

US Patent & Trademark Office

Patent Public Search | Text View

United States Patent Application Publication

20250261964

Kind Code

A1

Publication Date

August 21, 2025

Inventor(s)

Ji; Xiaofei et al.

ROTATIONAL ATHERECTOMY APPARATUS AND ROTATIONAL ATHERECTOMY DEVICE

Abstract

The present invention relates to a rotational atherectomy apparatus and a rotational atherectomy device. The rotational atherectomy apparatus includes a drive device and the rotational atherectomy device. The drive device is coupled to a drive shaft of the rotational atherectomy device in order to actuate rotation of the rotational atherectomy device. The rotational atherectomy device is used for vascular surgery and includes the drive shaft and a rotating abrasive head. The drive shaft has a distal connecting portion coupled to the rotating abrasive head. The rotating abrasive head and the drive shaft separately define hollow cavities axially extending therethrough. The hollow cavities are configured for insertion of a guide body therethrough. A centroid of a structure consisting of the rotating abrasive head and the connecting portion coupled thereto does not coincide with center axes of the hollow cavities. The present invention can reduce the risk of a surgical procedure using the rotational atherectomy apparatus to recanalize a blood vessel occluded by a lesion. It can also make the surgical procedure easier to perform.

Inventors: Ji; Xiaofei (Shanghai, CN), CHANG; Zhaohua (Shanghai, CN), YUE; Bin (Shanghai, CN), YAO; Yingzhong (Shanghai, CN)

Applicant: SHANGHAI MICROPORT ROTAPACE MEDTECH CO., LTD.
(Shanghai, CN)

Family ID: 1000008590703

Appl. No.: 18/860270

Filed (or PCT Filed): May 18, 2023

PCT No.: PCT/CN2023/094969

Foreign Application Priority Data

CN 202210615844.1

May. 31, 2022

Publication Classification

Int. Cl.: A61B17/3207 (20060101); A61B17/00 (20060101)

U.S. Cl.:

CPC A61B17/320758 (20130101); A61B2017/00778 (20130101)

Background/Summary

TECHNICAL FIELD

[0001] The present invention relates to the field of medical devices, and particularly to a rotational atherectomy device and a rotational atherectomy apparatus.

BACKGROUND

[0002] Atherosclerotic plaques are generally present in the coronary or peripheral vasculature and may have different characteristics depending on the texture. Heavily calcified lesions may require atherectomy pretreatment using a rotational atherectomy device, which can remove a calcified or fibrotic atherosclerotic plaque within a blood vessel by high-speed rotation and abrasion, thereby recanalizing the occluded blood vessel. The enlarged and smoothed vascular lumen allows easier subsequent implantation of a stent.

[0003] Existing rotational atherectomy devices mainly include a flexible drive shaft and a rotating abrasive head supported on the flexible drive shaft. The drive shaft drives high-speed rotation of the rotating abrasive head while pushing it forward into contact with and through a plaque, thereby abrading it away. The rotating abrasive head has a diameter not less than a diameter of the drive shaft. The rotating abrasive head is mostly disposed over a middle section of the drive shaft. In this case, there is a non-abrasive section of the drive shaft distally ahead of the rotating abrasive head, and this distal drive shaft section must be screwed or pushed through a stenotic lesion before the middle rotating abrasive head can be brought into contact with the lesion. This leads to poor atherectomy performance and crossability. Moreover, the distal drive shaft section may get stuck in the stenotic lesion during its screwing or pushing therethrough. This is risky and may even cause damage to the blood vessel due to excessive dilation. In particular, some lesions may be very stenotic or even completely occluded, and in these cases, it may be even difficult to bring the middle rotating abrasive head into contact with a lesion for abrasive atherectomy. Additionally, the rotating abrasive head may not be coated with an abrasive material over its entire surface and may therefore not be capable of atherectomy in both axial directions. Consequently, it is a frequent case that the rotating abrasive head can only abrade a lesion while being pushed forward therethrough, but cannot do the same thing while being retracted back through the lesion. This atherectomy approach is inefficient and associated with a high risk of the rotating abrasive head getting stuck in a vascular plaque and not being able to be moved anymore.

[0004] Apart from the above problems, the conventional rotating abrasive head cannot be adjusted in diameter during atherectomy of a lesion. Therefore, such atherectomy procedures typically involve the sequential use of multiple rotating abrasive heads in an order from the smallest diameter to the largest diameter. This, however, necessitates frequent interchanging of associated rotational atherectomy devices of different sizes, increasing the surgical time and the probability of blood vessel damage. In addition, a large rotating abrasive head diameter may add challenges to passage through a narrow blood vessel or catheter and arrival at a target vascular lesion in a surgical procedure, and may block blood flow in a stenotic blood vessel, as well as distal flow of a liquid coolant and/or lubricant. Some conventional rotational atherectomy devices include multiple

rotating abrasive heads sequentially disposed over a middle drive shaft section from distal to proximal in an increasing diameter order. Although this can circumvent frequent interchanging, it requires the drive shaft to have an increased axial length. As a consequence, normal blood vessel segments on distal and proximal sides of the target lesion tend to be affected during atherectomy. Moreover, the problems of blocked blood flow and blocked flow of a liquid coolant and/or lubricant remain unsolved due to possible excessively large diameters of one or more proximal ones of the rotating abrasive heads. In some of these conventional devices, the multiple rotating abrasive heads are disposed eccentrically. However, due to differences among these rotating abrasive heads of various static diameters in terms of centroid, weight and/or the like, their angular momenta may vary during atherectomy. Consequently, the resulting centrifugal forces may interact in an uncontrolled manner, leading to uncontrolled movement of the rotating abrasive heads and hence their uncontrolled influence on a blood vessel. This adds uncertainties to the surgical procedure and reduces its safety. Furthermore, the use of multiple rotating abrasive heads requires greater overall drive shaft stiffness, which means reduced drive shaft compliance and hence more difficulties in passage through a narrow blood vessel or catheter and arrival at a target lesion.

SUMMARY

[0005] It is an objective of the present invention to provide a rotational atherectomy device and a rotational atherectomy apparatus, which overcome at least one of the above-described problems associated with the conventional rotational atherectomy devices.

[0006] To this end, the present invention provides a rotational atherectomy device including a drive shaft and a rotating abrasive head, the drive shaft having a distal connecting portion connected to the rotating abrasive head, the rotating abrasive head and the drive shaft separately defining hollow cavities axially extending therethrough, the hollow cavities configured for insertion of a guide body therethrough, wherein a centroid of a structure consisting of the rotating abrasive head and the connecting portion connected thereto does not coincide with center axes of the hollow cavities.

[0007] In one embodiment, the rotating abrasive head has a distal portion, which has a diameter gradually increasing along its axis from distal to proximal and is coated on its outer surface with an abrasive layer.

