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OCCLUSIVE DEVICES WITH SPIRAL STRUTS FOR TREATING VASCULAR DEFECTS

Abstract

Devices for treating vascular defects and associated systems and methods are disclosed herein. In some embodiments, for example, an occlusive device for treating an aneurysm includes a tubular structure having a first end portion with a first opening, a second end portion with a second opening, and a mesh surface extending between the first and second end portions. The occlusive device also includes a plurality of spiral struts coupled to the first end portion of the tubular structure and extending over the first opening. When the occlusive device is deployed within the aneurysm, the tubular structure and the plurality of spiral struts can be configured to self-expand such that the plurality of spiral struts span a neck of the aneurysm substantially within a single plane and the mesh surface of the tubular structure engages a wall of the aneurysm near the neck.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of priority to U.S. patent application Ser. No. 17/649,920, filed Feb. 3, 2022, which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0002] The present application generally relates to medical devices, and in particular, to occlusive devices for treating vascular defects.

BACKGROUND

[0003] Intracranial saccular aneurysms occur in 1% to 2% of the general population and account for approximately 80% to 85% of non-traumatic subarachnoid hemorrhages. Recent studies show a case fatality rate of 8.3% to 66.7% in patients with subarachnoid hemorrhage. Endovascular treatment of intracranial aneurysms with coil embolization involves packing the aneurysm sac with metal coils to reduce or disrupt the flow of blood into the aneurysm, thereby enabling a local thrombus or clot to form which fills and ultimately closes off the aneurysm. Although coiling has proven to have better outcomes than surgical clipping for both ruptured and unruptured aneurysms, treating complex aneurysms using conventional coiling is challenging. This is especially true for wide-necked aneurysms because coil segments may protrude from the aneurysm sac through the neck of the aneurysm and into the parent vessel, causing serious complications for the patient.

[0004] To address this, some treatments include temporarily positioning a balloon within the parent vessel across the neck of the aneurysm to prevent the coils from migrating across the neck during delivery. Alternatively, some treatments include permanently positioning a neck-bridging stent within the parent vessel across the neck of the aneurysm to prevent the coils from migrating across the neck during delivery. While balloon-assisted or stent-assisted coiling for wide-necked aneurysms has shown better occlusion rates and lower recurrence than coiling alone, the recanalization rate of treated large/giant aneurysms can be as high as 18.2%. Moreover, the addition of a balloon or stent and its associated delivery system to the procedure increases the time, cost, and complexity of treatment. Deployment of the stent or balloon during the procedure also greatly increases the risk of an intraprocedural clot forming, and can damage the endothelial lining of the vessel wall. Permanently positioning a stent within the parent vessel increases the chronic risk of clot formation on the stent itself and associated ischemic complications, and thus necessitates the use of dual antiplatelet therapy (“DAPT”). DAPT, in turn, increases the risk and severity of hemorrhagic complications in patients with acutely ruptured aneurysms or other hemorrhagic risks. Thus, neck-bridging stents are not indicated for the treatment of ruptured aneurysms.

[0005] The above-noted drawbacks associated with balloon-and stent-assisted coiling techniques influenced the development of intraluminal flow diverting stents, or stent-like structures implanted in the parent vessel across the neck of the aneurysm that redirect blood flow away from the aneurysm, thereby promoting aneurysm thrombosis. Flow diverters have been successfully used for treating wide-necked, giant, fusiform, and blister-like aneurysms. However, because they are positioned in the parent vessel, flow diverters require DAPT to avoid clot formation on the stent itself and ischemic complications. This, in turn, increases the risk and severity of hemorrhagic complications in patients with acutely ruptured aneurysms or other hemorrhagic risks. Thus, flow diverters are not indicated for the treatment of ruptured aneurysms. Flow diverters have also shown limited efficacy in treating bifurcation aneurysms (35-50%).

[0006] Endosaccular flow disrupting devices have the potential to provide the intra-aneurysmal flow disruption of coiling with the definitive remodeling at the aneurysm-parent vessel interface achieved by intraluminal flow diverters. Endosaccular devices can be mesh devices configured to be deployed completely within the aneurysm sac, with the interstices of the mesh covering the aneurysm neck and reconstructing the aneurysm-parent vessel interface. The implant disrupts the blood flow entering and exiting the aneurysm sac (resulting in stasis and thrombosis) and supports neoendothelial overgrowth without requiring DAPT (unlike endoluminal flow diverters). Thus, endosaccular devices can be used to treat wide-necked aneurysms and ruptured aneurysms. Moreover, because the device is placed completely within the aneurysm sac, the parent and branch vessels are unimpeded and can be accessed for any further retreatment or subsequent deployment of adjunctive devices during treatment.

[0007] Accordingly, there is a need for improved devices, systems, and methods for treating aneurysms and other vascular defects.

SUMMARY

[0008] The subject technology is illustrated, for example, according to various aspects described below. These are provided as examples and do not limit the subject technology.

[0009] In one aspect of the present technology, an occlusive device for treating an aneurysm is provided. The occlusive device can include a tubular structure having a first end portion with a first opening, a second end portion with a second opening, and a mesh surface extending between the first and second end portions. The occlusive device can also include a plurality of spiral struts coupled to the first end portion of the tubular structure and extending over the first opening. When the occlusive device is deployed within the aneurysm, the tubular structure and the plurality of spiral struts can be configured to self-expand such that the plurality of spiral struts span a neck of the aneurysm substantially within a single plane and the mesh surface of the tubular structure engages a wall of the aneurysm near the neck.

[0010] In some embodiments, the tubular structure includes a stent including a plurality of cells.

