割成彼此不连续并且在中间完全分离的部分;此外,超声治疗能量转换器(21)之间的覆盖距离长(大于或等于1cm),从而避免了完全分离的神经纤维的相互趋化性和自我修复以及去除交感神经的稳定性。神经纤维是改进。