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Profile parameter selection algorithm for electroporation

Abstract

A pulsed field ablation medical device. Among other things, the medical device includes processing circuitry in communication with an electrosurgical generator and a plurality of electrodes. In one example, the processing circuitry is configured to determine a desired lesion characteristic; determine a first waveform parameter based on the desired lesion characteristic; deliver, via the plurality of electrodes, a first pulsed field waveform of the plurality of pulsed field waveforms based on the first waveform parameter to ablate the area of tissue; measure a second lesion characteristic based on a result of delivering the first pulsed field waveform; determine a second waveform parameter based on the second lesion characteristic; deliver, via the plurality of electrodes, a second pulsed field waveform of the plurality of pulsed field waveforms based on the second waveform parameter to ablate the area of tissue.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION (1) This application is a continuation application of and claims the benefit of U.S. application Ser. No. 17/577,775, filed Jan. 18, 2022, now U.S. Pat. No. 12,023,084, which is a divisional application of and claims the benefit of U.S. application Ser. No. 15/427,534, filed Feb. 8, 2017, now U.S. Pat. No. 11,229,478, the contents of each of which is hereby incorporated in its entirety.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT (1) n/a

TECHNICAL FIELD

(2) This disclosure relates to a method and system for determining electroporation parameters based on desired lesion characteristics.

BACKGROUND

(3) Electroporation is the application of an electric field to cells in order to increase the permeability of the cell membrane. Pulsed field ablation ("PFA") which can cause reversible or irreversible electroporation, is a non-thermal ablation technique that creates lesions in desired areas to treat conditions such as cardiac arrhythmias, and to ablate areas of tissues and/or organs in the body. For treating cardiac arrhythmias, for example, PFA can be performed to modify tissue, such as to stop aberrant electrical propagation and/or disrupt aberrant electrical conduction through cardiac tissue.

(4) PFA includes application of short pulsed electric fields (PEF), which may reversibly or irreversibly destabilize cell membranes through electropermeablization, but generally do not affect the structural integrity of the tissue components, including the acellular cardiac extracellular matrix. The nature of PFA allows for very brief periods of therapeutic energy delivery, on the order of tens or hundreds of milliseconds in duration. Further, when targeting cardiomyocytes, PFA may not cause collateral damage to non-targeted tissue as frequently or as severely as thermal ablation techniques. Additionally, therapeutic agents may be preferentially introduced into the cells of targeted tissue that are exposed to PEF having reversible membrane permeablization.

(5) In PFA systems, the user programs, or otherwise manually enters, the desired parameters of the PEF delivered to the tissue into an electrosurgical generator configured to deliver electrical energy to the target tissue through an electrosurgical hand piece. That is, for a given delivery tool, target tissue, or environment, the user may select from waveform parameters such as the amplitude, size, shape, frequency, and repetition of the waveform. Upon entry of those parameters, the size of the lesion may be determined. In such an application, the size of the lesion (or affected area) such as the depth or breadth of the affected area is often the desired result. However, no system or method exists that allows the users to input into the electrosurgical generator the desired characteristics of a lesion for a particular tissue, such as length, width, and depth for use with PFA. For cardiac ablation energy delivery electrodes designed for placement on the endocardial surface or epicardial surface of the heart, achieving a desired depth or extent of lesion formation into the tissue is generally the objective. Alternative electrodes may be designed to ablate from within a confined space within the tissue, such as within the vasculature. In such placements, the electric field and

resulting lesion extends radially outward from the electrode array, producing a lesion of a specific diameter surrounding the electrodes.

SUMMARY

(6) The present application advantageously provides for a method of determining a pulsed field ablation waveform parameter for creating a desired lesion characteristic in cardiac tissue. The method of provides an electrosurgical generator configured to deliver electroporation pulses, the generator configured to: load predetermined waveform parameters (y.sub.i); load predetermined modeling data (x.sub.i); accept entry of a user inputted desired lesion characteristic (u.sub.i); and determine at least one corresponding pulsed field ablation waveform parameter based on (u.sub.i), (y.sub.i); and (x.sub.i).