[0008] In one embodiment, the rotating abrasive head has a proximal portion, which has a diameter gradually decreasing along its axis from distal to proximal and is coated on its outer surface with the abrasive layer. Additionally or alternatively, an intermediate portion of the rotating abrasive head between the distal and proximal portions is coated on its outer surface with the abrasive layer.

[0009] In one embodiment, the intermediate portion has a constant diameter or a diameter gradually increasing and then gradually decreasing along its axis from distal to proximal.

[0010] In one embodiment, the rotating abrasive head includes a base, which defines the hollow cavity of the rotating abrasive head and is coated on its outer surface with the abrasive layer. The abrasive layer is made of abrasive grains made of one or more abrasive materials.

[0011] In one embodiment, the abrasive layer has a thickness of 20-120 μm , such as 20 μm , 40 μm , 50 μm or 100 μm .

[0012] In one embodiment, the rotating abrasive head has a diameter gradually decreasing along its axis both distally and proximally. Accordingly, the rotating abrasive head may, for example, be shaped like a spindle wider in the middle and tapering toward the ends. Moreover, the rotating abrasive head may have a smooth outer surface.

[0013] In one embodiment, the rotating abrasive head includes at least one of: [0014] a minimum diameter of the distal portion of the rotating abrasive head smaller than a minimum diameter of the proximal portion of the rotating abrasive head; [0015] a maximum diameter of the distal portion of the rotating abrasive head smaller than a maximum diameter of the proximal portion of the rotating abrasive head; and [0016] a radius of curvature of the distal portion of the rotating abrasive head greater than or equal to a radius of curvature of the proximal portion of the rotating abrasive head.

[0017] In one embodiment, the rotating abrasive head includes at least one of: [0018] the distal

portion of the rotating abrasive head having a diameter of 0.13-0.66 mm and for example, a minimum diameter of 0.13 mm, 0.2 mm or 0.3 mm and a maximum diameter of 0.66 mm; [0019] a maximum diameter of 0.66-4.0 mm, such as 0.66 mm, 1.25 mm, 2.0 mm or 4.0 mm, of the intermediate portion between the proximal and distal portions of the rotating abrasive head; [0020] the proximal portion of the rotating abrasive head having a diameter of 0.5-1.2 mm and for example, a minimum diameter of 0.5 mm, 0.75 mm or 1.0 mm and a maximum diameter of 1.2 mm.

[0021] In one embodiment, the rotational atherectomy device further includes the guide body, wherein the rotating abrasive head and the drive shaft are rotatable and axially movable relative to the guide body.

[0022] In one embodiment, the hollow cavity of the rotating abrasive head consists of distal and proximal hollow cavity sections in communication with each other, the distal hollow cavity section having a diameter matching a diameter of the guide body, the proximal hollow cavity section having a diameter greater than the diameter of the distal hollow cavity section, the proximal hollow cavity section secured to the connecting portion.

[0023] In one embodiment, the drive shaft is generally a hollow tubular structure with a constant diameter and has a center axis coincident with a center axis of the guide body.

[0024] In one embodiment, the drive shaft is a hollow tubular structure with a varying diameter, wherein the connecting portion has a diameter increasing along its axis from proximal to distal, and wherein the drive shaft further has a constant-diameter section joined to a proximal end of the connecting portion, the constant-diameter section having a center axis coincident with a center axis of the guide body.

[0025] In one embodiment, the connecting portion is inserted into the proximal hollow cavity section through a proximal opening of the rotating abrasive head, the proximal opening having a radial dimension smaller than or equal to a diameter of the connecting portion at its proximal end.

[0026] In one embodiment, the connecting portion is configured to be asymmetric about the center axis of the constant-diameter section. Additionally or alternatively, the connecting portion has a diameter gradually increasing and then gradually decreasing along its axis from proximal to distal.

[0027] In one embodiment, the rotating abrasive head is spindle-shaped, wherein the proximal hollow cavity section has a matching spindle-like shape, and the connecting portion has a similar spindle-like shape complementary to that of the proximal hollow cavity section. In this embodiment, the rotating abrasive head may be configured as a hollow shell. This allows the rotating abrasive head to have a reduced weight, which can mitigate the influence of a centrifugal force on movement of the rotating abrasive head.

[0028] To the above end, the present invention also provides a rotational atherectomy apparatus including a drive device and the rotational atherectomy device as defined above. The drive device is coupled to the drive shaft in the rotational atherectomy device and configured to actuate rotation of the rotational atherectomy device.

[0029] The present invention provides a rotational atherectomy device and a rotational atherectomy apparatus. The rotational atherectomy device includes a drive shaft and a rotating abrasive head. The drive shaft has a distal connecting portion coupled to the rotating abrasive head. The rotating abrasive head and the drive shaft separately define hollow cavities axially extending therethrough. The hollow cavities are configured for insertion of a guide body therethrough. A centroid of a structure consisting of the rotating abrasive head and the connecting portion coupled thereto does not coincide with center axes of the hollow cavities. With this arrangement, the present invention has at least the following advantages:

[0030] First, arranging the rotating abrasive head at the distal end of the drive shaft imparts atherectomy capabilities to the distal end of the rotational atherectomy device. Accordingly, in a surgical procedure, it is made unnecessary to screw or push a distal drive shaft section through a stenotic lesion. Instead, the rotating abrasive head can be directly brought into contact with the

lesion for atherectomy. In this way, better atherectomy performance and crossability can be achieved, reducing the risk of the surgical procedure and increasing its success rate.

[0031] Second, deviating the centroid of the structure consisting of the connecting portion of the drive shaft and the rotating abrasive head coupled thereto enables the rotating abrasive head to adapt a diameter of atherectomy to a lesion in need of atherectomy and recanalization, thereby allowing for effective removal of the lesion. This dispenses with the use of multiple rotating abrasive heads of various sizes, which requires frequent interchanging of associated devices and a longer surgical time and is associated with a higher surgical risk. In particular, the rotating abrasive head is allowed to have a smaller static diameter (i.e., a diameter in a non-rotating state), which enables the rotational atherectomy device to be more easily advanced through a narrow blood vessel and catheter to a target vascular lesion, reducing surgical difficulties and improving surgical treatment.

[0032] Third, a smaller static diameter of the rotating abrasive head is associated with a lower probability of the rotating abrasive head blocking blood flow in a stenotic blood vessel or blocking distal flow of a liquid coolant and/or lubricant. This further reduces the risk associated with a surgical procedure and increases its safety.

[0033] Fourth, as only one rotating abrasive head is included and disposed at the distal end of the drive shaft, the drive shaft is allowed to have a reduced axial length, which mitigates the influence of the drive shaft on distal side of a lesion in need of atherectomy and normal blood vessel segments on proximal side. In particular, the single rotating abrasive head is eccentrically disposed to allow for controlled centrifugation during atherectomy, which does not adversely affect movement of the rotating abrasive head or a blood vessel. In this way, uncertainties associated with a surgical procedure using the device can be reduced, increasing safety of the surgical procedure. Moreover, the use of only one rotating abrasive head does not increase overall stiffness of the drive shaft and ensures that it is compliant enough to facilitate its advancement through a blood vessel and catheter.