[0011] In some embodiments, the tubular structure includes a braid formed from a plurality of filaments. The plurality of spiral struts can be formed from the plurality of filaments.

[0012] In some embodiments, the plurality of spiral struts are arranged in a radial configuration.

[0013] In some embodiments, the occlusive device further includes a hub. Each spiral strut can include a first end region coupled to the hub, and a second end region coupled to the first end portion of the tubular structure. The second end region of each spiral strut can be coupled to a peripheral edge of the tubular structure. The second end regions of the plurality of spiral struts can be spaced apart along the peripheral edge of the tubular structure.

[0014] In some embodiments, the occlusive device further includes a detachment element configured to releasably couple the tubular structure and the plurality of spiral struts to a pusher member. The occlusive device can further include a hub. The detachment element can be coupled to the plurality of spiral struts via the hub. Optionally, the occlusive device includes an elongate member connecting the detachment element to the hub. The elongate member can be configured to transform from a first state to a second state when the occlusive device is deployed within the aneurysm. When in the first state, the elongate member can extend away from the tubular structure. When in the second state, the elongate member can be positioned at least partially within the tubular structure.

[0015] In some embodiments, when the occlusive device is deployed within the aneurysm, the plurality of spiral struts are contained entirely within the aneurysm. When the occlusive device is deployed within the aneurysm, the plurality of spiral struts can be configured to exert outwardly directed forces to enhance the engagement between the mesh surface and the wall of the aneurysm.

[0016] In some embodiments, the tubular structure is integrally formed with the plurality of spiral struts as a single unitary component.

[0017] In some embodiments, the tubular structure and the plurality of spiral struts are discrete components that are attached to each other.

[0018] In another aspect of the present technology, an occlusive device for treating an aneurysm is provided. The occlusive device can include a tubular structure having a first end portion and a second end portion opposite the first end portion. The occlusive device can also include a plurality of curved struts coupled to the first end portion of the tubular structure, each curved strut including a first end region and a second end region. The occlusive device can further include a hub. The plurality of curved struts can be arranged in a spiral configuration with the first end region of each curved strut coupled to the hub, and the second end region of each curved strut coupled to the first end portion of the tubular structure.
[0019] In some embodiments, the tubular structure includes a stent.
[0020] In some embodiments, the tubular structure includes a braid.
[0021] In some embodiments, the second end region of each curved strut is coupled to a peripheral edge of the tubular structure. The second end region of each curved strut can be spaced apart along the peripheral edge of the tubular structure.
[0022] In some embodiments, the first end portion of the tubular structure includes a first opening, and the plurality of curved struts are disposed over the first opening.
[0023] In some embodiments, the occlusive device further includes a detachment element configured to releasably couple the tubular structure and the plurality of curved struts to a pusher member. The detachment element can be coupled to the plurality of curved struts via the hub.
[0024] In some embodiments, the occlusive device further includes an elongate member connecting the detachment element to the hub. The elongate member can be configured to transform from a first state to a second state when the occlusive device is deployed within the aneurysm.
[0025] In some embodiments, the tubular structure and plurality of curved struts are configured to self-expand when deployed within the aneurysm. When deployed within the aneurysm, the plurality of curved struts can be disposed across a neck of the aneurysm and the tubular structure engages a wall of aneurysm near the neck. When deployed within the aneurysm, the plurality of curved struts can lie substantially within a single plane. When deployed within the aneurysm, the plurality of curved struts can be configured to exert outwardly directed forces to enhance the engagement between the tubular structure and the wall of the aneurysm.
[0026] In some embodiments, the tubular structure is integrally formed with the plurality of curved struts as a single unitary component.
[0027] In some embodiments, the tubular structure and the plurality of curved struts are discrete components that are attached to each other.
[0028] In a further aspect of the present technology, a method of treating an aneurysm is provided. The method can include introducing an occlusive device at least partially into the aneurysm. The occlusive device can include a tubular structure coupled to a plurality of spiral struts, the tubular structure having a mesh outer surface. The method can also include expanding the occlusive device such that the plurality of spiral struts extend across a neck of the aneurysm and the mesh outer surface of the tubular structure engages a wall of the aneurysm near the neck.
[0029] In some embodiments, the occlusive device is introduced to the aneurysm via a first elongate shaft. The occlusive device can be disposed within the first elongate shaft in a low-profile configuration. Expanding the occlusive device can include advancing the occlusive device out of the first elongate shaft such that the occlusive device self-expands into an expanded configuration. The plurality of spiral struts can be coupled to a proximal end portion of the tubular structure. When the occlusive device is in the low-profile configuration, the plurality of spiral struts can extend proximally from the proximal end portion of the tubular structure by at least a first distance. When the occlusive device is in the expanded configuration, the plurality of spiral struts can extend proximally from the proximal end portion of the tubular structure by no more than a second distance, the second distance being smaller than the first distance. When the occlusive device is in the expanded configuration, the plurality of spiral struts can lie substantially within a single plane. When the occlusive device is in the expanded configuration, the plurality of spiral struts can