(7) In another aspect of this embodiment, the method includes coupling an electrosurgical device having a plurality of electrodes with the electrosurgical generator, the plurality of electrodes being configured to deliver electroporation pulses between an adjacent one of the plurality of electrodes.

(8) In another aspect of this embodiment, wherein the predetermined modeling data (x.sub.i) is a function of the predetermined waveforms parameters (y.sub.i) and the user inputted desired lesion characteristic (u.sub.i).

(9) In another aspect of this embodiment, wherein the electrosurgical generator is configured to electrically couple with an electrosurgical medical device having a plurality of electrodes configured to deliver electroporation pulses between adjacent electrodes of the plurality of electrodes, and wherein the waveform parameters (y.sub.i) include at least one from the group consisting of a number of pulses, a duration of each pulse, a number of pulse trains, an applied voltage, electrode polarity configuration, and inter-pulse timing.

(10) In another aspect of this embodiment, wherein the user inputted desired lesion characteristic (u.sub.i) includes at least one of the group consisting of lesion depth, lesion surface area, lesion width, and lesion length.

(11) In another aspect of this embodiment, the method further includes delivering between 30-140 electroporation pulses to the cardiac tissue.

(12) In another aspect of this embodiment, wherein a pulse width between each of the delivered electroporation pulse is between 3-6 μs.

(13) In another aspect of this embodiment, wherein the electroporation pulses are delivered in at least 4 pulse trains.

(14) In another aspect of this embodiment, wherein the determined at least one corresponding pulsed field ablation waveform parameter is at least one from the group consisting of an applied voltage amplitude and an applied electric field of the pulsed field ablation waveform.

(15) In another aspect of this embodiment, wherein the method further includes determining whether the determined applied voltage amplitude is within a predetermined voltage threshold, and wherein the method further includes reducing the applied voltage amplitude when the determined applied voltage amplitude is above the predetermined voltage threshold.

(16) In another aspect of this embodiment, wherein the user inputted desired lesion characteristic (u.sub.i) is lesion depth, and wherein the method further includes setting accepting a user inputted range of lesion depth between 1 mm and 8 mm.

(17) In another embodiment, an electrosurgical generator configured to deliver pulsed field ablation pulses to electroporate cardiac tissue includes a processor having processing circuitry configured to: load predetermined waveform parameters (y.sub.i); load predetermined modeling data (x.sub.i); accept entry of a user inputted desired lesion characteristic (u.sub.i); and determine at least one corresponding pulsed field ablation waveform parameter based on (u.sub.i), (y.sub.i); and (x.sub.i).

(18) In another aspect of this embodiment, wherein the generator is further configured to electrically couple with an electrosurgical device having a plurality of electrodes, the plurality of electrodes being configured to deliver electroporation pulses between an adjacent one of the plurality of electrodes.