[0034] Apart from the above benefits, in the rotational atherectomy device and apparatus of the present invention, the distal portion of the rotating abrasive head is preferred to have a diameter gradually increasing along its axis from distal to proximal, and the outer surface of the distal portion of the rotating abrasive head is coated with an abrasive layer. This abrasive layer on the distal portion of the rotating abrasive head may be directly brought into contact with a lesion in need of atherectomy and can thereby abrade the lesion more efficiently. In addition, the proximal portion of the rotating abrasive head may have a diameter gradually decreasing along its axis from distal to proximal, and the outer surface of the proximal portion of the rotating abrasive head is coated with the abrasive layer. In this way, the rotating abrasive head is capable of bidirectional atherectomy. Thus, even when the rotating abrasive head gets stuck in a lesion after it drills through the lesion, it can be retracted while abrading the lesion. As a result, not only more efficient atherectomy can be achieved, the risk of a surgical procedure using the device can be further reduced.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] Those of ordinary skill in the art would appreciate that the following drawings are presented to enable a better understanding of the present invention and do not limit the scope thereof in any sense, in which:

[0036] FIG. 1 is a perspective view of a rotational atherectomy device according to an embodiment of the present invention;

[0037] FIG. 2 is a cross-sectional view of a rotational atherectomy device according to an

embodiment of the present invention;

[0038] FIG. **3** is an end view showing a centroid of a structure consisting of a connecting portion and a rotating abrasive head coupled thereto being deviated from center axes of hollow cavities according to an embodiment of the present invention;

[0039] FIG. **4** illustrates how a rotating abrasive head in a rotational atherectomy device according to an embodiment of the present invention comes into contact with a lesion first for atherectomy and recanalization during use;

[0040] FIG. **5** shows a rotating abrasive head having been advanced on a guide body through a stenotic lesion during use of a rotational atherectomy device according to an embodiment of the present invention;

[0041] FIG. **6** shows a drive shaft having a distal connecting portion, which has an increased diameter and is fixedly coupled to a hollow rotating abrasive head, in a rotational atherectomy device according to an embodiment of the present invention;

[0042] FIG. **7** shows variation of a centrifugal force on a rotating abrasive head as a function of a speed of rotation according to an embodiment of the present invention; and

[0043] FIG. **8** shows variation of a centrifugal force on a rotating abrasive head as a function of a diameter of atherectomy according to an embodiment of the present invention.

LIST OF REFERENCE NUMERALS

[0044] **10** rotational atherectomy device; **11** rotating abrasive head; **11a** distal portion; **11b** proximal portion; **11c** intermediate portion; **111** abrasive layer; **112** base; **113** proximal hollow cavity section; **114** distal hollow cavity section; **12** drive shaft; **121** connecting portion; **122** constant-diameter section; **13** guide body; **14** centroid; **31** blood vessel; **32** stenotic lesion; **41** catheter.

DETAILED DESCRIPTION

[0045] Objectives, advantages and features of the present invention will become more apparent upon reading the following more detailed description thereof in conjunction with the accompanying drawings. Note that the figures are provided in a very simplified form not necessarily drawn to exact scale for the only purpose of helping explain embodiments of the invention disclosed herein in a more convenient and clearer way.

[0046] As used herein, the singular forms “a”, “an” and “the” include plural referents, unless the context clearly dictates otherwise. As used herein, the term “or” is generally employed in the sense including “and/or”, unless the context clearly dictates otherwise. As used herein, the term “plurality” means “two or more”, and the term “several” refers to a non-limited number, unless otherwise specified. The following description sets forth numerous specific details in order to provide a more thorough understanding of the present invention. However, it will be apparent to those skilled in the art that the present invention can be practiced without one or more of these specific details. In other instances, well-known technical features have not been described in order to avoid unnecessary obscuring of the invention. In the following, for ease of description, the terms “distal”, “proximal”, “axial” and “circumferential” may be used. “Distal” refers to a side away from an operator operating a rotational atherectomy apparatus, while “proximal” refers to a side closer to the operator. “Axial” refers to a direction along a center axis of the rotational atherectomy apparatus, or of a rotational atherectomy device thereof, while “circumferential” refers to a direction about the axis. The center axis is oriented in a lengthwise direction of the rotational atherectomy device, or of a blood vessel in which the device is deployed. As used herein, the term “diameter” refers to an outer diameter of a structure. A diameter of a rotating abrasive head includes that of an abrasive layer thereof.

[0047] Preferred embodiments of the present invention will be described in greater detail below with reference to the accompanying drawings. If there is no conflict, the embodiments described below and features thereof can complement or be combined with each other.

[0048] As shown in FIGS. **1** to **8**, in some embodiments of the present invention, there are

disclosed a rotational atherectomy apparatus and a rotational atherectomy device thereof. The rotational atherectomy apparatus includes a rotational atherectomy device **10** and a drive device (not shown). The drive device is coupled to a proximal end of a drive shaft **12** in the rotational atherectomy device **10** and is thereby able to actuate rotation of the rotational atherectomy device **10**. The rotational atherectomy apparatus and the rotational atherectomy device thereof are used for vascular surgery for, for example, removing tissue from a body channel. For example, the rotational atherectomy device may be used to remove a calcified or fibrotic atherosclerotic plaque from a blood vessel (e.g., a coronary, peripheral or other blood vessel), thereby recanalizing the blood vessel occluded by the plaque and smoothing its inner side.

[0049] The rotational atherectomy device **10** includes a rotating abrasive head **11** and the drive shaft **12**. The drive shaft **12** has a distal connecting portion **121**, and the rotating abrasive head **11** is coupled to the connecting portion **121**. Generally, the rotating abrasive head **11** and the drive shaft **12** are separately fabricated and then assembled together. The drive shaft **12** is an integral one-piece structure. Preferably, the drive shaft **12** is a flexible drive shaft, which may be implemented as a spring coil. The drive shaft **12** may be actuated by the drive device to rotate, causing rotation of the rotating abrasive head **11**.

[0050] Differing from the conventional devices, in which a rotating abrasive head is disposed over a middle portion of a drive shaft, according to the present invention, the rotating abrasive head **11** is disposed at the distal end of the drive shaft **12**. In this way, the rotating abrasive head **11** can first come into contact with a vascular lesion and drill into a stenotic portion thereof, overcoming the problem associated with the conventional device that the middle rotating abrasive head can come into contact with a stenotic lesion only after a distal section of the drive shaft is screwed or pushed through the lesion. Therefore, the present invention can achieve better atherectomy performance and crossability can be achieved and reduce the risk associated with a surgical procedure.