conform to a diameter of the neck of the aneurysm.
[0030] In some embodiments, the method further includes introducing the first elongate shaft into the aneurysm, and delivering an embolization element into the aneurysm via the first elongate shaft. Introducing the first elongate shaft into the aneurysm can include positioning a distal tip portion of the first elongate shaft between the plurality of spiral struts. The method can further include retaining the embolization element within the aneurysm via the occlusive device.
[0031] In some embodiments, the tubular structure includes a stent.
[0032] In some embodiments, the tubular structure includes a braid.
[0033] In some embodiments, the method further includes releasing the occlusive device from a pusher member. The occlusive device can be coupled to the pusher member via a hub. Each spiral strut can include a first end region coupled to the hub, and a second end region coupled to the tubular structure. Optionally, the hub includes a detachment element configured to releasably couple to the pusher member.
[0034] In some embodiments, the method further includes introducing a second elongate shaft into the aneurysm, and delivering an embolization element into the aneurysm via the second elongate shaft. Introducing the second elongate shaft can include positioning a distal tip portion of the second elongate shaft between the plurality of spiral struts. The method can also include retaining the embolization element within the aneurysm via the occlusive device.
[0035] Additional features and advantages of the present technology will be set forth in the description below, and in part will be apparent from the description, or may be learned by practice of the present technology. The advantages of the present technology will be realized and attained by the structure particularly pointed out in the written description and claims hereof as well as the appended drawings.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0036] Many aspects of the present disclosure can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.
[0037] FIG. **1**A is a side view of an occlusive device in an expanded configuration, in accordance with embodiments of the present technology.
[0038] FIG. **1**B is a bottom view of the occlusive device of FIG. **1**A.
[0039] FIG. **2**A is a partially schematic side view of an occlusive device being introduced into an aneurysm, in accordance with embodiments of the present technology.
[0040] FIG. **2**B is a partially schematic side view of the occlusive device of FIG. **2**A being deployed in the aneurysm.
[0041] FIG. **2**C is a partially schematic side view of the occlusive device of FIG. **2**B after
[0042] detachment from a pusher member.
[0043] FIG. **2**D is a partially schematic side view of the occlusive device of FIG. **2**C after deployment.
[0044] FIG. **2**E is a partially schematic bottom view of the occlusive device of FIG. **2**D.
[0045] FIG. **2**F is a partially schematic side view of an embolization coil being introduced into the aneurysm, together with the occlusive device of FIG. **2**D.
[0046] FIG. **2**G is a partially schematic side view of the occlusive device and the embolization coil of FIG. **2**F after deployment.
[0047] FIG. **3**A is a side view of an occlusive device with a connector in an expanded configuration, in accordance with embodiments of the present technology.
[0048] FIG. **3**B is a side view of the occlusive device of FIG. **3**A in a low-profile configuration.

[0049] FIG. **4**A is a side view of an occlusive device including a braided tubular structure in an expanded configuration, in accordance with embodiments of the present technology.
[0050] FIG. **4**B is a side view of the occlusive device of FIG. **4**A in a low-profile configuration.

DETAILED DESCRIPTION

[0051] The present technology relates to devices for treating vascular defects such as aneurysms, and associated systems and methods. In some embodiments, for example, an occlusive device for treating an aneurysm includes a tubular structure (e.g., a tubular stent or braid) having a first end portion with a first opening, a second end portion with a second opening, and a mesh surface extending between the first and second end portions. The occlusive device can also include a plurality of spiral struts coupled to the first end portion of the tubular structure and extending over the first opening. When the occlusive device is deployed within the aneurysm, the tubular structure and the plurality of spiral struts can self-expand such that the plurality of spiral struts span a neck of the aneurysm and the mesh surface of the tubular structure engages a wall of the aneurysm near the neck.

[0052] The occlusive devices of the present technology can provide many advantages compared to conventional device for treating an aneurysm. For example, the use of spiral struts enables the occlusive device to expand outward to conform to different neck geometries, while keeping the struts substantially in-plane with the aneurysm neck and/or out of the parent vessel. Accordingly, the occlusive devices disclosed herein can be used to treat a wider range of aneurysm sizes (e.g., aneurysms having a neck diameter from 3 mm to 5 mm) and/or shapes (e.g., aneurysm necks having a non-circular shape, such as oblong or peanut-shaped), as well as challenging aneurysm types such as wide-necked aneurysms (e.g., aneurysms having a neck diameter greater than 4 mm and/or a dome-to-neck ratio less than 2). Additionally, the spiral struts can brace the tubular structure radially outward against the wall of the aneurysm near the neck, thus reducing the likelihood of the device becoming dislodged and/or prolapsing into the parent vessel. Once deployed, the devices herein can be contained partially or entirely within the aneurysm sac with little or no protrusion into the parent vessel, thus reducing the likelihood of clot formation and/or avoiding the need for concomitant DAPT.

[0053] Embodiments of the present disclosure will be described more fully hereinafter with reference to the accompanying drawings in which like numerals represent like elements throughout the several figures, and in which example embodiments are shown. Embodiments of the claims may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. The examples set forth herein are non-limiting examples and are merely examples among other possible examples.

[0054] As used herein, the terms “vertical,” “lateral,” “upper,” and “lower” can refer to relative directions or positions of features of the embodiments disclosed herein in view of the orientation shown in the Figures. For example, “upper” or “uppermost” can refer to a feature positioned closer to the top of a page than another feature. These terms, however, should be construed broadly to include embodiments having other orientations, such as inverted or inclined orientations where top/bottom, over/under, above/below, up/down, and left/right can be interchanged depending on the orientation.

[0055] FIGS. **1**A and **1**B are perspective and bottom views, respectively, of an occlusive device **100** (“device **100**”) for treating an aneurysm, in accordance with embodiments of the present technology. Referring first to FIG. **1**A, the device **100** is configured to be deployed within an aneurysm sac. As described further below, the device **100** can be positioned over the neck of the aneurysm to prevent an embolization element (e.g., a coil) from prolapsing from the aneurysm sac into the parent vessel. The device **100** can also reduce or prevent blood flow from the parent vessel into the aneurysm sac, and/or provide a scaffold for endothelial cell attachment. The growth and development of an endothelial layer over the aneurysm neck can wall off the aneurysm from the parent vessel and allow flow dynamics to equilibrate at the defect. Upon endothelialization, the fluid pressure can be evenly distributed along the parent vessel in a manner that prevents recanalization at the defect post-treatment. Moreover, blood from within the parent vessel no longer has access to the walled-off defect once the endothelialization process is complete. Accordingly, the device **100** can facilitate healing of the defect and/or prevent recanalization.