(19) In another aspect of this embodiment, wherein the predetermined modeling data (x.sub.i) is a function of the predetermined waveforms parameters (y.sub.i) and the user inputted desired lesion characteristic (u.sub.i).
(20) In another aspect of this embodiment, wherein the electrosurgical generator is configured to electrically couple with an electrosurgical medical device having a plurality of electrodes configured to deliver electroporation pulses between adjacent electrodes of the plurality of electrodes, and wherein the waveform parameters (y.sub.i) include at least one from the group consisting of a number of pulses, a duration of each pulse, a number of pulse trains, an applied voltage, electrode polarity configuration, and inter-pulse timing.
(21) In another aspect of this embodiment, wherein the user inputted desired lesion characteristic (u.sub.i) includes at least one of the group consisting of lesion depth, lesion surface area, lesion width, and lesion length.
(22) In another aspect of this embodiment, wherein the determined at least one corresponding pulsed field ablation waveform parameter is at least one from the group consisting of an applied voltage amplitude and an applied electric field of the pulsed field ablation waveform.
(23) In another aspect of this embodiment, the processing circuitry is further configured to determine whether the applied voltage amplitude is within a predetermined voltage threshold, and wherein the processing circuitry is further configured to reduce the applied voltage amplitude when the determined applied voltage amplitude is above the predetermined voltage threshold
(24) In another aspect of this embodiment, wherein the user inputted desired lesion characteristic (u.sub.i) is lesion depth, and wherein the processing circuity is configured to accept a user inputted range of lesion depth between 1 mm and 8 mm.
(25) In yet another embodiment, an electrosurgical generator configured to deliver pulsed field ablation pulses to electroporate cardiac tissue includes a processor having processing circuitry configured to: load predetermined waveform parameters (y.sub.i); load predetermined modeling data (x.sub.i); accept entry of a user inputted desired lesion characteristic (u.sub.i); determine an applied voltage amplitude based on (u.sub.i), (y.sub.i); and (x.sub.i). The generator is configured to electrically couple with an electrosurgical device having a plurality of electrodes, the plurality of electrodes being configured to deliver electroporation pulses between an adjacent one of the plurality of electrodes, the plurality of electrodes being configured to define a substantially circumferential configuration. The processing circuitry is further configured to determine whether the applied voltage amplitude is within a predetermined voltage threshold, and wherein the processing circuitry is further configured to reduce the applied voltage amplitude when the determined applied voltage amplitude is above the predetermined voltage threshold.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) A more complete understanding of embodiments described herein, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:
(2) FIG. **1** is an exemplary electrosurgical generator with an associated handpiece and multi-electrode array for the delivery of PFA;
(3) FIG. **2** is a flow chart illustrating the steps of determining a PFA waveform from a desired lesion characteristic;
(4) FIG. **3** shows an exemplary PFA waveform and its parameters; and
(5) FIG. **4** shows residual plots for average cross-section lesion depth as compared to the exemplary model's predicted results.
DETAILED DESCRIPTION

(6) Before describing in detail exemplary embodiments, it is noted that the embodiments reside primarily in combinations of apparatus components and processing steps related to a PFA waveform profile parameter selection based on an a desired lesion characteristic. Accordingly, the system and method components have been represented where appropriate by conventional symbols in the drawings, showing only those specific details that are pertinent to understanding the embodiments of the present disclosure so as not to obscure the disclosure with details that will be readily apparent to those of ordinary skill in the art having the benefit of the description herein.
(7) Referring now to the drawings where like reference designators refer to like elements there is shown in FIG. **1** an exemplary electrosurgical general configured to deliver electrical energy to irreversibly electroporate tissue and designated generally as "**10**." The system **10** generally includes a medical device **12** that may be coupled directly to an energy supply, for example, a pulsed field ablation generator **14** including an energy control, delivering and monitoring system or indirectly through a catheter electrode distribution system **13**. A remote controller **15** may further be included in communication with the generator for operating and controlling the various functions of the generator **14**. The medical device **12** may generally include one or more diagnostic or treatment regions for energetic, therapeutic and/or investigatory interaction between the medical device **12** and a treatment site. The treatment region(s) may deliver, for example, pulsed electroporation energy to a tissue area in proximity to the treatment region(s).
(8) The medical device **12** may include an elongate body **16** passable through a patient's vasculature and/or positionable proximate to a tissue region for diagnosis or treatment, such as a catheter, sheath, or intravascular introducer. The elongate body **16** may define a proximal portion **18** and a distal portion **20**, and may further include one or more lumens disposed within the elongate body **16** thereby providing mechanical, electrical, and/or fluid communication between the proximal portion of the elongate body **16** and the distal portion of the elongate body **16**. The distal portion **20** may generally define the one or more treatment region(s) of the medical device **12** that are operable to monitor, diagnose, and/or treat a portion of a patient. The treatment region(s) may have a variety of configurations to facilitate such operation. In the case of purely bipolar pulsed field delivery, distal portion **20** includes electrodes that form the bipolar configuration for energy delivery where energy passes between one or more electrodes and one or more different electrodes on the same electrode array. In an alternate configuration, a plurality of the electrodes **24** may serve as one pole while a second device containing one or more electrodes (not pictured) would be placed to serve as the opposing pole of the bipolar configuration. For example, as shown in FIG. **1**, the distal portion **20** may include an electrode carrier arm **22** that is transitionable between a linear configuration and an expanded configuration in which the carrier arm **22** has an arcuate or substantially circular configuration. The carrier arm **22** may include the plurality of electrodes **24** (for example, nine electrodes **24**, as shown in FIG. **1**) that are configured to deliver pulsed-field energy. Further, the carrier arm **22** when in the expanded configuration may lie in a plane that is substantially orthogonal to the longitudinal axis of the elongate body **16**. The planar orientation of the expanded carrier arm **22** may facilitate ease of placement of the plurality of electrodes **24** in contact with the target tissue. Alternatively, the medical device **12** may be have a linear configuration with the plurality of electrodes **24**. For example, the distal portion **20** may include six electrodes **24** linearly disposed along a common longitudinal axis.
(9) The generator **14** may include processing circuitry including a first processor **17** in communication with one or more controllers and/or memories containing software modules containing instructions or algorithms to provide for the automated operation and performance of the features, sequences, calculations, or procedures described herein. The system **10** may further include three or more surface ECG electrodes **26** on the patient in communication with the generator **14** through the catheter electrode distribution system **13** to monitor the patient's cardiac activity for use in determining pulse train delivery timing at the desired portion of the cardiac cycle, for example, during the ventricular refractory period. In addition to monitoring, recording or