Moreover, as only one rotating abrasive head **11** may be included, an overall axial length of the drive shaft **12** is reduced, reducing the influence of the drive shaft **12** on distal side of a lesion in need of atherectomy and normal blood vessel segments on proximal side and thereby additionally reducing the risk associated with a surgical procedure.

[0051] In addition, both the rotating abrasive head **11** and the drive shaft **12** define hollow cavities axial extending therethrough, a guide body **13** can be inserted through the hollow cavities of the rotating abrasive head **11** and the drive shaft **12**. The guide body **13** may be, for example, a guidewire for guiding the rotational atherectomy device **10** through a diseased blood vessel. Center axes of the hollow cavities of the rotating abrasive head **11** and the drive shaft **12** coincide with each other.

[0052] The rotating abrasive head **11** may be coupled to the connecting portion **121** so that a centroid **14** of the resulting coupled structure does not coincide with the center axes of the hollow cavities. In this case, as the rotating abrasive head **11** and the drive shaft **12** are spun about the center axes of the hollow cavities, the rotating abrasive head **11** will also revolve under the action of a centrifugal force about an axis deviated from the center axes of the hollow cavities. Moreover, speeding up the rotation of the rotating abrasive head **11** (i.e., increasing its speed of rotation n) can increase the diameter of revolution of the rotating abrasive head **11** (i.e., its diameter of atherectomy D). The diameter of atherectomy D is greater than a static diameter of the rotating abrasive head **11**. With this arrangement, the rotating abrasive head **11** can adapt the diameter of atherectomy D to lesions of various sizes in need of atherectomy and recanalization. In this way, it can remove various lesions in a desired manner, while avoiding the use of multiple rotating abrasive heads of different sizes and hence frequent interchanging of them. This allows a surgical procedure using the device to be completed within a shorter time and associated with a lower risk. Moreover, the rotating abrasive head **11** is allowed to have an even smaller static diameter, which enables the rotational atherectomy device **10** to be more easily advanced through a narrow blood vessel and catheter to a target site in a diseased blood vessel, reducing surgical difficulties. Further,

it will be understood that, a smaller static diameter of the rotating abrasive head **11** is associated with a lower probability of the rotating abrasive head **11** blocking blood flow in a stenotic blood vessel or blocking distal flow of a liquid coolant and/or lubricant. This further reduces the risk associated with a surgical procedure and increases its safety.

[0053] It will be understood that, since only one rotating abrasive head **11** may be used and the single rotating abrasive head **11** can be disposed at the distal end of the drive shaft **12**, an overall axial length of the drive shaft **12** is reduced, and the influence of the drive shaft **12** on distal side of a lesion in need of atherectomy and normal blood vessel segments on proximal side can be induced during atherectomy. In particular, the single rotating abrasive head **11** may be eccentrically disposed to allow for controlled centrifugation during atherectomy, which does not adversely affect movement of the rotating abrasive head or a blood vessel. In this way, uncertainties associated with a surgical procedure using the device can be reduced, increasing safety of the surgical procedure. Moreover, the use of only one rotating abrasive head **11** does not increase overall stiffness of the drive shaft **12** and ensures that it is compliant enough to facilitate its advancement through a blood vessel and catheter. It will be understood that, as used herein, the term “static” refers to a non-rotating state of the rotating abrasive head **11**. Accordingly, the term “static diameter” refers to a diameter of the rotating abrasive head **11** in the non-rotating state. Further, the diameter of atherectomy **D** is a diameter of revolution of the rotating abrasive head **11**.

[0054] In practical use, the diameter of revolution (i.e., the diameter of atherectomy) of the rotating abrasive head **11** can be adjusted by changing the speed of rotation of the rotating abrasive head **11**. Accordingly, the diameter of atherectomy **D** of the rotating abrasive head **11** can be varied, for example, increased or reduced, to adapt the single rotating abrasive head **11** to lesions of various sizes, for example, both big and small lesions.

[0055] In one embodiment, a centrifugal force on the rotating abrasive head **11** may be calculated according to:

$$F_c = m \Delta x (\pi n / 30)^2$$

[0056] where F_c represents the centrifugal force; m is the weight of the structure consisting of the connecting portion **121** and the rotating abrasive head **11** coupled thereto; Δx is a distance that the centroid **14** of the structure consisting of the connecting portion **121** and the rotating abrasive head **11** coupled thereto is deviated from the center axes of the hollow cavities; and n is the speed of rotation of the rotating abrasive head **11**. The present invention is not limited to any particular values of these parameters, and those skilled in the art would know how to calculate a centrifugal force according to the above formula and how it varies as a function of the various factors.

Therefore, the centrifugal force F_c on the rotating abrasive head **11** is related to the weight m of the structure, the deviation of its centroid and the speed of rotation of the rotating abrasive head.

[0057] It will also be understood that the center axes of the hollow cavities correspond to an axis of spin, and a center axis of a diseased blood vessel in which the device is deployed corresponds to an axis of revolution. It will also be understood that as the speed of rotation n increases, the distance between the axis of revolution and the centroid **14** varies. Therefore, the diameter of atherectomy **D** increases with the speed of rotation n . However, during atherectomy of a stenotic lesion **32** using the rotating abrasive head **11** rotating a given speed n , the diameter of atherectomy **D** increases, but the centrifugal force F_c decreases. Moreover, when the diameter of atherectomy **D** increases and reaches a maximum diameter, the centrifugal force F_c tends to 0. Therefore, no damage will be caused to any normal blood vessel segment. Reference can be made to FIGS. 7 and 8 for more details of this process.

[0058] As shown in FIG. 7, as the speed of rotation n increases, the centrifugal force F_c on the rotating abrasive head **11** also increases. Accordingly, the centrifugal force F_c , and hence the diameter of atherectomy **D**, can be increased by adjusting the speed of rotation n , adapting the device to a larger lesion. As shown in FIG. 8, at a given speed of rotation n , as the diameter of

atherectomy D of the rotating abrasive head increases, the centrifugal force F_c acting thereon decreases and tends to 0. Finally, the diameter of atherectomy D becomes increasingly constant and reaches a maximum diameter. At the same time, the centrifugal force F_c tends to 0 or becomes very weak, and the rotating abrasive head **11** will cause no damage to any normal blood vessel segment. Therefore, throughout the atherectomy process, the centrifugal force remains in a predictable, controlled range, making movement of the rotating abrasive head **11** and the force's influence on a blood vessel controllable and ensuring surgical safety.

