electrical energy may have a tendency to flow from the active electrode through intervening tissue and to the passive electrode. In this way, the electrode pair may help prevent energy loss to surrounding tissue.

[0039] In some instances one or more electrodes may be connected to an electrosurgical generator, power supply, or other waveform generator that is configured to generate an alternating current. In some of these variations, two or more electrodes may be connected to the bipolar outputs of a generator. In other variations, one or more electrodes may be connected to a monopolar output of a generator. In some of these variations, a first electrode is attached to the active output of the generator, and a return electrode (e.g., a large metal plate or flexible metalized pad) may be temporarily attached or affixed to the patient and connected to the return output of the generator. In others of these variations, two or more electrodes may be attached to an active output of the generator, and a return electrode may be temporarily attached or affixed to the patient and connected to the return output of the generator. In still other variations, a first electrode may be attached to the active output of the generator, and a second electrode may be attached to the return output of the generator in a "focus monopolar" configuration.

[0040] Generally, at least a portion of each electrode may be exposed to the surrounding environment (e.g., through one or more apertures or openings in the catheter body). This exposed surface may be configured to contact surrounding tissue (e.g., a blood vessel wall) or fluids, and may act as an ablation surface such that current may be supplied to and/or carried from tissue via the ablation surface to facilitate ablation or vaporization of tissue. In some variations, the ablation surface may be temporarily covered (e.g., by a sheath or tubing) such that the ablation surface does not contact tissue. In these instances, the temporary covering may be moved or removed to expose the ablation surface to the surrounding environment. In other variations, the ablation surface may be temporarily recessed or held within the catheter, and in some of these instances may be advanced out of the catheter to contact tissue. The ablation surface need not be movable, and may instead be fixed relative to the catheter. Additionally or alternatively, in some variations an exposed electrode surface may comprise a porous coating that allows conduction of current thereto or therefrom while preventing direct contact between two electrodes, as will be described in more detail below. The electrodes may be made from any suitable material or combination of materials. In some variations the electrode may comprise one or more refractory metals. For example, an electrode may comprise tungsten, molybdenum, niobium, tantalum, rhenium, combinations or alloys thereof.

[0041] The electrode ablation surface may have any shape or size suitable for ablating tissue. For example, the ablation surface may be oval-shaped, circular, rectangular, triangular,

pentagonal, hexagonal, polygonal, irregularly shaped, or the like. Alternatively or additionally, the ablation surface may be roughened or otherwise patterned, as will be described in more detail below. In variations where the ablation surface is exposed through one or more apertures or openings in the catheter body, these apertures or openings may at least partially define the size and shape of the ablation surface. In variations where the catheter comprises a nesting material, as will be described in more detail below, the nesting material may at least partially define the size and shape of the ablation surface. The size and shape of the ablation surface may help determine the size and shape of the resulting fistula. The ablation surface may have any suitable length (e.g., about 0.0625 in, about 0.1875 in, between about 0.05 in and about 0.2 in, between about 0.05 in and about 0.075 in, between about 0.15 in and about 0.2 in, and the like) and any suitable width (e.g., about 0.0313 in., about 0.0625 in, between about 0.025 in and about 0.075 in, between about 0.025 and about 0.05 in, between about 0.05 and about 0.075 in, and the like). In variations where the ablation surface is circular, cylindrical, or semi-spherical, the ablation surface may have any suitable radius (e.g., about 0.03 in, about 0.04 in, about 0.05 in, and the like). In variations where a portion of the electrode extends out of a portion of the catheter, as will be described in more detail below, the ablation surface may have any suitable height (e.g., about .25 mm, about .5 mm, about .75 mm, about 1 mm, between about .1 and about 1.5 mm, between about .25 and about 1 mm, between about .25 and about .75 mm, greater than about 1.5 mm, or the like).

[0042] When two or more electrodes are used in conjunction to form a fistula, the two or more electrodes may have different sizes. For examples, in some variations, a first electrode having a larger ablation surface (e.g., a rectangular ablation surface of about 0.2 inches by about 0.05 inches) may be placed in an artery, and a second electrode having a smaller ablation surface (e.g., a rectangular ablation surface of about 0.1 inches by about 0.05 inches) may be placed in a vein. In these variations, when an RF signal (e.g., a sinusoidal waveform, or the like) of a certain power (e.g., 40 W) is applied to the electrodes to form a fistula between the artery and the vein, the second electrode may have a larger current density than the first electrode by virtue of its smaller ablation surface. This may cause the formation of the fistula to begin in the vein, and propagate through the artery. Directional formation of fistula may help prevent extravasation (e.g., blood loss to surrounding tissue) in instances where a fistula is not fully formed between an artery and a vein (as partial fistula formation beginning in an artery may have a greater risk of extravasation than partial fistula formation beginning an a vein).