otherwise conveying measurements or conditions within the medical device **12** or the ambient environment at the distal portion of the medical device **12**, additional measurements may be made through connections to the multi-electrode catheter including for example temperature, electrode-tissue interface impedance, delivered charge, current, power, voltage, work, or the like in the generator **14** and/or the medical device **12**. The surface ECG electrodes **26** may be in communication with the generator **14** for initiating or triggering one or more alerts or therapeutic deliveries during operation of the medical device **12**. Additional neutral electrode patient ground patches (not pictured) may be employed to evaluate the desired bipolar electrical path impedance, as well as monitor and alert the operator upon detection of inappropriate and/or unsafe conditions. which include, for example, improper (either excessive or inadequate) delivery of charge, current, power, voltage and work performed by the plurality of electrodes **24**; improper and/or excessive temperatures of the plurality of electrodes **24**, improper electrode-tissue interface impedances; improper and/or inadvertent electrical connection to the patient prior to delivery of high voltage energy by delivering one or more low voltage test pulses to evaluate the integrity of the tissue electrical path.

(10) The generator **14** may include an electrical current or pulse generator having a plurality of output channels, with each channel coupled to an individual electrode of the plurality of electrodes **24** or multiple electrodes of the plurality of electrodes **24** of the medical device **12**. The generator **14** may be operable in one or more modes of operation, including for example: (i) bipolar energy delivery between at least two electrodes **24** or electrically-conductive portions of the medical device **12** within a patient's body, (ii) monopolar or unipolar energy delivery to one or more of the electrodes or electrically-conductive portions on the medical device **12** within a patient's body and through either a second device within the body (not shown) or a patient return or ground electrode (not shown) spaced apart from the plurality of electrodes **24** of the medical device **12**, such as on a patient's skin or on an auxiliary device positioned within the patient away from the medical device **12**, for example, and (iii) a combination of the monopolar and bipolar modes.