[0059] In one embodiment, as shown in FIGS. **1** to **3**, the deviation of the centroid **14** from the center axes of the hollow cavities is accomplished by structural asymmetry of the rotating abrasive head **11** about the center axes of the hollow cavities. For example, as viewed from the perspective of FIG. **2**, a portion of the rotating abrasive head **11** above the guide body **13** may have a greater weight than the rest thereof below the guide body **13**, and the drive shaft **12** may be generally a constant-diameter hollow tubular structure with a center axis coincident with a center axis of the guide body **13**. In this case, due to the structural asymmetry of the rotating abrasive head **11**, the centroid **14** is located above the center axes of the hollow cavities for insertion of the guide body **13** therethrough.

[0060] In an alternative embodiment, as shown in FIG. **6**, the deviation of the centroid **14** from the center axes of the hollow cavities is accomplished by structural asymmetry of the rotating abrasive head **11** about the center axes of the hollow cavities. For example, as viewed from the perspective of FIG. **6**, a portion of the rotating abrasive head **11** above the guide body **13** may have a greater weight than the rest thereof below the guide body **13**, and the drive shaft **12** may be a varying-diameter hollow tubular structure. The connecting portion **121** may have a diameter, which axially increases from proximal to distal. The drive shaft **12** may further include a constant-diameter section **122** joined to a proximal end of the connecting portion **121**. In this case, the center axis of the drive shaft **12** may partially coincide with that of the guide body **13**. For example, the constant-diameter section **122** may have a center axis coincident with that of the guide body **13**, while the connecting portion **121** may be asymmetric about the center axes of the hollow cavities. Due to both the structural asymmetry of the rotating abrasive head **11** and the structural asymmetry of the connecting portion **121**, the centroid **14** of the structure consisting of the connecting portion **121** and the rotating abrasive head **11** coupled thereto is located above the center axes of the hollow cavities for insertion of the guide body **13** therethrough. However, in further alternative embodiments of this application, the connecting portion **121** may be symmetrically configured about the center axis of the constant-diameter section **122**, i.e., about the center axes of the hollow cavities.

[0061] In order to enable more effective removal of a lesion, a distal portion **11a** of the rotating abrasive head **11** may have a diameter gradually increasing along its axis from distal to proximal. Accordingly, the distal portion **11a** of the rotating abrasive head **11** may have a smooth tapered surface, which can facilitate passage through a lesion. Moreover, the distal portion **11a** of the rotating abrasive head **11** may be coated on its outer surface with an abrasive layer **111** (see FIGS. **2** and **6**). Once the distal portion **11a** of the rotating abrasive head **11** comes into contact with a lesion, it can start abrasively removing the lesion with high efficiency using the abrasive layer **111**.

[0062] Conventional rotating abrasive heads can only abrade a lesion while being pushed forward therethrough, but cannot do the same thing while being retracted back through the lesion. In view of this, a proximal portion **11b** of the rotating abrasive head **11** has a diameter gradually decreasing along its axis from distal to proximal. Accordingly, the proximal portion **11b** of the rotating abrasive head **11** may have a smooth tapered surface, which can facilitate passage through a lesion during retraction. Moreover, the proximal portion **11b** of the rotating abrasive head **11** may also be coated on its outer surface with the abrasive layer **111** (see FIGS. **2** and **6**). With this arrangement, the rotating abrasive head **11** can provide bidirectional atherectomy in both distal, forward and proximal, backward directions. Thus, even when the rotating abrasive head **11** gets stuck in a lesion

during its forward movement under the action of a pushing force, it can be retracted while abrading the lesion. As a result, not only more efficient atherectomy can be achieved, but the rotating abrasive head **11** can be prevented from getting stuck in a vascular plaque and being not able to move anymore, further reducing the risk of a surgical procedure.

[0063] Preferably, the entire outer surface of the rotating abrasive head **11** is coated with the abrasive layer **111**. In one embodiment, in addition to the proximal portion **11b** and the distal portion **11a**, an intermediate portion **11c** of the rotating abrasive head **11** between the distal portion **11a** and the proximal portion **11b** is also coated on its outer surface with the abrasive layer **111**. This allows for even more efficient atherectomy. The intermediate portion **11c** may have a constant diameter, hence the intermediate portion **11c** has a cylindrical shape. That is, the rotating abrasive head **11** may be cylindrical in the middle and tapered at both ends. Accordingly, the intermediate portion **11c** may have a diameter, which is equal to maximum diameters of the proximal portion **11b** and the distal portion **11a**. Alternatively, the intermediate portion **11c** may have a diameter, which gradually increases and then gradually decreases along its axis from distal to proximal. In this case, the outer surface of the intermediate portion **11c** may be curved, and the rotating abrasive head **11** may be generally spindle-shaped. Moreover, a diameter of the intermediate portion **11c** at its distal end may be equal to a maximum diameter of the distal portion **11a** at its proximal end, and a diameter of the intermediate portion **11c** at its proximal end may be equal to a maximum diameter of the proximal portion **11b** at its distal end, as shown in FIGS. **1** to **6**.

[0064] In a specific embodiment, the rotating abrasive head **11** may include a base **112**, the base **112** may define the aforementioned hollow cavity of the rotating abrasive head **11**. The abrasive layer **111** may be coated on an outer surface of the base **112**. The abrasive layer **111** may be composed of abrasive grains, which may be made of one or more abrasive materials. The abrasive grains may be fixed to the base **112** by being partially embedded therein. A thickness of the abrasive layer **111** may be in the range of 20-120 μm , such as 20 μm , 40 μm , 50 μm or 100 μm . It will be understood that the thickness of the abrasive layer **111** refers to its thickness above a surface of the base **112**. Desirably, the thickness of the abrasive layer **111** is not too large or too small. The larger the thickness of the abrasive layer **111**, the larger the static diameter of the rotating abrasive head. An excessively thickness of the abrasive layer **111** is not conducive to atherectomy performance.

[0065] The present invention is not limited to any particular material of the abrasive grains. The abrasive grains may be made of one or more suitable abrasive materials. As an illustrative example, the abrasive grains may be made of one or more of diamond, fused silica, titanium nitride, tungsten carbide, silicon carbide, etc. The present invention is not limited to any particular material of the base **112**. The base **112** may be made of one or more suitable materials, such as metallic and non-metallic materials. As an illustrative example, the base **112** may be made of one or more metallic materials such as stainless steel, nickel, etc. The material of the base **112** may further include a radiopaque material, for example, one or more of radiopaque materials such as tungsten, platinum, iridium, etc.

