A ring electrode structure having a raised radial dimension. The electrode projects from the outer diameter of the catheter when mounted thereon. The upstanding ring electrode has a tissue contacting surface that generally contacts tissue within a patient before the catheter itself comes into contact with the tissue. The electrode ensures good and uniform tissue contact for each electrode mounted on the distal end of a catheter. The electrode also enables greater pressure to be applied to this tissue with a reduced force as compared to a conventional electrode catheter configuration, due to the reduced contact area presented by the upstanding ring electrode. In a preferred configuration, the upstanding electrode has smooth, curved edges to prevent tissue damage when the catheter is advanced and withdrawn from a patient.
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RING ELECTRODE STRUCTURE
FOR DIAGNOSTIC AND ABLATION CATHETERS

Field of the Invention

This invention relates to diagnostic and ablation catheters and, more particularly, to a ring electrode structure for diagnostic and ablation catheters.

Background of the Invention

Cardiac dysrhythmias are commonly known as irregular heart beats or racing heart. Two such heart rhythm irregularities are the Wolff-Parkinson-White syndrome and AV nodal reentrant tachycardia. These conditions are caused by an extraneous strand of muscle fiber in the heart that provides an abnormal short-circuit pathway for electric impulses normally existing in the heart. For example, in one type of Wolff-Parkinson-White syndrome, the accessory pathway causes the electric impulses that normally travel from the upper to the lower chamber of the heart to be fed back to the upper chamber. Another common type of cardiac dysrhythmia is ventricular tachycardia (VT), which may be a complication of a heart attack or reduction of blood supply to an area of heart muscle. This latter type of cardiac dysrhythmia is a life-threatening arrhythmia.

Atrial fibrillation (AF) is the most commonly occurring type of arrhythmia. It is associated with increased morbidity and mortality due to a higher incidence of thromboembolic events and hemodynamic compromise. In patients with disabling drug resistant AF, the ventricular response can be controlled by catheter ablation or modification
of the atrioventricular (AV) nodal region, but this procedure is palliative since AF and its related risks persist afterwards. Pacemakers may be used to prevent recurrence of paroxysmal AF by either preventing the sinus bradycardia that triggers AF or reducing the interatrial conduction delay.

Non-surgical procedures such as management with drugs are favored in the treatment of cardiac dysrhythmias. However, some arrhythmias are not treatable with drugs, for example, disabling drug resistant AF, and have previously required surgery. According to these procedures, various incisions are made in the heart to block conduction pathways and thus divide the atrial area available for multiple wavelet reentry and abolish the arrhythmia. Alternatively, an Automatic Implantable Cardioverter/Defibrillator (AICD) can be surgically implanted into the patient, as described in U.S. Patent No. 4,817,608 to Shapland et al. While these surgical procedures can be curative, they are associated with increased morbidity and mortality rates, and are extremely expensive. Even the use of an AICD requires major surgical intervention. However, patients of advanced age or illness, for example, cannot tolerate invasive surgery to excise the tachycardia focus which causes dysrhythmias.