(11) Referring now to FIG. **2**, a PFA waveform parameter selection algorithm may be programmed into the first processor configured to correlate a desired treatment outcome to energy settings in the generator. For example, the user may be desirous to create a lesion of a particular length, width, surface area, and/or depth for a particular tissue, but does not know the waveform parameters to create such a lesion. The exemplary algorithm described herein correlates the desired lesion characteristics to outputted waveform parameters. In one configuration, modeled lesion characteristics (x.sub.i) are a function of the delivered waveform parameters (y.sub.i) and user inputs (u.sub.i). The delivered waveform parameters (y.sub.i) may include, but are not limited to, the number of pulses, duration of each pulse, number of pulse trains, applied voltage, electrode polarity configuration, inter-pulse timing and the timing of the cycle length. Exemplary parameters of the delivered waveform are shown in FIG. **3**. The user inputs (u.sub.i) may include, but are not limited to, the type of catheter being used, i.e. the particular arrangement, inter-electrode spacing, and number of electrodes **26** at the distal portion of the medical device **12**, which may be linear, spiral shaped, circular, or other electrodes **26** arrangements, which is a function of a particular medical device **12**; the type of target tissue, for example, cardiac tissue, vascular tissue, cancerous tissue, or other types of tissue; the desired lesion characteristics, for example, depth, for example 1-10 mm, the desired lesion surface are, the desire lesion length, the design lesion width, and the desired inter-electrode lesion depth.

(12) Through experimental modeling, the following are examples of calculations to determine various lesion characteristics (x.sub.i) in myocardial tissue which function as the modeling data and parameters for the medical device **12**, most exemplary for medical device **20** with distal portion **20** having a plurality of electrodes of a diameter of 1-2 mm, a length of 3-4 mm, and an inter-electrode spacing of 3-5 mm whereas the energy is passing between the positive and negative electrodes as designated in FIG. **1**: Average (x.sub.i) Depth=0.276+0.001943 Voltage−0.0650 Pulse

Width+0.01874 Pulses+0.0980 Trains+0.00186 Pulse Width*Pulse Width−0.000070 Pulses*Pulses. Average (x.sub.i) Surface Width=−0.65+0.00617 Voltage+0.1454 Pulse Width+0.03167 Pulses+0.1881 Trains−0.000124 Pulses*Pulses−0.000192 Voltage*Pulse Width. Average (x.sub.i) Depth (inter-electrode)=−6.40+0.01135 Voltage+0.1471 Pulse Width+0.02005 Pulses+0.329 Trains−0.000005 Voltage*Voltage−0.000104 Pulses*Pulses−0.01612 Trains*Trains−0.000116 Voltage*Pulse Width−0.00957 Pulse Width*Trains+0.001306 Pulses*Trains.

(13) Experimental modeling indicates certain of the waveform parameters (y) which are divided into variable (y.sub.k) which are statistically significant ablation variables in determining modeled lesion characteristics (x.sub.i) and thus are represented in the above models, and other waveform parameters are not statistically significant for a given characteristic, that may be set by other means such as safety considerations, and thus are preset as constant waveform parameters (y.sub.j) to either limit the amount of energy delivered, limit bubble production from the electrodes, limit to time of delivery, limit embolic loads, reduce unintended muscle stimulation, or a combination of each. In one embodiment, inter-pulse timing and inter-phase timing are parameters that are set as constants and cannot be modified by the user. Other parameters, for example, pulse width are set at values to minimize bubble formation at the electrodes **24**. In particular, when the pulse width is set at between 1-6 μs and in an exemplary configuration 5 μs, bubble formation is minimized while maximizing lesion formation. Moreover, the number of pulses may also be set as a constant to achieve a maximized lesion depth as adding additional pulses may not reduce the existing tissue damage, but does contribute to unnecessary bubble, energy, time, and/or coagulation delivery. Thus, the number of pulses is set to provide the most efficacious use of the energy given other potential concerns. For example, the number of pulses may be set as a constant at between 30-140 pulses (120 pulses in an exemplary configuration) and may not be modified by the user. Thus, voltage and/or electric field and the number of pulse trains delivered are the remaining parameters that the model determines and optimizes as a function of the user inputs (u.sub.i). The voltage and the number of pulse trains delivered are identified as waveform parameters (y.sub.k) which may be optimized and determined based on the model. Moreover, the number of applications is also a factor that has been identified as contributing to lesion depth.