[0066] In order to make the rotating abrasive head **11** more powerful in passing through a stenotic lesion, the rotating abrasive head **11** is preferred to have a diameter gradually decreasing along its axis both distally and proximally. The gradually distally decreasing diameter of the rotating abrasive head **11** along its axis can facilitate atherectomy by the distal portion **11a** in the forward direction. Moreover, since the diameter of the distal portion **11a** is smaller than that of the intermediate portion **11c**, the distal portion **11a** of the rotating abrasive head **11** can more easily first come into contact with a lesion in need of atherectomy. The gradually proximally decreasing diameter of the rotating abrasive head **11** along its axis enables atherectomy by the proximal portion **11b** during its retraction in the backward direction. Moreover, since the diameter of the proximal portion **11b** is smaller than that of the intermediate portion **11c**, the proximal portion **11b** of the rotating abrasive head **11** can more easily first come into contact with a lesion in need of

atherectomy during its retraction. Further, a minimum diameter of the distal portion **11a** of the rotating abrasive head **11** may be smaller than a minimum diameter of the proximal portion **11b** of the rotating abrasive head **11**. With this arrangement, the rotating abrasive head **11** is narrowest at its distal end. This can additionally facilitate advancement of the rotating abrasive head **11** through a narrow blood vessel and catheter and its arrival at a target vascular lesion. Furthermore, the maximum diameter of the distal portion **11a** of the rotating abrasive head **11** may be smaller than that of the proximal portion **11b** of the rotating abrasive head **11**. This allows the distal portion **11a** to have a greater lengthwise extent, which is also conducive to advancement of the rotating abrasive head **11** through a narrow blood vessel and catheter and its arrival at a target vascular lesion. For example, in the illustrated embodiment, the rotating abrasive head **11** may be shaped like a spindle wider in the middle and tapering toward the ends. The spindle-shaped rotating abrasive head **11** may have a smooth outer surface and define certain degrees of curvature at the ends.

[0067] In general, the diameter of the distal portion **11a** of the rotating abrasive head **11** may be configured based on a diameter of the guide body **13**. In one embodiment, the diameter of the distal portion **11a** of the rotating abrasive head **11** may be 0.13-0.66 mm. For example, the minimum diameter of the distal portion **11a** may be configured to be 0.13 mm, 0.2 mm or 0.3 mm, and the maximum diameter thereof may be configured to be 0.66 mm.

[0068] In general, the diameter of the proximal portion **11b** of the rotating abrasive head **11** may also be configured based on the diameter of the drive shaft **12**. In one embodiment, the diameter of the proximal portion **11b** of the rotating abrasive head **11** may be 0.5-1.2 mm. For example, the minimum diameter of the proximal portion **11b** may be configured to be 0.5 mm, 0.7 mm or 1.0 mm, and the maximum diameter thereof may be configured to be 1.2 mm.

[0069] Considering that the rotating abrasive head **11** accommodates both the guide body **13** and the connecting portion **121** of the drive shaft **12** that it is coupled to, the guide body **13** is inserted through the drive shaft **12**, the intermediate portion **11c** of the rotating abrasive head **11** may have a maximum diameter configured based on the diameters of both the guide body **13** and the drive shaft **12**. In one embodiment, the maximum diameter of the intermediate portion **11c** of the rotating abrasive head **11** may be 0.66-4.0 mm, such as 0.66 mm, 1.25 mm, 2.0 mm or 4.0 mm. It will also be understood that the intermediate portion **11c** of the rotating abrasive head **11** should not be narrowly interpreted as being defined absolutely at the middle thereof; rather, it may be defined at any location between the distal portion **11a** and the proximal portion **11b**.

[0070] In a preferred embodiment, the guide body **13** may form part of the rotational atherectomy device **10**, the guide body **13** be configured to be inserted through the hollow cavities of both the drive shaft **12** and the rotating abrasive head **11**, the guide body **13** protrude out of the distal end of the rotating abrasive head **11**. The rotating abrasive head **11** and the drive shaft **12** may be rotatable and axially movable relative to the guide body **13** to allow the drive shaft **12** to translate and rotate on the guide body **13**. However, in alternative embodiments of the present application, the guide body **13** may be provided as a separate component for use in cooperation with the rotational atherectomy device **10**.

[0071] In order to ensure sufficiently strong coupling of the rotating abrasive head **11** to the distal end of the drive shaft **12**, the coupling is generally accomplished by inserting the connecting portion **121** of the drive shaft **12** into the hollow cavity of the rotating abrasive head **11**. In one embodiment, the hollow cavity of the rotating abrasive head **11** may consist of distal and proximal hollow cavity sections in communication with each other. The distal hollow cavity section may have a diameter matching the diameter of the guide body **13**, and the proximal hollow cavity section may have a diameter greater than the diameter of the distal hollow cavity section.

Moreover, the connecting portion **121** may be secured to the proximal hollow cavity section. It will be understood that the distal hollow cavity section is configured for insertion of the guide body **13** therethrough, and the proximal hollow cavity section is configured for insertion of the connecting

portion **121** of the drive shaft **12** therethrough, with the guide body **13** being in turn inserted through the drive shaft **12**.

[0072] FIGS. **1** and **2** show an optional embodiment of coupling the drive shaft **12** to the rotating abrasive head **11**. In this exemplary embodiment, the hollow cavity of the rotating abrasive head **11** consists of a distal hollow cavity section **113** and a proximal hollow cavity section **114**, which communicate with each other. Both the distal cavity section **113** and the proximal cavity section **114** are cylindrical and their center axes coincide with each other. The distal hollow cavity section **113** has a diameter matching a diameter of a guidewire, and the proximal hollow cavity section **114** has a diameter matching an overall diameter of the drive shaft **12**. Additionally, the drive shaft **12** is a constant-diameter hollow tubular structure, and the connecting portion **121** of the drive shaft **12** is inserted into the proximal hollow cavity section **114** and secured to the proximal hollow cavity section **114**, for example, the connecting portion **121** is secured to the proximal hollow cavity section **114** by crimping. Here, by “crimping”, it is intended to mean that the diameter of the drive shaft **12** may be greater than that of the proximal hollow cavity section **114** and the connecting portion **121** may be secured to the proximal hollow cavity section **114** by being deformed and inserted therein. In this embodiment, center axes of the distal cavity section **113** and the proximal cavity section **114** both coincide with the center axis of the drive shaft **12**.

[0073] However, the present invention is not limited to any method of coupling the rotating abrasive head **11** to the connecting portion **121**. Apart from crimping, the coupling may also be accomplished by, for example, welding, gluing or other mechanical coupling methods.

[0074] In an alternative embodiment, the drive shaft **12** may be a varying-diameter hollow tubular structure. FIG. **6** shows another optional embodiment of coupling the drive shaft **12** to the rotating abrasive head **11**. In this exemplary embodiment, the connecting portion **121** is inserted into the proximal hollow cavity section **114** through a proximal opening of the rotating abrasive head **11**. The proximal opening has a radial dimension smaller than or equal to the diameter of the proximal end of the connecting portion **121**, thereby restricting the drive shaft **12** from moving away from the rotating abrasive head **11**. In this way, the drive shaft **12** is prevented from separation from the rotating abrasive head **11** during an atherectomy procedure. Additionally, the connecting portion **121** may be welded, glued or otherwise secured to the proximal hollow cavity section **114**. In this embodiment, the center axes of the distal cavity section **113** and the proximal cavity section **114** both coincide with the center axis of the drive shaft **12**.