Non-surgical, minimally invasive techniques have been developed which are used to locate cardiac regions responsible for tachycardia, and also to disable the short-circuit function of these areas. According to these techniques, electrical energy shocks are applied to the endomyocardium to ablate cardiac tissue in the arrhythmogenic regions and produce scars which interrupt the reentrant conduction pathways. The regions to be ablated are usually first determined by endocardial mapping techniques. Mapping typically involves percutaneously introducing a diagnostic catheter having one or more electrodes into the patient, passing the diagnostic catheter through a blood vessel (e.g., the femoral vein or aorta) and into an endocardial site (e.g., the atrium or ventricle of the heart), and inducing a tachycardia so that a continuous, simultaneous recording can be made with a multichannel recorder at each of several different endocardial positions. When a tachycardial focus is located, as indicated in the electrocardiogram recording, it is marked by means of a fluoroscopic image so that cardiac arrhythmias at the located site can be ablated. A conventional electrode catheter, having electrodes with a greater surface-area than the diagnostic catheter’s electrodes, can then provide electrical energy to the tissue adjacent the electrode to create a lesion in the tissue. One or more suitably positioned lesions will create a region of necrotic tissue to disable the malfunction caused by the tachycardial focus.
Conventional catheter ablation techniques have used catheters each having a single electrode fitted at its tip as one electrical pole. The other electrical pole is conventionally provided by a backplate in contact with a patient's external body part to form a capacitive coupling of the ablation energy source (DC, laser, RF, etc.). Other ablation catheters are known in which multiple electrodes are provided, such as the catheter disclosed in allowed U.S. Patent Application Serial No. 08/569,771, filed December 8, 1995, of Mackey, the entirety of which is hereby incorporated by reference as if set forth herein. Still other ablation catheters having multiple electrodes are known, from, for example, U.S. Patent 5,779,669 to Haissaguerre, et al., the disclosure of which is hereby incorporated by reference as if set forth herein.

Ablation is effected by applying energy to the catheter electrodes once the electrodes are in contact with the cardiac tissue. The energy can be, for example, RF, DC, ultrasound, microwave, or laser radiation. When RF energy is delivered between the distal tip of a standard electrode catheter and a backplate, there is a localized RF heating effect. This creates a well-defined, discrete lesion slightly larger than the tip electrode, and also causes the temperature of the tissue in contact with the electrode to rise. The rising tissue temperature and changes in impedance at the electrode/tissue interface are sometimes monitored, as disclosed in the aforementioned Mackey patent, to better avoid undesirable complications such as tissue desiccation, blood coagulation, charring at the electrode, thrombus formation, or adhesion of the catheter to the tissue. To stem rising temperature, saline-perfused catheters have been used to cool the tip electrode/tissue interface, thereby allowing more power to be delivered without the foregoing undesirable complications.

The small size and shallow depth of the lesions produced by RF ablation has been perceived as one of the limitations of this technique. Conventional thinking has been that a large contact region is required to create either a sufficiently large or deep lesion using RF to block ventricular tachycardia. Along this line of thought, improvements in electrode design have concerned changes in the length of the electrode, as viewed in the direction of elongation of the catheter. Proposed elongated electrodes have been six, eight, ten or even twelve millimeters in length to promote longer lesion formation and to allow more power to be delivered to the tissue through increased contact area. However, attendant with increased electrode length is a decrease in the flexibility of the catheter on which such elongated
electrodes are mounted and a concomitant increase in the risk of myocardial wall perforation and morbidity rate.

In addition, an unresolved problem remains how to ensure good and uniform tissue contact at each of the elongated electrodes at the distal end of the catheter. Complicating this problem is the fact that the endomycocardium, and the pectinate muscles of the atrium in particular, have an irregular surface. Therefore, contact pressure must be applied to each of the electrodes over the length of the catheter that supports the electrodes to ensure that each electrode makes good contact with tissue.

What is needed in the art and has heretofore not been available is a ring electrode structure configured to map tachycardial foci and to form deep lesions in tissue without unduly heating the tissue at the electrode/tissue interface. What is further needed in the art is a multielectrode catheter having such an electrode structure with the electrodes being axially spaced from one another for enhanced diagnostic and ablation applications, without sacrificing catheter flexibility.

**Summary of the Invention**

According to one aspect of the invention, a ring electrode structure is disclosed which has a raised radial dimension such that the electrode projects from the outer diameter of the catheter when mounted thereon. In other words, the outer diameter of the electrode exceeds that of the catheter on which it is mounted. The raised or upstanding ring electrode has a tissue contacting surface that generally contacts tissue within a patient before the catheter itself comes into contact with the tissue. This arrangement ensures good and uniform tissue contact for each electrode mounted on the distal end of a catheter. This arrangement also enables greater pressure to be applied to this tissue with a reduced force as compared to a conventional electrode catheter configuration, due to the reduced contact area presented by the upstanding ring electrode. Preferably, the ring electrode projects from the catheter on which it is mounted by between about 0.25 french and about 2 french.