(14) In an exemplary configuration based on the parameters discussed above, for a single train delivery to achieve a given lesion depth, the following equation applies: Depth=f(Voltage)+C=A*Voltage+C±model error, where C is a function of (y.sub.k) and (y.sub.i) and depth is (u.sub.i). So in specifying the desired depth (u.sub.i), the model may set (for example) the voltage level of the delivery from reversing the determined relationship to, for example: Voltage delivered=(DepthDesired−C (+model error))/A; or stated more generally: (*y*.sub.k)=*f*((*y*.sub.i),(*u*.sub.i), and (*x*.sub.i))

(15) The voltage level may be subject to a minimum and maximum achievable level as set by the generator **14** for, for example, safety precautions. So if the above relationship does not have a satisfactory solution (i.e. required depth is too large for the maximum allowable voltage), it could additionally specify the required number of deliveries (number of pulsed trains) to ensure the value is achieved or alert the user to unacceptable inputs. However, the model may assume a constant four pulse trains, with acceptable embolic loads, across a range of depths that correspond to different profiles, safety concerns, and a nominal dosing set. For example, the model assumes that the user would input a desired lesion depth between 1 mm and 8 mm, which correspondingly leads to the pre-set waveform parameters. The above model is also dependent on the medical device **12** and the arrangement of the plurality of electrodes **26** and is dependent on the type of tissue being treated, namely, cardiac tissue.

(16) The above model uses electroporation to non-encompassed tissue, effectively causing the electroporated region to be that volume projecting away from the electrodes **26** instead of between those electrodes **26**. This results in well-defined and repeatable lesion regions, which is distinct from encompassed tissue treated by monopolar radio frequency (RF) or traditional electroporation

procedures, which would have a much larger error in lesion depth calculations. Indeed, residual plot analysis of the model, as shown in FIG. **4**, illustrates that the model results are accurate and illustrates a quadratic relationship between the variables. Therefore, the model provides results that represent the measured actual data,

(17) It will be appreciated by persons skilled in the art that the present embodiments are not limited to what has been particularly shown and described herein above. In addition, unless mention was made above to the contrary, it should be noted that all of the accompanying drawings are not to scale. A variety of modifications and variations are possible in light of the above teachings without departing from the scope of the application

Claims

1. A pulsed field ablation medical device, comprising: an electrosurgical generator configured to generate a plurality of pulsed field waveforms; a plurality of electrodes coupled to the electrosurgical generator, the plurality of electrodes configured to deliver each of the plurality of pulsed field waveforms to ablate an area of tissue; and a processing circuitry in communication with the electrosurgical generator and the plurality of electrodes, the processing circuitry configured to: determine a desired lesion characteristic; determine a first waveform parameter based on the desired lesion characteristic; deliver, via the plurality of electrodes, a first pulsed field waveform of the plurality of pulsed field waveforms based on the first waveform parameter to ablate the area of tissue; measure a second lesion characteristic based on a result of delivering the first pulsed field waveform; determine a second waveform parameter based on the second lesion characteristic; and deliver, via the plurality of electrodes, a second pulsed field waveform of the plurality of pulsed field waveforms based on the second waveform parameter to ablate the area of tissue.

2. The pulsed field ablation medical device of claim 1, wherein the second waveform parameter is different than the first waveform parameter and the second pulsed field waveform is different than the first pulsed field waveform.

3. The pulsed field ablation medical device of claim 1, wherein the result of delivering the first pulsed field waveform is a lesion created by the plurality of electrodes.

4. The pulsed field ablation medical device of claim 1, wherein the processing circuitry optimizes the first waveform parameter based on the desired lesion characteristic and the second waveform parameter based on the second lesion characteristic.

5. The pulsed field ablation medical device of claim 1, wherein the processing circuitry determines the first waveform parameter and the second waveform parameter based on a waveform parameter threshold limiting a range of the first waveform parameter and the second waveform parameter corresponding to the waveform parameter threshold.