[0075] Further, when the rotating abrasive head **11** is spindle-shaped, the proximal hollow cavity section **114** may have a matching spindle-like shape, and the connecting portion **121** may have a similar spindle-like shape complementary to that of the proximal hollow cavity section **114**. For example, the diameter of the connecting portion **121** may gradually increase and then gradually decrease along its axis from proximal to distal. In this case, the rotating abrasive head **11** may be configured as a hollow shell. This allows the rotating abrasive head **11** to have a reduced weight, which can mitigate the influence of a centrifugal force on movement of the rotating abrasive head **11**.

[0076] The distal portion **11a** and proximal portion **11b** of the rotating abrasive head **11** may have the same or different radii of curvature. In general, the radius of curvature of the distal portion **11a** of the rotating abrasive head **11** may be greater than or equal to that of the proximal portion **11b** of the rotating abrasive head **11**. The radius of curvature of the distal portion **11a** of the rotating abrasive head **11** is preferred to be greater than that of the proximal portion **11b** of the rotating abrasive head **11** because this allows the distal portion **11a** to be less steep and can more easily pass through a lesion.

[0077] The structure of the rotating abrasive head **11** is further explained below with respect to specific embodiments.

[0078] FIGS. **1** to **3** show an exemplary embodiment of the rotating abrasive head **11**. As shown in FIGS. **1** to **3**, the abrasive layer **111** has an average thickness of 50 μm , and the abrasive layer **111**

is made of diamond abrasive grains. The base **112** is made of a combination of stainless steel and nickel, and the rotating abrasive head **11** has a spindle-like shape tapered at both ends. Moreover, the distal portion **11a** of the rotating abrasive head **11** defines a minimum diameter, which allows for better atherectomy and drilling into a stenotic portion. The radius of curvature of the distal portion **11a** of the rotating abrasive head **11** is 4.5 mm, and the radius of curvature of the proximal portion **11b** of the rotating abrasive head **11** is 3.5 mm. The minimum diameter of the distal portion **11a** of the rotating abrasive head **11** is 0.30 mm, and the maximum diameter of the intermediate portion **11c** of the rotating abrasive head **11** is 1.25 mm. The minimum diameter of the proximal portion **11b** of the rotating abrasive head **11** is 0.75 mm. In practical use, after the rotating abrasive head **11** drills through a lesion, it may be further caused to revolve under the action of a centrifugal force to increase the diameter of atherectomy. Since there is only a single rotating abrasive head **11** provided at the distal end of the drive shaft **12**, the distance the centroid **14** is deviated from the center axes of the hollow cavities will not change due to absence of interference from any other rotating abrasive head **11**. Therefore, both the centrifugal force and the diameter of revolution can be stably controlled, making the atherectomy process controllable.

[0079] In more detail, as shown in FIG. 4, the rotating abrasive head **11** coupled to the connecting portion **121** of the drive shaft **12** may be deployed in a blood vessel **31**, the entire outer surface of the rotating abrasive head **11** is coated with the abrasive layer **111**, the distal portion **11a** of the rotating abrasive head **11** has a minimum diameter. The abrasive layer **111** on the distal portion **11a** of the rotating abrasive head **11** may first come into contact with a stenotic lesion **32** for atherectomy and recanalization. As shown in FIG. 5, in a conventional scenario, due to elasticity of the blood vessel **31**, a rotational atherectomy device **10** may be advanced on the guide body **13** through the stenotic lesion **32** as a result of being pushed distally by an operator. At this time, since a diameter defined by the stenotic lesion **32** may be smaller than a maximum diameter of the rotating abrasive head **11**, the rotating abrasive head **11** may get stuck in the stenotic lesion **32** and not be able to be retracted back through the lesion. In contrast, according to the present invention, as the proximal portion of the rotating abrasive head **11** is also tapered and covered with the abrasive layer **111**, it is capable of atherectomy and recanalization while being retracted backward.

[0080] FIG. 6 shows another exemplary embodiment of the rotating abrasive head **11**. As shown in FIG. 6, the abrasive layer **111** has an average thickness of 100 μm , and the base **112** is made of nickel and structured like a shell. The abrasive layer **111** is made of diamond abrasive grains, and the rotating abrasive head **11** is shaped like a spindle tapered at both ends. Moreover, the rotating abrasive head **11** defines a minimum diameter at the distal portion **11a**, which allows for better atherectomy and drilling into a stenotic portion. The radius of curvature of the distal portion **11a** of the rotating abrasive head **11** is 3 mm, and the radius of curvature of the proximal portion **11b** of the rotating abrasive head **11** is 3 mm. The minimum diameter of the rotating abrasive head **11** defined at the distal portion **11a** is 0.20 mm, and the maximum diameter of the intermediate portion **11c** of the rotating abrasive head **11** is 2.0 mm. The minimum diameter of the proximal portion **11b** of the rotating abrasive head **11** is 1.0 mm. This embodiment operates in a similar way to that of the embodiment shown in FIGS. 4 and 5 and, therefore, needs not be described in further detail herein.

[0081] Referring to FIGS. 4 and 5, the rotational atherectomy device **10** may be delivered to an in vivo target site through a catheter **41**. Additionally, a liquid coolant and/or lubricant (typically saline or other biocompatible liquids) may be supplied to the rotational atherectomy device **10** through a passage in the catheter **41**.

[0082] In summary, the rotational atherectomy device and apparatus have at least the following advantages:

[0083] 1) Arranging the rotating abrasive head at the distal end of the drive shaft imparts atherectomy capabilities to the distal end of the rotational atherectomy device. Accordingly, in a surgical procedure, it is made unnecessary to screw or push a distal drive shaft section through a stenotic lesion. Instead, the rotating abrasive head can be directly brought into contact with the

lesion for atherectomy. In this way, better atherectomy performance and crossability can be achieved, reducing the risk of the surgical procedure and increasing its success rate.

[0084] 2) Deviating the centroid of the structure consisting of the connecting portion of the drive shaft and the rotating abrasive head coupled thereto enables the rotating abrasive head to adapt a diameter of atherectomy to a lesion in need of atherectomy and recanalization, thereby allowing for effective removal of the lesion. This dispenses with the use of multiple rotating abrasive heads of various sizes, which requires frequent interchanging of associated devices and a longer surgical time and is associated with a higher surgical risk. In particular, the rotating abrasive head is allowed to have a smaller static diameter, which enables the rotational atherectomy device to be more easily advanced through a narrow blood vessel and catheter to a target vascular lesion, reducing surgical difficulties. Further, a smaller static diameter of the rotating abrasive head is associated with a lower probability of the rotating abrasive head blocking blood flow in a stenotic blood vessel or blocking distal flow of a liquid coolant and/or lubricant. This further reduces the risk associated with a surgical procedure and increases its safety.

