

THERAPY IN THE EVENT OF ELECTRODE FAILURE

The invention relates to an implantable medical device for the defibrillation of a patient's heart and to a method for controlling such a medical device.

Such implantable medical devices are also referred to as implantable cardioverter defibrillators (ICDs for short). Such a medical device is designed to detect ventricular fibrillation of the patient's heart and to treat it by delivering an electric shock or a current pulse.

The problem with an implantable medical device having a defibrillation function is the circumstance that, due to the comparatively high voltage for generating a current pulse, high voltage flashovers may occur in the event of an insulation defect of an electrode, causing a very high fault current. Current ICDs include an electronic short circuit fuse for this failure event, so that the ICD does not experience any component damage in the event of a short circuit, and furthermore is able to carry out the diagnostic and therapeutic functions thereof, however with the limitation that the high voltage therapy remains ineffective.

In this regard, US2010228307 describes a reduction of the shocking energy in the ICD when electrode failures are identified so as to prevent a voltage flashover from the electrode failure site to the device housing.

In the event of an identified short circuit in the shock electrode path, it is furthermore known in the prior art to switch the shock electrode configuration or the shock path for subsequent therapy attempts, provided that a so-called dual coil electrode is used. Dual coil electrodes comprise a right ventricular shock coil (RV coil) and a second shock coil in the superior vena cava (superior vena cava coil, SVC coil). Different shock paths between the RV coil, the SVC coil and the implant housing can be selected. In this regard, refer to Swerdlow et al, "Implantable Cardiac Defibrillator Lead Failure and Management," JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY, VOL. 67, NO. 11, 2016.

However, the absence of a high voltage therapy due to short circuit protection is not desirable since the patient may thus possibly not be provided with a necessary therapy. In principle, it is desirable to be able to provide the patient with a high voltage therapy/defibrillation even in the above-described failure case, which in particular is not limited by the use of a specific shock electrode.

Aspects of the invention are defined in the independent claims. Some optional features of the invention are defined in the dependent claims.

Thus, it may be possible to provide an implantable medical device for the defibrillation of a patient's heart which, in the event of an insulation defect of a defibrillation electrode with short circuit identification and triggering of the short circuit fuse in the device, is nonetheless able to carry out further therapy attempts, which have an increased likelihood of being successful in this situation for terminating life-threatening ventricular tachyarrhythmia.

Further, it may be possible to provide a corresponding method for controlling such an implantable medical device.

According to claim 1, an implantable medical device is disclosed, which is designed for the defibrillation of a patient's heart and further comprises:

- an energy storage, which comprises at least two capacitors for providing a voltage;
- at least one electrode for delivering an electrical current pulse by way of the voltage;
- and
- a short circuit fuse, which is designed to be triggered in the event of a short circuit of the at least one electrode and to terminate or to prevent a delivery of an electrical current pulse, wherein the implantable medical device is designed, in the event of the short circuit, to prompt the delivery of a further current pulse, in particular by way of a reduced voltage, from a parallel connection of the at least two capacitors.

A reduced voltage shall be understood to mean here that the further current pulse is delivered with a voltage that is reduced compared to the voltage of the terminated or prevented current pulse.

The implantable medical device may thus allow an adapted high voltage therapy attempt (defibrillation) to be delivered in the event that an electrode defect is present in the high voltage therapy path, by preferably reducing the therapy voltage, in the event that an electrode failure is identified, in such a way that a higher likelihood of the therapy being successful is achieved in this situation.

The approach may have the advantage that the therapy or shock voltage can be reduced compared to that of a normal defibrillation shock, while the delivered shocking energy substantially remains the same.

The implantable medical device can, in particular, utilize the mechanism of a typical short circuit in the defibrillation path of the device. During an insulation defect of the electrode used for shocking, in general no purely metallic contact exists between the high voltage-conducting conductors or components, but a voltage flashover or arc may occur at the moment the high voltage is delivered. The likelihood of such a flashover increases with the applied maximum voltage, and can therefore be reduced if the maximum voltage is reduced in subsequent therapy attempts, however only to the extent that sufficient therapy success continues to be possible.

According to a preferred embodiment of the implantable medical device, it is further provided that the implantable medical device may comprise an identification device, which is designed to identify the triggering of the short circuit fuse, and to signal this to a control unit of the implantable medical device, wherein the control unit is designed to deliver the further current pulse having the preferably reduced voltage if it has been identified that the short circuit fuse was triggered.

According to one embodiment, it is further provided that the control unit may be designed to prompt a switch of a series connection of capacitors to the parallel connection of the at least two capacitors if it has been identified that the short circuit fuse was triggered. For example, an overall voltage present at the two capacitors connected in series can be reduced in the process to a lower voltage that is present at the capacitors now connected in parallel.

According to a preferred embodiment of the implantable medical device, it is further provided that the at least one electrode of the implantable medical device may be designed to be inserted into the ventricle of the patient via a vein (that is, the medical device is a so-called transvenous cardioverter defibrillator).

According to a preferred embodiment of the implantable medical device, it is further provided that the at least one electrode of the implantable medical device may be designed to be subcutaneously implanted, and more particularly above the patient's sternum.