In accordance with another aspect of the invention, the upstanding electrode has smooth, curved edges to prevent tissue damage when the catheter is advanced and withdrawn from a patient.
Description of the Drawings

Other objects and aspects of the invention should be apparent from the following detailed description of the preferred embodiments taken in conjunction with the following drawings in which:

Fig. 1 illustrates, in plan view, the ring electrode structure of the present invention supported on an ablation catheter;

Fig. 2 is a cross-sectional view taken along lines 2-2 of Fig. 1;

Fig. 3 is a cross-sectional view of a modified ring electrode structure according to the present invention;

Fig. 4 illustrates the results of an in vitro comparative ablation experiment in which ablation energy was applied for 60 seconds and controlled to not exceed 65°C;

Fig. 5 illustrates the results of an in vitro comparative ablation experiment in which ablation energy was applied for 90 seconds and controlled to not exceed 65°C; and

Fig. 6 illustrates the results of an in vitro comparative ablation experiment in which ablation energy was applied for 120 seconds and controlled to not exceed 65°C.

Detailed Description of the Preferred Embodiments

By way of overview and introduction, there is seen in Fig. 1 a ring electrode structure 10 according to the invention supported on a combination diagnostic (mapping) and ablation catheter 12, along a distal portion 14 thereof. Preferably, a tip electrode 16 is provided at the catheter distal end, which may be of conventional design. A particularly suitable assembly for the distal tip electrode 16 is described in U.S. Patent No. 5,685,878, issued November 11, 1997, which is hereby incorporated by reference as if set forth in its entirety herein. Conventionally, the tip electrode 16 is made of platinum and is attached directly to the distal end of the catheter 12. Alternatively, a refractive material (not shown) may be interposed between the tip electrode 16 (or the other electrodes) and the catheter 12 to protect the supporting catheter from heat during and just after ablation energy has been applied to the electrodes 10, 16.

The ring electrode structure 10 preferably has the same inner diameter as a conventional electrode, that is, slightly smaller than the outer diameter of the catheter 12. Each ring electrode is mountable on the catheter 12, for example, by threading a conductive wire 18 soldered or welded to the electrode 10 into a lumen 20 of the catheter through an
aperture 22, temporarily stretching the distal portion 14 of the catheter to neck down its outer
diameter, slipping the ring electrode 10 over the catheter 12, and releasing the tension on the
catheter once the ring electrode is positioned over the aperture 22 (see Fig. 2). Also, each ring
electrode 10 preferably has a temperature sensor 23 mounted along its inner diameter which
is seated against the catheter 12, preferably within a cavity in the outer wall of the catheter or
in register with the aperture 22, when the ring electrode 10 is mounted to the catheter. The
temperature sensor 23 can be a thermocouple, thermistor, or resistive thermal device ("RTD").
Each temperature sensor 23 has an associated conductive lead (not shown) which also extends
proximally to the connector.