[0085] 3) As only one rotating abrasive head is included and disposed at the distal end of the drive shaft, the drive shaft is allowed to have a reduced axial length, which mitigates the influence of the drive shaft on distal side of a lesion in need of atherectomy and normal blood vessel segments on proximal side. In particular, the single rotating abrasive head is eccentrically disposed to allow for controlled centrifugation during atherectomy, which does not adversely affect movement of the rotating abrasive head or a blood vessel. In this way, uncertainties associated with a surgical procedure using the device can be reduced, increasing safety of the surgical procedure. Moreover, the use of only one rotating abrasive head does not increase overall stiffness of the drive shaft and ensures that it is compliant enough to facilitate its advancement through a blood vessel and catheter.

[0086] Further, when the rotating abrasive head is coated on its entire outer surface with the abrasive layer, it is capable of bidirectional atherectomy. Thus, even when the rotating abrasive head gets stuck in a lesion during its forward movement under the action of a pushing force, it can be retracted while abrading the lesion. As a result, not only more efficient atherectomy can be achieved, the risk of a surgical procedure using the device can be further reduced.

[0087] It will be understood that, since the centroid of the structure does not coincide with the center axes of the hollow cavities, as the rotating abrasive head and the drive shaft are spun about the center axes of the hollow cavities, the rotating abrasive head will revolve under the action of a centrifugal force about an axis deviated from the center axes of the hollow cavities. Moreover, the diameter of revolution of the rotating abrasive head can be controlled by adjusting its speed of rotation. For example, the diameter of atherectomy may increase with the speed of rotation beyond the static diameter of the rotating abrasive head. In this way, the rotating abrasive head is allowed to have a smaller static diameter, and the use of multiple rotating abrasive heads of various static diameters can be avoided, which may require interchanging of these rotating abrasive heads during surgery. Further, the diameter of atherectomy that is larger than the static diameter of the rotating abrasive head can facilitate flow of blood, a liquid coolant and/or a liquid lubricant to flow around the rotating abrasive head and reduce the risk of the rotating abrasive head blocking blood flow in a blood vessel.

[0088] It will be understood that while a few preferred embodiments of the present invention have been described above, the scope of the invention is in no way limited to these disclosed embodiments. Any and all changes made to the configurations of the above embodiments are intended to fall within the scope of the present invention. Those skilled in the art can devise other embodiments on the basis of the description of the foregoing embodiments.

Claims

- 1.** A rotational atherectomy device for use in vascular surgery, comprising a drive shaft and a rotating abrasive head, the drive shaft provided with a connecting portion located at a distal end, the connecting portion connected to the rotating abrasive head, the rotating abrasive head and the drive shaft separately defining hollow cavities axially extending therethrough, the hollow cavities configured for insertion of a guide body therethrough, wherein a centroid of a structure consisting of the rotating abrasive head and the connecting portion connected thereto does not coincide with center axes of the hollow cavities.
- 2.** The rotational atherectomy device according to claim 1, wherein a diameter of a distal portion of the rotating abrasive head gradually increases from distal to proximal in an axial direction, and an outer surface of the distal portion of the rotating abrasive head is coated with an abrasive layer.
- 3.** The rotational atherectomy device according to claim 2, wherein a diameter of a proximal portion of the rotating abrasive head gradually decreases from distal to proximal in the axial direction, and an outer surface of the proximal portion of the rotating abrasive head is coated with the abrasive layer, and/or an outer surface of an intermediate portion of the rotating abrasive head between the distal portion and the proximal portion is coated with the abrasive layer.
- 4.** The rotational atherectomy device according to claim 3, wherein the intermediate portion has a constant diameter, or wherein a diameter of the intermediate portion gradually increasing and then gradually decreasing from distal to proximal in the axial direction.
- 5.** The rotational atherectomy device according to claim 1, wherein the abrasive layer has a thickness of 20-120 μm .
- 6.** The rotational atherectomy device according to claim 1, wherein a diameter of the rotating abrasive head gradually decreases distally in the axial direction and the diameter of the rotating abrasive head gradually decreases proximally in the axial direction.
- 7.** The rotational atherectomy device according to claim 6, wherein the rotating abrasive head comprises at least one of: a minimum diameter of the distal portion of the rotating abrasive head smaller than a minimum diameter of the proximal portion of the rotating abrasive head; a maximum diameter of the distal portion of the rotating abrasive head smaller than a maximum diameter of the proximal portion of the rotating abrasive head; and a radius of curvature of the distal portion of the rotating abrasive head greater than or equal to a radius of curvature of the proximal portion of the rotating abrasive head.
- 8.** The rotational atherectomy device according to claim 6, wherein the rotating abrasive head comprises at least one of: a diameter of the distal portion of the rotating abrasive head is 0.13-0.66 mm; a maximum diameter of the intermediate portion between the proximal portion and the distal portion of the rotating abrasive head is 0.66-4.0 mm; and a diameter of the proximal portion of the rotating abrasive head is 0.5-1.2 mm.
- 9.** The rotational atherectomy device according to claim 1, further comprising the guide body, wherein the rotating abrasive head and the drive shaft are rotatable and axially movable relative to the guide body.
- 10.** The rotational atherectomy device according to claim 1, wherein the hollow cavity of the rotating abrasive head consists of a distal hollow cavity section and a proximal hollow cavity section in communication with each other, the distal hollow cavity section having a diameter matching a diameter of the guide body, the proximal hollow cavity section having a diameter greater than the diameter of the distal hollow cavity section, the proximal hollow cavity section secured to the connecting portion.
- 11.** The rotational atherectomy device according to claim 10, wherein the drive shaft is generally a hollow tubular structure with a constant diameter, and wherein a center axis of the drive shaft is coincident with a center axis of the guide body.
- 12.** The rotational atherectomy device according to claim 10, wherein the drive shaft is a hollow tubular structure with a varying diameter, wherein the connecting portion has a diameter increasing

from proximal to distal in the axial direction, and wherein the drive shaft further has a constant-diameter section joined to a proximal end of the connecting portion, the constant-diameter section having a center axis coincident with a center axis of the guide body.

13. The rotational atherectomy device according to claim 12, wherein the connecting portion is inserted into the proximal hollow cavity section through a proximal opening of the rotating abrasive head, the proximal opening having a radial dimension smaller than or equal to a diameter of a proximal end of the connecting portion.

14. The rotational atherectomy device according to claim 13, wherein the connecting portion is configured to be asymmetric about the center axis of the constant-diameter section, and/or wherein the connecting portion has a diameter gradually increasing and then gradually decreasing from proximal to distal in the axial direction.

15. A rotational atherectomy apparatus, comprising a drive device and the rotational atherectomy device of claim 1, the drive device coupled to the drive shaft in the rotational atherectomy device and configured to actuate rotation of the rotational atherectomy device.