[0056] The device **100** includes a tubular structure **102** coupled to a plurality of curved struts **104**. The tubular structure **102** is configured to anchor the device **100** at or near the neck of the aneurysm, while the curved struts **104** are configured to retain an embolization element within the device **100**, as described in further detail below. The tubular structure **102** includes a proximal end portion **106**, a distal end portion **108**, and a mesh surface **110** extending between the proximal end portion **106** and distal end portion **108**. In some embodiments, the proximal end portion **106** and distal end portion **108** each have a respective opening, such that the tubular structure **102** includes a lumen extending between the proximal end portion **106** and distal end portion **108**, and surrounded by the mesh surface **110**. The length L of the tubular structure **102** (e.g., as measured from the proximal end portion **106** to the distal end portion **108** when the device **100** is fully expanded) can be no more than 4 mm, 3.5 mm, 3 mm, 2.5 mm, 2 mm, 1.5 mm, or 1 mm. The width W or diameter of the tubular structure **102** (e.g., as measured when the device **100** is fully expanded) can be at least 5 mm, 4.5 mm, 4 mm, 3.5 mm, 3 mm, 2.5 mm, 2 mm, 1.5 mm, or 1 mm. Although FIG. **1**B depicts the tubular structure **102** as having a circular cross-sectional shape, in other embodiments, the tubular structure **102** can have a different shape (e.g., oval, triangular, square, pentagonal, hexagonal, heptagonal, octagonal).

[0057] In the embodiment of FIGS. **1**A and **1**B, the tubular structure **102** is a stent or stent-type structure, with the mesh surface **110** including a plurality of elongate members **112** (e.g., struts) that are interconnected to form cells **114**. The geometry of the cells **114** and elongate members **114** can be configured in many different ways. In the illustrated embodiment, for example, the cells **114** are six-sided (e.g., hexagonal) closed cells. The distal apices **115** of the cells **114** can be rounded to reduce the likelihood of tissue perforation when deploying the device **100** in the aneurysm. In other embodiments, however, some or all of the cells **114** can have a different number of sides (e.g., three, four, five, or more), shape (e.g., triangular, square, rectangular, diamond, trapezoidal, parallelogram, pentagonal), be open rather than closed, have sharp distal apices **115** rather than rounded distal apices **115**, and/or any other suitable configuration. Additionally, although the tubular structure **102** in FIG. **1**A includes a single circumferential ring of cells **114**, in other embodiments, the tubular structure **102** can include multiple circumferential rings of cells **114** arranged longitudinally between the proximal end portion **106** and the distal end portion **108**. Moreover, although the elongate members **112** are shown as being linear, in other embodiments, some or all of the elongate members **112** can be curved (e.g., sinusoidal, serpentine), curvilinear, or any other suitable geometry. The size (e.g., length, width, height, perimeter, cell area) of the cells **114** can also be varied as desired.

[0058] The curved struts **104** are connected to the proximal end portion **106** of the tubular structure **102**. As best seen in FIG. **1**B, the curved struts **104** are disposed over the opening of the proximal end portion **106** of the tubular structure **102** in a spiral and/or helical configuration. Accordingly, the curved struts **104** may also be referred to interchangeably herein as “spiral struts” or “helical struts.” The curvature of the curved struts **104** can be oriented in the same direction, such as in a clockwise direction or a counterclockwise direction, to form the spiral and/or helical configuration.

[0059] In some embodiments, each curved strut **104** includes a first end region **116** (e.g., a proximal end region) coupled to a hub **120** and a second end region **118** (e.g., a distal end region) coupled to the proximal end portion **106** of the tubular structure **102**. The second end region **118** of each curved strut **104** can be coupled to a proximal apex **119** of a respective cell **114** of the tubular structure **102**. In other embodiments, however, the second end region **118** can be coupled to a different portion of the cell **114**, such as to a lateral edge of the cell **114**. The hub **120** can be generally aligned with the center of the opening of the proximal end portion **106**, and the second end regions **118** of the curved struts **104** can be spaced apart along the peripheral edge of the proximal end portion **106**, such the separation distance between the curved struts **104** increases as the curved struts **104** radiate outward from the hub **120**. The spacing between the curved struts **104** can be sufficiently large to permit an embolization element delivery device (e.g., a microcatheter or other elongate shaft) to pass through, but sufficiently small such that the embolization element does not prolapse into the parent vessel. In some embodiments, the average and/or maximum distance between neighboring curved struts **104** is no more than 2.5 mm, 2.25 mm, 2 mm, 1.75 mm, 1.5 mm, 1.25 mm, 1 mm, 0.75 mm, or 0.5 mm.

[0060] The configuration of the curved struts **104** can be varied in many different ways. For example, although FIG. **1**B depicts the device **100** as including six curved struts **104**, in other embodiments, the device **100** can include a different number of curved struts **104** (e.g., two, three, four, five, seven, eight, nine, ten, 20, or more). As another example, although each curved strut **104** is shown as having the same geometry (e.g., length, width, thickness, curvature), in other embodiments, some or all of the curved struts **104** can have different geometries. In a further example, although FIG. **1**B depicts the curved struts **104** as being evenly spaced, in other embodiments the spacing can be varied as desired (e.g., the struts **104** can be clustered into one or more groups that are separated by larger gaps).