[0043] In some variations, the ablation surface may be flush with an outer surface of the catheter body. FIG. 2 illustrates one such variation of catheter (200) comprising an electrode body (202) having ablation surface (205). Also shown there are lead wire (204), proximal

[0098] A catheter may comprise any number of individual magnets (e.g., zero, one, two, three, four, five, six, seven, or eight or more, etc.). Each magnetic component may be any suitable magnet or magnetic material. For example, in some variations, a catheter may comprise one or more rare-earth magnets (e.g., neodymium magnets or samarium-cobalt magnets) and/or one or more selectively-activated electromagnets. In variations where a catheter comprises a plurality of magnets, these magnets may be grouped into one or more arrays. These magnetic arrays may located inside or outside of a catheter (or a combination thereof), and may be positioned anywhere along the length of the catheter. When two or more catheters comprise magnets or magnet arrays, each magnet or magnet array may be configured or arranged to align with one or more magnets or magnet arrays from a second catheter. Each magnet may be fixed in or on a catheter by any suitable method. For example, in some variations one or more magnets may be embedded in, adhered to or friction fit within a catheter. Each magnet may have any suitable diameter (e.g., about 0.075 in., about 0.080 in., about 0.029 inch, about 0.110 inch, or the like) or length (e.g., about 5 mm, about 10 mm, about 15 mm, about 20 mm, or the like), and may be separated from adjoining magnets by any suitable distance (e.g., about 1 mm, about 5 mm, and the like). In some variations, the magnets of an array may have alternating polarity (e.g., each magnet will have the opposite polarity as any adjacent magnets), matching polarity, or combinations thereof. In other variations, one or more portions of the catheter may be made from a magnetic material, and/or may be embedded with one or more magnetic particles/materials.

[0099] Each magnet may have any suitable shape for placement inside or outside of the catheter. Magnets may be cylindrical, semi-cylindrical, tube-shaped, box-shaped, or the like. For example, in the variation of catheter (200) shown in FIG. 2 and described in more detail above, catheter (200) may comprise a proximal anchoring magnet array (206) and a distal anchoring magnet array (208), the magnets of each of which are cylindrical. Alternatively, in the variation of catheter (600) shown in FIG. 6A, catheter (600) may comprise a proximal anchoring magnet array (604) and a distal anchoring magnet array (606), the magnets of each of which are semi-cylindrical. In these variations, a lumen and/or lead wire (such as lumen (608) and lead wire (605)) may pass by or along the anchoring magnet arrays, because the semi-cylindrical magnets only take up a portion of the interior of catheter (600).

[0100] While the magnets of proximal (604) and distal (606) magnet assemblies are shown in FIG. 6A as being configured such that the apex of each semi-cylinder is aligned with ablation surface (603), it should be appreciated that the magnets may be positioned in any manner relative to a fistula forming component. For example, FIG. 6B shows another variation of catheter (610) comprising electrode body (612) having ablation surface (613), proximal anchoring magnet array (614), distal anchoring magnet array (616), lead wire (615) and lumen (618). In this variation,

CLAIMS

We claim:

1. A system for forming a fistula between two blood vessels comprising:

   a first catheter, comprising a catheter body, a lead wire and at least one alignment element, wherein the lead wire is moveable between a low-profile configuration and an extended position wherein at least a portion of the lead wire extends away from catheter body.

2. The system of claim 1 further comprising a second catheter.

3. The system of claim 2 wherein the second catheter comprises a recessed region.

4. The system of claim 3 wherein the recessed region is a pocket configured to receive at least a portion of lead wire when lead wire extends away from the catheter body of the first catheter.

5. The system of claim 4 wherein the second catheter comprises at least one alignment element, and wherein the at least one alignment element of the first catheter and the at least one alignment element of the second catheter are configured to align the first catheter and the second catheter such that lead wire at least partially enters pocket when lead wire extends away from the catheter body of the first catheter.

6. The system of claim 4 wherein the pocket is formed in a nesting material housed at least partially within the catheter body of the second catheter.

