

dimensional ball-like structure of the first and second portions of the tubular mesh; and (4) swaging the free end of the tubular mesh with a third fastener to form an exterior 3-dimensional ball-like structure having a second diameter portion, within which the 3-dimensional ball-like structure of first diameter portion is disposed.

[0020] The mesh is removably is secured to at least one or more bases of the frame, and positioned between the arms thereof. In a preferred embodiment, the bases of the frame and the fasteners which secure the tubular mesh are collars, having central lumens. The aforementioned third-fastener is insertable into the lumen of at least one of the bases of the frame in order to secure the mesh to the frame. The lumens of the fasteners and bases are aligned along a common axis in order that a the embolic filtering device can be loaded onto a guide wire.

[0021] In an exemplary embodiment, the frame, preferably composed of metal, fabric and/or a polymer, includes at least one base and at least two arms which extend therefrom, between which the mesh is at least partially disposed. The arms are positioned opposite one another and, in their resting state, are spaced apart from one another. When, as in a preferred embodiment, the device is composed of a shape memory metal, such as nitinol, the device can be collapsed into a catheter tube by compressing the arms of the frame toward one another, causing the length of the device to increase, and the width to decrease. As the device is released from the catheter tube, it reverts to its functional, relaxed state. The embolic filtering device may also be composed of non-shape memory metals, such as elgiloy, cobalt chromium, and stainless steel, for example. Each arm includes at least one anchor positioned on the arms of the frames. The anchors can either be arcuate or linear in formation, depending on the shape of the patent foramen ovale to be treated, and are of sufficient rigidity to secure the device within the lumen of a septal defect.

[0022] To allow for non-invasive visualization of the device within a subject at least a portion of the frame or mesh is composed of or coated with a radiopaque material, such as tantalum. The device may also be treated with thrombin, collagen, hyaluron, or a host growth factor to encourage and facilitate growth of tissue onto the device so as to further secure the device within the septal defect. The device can also be coated with an anticoagulant to deter formation of blood clots on the surface of the device.

[0023] In an exemplary embodiment, the mesh is composed of at least 96 strands of 0.002" diameter wire braided such that the wires are situated at an angle of 35° relative to the longitudinal axis of the device. The interstices created by the braided wires are small enough such as to effectively filter emboli, thereby preventing emboli from passing through the patent foramen ovale, or other septal defect.

[0024] In another aspect of the invention, provided is a method of preventing the passage of emboli between a venous blood pool and an arterial blood pool by delivering the embolic filtering device to within, proximate to and/or adjacent to a passage between a venous blood pool and an arterial blood pool; and securing the device within, proximate to, and/or adjacent to said passage. The delivery of the device is preferably delivered by means of a catheter to within and/or adjacent to the passage between the venous blood pool and the arterial blood pool.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] FIG. 1 is a schematic diagram of the fetal circulation;

[0026] FIG. 2A illustrates a preferred embolic filtering device;

[0027] FIG. 2B illustrates another preferred embolic filtering device;

[0028] FIG. 2C illustrates a top view of the embolic filtering device illustrated in FIG. 2B;

[0029] FIG. 2D illustrates a preferred frame of the embolic filtering having two bases;

[0030] FIG. 3 illustrates another preferred embolic filtering device with a frame having one base;

[0031] FIG. 4 illustrates a preferred embolic filtering device and delivery mechanism;

[0032] FIG. 5A illustrates another preferred embolic filtering device;

[0033] FIG. 5B and 5C illustrate a preferred embolic filtering device within a patent foramen ovale;

[0034] FIGS. 6A and 6B illustrate another preferred embolic filter device; and

[0035] FIGS. 7A and 7B illustrated another preferred embolic filter device.

DETAILED DESCRIPTION OF THE INVENTION

[0036] The present invention is directed generally to methods and apparatus for preventing the passage of emboli between a venous blood pool and an arterial blood pools using devices for creating a barrier to the conducting of emboli at a passage between a venous blood pool and an arterial blood pool. The device is particularly suitable for treating cardiac defects, such as patent foramen ovale or other atrium septal defects. In a preferred embodiment, exemplified at FIG. 2A, provided is a embolic filtering device 10 comprising a frame 12 and an embolic filter 14 comprising a mesh of stranded fabric, wire, or polymer. FIG. 2D illustrates one embodiment of frame 12 without embolic filter 14 attached. In this embodiment, frame 12 consists of a first base 16 and a second base 18. Each end of arms 20 and 22 are connected to first base 16 and second base 18, such that the lumens of first base 16 and second base 18 are in line with longitudinal axis 24 of frame 12. Arms 20 and 22 are preferably formed of a shape memory metal, e.g., nitinol, and formed such that, in the resting state, they are spaced apart from one another.

[0037] Referring to FIG. 2A, extending laterally from each of arms 20 and 22 proximate to first base 16 are right anchors 24. Right anchors 24 can be of any shape or formation suitable for delivering embolic filtering device 10 to the desired location and securing it in place. In a preferred embodiment, right anchors 24 are preferably linear or arcuate, and extend outward from frame 12 and away from first base 16, in the direction of second base 18, at an acute angle relative to longitudinal axis 25. The desired length of right anchors 24 and the position from which they extend from arms 20 and 22 will depend primarily on the size of the passage or defect to be treated. In any event, the right