[0061] Referring to FIGS. **1**A and **1**B together, when the device **100** is deployed within the aneurysm, the tubular structure **102** is configured to self-expand such that the mesh surface **110** engages the inner wall of the aneurysm sac and applies a radially outward bracing force to anchor the device **100** at the desired location. The curved struts **104** also self-expand together with the tubular structure **102** to bridge the aneurysm neck. Optionally, the expansion of the curved struts **104** can also exert forces in a radially outward direction to further enhance engagement of the tubular structure **102** with the aneurysm wall. In yet another option, the expansion of the curved struts **104** is at least partially caused by the expansion of the tubular structure **102**. In some embodiments, the spiral and/or helical configuration of the curved struts **104** enables the curved struts **104** to expand to a wider range of neck diameters while lying substantially within a single plane. Stated differently, the height H (FIG. **1**A) of each curved strut **104** in its expanded configuration (e.g., as measured vertically from the first end region **116** to the second end region **118**) can be no more than 25%, 20%, 15%, 10%, 5%, 2%, 1%, or 0.1% of the width W of the tubular structure **102**. For example, the height H in the expanded configuration can be no more than 1.25 mm, 1 mm, 0.5 mm, 0.25 mm, or 0.1 mm. Accordingly, when deployed, the curved struts **104** can be contained partially or entirely within the aneurysm sac with little or no protrusion into the parent vessel, even if the device **100** is not fully expanded to its maximum diameter. In contrast, other strut designs (e.g., straight struts) may not be substantially planar if the device is not fully expanded, and thus may extend significantly out of the aneurysm and into the parent vessel after deployment.

[0062] In the illustrated embodiment, the hub **120** is a collar, band, ring, etc., that crimps or otherwise holds the first end regions **116** of the curved struts **104** together. Alternatively, the hub **120** can simply be the location where the first end regions **116** are connected to each other (e.g., via welding, bonding, adhesives), rather than a separate component. As best seen in FIG. **1**A, the hub **120** can be coupled to a detachment element **122** configured to releasably couple to a pusher member (not shown). The pusher member can be an elongate rod, shaft, wire, etc., that is configured to push the device **100** through a distal end of a delivery catheter to deploy the device **100** within the aneurysm, as described further below. Optionally, the pusher member can also be used to pull the device **100** partially or fully back into the delivery catheter, e.g., for repositioning purposes. The detachment element **122** can utilize any suitable detachment technique known to those of skill in the art, such as electrolytic detachment, mechanical detachment, thermal detachment, electromagnetic detachment, or combinations thereof. An example of a detachment element for suitable use with the present technology is the Axium™ or Axium™ Prime Detachable

Coil System (Medtronic).

[0063] Optionally, the device **100** can include one or more radiopaque portions so the physician can visualize the location and configuration of the device **100** during deployment in the aneurysm. For example, radiopaque markers (not shown) can be incorporated into the device **100** at or near the distal apices **115**, at or near the proximal apices **119**, at or near the intersections of adjacent cells **114**, at or near the second end regions **118** of the curved struts **104**, at or near the first end regions **116** of the curved struts **104**, and/or on or within the hub **120**.

[0064] The device **100** can be manufactured in many different ways. For example, the tubular structure **102** and/or curved struts **104** can be formed by laser-cutting of a tube or sheet, etching, metal injection molding, braiding, or any other suitable manufacturing process. In some embodiments, the tubular structure **102** and curved struts **104** are integrally formed as a single unitary component. In other embodiments, the tubular structure **102** and curved struts **104** can be discrete components that are attached to each other, e.g., using welding, adhesives, fasteners, or other suitable techniques. The tubular structure **102** and/or curved struts **104** can be formed of known flexible materials, including shape memory and/or superelastic materials (e.g., Nitinol), cobalt chromium, platinum, stainless steel, other metals or metal alloys, or a combination thereof. Optionally, portions of the tubular structure **102** and/or curved struts **104**, or the entirety of the tubular structure **102** and/or curved struts **104**, can include one or more coatings or surface treatments, such as coatings or treatments to increase lubricity and/or reduce the delivery force as the device **100** is advanced through the delivery catheter, increase hydrophilicity, and/or enhance blood compatibility and reduce thrombogenic surface activity. For example, an anti-thrombogenic coating or treatment can be applied to the curved struts **104**, hub **120**, and/or detachment element **122**.

[0065] In some embodiments, the device **100** is configured to transform between a first, low-profile configuration suitable for delivery via an elongate shaft (e.g., a delivery catheter) and a second, expanded configuration suitable for bridging the neck of an aneurysm (e.g., the configuration illustrated in FIGS. **1**A and **1**B). In such embodiments, the tubular structure **102** and/or curved struts **104** can be shape set (e.g., heat set) in the expanded configuration, such that the device **100** self-expands into the expanded configuration when deployed into the aneurysm. For example, the tubular structure **102** and curved struts **104** can both be shape set into a fully expanded configuration in which the tubular structure **102** is opened to its maximum width and/or diameter, and/or the distance spanned by the curved struts **104** is substantially equal to the maximum width and/or diameter of the tubular structure **102**. In such embodiments, the self- expansion of the curved struts **104** can actively push the tubular structure **102** radially outward to further enhance engagement with the aneurysm wall. Alternatively, the tubular structure **102** can be shape set in the fully expanded configuration, while the curved struts **104** are shape set into a partially expanded configuration in which the distance spanned by the curved struts **104** is less than the maximum width and/or diameter of the tubular structure **102**. In such embodiments, the curved struts **104** can be "passive" elements that are pulled open by the self-expansion of the tubular structure **102**.