7. The system of claim 4 wherein the pocket is formed in an electrode housed at least partially within the catheter body of the second catheter.

8. The system of claim 4 wherein the pocket is at least partially coated by an insulating material.

9. The system of claim 8 wherein the coating is porous.

10. The system of claim 1 wherein the lead wire comprises a first segment housed at least partially inside of the catheter body of the first catheter, a first angled segment extending from a distal end of the first segment, and a second angled segment extending from a distal end of the first angled segment.

11. The system of claim 10 wherein at least one insulating material covers the first segment and the first angled segment of the lead wire.

12. The system of claim 10 wherein at least one insulating material covers the first segment of the lead wire and partially covers the first angled segment of the lead wire.

13. A method of forming a fistula between a first blood vessel and a second blood vessel comprising:

advancing a first catheter into the first blood vessel, wherein the first catheter comprises a catheter body, a lead wire and at least one alignment element, wherein the lead wire is moveable between a low-profile position and an extended position wherein at least a portion of the lead wire extends away from catheter body;

advancing a second catheter into the second blood vessel, wherein the second blood vessel comprises at least one alignment element;

positioning first catheter and second catheter such that lead wire is aligned with the second catheter;

moving the lead wire from a low-profile position to an extended position; and

ablating tissue with the lead wire to form the fistula.

14. The method of claim 13 wherein the second catheter comprises a pocket, wherein positioning first catheter and second catheter comprises aligning lead wire with pocket.

15. The method of claim 13 wherein the second catheter comprises a balloon, and wherein ablation tissue with the lead wire comprises puncturing the balloon with the lead wire.

16. The method of claim 13 wherein the first blood vessel is a vein and the second blood vessel is an artery.

17. The method of claim 13 further comprising placing a ground electrode external to the first blood vessel and the second blood vessel, and wherein ablating tissue comprises passing current between the lead wire and the ground electrode.

18. The method of claim 13 wherein the lead wire comprises a first segment housed at least partially inside of the catheter body of the first catheter, a first angled segment extending from a distal end of the first segment, and a second angled segment extending from a distal end of the first angled segment.

19. The method of claim 18 wherein at least one insulating material covers the first segment and the first angled segment of the lead wire.

20. The method of claim 18 wherein at least one insulating material covers the first segment of the lead wire and partially covers the first angled segment of the lead wire.

21. The method of claim 13 wherein the first catheter comprises a shape-changing element, and further comprising repositioning the first blood vessel by changing the shape of the first catheter with the shape-changing element of the first catheter.

22. The method of claim 21 wherein the second catheter comprises a shape-changing element, and further comprising repositioning the second blood vessel by changing the shape of the second catheter with the shape-changing element of the second catheter.

23. The method of claim 22 wherein the second catheter comprises at least one expandable member, and wherein positioning the first and second catheters comprises expanding the at least one expandable member of the second catheter to hold the second catheter in place relative to the second blood vessel.

24. The method of claim 21 wherein the first catheter comprises at least one expandable member, and wherein positioning the first and second catheters comprises expanding the at least one expandable member of the first catheter to hold the first catheter in place relative to the first blood vessel.

electrical energy may have a tendency to flow from the active electrode through intervening tissue and to the passive electrode. In this way, the electrode pair may help prevent energy loss to surrounding tissue.

[0039] In some instances one or more electrodes may be connected to an electrosurgical generator, power supply, or other waveform generator that is configured to generate an alternating current. In some of these variations, two or more electrodes may be connected to the bipolar outputs of a generator. In other variations, one or more electrodes may be connected to a monopolar output of a generator. In some of these variations, a first electrode is attached to the active output of the generator, and a return electrode (e.g., a large metal plate or flexible metalized pad) may be temporarily attached or affixed to the patient and connected to the return output of the generator. In others of these variations, two or more electrodes may be attached to an active output of the generator, and a return electrode may be temporarily attached or affixed to the patient and connected to the return output of the generator. In still other variations, a first electrode may be attached to the active output of the generator, and a second electrode may be attached to the return output of the generator in a "focus monopolar" configuration.