In accordance with the present invention, the ring electrode 10 has a thickness,
as measured in the radial direction R (see Fig. 2), sufficient to cause a contact surface 24
thereof to project from the catheter 12. As a result, the contact surface 24 generally contacts
tissue 26 before the catheter 12 comes into contact with the tissue, even at locations where the
tissue has an irregular surface. To ensure good tissue contact, a force is applied in a
conventional manner from the proximal end 28 of the catheter 12 to press the electrodes 10,
16 against the tissue 26. The upstanding electrodes concentrate the points of tissue contact
on the surfaces 24 rather than on the insulating portions 30 of the distal portion 14 of the
catheter. In contrast, conventional electrode designs are flush with the outer diameter of the
catheter and therefore present a significantly greater contact area with the tissue 26. Because
applied pressure is inversely related to the size of the contact area (P=F/A), the upstanding
ring electrodes 10 of the present invention achieve comparable pressure as is achieved in
conventional designs with significantly less applied force. This provides benefits for both
mapping and ablation procedures. For example, a catheter which includes the electrode 10
is less sensitive to less than optimum tissue contact pressure situations because more electrode
surface area of the upstanding electrodes is available to contact the tissue, more RF energy
is radiated from the electrode 10, particularly at the electrode edges, and there is a greater
likelihood that the electrode will affirmatively engage an irregular tissue surface and focus the
contact pressure at the electrodes 10 instead spreading a lessened pressure over a greater
contact area which includes both electrodes and the insulative regions 30 (as in conventional
designs).

Surprisingly, the upstanding ring electrodes 10 enable significantly deeper and
wider lesions to be formed (as taken along the z- and y-axes of Fig. 1, respectively) than
conventional electrode designs permit for the same degree of surface tissue temperature and ablation time. An in vitro experiment was performed in which the volume of a lesion produced using a conventional electrode (2.5 mils thick) mounted flush with a catheter was compared with the volume of lesion formed using an upstanding ring electrode (10 mils thick) according to the present invention. (1 mil = 0.0254 mm.) Each of the ring electrodes was of the same length (4 mm, as taken along the x-axis of Fig. 1) and was mounted on a separate catheter (having an outside diameter of 91 mils (7 French)). A thermocouple was attached to the inside diameter of each ring electrode at the electrode centerline for sensing the surface tissue temperature. Once mounted, the conventional electrode was flush with the catheter, and the upstanding ring electrode projected by approximately fifteen mils (that is, more than one French). Fifteen grams of force was applied to each electrode to hold it in contact with a tissue sample, and using controlled temperature feedback set to 65°C, energy was delivered to the electrodes for sixty seconds while 1400 ml/min of saline was flowed.

More particularly, the in vitro experiment examined lesion results on a tissue specimen comprising a transverse cross-section of bovine striated muscle tissue approximately 1" long, 0.75" wide, and 0.50" deep. An immersible fixture was used to position the electrode with its thermocouple-bearing side was in contact with the tissue specimen. In addition, fifteen grams of weight was applied to the catheter shaft on either side of the electrode to ensure that the electrode was held firmly against the specimen. The fixture enables controlled placement and alignment of an additional thermocouple within the specimen directly below the axial and radial center of the electrode.

With the tissue specimen and electrode mounted and supported as described above, the assembly was submerged in a tank of 37°C saline/DI water mixture balanced to a 100Ω initial impedance and circulated at 1400 ml/min by a peristaltic pump. The ablation procedure and data collection commenced after the assembly equilibrated with the saline/DI water mixture. Ablation energy was applied to the specimen for a predetermined duration (e.g., 60 sec., 90 sec., and 120 sec.) in a temperature controlled mode with a 65°C set-point.

A comparative test of the electrode 10 according to the invention and a conventional electrode was then performed using Radionics brand Lesion Generators (Model 3E), with personal computers attached thereto, to control the ablation procedure and capture the lesion parameter data. The results are shown below:
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<td>Upstanding electrode</td>
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<td>8.3</td>
<td>180 mm³</td>
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wherein D is the cross-sectional depth from the center point of the surface burn to the deepest margin of the lesion, W is the surface width, L is the cross-sectional length at the longest margin, and the calculated lesion volume is equal to \((\pi/6)(DWL)\):

The upstanding electrode according to the invention outperformed the conventional electrode for each parameter that was measured, as shown in Figs. 4-6 which illustrate the results for three different ablation duration cycles (60, 90 and 120 second cycles, respectively), wherein the “thick” electrode is the electrode 10 and the “thin” electrode is the conventional electrode.