[0066] FIGS. **2**A-**2**G illustrate a method of treating an aneurysm with an occlusive device, in accordance with embodiments of the present technology. Although the illustrated embodiment is shown and described in terms of the device **100** of FIGS. **1**A and **1**B, the method can be applied to any embodiment of the occlusive devices described herein (e.g., the devices **300**, **400** of FIGS. **3**A-**4**B).

[0067] Referring first to FIG. **2**A, the device **100** can be loaded within a first elongate shaft **202** (e.g., a delivery catheter such as a microcatheter) in a low-profile configuration. When in the low-profile configuration, the tubular structure **102** and curved struts **104** of the device **100** can be compressed, flattened, or otherwise compacted in a generally linear configuration to conform to the interior lumen of the first elongate shaft **202**. In the illustrated embodiment, for example, the curved struts **104** are constrained in a generally straightened state and extend proximally away from the tubular structure **102**. The distance between the most proximal portion of the curved struts **104** and the most proximal portion of the tubular structure **102** can be at least 1 mm, 2 mm, 3 mm, 4 mm, or 5 mm. The device **100** can then be intravascularly delivered to a location within a blood vessel V adjacent a target aneurysm A via the first elongate shaft **202**. As shown in FIG. **2**A, a distal tip **204** of the first elongate shaft **202** can be advanced through the neck N of the aneurysm A and into an interior cavity of the aneurysm A.

[0068] Referring next to FIG. **2**B, the device **100** can then be deployed by pushing the device **100** distally through the opening in the distal tip **204** of the first elongate shaft **202** and into the aneurysm cavity, e.g., using a pusher member **206** coupled to the detachment element **122** and/or hub **120**. As the tubular structure **102** and curved struts **104** of the device **100** exit the first elongate shaft **202**, these components can self-expand from the low-profile configuration into the expanded configuration.

[0069] Referring next to FIG. **2**C, once the device **100** is deployed, the detachment element **122** and/or hub **120** can be detached from the pusher member **206**. The pusher member **206** and first elongate shaft **202** can then be withdrawn from the aneurysm A.

[0070] Referring next to FIG. **2**D, when the device **100** is deployed, the curved struts **104** are arranged in a spiral and/or helical configuration bridging the aneurysm neck N, while the tubular structure **102** engages the inner wall of the aneurysm A at or near the neck N. The tubular structure **102** and curved struts **104** can collectively generate a bracing force directly radially outward against the aneurysm wall that prevents the device **100** from being displaced out of the aneurysm A and into the vessel V. As previously described, when in the expanded configuration, the curved struts **104** can lie substantially within a single plane (e.g., the plane of the aneurysm neck N), such that there is little or no protrusion of the curved struts **104** into the vessel V. For example, when expanded, the distance between the most proximal portion of the curved struts **104** and the most proximal portion of the tubular structure **102** can be smaller than the initial distance in the low-profile configuration, such as no more than 1 mm, 0.5 mm, 0.25 mm, or 0.1 mm. This approach can be advantageous for reducing disruptions to blood flow in the vessel V, which may lead to thrombus formation. As best seen in FIG. **2**E (showing a bottom view of FIG. **2**D), the curved struts **104** can only partially occlude the aneurysm neck N, thus leaving one or more gaps **208** providing a passageway from the vessel V into the aneurysm A.

[0071] Referring next to FIG. **2**F, a second elongate shaft **210** (e.g., a second delivery catheter, such as a microcatheter) can subsequently be used to introduce an embolization coil **212**, or a plurality of embolization coils, or other embolization element into the aneurysm A. The second elongate shaft **210** can be advanced through one of the gaps **208** (FIG. **2**E) between the curved struts **104** and into the interior of the aneurysm A. The coil **212** can then be deployed out of the distal opening of the second elongate shaft **210** and into the aneurysm A. In other embodiments, however, the first elongate shaft **202** can be used to introduce both the device **100** and the coil **212** into the aneurysm A.

[0072] Referring next to FIG. **2**G, once fully deployed, the coil(s) **212** can fill most or substantially all of the space within the aneurysm A. The coil **212** can be formed of one or more wires wound in a helical fashion about an axis to form an elongate tubular member. The wire(s) forming the coil **212** can be circular, square, or rectangular in cross-section, and can have a cross-sectional dimension (e.g., width, radius) from 0.001 inches to 0.003 inches, or from 0.0015 inches to 0.0025 inches. In some embodiments, the wire(s) forming the coil **212** have a cross-sectional dimension no greater than 0.003 inches, 0.0025 inches, or 0.002 inches. The coil **212** can be circular, square, or rectangular in cross-section, and can have a cross-sectional dimension (e.g., width, radius) from 0.01 inches to 0.02 inches, from 0.012 inches to 0.018 inches, or from 0.014 inches to 0.016 inches. In some embodiments, the coil **212** has a cross-sectional dimension that is no greater than 0.0145 inches or 0.0140 inches.

[0073] The coil **212** can have a length from 2 cm to 30 cm, from 3 cm to 25 cm, or from 4 cm to 20 cm. In some embodiments, the length of the coil **212** depends on the size of the aneurysm being treated. For example: for an aneurysm 4 mm in diameter or less, the coil **212** can have a length of about 6 cm; for an aneurysm 5 mm in diameter or less, the coil **212** can have a length of about 8 cm; for an aneurysm 6 mm in diameter or less, the coil **212** can have a length of about 15 cm; for an aneurysm 7 mm in diameter or less, the coil **212** can have a length of about 15 cm; for an aneurysm 8 mm in diameter or less, the coil **212** can have a length of about 20 cm; and, for an aneurysm 9 mm in diameter or less, the coil **212** can have a length of about 20 cm.