6. The pulsed field ablation medical device of claim 1, wherein the first waveform parameter and the second waveform parameter each includes at least one selected from the group consisting of a number of pulses, a duration of a pulse, a number of pulse trains, and an applied voltage.

7. The pulsed field ablation medical device of claim 1, wherein the processing circuitry determines the first waveform parameter and the second waveform parameter based on at least one selected from the group consisting of a type of pulsed field ablation catheter to deliver the first pulsed field waveform and the second pulsed field waveform, a configuration of the plurality of electrodes, and a shape of an electrode of the plurality of electrodes.

8. The pulsed field ablation medical device of claim 1, wherein each of the desired lesion characteristic and the second lesion characteristic is at least one selected from the group consisting of a lesion depth, lesion width, lesion surface area, and an inter-electrode lesion depth.

9. The pulsed field ablation medical device of claim 1, wherein the processing circuitry determines the first waveform parameter and the second waveform parameter based on a correlation between a

corresponding lesion characteristic and waveform parameters of a pulsed field waveform.
10. The pulsed field ablation medical device of claim 1, wherein the processing circuitry determines the first waveform parameter and the second waveform parameter based on at least one selected from the group consisting of a limit on energy of a pulse, a limit on time of delivery of pulses, and a limit to bubble production from the plurality of electrodes.
11. A method of delivering a pulsed field waveform with a pulsed field ablation medical device, the method comprising: determining, via a processor having a processing circuitry, a desired lesion characteristic; determining, via the processing circuitry, a first waveform parameter based on the desired lesion characteristic; delivering, via an electrosurgical generator coupled to a plurality of electrodes, a first pulsed field waveform based on the first waveform parameter to ablate an area of tissue; measuring, via the processing circuitry, a second lesion characteristic based on a result of delivering the first pulsed field waveform; determining, via the processing circuitry, a second waveform parameter based on the second lesion characteristic; and delivering, via the electrosurgical generator coupled to the plurality of electrodes, a second pulsed field waveform based on the second waveform parameter to ablate the area of tissue.
12. The method of claim 11, wherein the second waveform parameter is different than the first waveform parameter and the second pulsed field waveform is different than the first pulsed field waveform.
13. The method of claim 11, wherein the result of delivering the first pulsed field waveform is a lesion created by the plurality of electrodes.
14. The method of claim 11, further comprising optimizing, via the processing circuitry, the first waveform parameter based on the desired lesion characteristic and the second waveform parameter based on the second lesion characteristic.
15. The method of claim 11, wherein determining the first waveform parameter and the second waveform parameter is based on a waveform parameter threshold limiting a range of the first waveform parameter and the second waveform parameter corresponding to the waveform parameter threshold.
16. The method of claim 11, wherein the first waveform parameter and the second waveform parameter each includes at least one selected from the group consisting of a number of pulses, a duration of a pulse, a number of pulse trains, and an applied voltage.
17. The method of claim 11, wherein determining the first waveform parameter and the second waveform parameter is based on at least one selected from the group consisting of a type of pulsed field ablation catheter to deliver the first pulsed field waveform and the second pulsed field waveform, a configuration of the plurality of electrodes, and a shape of an electrode of the plurality of electrodes.
18. The method of claim 11, wherein each of the desired lesion characteristic and the second lesion characteristic is at least one selected from the group consisting of a lesion depth, lesion width, lesion surface area, and an inter-electrode lesion depth.
19. The method of claim 11, wherein determining the first waveform parameter and the second waveform parameter is based on a correlation between a corresponding lesion characteristic and waveform parameters of a pulsed field waveform.
20. The method of claim 11, wherein determining the first waveform parameter and the second waveform parameter is based on at least one selected from the group consisting of a limit on energy of a pulse, a limit on time of delivery of pulses, and a limit to bubble production from the plurality of electrodes.