[0040] Generally, at least a portion of each electrode may be exposed to the surrounding environment (e.g., through one or more apertures or openings in the catheter body). This exposed surface may be configured to contact surrounding tissue (e.g., a blood vessel wall) or fluids, and may act as an ablation surface such that current may be supplied to and/or carried from tissue via the ablation surface to facilitate ablation or vaporization of tissue. In some variations, the ablation surface may be temporarily covered (e.g., by a sheath or tubing) such that the ablation surface does not contact tissue. In these instances, the temporary covering may be moved or removed to expose the ablation surface to the surrounding environment. In other variations, the ablation surface may be temporarily recessed or held within the catheter, and in some of these instances may be advanced out of the catheter to contact tissue. The ablation surface need not be movable, and may instead be fixed relative to the catheter. Additionally or alternatively, in some variations an exposed electrode surface may comprise a porous coating that allows conduction of current thereto or therefrom while preventing direct contact between two electrodes, as will be described in more detail below. The electrodes may be made from any suitable material or combination of materials. In some variations the electrode may comprise one or more refractory metals. For example, an electrode may comprise tungsten, molybdenum, niobium, tantalum, rhenium, combinations or alloys thereof.

[0041] The electrode ablation surface may have any shape or size suitable for ablating tissue. For example, the ablation surface may be oval-shaped, circular, rectangular, triangular, pentagonal, hexagonal, polygonal, irregularly shaped, or the like. Alternatively or additionally, the ablation surface may be roughened or otherwise patterned, as will be described in more detail below. In variations where the ablation surface is exposed through one or more apertures or openings in the catheter body, these apertures or openings may at least partially define the size and shape of the ablation surface. In variations where the catheter comprises a nesting material, as will be described in more detail below, the nesting material may at least partially define the size and shape of the ablation surface. The size and shape of the ablation surface may help determine the size and shape of the resulting fistula. The ablation surface may have any suitable length (e.g., about 1.59 mm (0.0625 in), about 4.76 mm (0.1875 in), between about 1.27 mm and about 5.08 mm (about 0.05 in and about 0.2 in), between about 1.27 mm and about 1.91 mm (about 0.05 in and about 0.075 in), between about 3.81 mm and about 5.08 mm (about 0.15 in and about 0.2 in), and the like) and any suitable width (e.g., about 0.80 mm (0.0313 in.), about 1.59 mm (0.0625 in), between about 0.64 mm and about 1.91 mm (about 0.025 in and about 0.075 in), between about 0.64 mm and about 1.27 mm (about 0.025 in and about 0.05 in), between about 1.27 mm and about 1.91 mm (about 0.05 in and about 0.075 in), and the like). In variations where the ablation surface is circular, cylindrical, or semi-spherical, the ablation surface may have any suitable radius (e.g., about 0.76 mm (0.03 in), about 1.02 mm (0.04 in), about 1.27 mm (0.05 in), and the like). In variations where a portion of the electrode extends out of a portion of the catheter, as will be described in more detail below, the ablation surface may have any suitable height (e.g., about .25 mm, about .5 mm, about .75 mm, about 1 mm, between about .1 and about 1.5 mm, between about .25 and about 1 mm, between about .25 and about .75 mm, greater than about 1.5 mm, or the like).

[0042] When two or more electrodes are used in conjunction to form a fistula, the two or more electrodes may have different sizes. For examples, in some variations, a first electrode having a larger ablation surface (e.g., a rectangular ablation surface of about 0.2 inches by about 0.05 inches) may be placed in an artery, and a second electrode having a smaller ablation surface (e.g., a rectangular ablation surface of about 0.1 inches by about 0.05 inches) may be placed in a vein. In these variations, when an RF signal (e.g., a sinusoidal waveform, or the like) of a certain power (e.g., 40 W) is applied to the electrodes to form a fistula between the artery and the vein, the second electrode may have a larger current density than the first electrode by virtue of its smaller ablation surface. This may cause the formation of the fistula to begin in the vein, and propagate through the artery. Directional formation of fistula may help prevent extravasation (e.g., blood loss to surrounding tissue) in instances where a fistula is not fully formed between an artery and a vein (as partial fistula formation beginning in an artery may have a greater risk of extravasation than partial fistula formation beginning an a vein).