[0074] The coil **212** can be made from metals, alloys, polymers, shape memory materials (e.g., Nitinol), platinum, rhodium, palladium, tungsten, gold, silver, cobalt-chromium, platinum tungsten, and/or various alloys of these materials. In some embodiments, the coil **212** is heat set to form a tertiary structure (e.g., a pre-determined three-dimensional structure) when in a deployed state. For example, the coil **212** can have a preset tertiary structure that biases the coil into a bundled or more globular state that facilitates positioning of the coil **212** between the deployed device **100** and the aneurysm wall. In other embodiments, however, the coil **212** may not have a tertiary structure.

[0075] As previously mentioned, embolic coils such as the coil **212** can be very effective at filling space within the aneurysm cavity. However, there is a risk that the coil **212** may prolapse through the neck N of the aneurysm A into the vessel V, particularly if the aneurysm A is a wide-necked aneurysm. The device **100** can address this challenge via the curved struts **104** that are positioned over the aneurysm neck N to support the coil **212** and prevent the coil **212** from protruding into the neck, while the tubular structure **102** braces against the aneurysm wall to resist the outward pressure toward the vessel V exerted by the packed coil **212** so the device **100** does not bulge into the vessel V.

[0076] The methods of the present technology can be performed under fluoroscopy such that the radiopaque portions of the device **100** can be visualized by the physician to ensure proper neck coverage. If the device **100** is not positioned properly, the physician can withdraw the device **100** into the first elongate shaft **202**, reposition, and deploy again. Additionally, in embodiments where the coil **212** is radiopaque, the physician can use fluoroscopy to confirm that the coil **212** does not protrude from the neck N of the aneurysm A after deployment.

[0077] FIGS. **3**A-**4**B illustrate additional examples of occlusive devices **300**, **400** for treating an aneurysm, in accordance with embodiments of the present technology. The devices **300**, **400** of FIGS. **3**A-**4**B can be generally similar to the device **100** of FIGS. **1**A and **1**B. Accordingly, like numbers (e.g., curved strut **104** versus curved strut **304**) are used to identify similar or identical structures, and discussion of the devices **300**, **400** of FIGS. **3**A-**4**B will be limited to those features that differ from the device **100** of FIGS. **1**A and **1**B. Additionally, any of the features of the devices **100**, **300**, and **400** can be combined with each other.

[0078] Referring to FIG. **3**A, the device **300** is generally similar to the device **100** of FIGS. **1**A and **1**B, except that the device **300** includes a connector **324** (e.g., a filament, wire, shaft, strut, or other elongate member) coupling the hub **320** to the detachment element **322**. The connector **324** can have any suitable length, such as a length of at least 1 mm, 2 mm, 3 mm, 4 mm, 5 mm, 10 mm, or more. The connector **324** can be made of a flexible material having shape memory and/or superelastic properties (e.g., Nitinol), such that the connector **324** can be shape set to transform from a first (e.g., constrained) state for delivery to a second (e.g., unconstrained) state for deployment in an aneurysm.

[0079] FIG. **3**B illustrates the device **300** in a low-profile configuration within the first elongate shaft **202**. In the illustrated embodiment, when the device **300** is in the low-profile configuration, the connector **324** is in the first state and has a generally straightened shape that extends proximally away from the tubular structure **302** and curved struts **304**. Accordingly, the detachment element **322** is accessible by and can be coupled to the pusher member **206**.

[0080] Referring again to FIG. **3**A, when the device **300** is deployed from the first elongate shaft **202** and separated from the pusher member **206** (e.g., in accordance with the techniques described above with respect to FIGS. **2**A-**2**G), the connector **324** is no longer constrained and thus transforms to the second state. In the second state, the connector **324** can be bent and/or curved (e.g., coiled) in a distal direction such that at least a portion of the connector **324** and the detachment element **322** pass through the gaps between the curved struts **304** and are disposed within the lumen of the tubular structure **302** distal to the proximal end portion **306** of the tubular structure **302**. Accordingly, when the device **300** is deployed in the aneurysm, the connector **324** and detachment element **322** can be contained partially or entirely within the aneurysm sac, thus avoiding disruptions to blood flow in the parent vessel.

[0081] Referring next to FIG. **4**A, the device **400** is generally similar to the device **100** of FIGS. **1**A and **1**B, except that the tubular structure **402** is a braid formed from a plurality of filaments **426** (e.g., wires). The filaments **426** are braided, woven, or otherwise interconnected to form the mesh surface **410** of the tubular structure **402**. The braid can be self-expandable such that the device **400** can transform from a low-profile configuration (FIG. **4**B) in which the braid is radially constrained and/or compressed, to an expanded configuration (FIG. **4**A) in which the braid is expanded radially outward to engage the aneurysm wall.

[0082] In some embodiments, some or all of the filaments **426** (e.g., at least 25%, 50%, 80%, or 100% of the filaments **426**) are made of one or more shape memory and/or superelastic materials (e.g., Nitinol). The braid can have, for example, from 32 to 144 filaments **426**, such as 64 or 72 filaments **426**. Some or all of the filaments **426** can have a diameter from 0.0010 inches to 0.0012 inches, such as a diameter of 0.0010 inches, 0.0011 inches, or 0.0012 inches (at least prior to etching). In some embodiments, some or all of the filaments **426** are drawn-filled tubes ("DFT") having a radiopaque core (e.g., platinum) surrounded by a shape memory alloy and/or superelastic alloy (e.g., Nitinol, cobalt chromium, etc.). Radiopaque markers can alternatively or additionally be incorporated into other portions of the device **400**, e.g., at or near the distal end portion **408**, proximal end portion **406**, curved struts **404**, hub **420**, etc. All or a portion of the length of some or all of the filaments **426** can have one or more coatings or surface treatments. For example, some or all of the filaments **426** can have a lubricious coating or treatment that reduces the delivery force as the device **400** is advanced through the delivery catheter. In some embodiments, the coating is relatively hydrophilic, such as a phosphorocholine compound. Additionally or alternatively, some or all of the filaments **426** can have a coating or treatment (the same as the lubricious coating, or a different coating) that enhances blood compatibility and reduces the thrombogenic surface activity of the braid. Optionally, at least a portion of the filaments **426** can be made of other suitable materials.