To achieve the results obtained with the electrode 10, a conventional electrode would have to be energized for a greater period of time, or a higher surface tissue temperature would have to be tolerated along with greater risk of tissue desiccation, electrode charring, blood coagulation, and the like. Thus, the ring electrode structure 10 allows more power delivery to better promote lesion formation, as compared to conventional electrode constructions, without increasing tissue surface temperature beyond a clinically acceptable level. Further, enhanced power delivery was obtained without increasing the length of the electrode and without compromising catheter flexibility. As a result, the ring electrodes 10 can be provided with a thickness and axial length suitable for high power ablation. Because the ring electrodes 10 have a smaller contact area than conventional, flush electrodes, they are also suitable for mapping tachycardial foci without blurring the situs of the sensed signal. The smaller contact surface 24 of the ring electrode 10 enables both fine signal sensing (like a small antenna), and ablation.

The power to the electrode 10 may be delivered for durations of about 120 seconds or less to reduce the risk of the electrode 10 adhering to the tissue being ablated and to minimize any tendency that the tissue may have to wrap around the tissue, for example, as a result of tissue dessication. As the ablation time is increased above, for example, sixty seconds, the lesion cross-sections were observed as being progressively more dense and rubbery to the touch, which may be an indication of increased tissue dessication and a
concomitant rise in lesion density. This suggests that the final lesion volume which was measured is less than the actual volume of tissue that was affected by the procedure, particularly in the case of the longer ablation energy cycle durations.

Fig. 3 illustrates a modification of the ring electrode illustrated in Fig. 1. In Fig. 3, the ring electrode 10′ lacks any sharp edges that may cause tissue damage when the catheter 12 is moved within a patient. Specifically, the ring electrode 10′ has smooth, curved edges. Of course, a sheath can be used with this embodiment or the embodiment of Fig. 1 to ensure atraumatic delivery and retraction of the catheter 12.

While two ring electrodes 10 are shown spaced in serial manner along the catheter 12, the catheter 12 may support only one or an arbitrarily large number of ring electrodes 10. The ring electrodes 10 are spaced from each other (and the tip electrode 16) by insulative regions 30, and each can be of an arbitrary axial length. To create linear lesions during ablation, the electrodes may be spaced, for example, 1 to 3 mm apart, depending on the thickness of the electrode (as measured in the radial direction) and the range of power to be applied. The electrode spacing can also be established with regard to diagnostic considerations such that the electrodes are suitably spaced to map electrical signals within the heart.

As compared to conventional electrodes, the increased lesion volume resulting from the ring electrode structure of the present invention permits an increase in the inter-electrode spacing along the distal end of the catheter shaft and/or a reduction in the electrode’s axial length without sacrificing the ability to create a continuous, linear lesion in the regions between the electrodes 10, that is, beneath insulative regions 30. Whether the inter-electrode spacing is increased or whether the electrode is axially shortened, the electrode structure of the present invention permits an increase in tip flexibility by exposing more of the insulative regions 30 of the catheter 12.

The radial thickness of the ring electrode 10 multiplied by its axial length, that is, its length along the x-axis in Fig. 1 (which corresponds to the direction of elongation of the catheter), defines the mass of the ring electrode. The thickness of the ring electrode 10 may be selected to ensure that the ring electrode has approximately the same mass as the tip electrode 16 or some other predetermined mass. As described above, it is generally desirable to have an axially short electrode 10 so that the focus of a tachycardia signal is not blurred across the length of the electrode. However, the electrode 10 cannot be made to project from
the catheter too far or else the catheter will not be readily maneuverable into a desired passageway. Accordingly, a designer must strike a balance between the axial length of the ring electrode 10 and its radial thickness to achieve a predetermined mass. Preferably, the mass of the ring electrode is made to generally match that of the tip electrode 16, and more preferably to substantially match the mass of the tip electrode.