[0043] In some variations, the ablation surface may be flush with an outer surface of the catheter body. FIG. 2 illustrates one such variation of catheter (200) comprising an electrode body (202) having ablation surface (205). Also shown there are lead wire (204), proximal

[0098] A catheter may comprise any number of individual magnets (e.g., zero, one, two, three, four, five, six, seven, or eight or more, etc.). Each magnetic component may be any suitable magnet or magnetic material. For example, in some variations, a catheter may comprise one or more rare-earth magnets (e.g., neodymium magnets or samarium-cobalt magnets) and/or one or more selectively-activated electromagnets. In variations where a catheter comprises a plurality of magnets, these magnets may be grouped into one or more arrays. These magnetic arrays may located inside or outside of a catheter (or a combination thereof), and may be positioned anywhere along the length of the catheter. When two or more catheters comprise magnets or magnet arrays, each magnet or magnet array may be configured or arranged to align with one or more magnets or magnet arrays from a second catheter. Each magnet may be fixed in or on a catheter by any suitable method. For example, in some variations one or more magnets may be embedded in, adhered to or friction fit within a catheter. Each magnet may have any suitable diameter (e.g., about 1.91 mm (0.075 in.), about 2.03 mm (0.080 in.), about 0.74 mm (0.029 inch), about 2.79 mm (0.110 inch), or the like) or length (e.g., about 5 mm, about 10 mm, about 15 mm, about 20 mm, or the like), and may be separated from adjoining magnets by any suitable distance (e.g., about 1 mm, about 5 mm, and the like). In some variations, the magnets of an array may have alternating polarity (e.g., each magnet will have the opposite polarity as any adjacent magnets), matching polarity, or combinations thereof. In other variations, one or more portions of the catheter may be made from a magnetic material, and/or may be embedded with one or more magnetic particles/materials.

[0099] Each magnet may have any suitable shape for placement inside or outside of the catheter. Magnets may be cylindrical, semi-cylindrical, tube-shaped, box-shaped, or the like. For example, in the variation of catheter (200) shown in FIG. 2 and described in more detail above, catheter (200) may comprise a proximal anchoring magnet array (206) and a distal anchoring magnet array (208), the magnets of each of which are cylindrical. Alternatively, in the variation of catheter (600) shown in FIG. 6A, catheter (600) may comprise a proximal anchoring magnet array (604) and a distal anchoring magnet array (606), the magnets of each of which are semi-cylindrical. In these variations, a lumen and/or lead wire (such as lumen (608) and lead wire (605)) may pass by or along the anchoring magnet arrays, because the semi-cylindrical magnets only take up a portion of the interior of catheter (600).

[0100] While the magnets of proximal (604) and distal (606) magnet assemblies are shown in FIG. 6A as being configured such that the apex of each semi-cylinder is aligned with ablation surface (603), it should be appreciated that the magnets may be positioned in any manner relative to a fistula forming component. For example, FIG. 6B shows another variation of catheter (610) comprising electrode body (612) having ablation surface (613), proximal anchoring magnet array (614), distal anchoring magnet array (616), lead wire (615) and lumen (618). In this variation,

CLAIMS

1. A system for forming a fistula between two blood vessels comprising:

   a first catheter, comprising a catheter body, a lead wire and at least one alignment element, wherein the lead wire is moveable between a low-profile configuration and an extended position wherein at least a portion of the lead wire extends away from the catheter body, and wherein the lead wire is spring biased toward the extended position.

2. The system of claim 1 further comprising a second catheter.

3. The system of claim 2 wherein the second catheter comprises a recessed region.

4. The system of claim 3 wherein the recessed region is a pocket configured to receive at least a portion of the lead wire when the lead wire extends away from the catheter body of the first catheter.

5. The system of claim 4 wherein the second catheter comprises at least one alignment element, and wherein the at least one alignment element of the first catheter and the at least one alignment element of the second catheter are configured to align the first catheter and the second catheter such that the lead wire at least partially enters the pocket when the lead wire extends away from the catheter body of the first catheter.

6. The system of claim 4 wherein the pocket is formed in a nesting material housed at least partially within the catheter body of the second catheter.

7. The system of claim 4 wherein the pocket is formed in an electrode housed at least partially within the catheter body of the second catheter.

8. The system of claim 4 wherein the pocket is at least partially coated by an insulating material.

9. The system of claim 8 wherein the insulating material is porous.

10. The system of claim 1 wherein the lead wire comprises a first segment housed at least partially inside of the catheter body of the first catheter, a first angled segment extending from a distal end of the first segment, and a second angled segment extending from a distal end of the first angled segment.

11. The system of claim 10 wherein at least one insulating material covers the first segment and the first angled segment of the lead wire.

12. The system of claim 10 wherein at least one insulating material covers the first segment of the lead wire and partially covers the first angled segment of the lead wire.