[0083] In some embodiments, the tubular structure **402** and curved struts **404** are integrally formed as a single unitary component. For example, the curved struts **404** can be formed from the same filaments **426** used to form the braid of the tubular structure **402**. In such embodiments, each curved strut **404** can be made from one or more filaments **426** that are bundled, twisted, braided, or otherwise assembled into a single elongate component. Alternatively, the tubular structure **402** and curved struts **404** can be discrete components that are attached to each other, e.g., using welding, adhesives, fasteners, or other suitable techniques. In such embodiments, the curved struts **404** can be formed of known flexible materials, including shape memory and/or superelastic materials (e.g., Nitinol), cobalt chromium, platinum, stainless steel, other metals or metal alloys, or a combination thereof, and can be manufactured by laser-cutting, etching, metal injection molding, braiding, etc.

CONCLUSION

[0084] Although many of the embodiments are described above with respect to systems, devices, and methods for treating a cerebral aneurysm, the technology is applicable to other applications and/or other approaches. For example, the occlusive devices, systems, and methods of the present technology can be used to treat any vascular defect and/or fill or partially fill any body cavity or lumen or walls thereof, such as for parent vessel take down, endovascular aneurysms outside of the brain, arterial-venous malformations, embolization, atrial and ventricular septal defects, patent

ductus arteriosus, and patent foramen ovale. Additionally, several other embodiments of the technology can have different states, components, or procedures than those described herein. It will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described above with reference to FIGS. **1**A-**4**B.
[0085] The descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Where the context permits, singular or plural terms may also include the plural or singular term, respectively. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology, as those skilled in the relevant art will recognize. For example, while steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.
[0086] As used herein, the terms “generally,” “substantially,” “about,” and similar terms are used as terms of approximation and not as terms of degree, and are intended to account for the inherent variations in measured or calculated values that would be recognized by those of ordinary skill in the art.
[0087] Moreover, unless the word “or” is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of “or” in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. As used herein, the phrase “and/or” as in “A and/or B” refers to A alone, B alone, and A and B. Additionally, the term “comprising” is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded.
[0088] It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with certain embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

Claims

1-51. (canceled)
52. An occlusive device for treating an aneurysm, the occlusive device comprising: a tubular structure having a first end portion and a second end portion opposite the first end portion; a plurality of curved struts coupled to the first end portion of the tubular structure, each curved strut including a first end region and a second end region; and a hub, wherein the plurality of curved struts are arranged in a spiral configuration with the first end region of each curved strut coupled to the hub, and the second end region of each curved strut coupled to the first end portion of the tubular structure.
53. The occlusive device of claim 52, wherein the tubular structure comprises a stent.
54. The occlusive device of claim 52, wherein the tubular structure comprises a braid.
55. The occlusive device of claim 52, wherein the second end region of each curved strut is coupled to a peripheral edge of the tubular structure.
56. The occlusive device of claim 55, wherein the second end region of each curved strut is spaced

apart along the peripheral edge of the tubular structure.
57. The occlusive device of claim 52, wherein the first end portion of the tubular structure includes a first opening, and the plurality of curved struts are disposed over the first opening.
58. The occlusive device of claim 52, wherein the tubular structure and plurality of curved struts are configured to self-expand when deployed within the aneurysm.
59. The occlusive device of claim 52, wherein, when deployed within the aneurysm, the plurality of curved struts are disposed across a neck of the aneurysm and the tubular structure engages a wall of aneurysm near the neck.
60. The occlusive device of claim 52, wherein, when deployed within the aneurysm, the plurality of curved struts lie substantially within a single plane.
61. The occlusive device of claim 52, further comprising a detachment element configured to releasably couple the tubular structure and the plurality of curved struts to a pusher member.
62. The occlusive device of claim 61, wherein the detachment element is coupled to the plurality of curved struts via the hub.
63. The occlusive device of claim 61, further comprising an elongate member connecting the detachment element to the hub, wherein the elongate member is configured to transform from a first state to a second state when the occlusive device is deployed within the aneurysm.
64. The occlusive device of claim 61, wherein the detachment element utilizes a mechanical detachment technique.
65. The occlusive device of claim 61, wherein the detachment element utilizes one or more of an electrolytic detachment technique, a thermal detachment technique, or an electromagnetic detachment technique.
66. The occlusive device of claim 52, wherein one or both of the tubular structure and curved struts are formed at least in part by laser-cutting or etching a tube or sheet.
67. The occlusive device of claim 52, wherein the tubular structure and the curved struts are integrally formed as a single unitary component.
68. The occlusive device of claim 52, wherein the tubular structure and the curved struts are formed as discrete components, and the curved struts are attached to the tubular structure.
69. The occlusive device of claim 52, wherein the occlusive device comprises at least one radiopaque portion.
70. The occlusive device of claim 52, wherein at least one of the tubular structure or the curved struts includes an anti-thrombogenic coating or surface treatment.
71. The occlusive device of claim 52, wherein the occlusive device is configured to be loaded in a low-profile configuration in a delivery catheter.