In operation, the arrhythmogenic site is determined by positioning the distal portion 14 of the catheter 12 in the heart and sensing the electrical signals using the ring electrodes 10. Once the arrhythmogenic site is located, a power supply (not shown) is configured to energize the electrodes 10, 16 in either a constant voltage, power, or temperature mode as described in detail in the aforementioned Mackey patent. The electrodes can be energized simultaneously, sequentially, or in accordance with some other pattern. Radio-frequency energy in the range typically of about 250 Khz to 500 Khz is delivered to the electrodes 10,16 to ablate tissue. Energy flows from the electrodes 10,16 through the tissue 26 to a return plate, which is connected to the ground potential of the power supply, to complete the circuit. The flow of current through the circuit to the tissue 26 causes heating which results in the destruction of the tissue 26 near the electrodes 10, 16, and ideally the arrhythmogenic site. If performed successfully, permanent interruption of the arrhythmia occurs and the patient is cured.

A catheter in accordance with the invention can be packaged with a guide sheath which is sized to accommodate the ring electrodes 10. Thus, if a 7 Fr catheter is provided with 7.5 Fr ring electrodes 10, then the guide sheath can be a conventional 8 Fr guide, or may be a custom guide sheath which is sized larger than 7.5 Fr.

Having thus described preferred embodiments of the present invention, it is to be understood that the above described arrangement and system is merely illustrative of the principles of the present invention, and that other arrangements and systems may be devised by those skilled in the art without departing from the spirit and scope of the invention as claimed below.
We Claim:

1. An electrode catheter for ablating tissue within a patient, comprising:
   an elongated catheter including a distal portion having a predetermined
   outside diameter and a lumen therein;
   at least one ring electrode supported on the distal portion;
   a conductive wire disposed within the lumen and having one end
   connected to the ring electrode;
   a temperature sensor disposed beneath the ring electrode, wherein
   the ring electrode has a thickness such that the electrode projects in a
   direction generally transverse to the direction of elongation of the catheter by a distance which
   is sufficient to space the distal portion of the catheter from the tissue to be ablated.

2. The electrode catheter as in Claim 1, wherein the ring electrode has an
   inner diameter smaller than the predetermined outer diameter of the catheter.

3. The electrode catheter as in Claim 1, wherein the temperature sensor
   is selected from the group consisting of a thermocouple, a thermistor, and a resistive thermal
   device.

4. The electrode catheter as in Claim 1, wherein the ring electrode projects
   from the catheter 4 mils or more in the radial direction.

5. The electrode catheter as in Claim 1, wherein the ring electrode has
   smooth, curved edges.

6. The electrode catheter as in Claim 1, wherein there are plural ring
   electrodes supported on the catheter.

7. The electrode catheter as in Claim 1, wherein the catheter has a slot
   sized to accommodate the temperature sensor and permit the ring electrode to be coaxially
   supported on the catheter.
8. The electrode catheter as in Claim 7, wherein the ring electrodes are spaced in the direction of elongation of the catheter by insulative regions.

9. The electrode catheter as in Claim 1, further comprising a tip electrode at a distal tip of the catheter.

10. The electrode catheter as in Claim 9, further comprising a refractive element interposed between the distal tip of the catheter and the tip electrode.

11. The electrode catheter as in claim 1, wherein the ring electrode has a length in the direction of elongation of the catheter and wherein the thickness of the ring electrode is selected such that its length times its thickness is equal to a predetermined mass.

12. The electrode catheter as in claim 11, further comprising a tip electrode having a mass at a distal tip of the catheter, wherein the mass of the tip electrode is substantially equal to the predetermined mass.
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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<th>Relevant to claim No.</th>
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<td>1, 6, 8, 9, 11, 12</td>
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Patent family members are listed in annex.

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Date of the actual completion of the international search: 19 February 1999

Date of mailing of the international search report: 02/03/1999

Name and mailing address of the ISA

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Tel. (+31-70) 3403040, Tx. 31 651 epo nl
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