According to a preferred embodiment of the implantable medical device, it is further provided that the at least one electrode of the implantable medical device may be designed to be substernally implanted (that is, under the patient's sternum).

The implantable medical device may preferably comprise a housing for accommodating the at least two capacitors or the energy storage, as well as in particular the further components (such as the short circuit fuse and/or the control unit and/or identification device). The at least one electrode may be connected to the housing.

In the case of a subcutaneous or transvenous electrode, the housing can be designed, for example, to be implanted into the patient's chest (for example, on the left next to the thorax, below the axilla). The housing can also be implanted in the patient's chest in the case of a substernal electrode.

A further aspect relates to a method for controlling an implantable medical device, comprising the following steps:

- providing a voltage by way of at least two capacitors of the implantable medical device for delivering a current pulse;
- terminating or preventing a delivery of the electrical current pulse in the event a short circuit of an electrode of the implantable medical device is identified; and
- delivering a further current pulse from a parallel connection of the at least two capacitors.

According to a preferred embodiment of the method, it is provided that a short circuit fuse of the implantable medical device may be triggered in the event of a short circuit of an electrode, and a delivery of an electrical current pulse by way of the implantable medical device may be thereby terminated or prevented, wherein, in particular in the case of a short circuit, the further current pulse may be delivered from the parallel connection of the at least two capacitors.

According to a preferred embodiment of the method, it is further provided that the triggering of the short circuit fuse may be automatically identified by way of an identification device, wherein the identification device may signal the triggering of the short circuit fuse to a control unit of the implantable medical device, and wherein the control unit may prompt the delivery of the further current pulse if it has been identified that the short circuit fuse was triggered.

According to a preferred embodiment of the method, it is provided that a switch of a series connection of the capacitors to the parallel connection of the at least two capacitors may be automatically prompted by the implantable medical device in the event of a short circuit (for example, by the control unit), and thereafter the delivery of the further current pulse may be prompted.

Embodiments of the invention and further features and advantages of the invention will be described hereafter by way of example only and based on the figures. In the drawings:

FIG. 1 shows a schematic representation of a typical failure mechanism of the implantable medical device, which can result in a short circuit of an electrode of the device;

FIG. 2 shows a reduction of the voltage of the medical device for generating an electrical current pulse for the defibrillation;

FIG. 3 shows a schematic representation of the switch between a series connection of the capacitors of the implantable medical device and a parallel connection of the capacitors for reducing said voltage; and

FIG. 4 shows a further option for reducing the voltage for the defibrillation.

FIG. 1 illustrates a typical failure mechanism of an insulation defect during a defibrillation shock delivery (that is, delivery of an electrical current pulse) by an implantable medical device 1. The at least one electrode 100 is implemented as an electrode lead 100 and comprises, in particular, an electrical conductor 110 and an insulator 120 surrounding the same, wherein this insulator 120 has an insulation defect 130 in the event of a failure. The counter electrode for the defibrillation is a housing 140 of the implantable medical device 1 or defibrillator 1 in this case.

Since, in this system, the electrical conductor 110 and the housing 140 typically cannot touch one another even in the area of the insulation defect 130, an identification of this insulation defect is not possible by way of a low voltage measurement, that is, the so-called painless shock impedance measurement does not show any abnormality here.

If, however, a high voltage therapy is now delivered by way of the electrode 100 and the counter electrode 140, a high voltage flashover 150 may occur in the area of the insulation defect, resulting in a very high fault current. The implantable electronic device 1 therefore comprises an electronic short circuit fuse 160 for this failure event, so that the device 1 does not experience any component damage in the event of a short circuit, and continues to be able to carry out the diagnostic and therapeutic functions thereof, however with the limitation that the high voltage therapy remains ineffective.

The short circuit fuse 160 is designed to be triggered in the event of a short circuit of the at least one electrode 100 and to terminate or to prevent a delivery of an electrical current pulse by the implantable medical device 1. The implantable medical device 1 further preferably comprises an identification device 170 (refer to FIG. 1), which is designed to identify the triggering of the short circuit fuse 160 and to signal this to a control unit 180 of the

implantable medical device 1, wherein the control unit 180 is designed to prompt a further electrical current pulse from a parallel connection of at least two capacitors C1, C2 if it has been identified that the short circuit fuse 160 was triggered. According to one embodiment, the control unit 180 or the medical device 1 is configured to carry out a switch from a previous series connection of the capacitors C1, C2 to a parallel connection (dotted line between C1 and C2 in FIG. 1) in such a way that the delivery of the further current pulse from the parallel connection takes place with a voltage that is reduced compared to the voltage of the series connection of the capacitors intended with the terminated or with the prevented current pulse.

FIG. 2 shows a schematic representation of the reduction of the voltage during the delivery of the shock therapy in the event of an insulation defect. The first delivered defibrillation shock or electrical current pulse 200 is delivered with the programmed or maximum voltage U1, which causes a high voltage flashover 150 in the area of the insulation defect 130, and the shock delivery is thereupon terminated by the electronic short circuit fuse 160. The shocking energy 240 to be delivered thus does not become effective for the defibrillation.

In this implementation example, the maximum voltage is set to a reduced value U2 (in particular by the above-described switch of the capacitors C1 and C2) during the next defibrillation attempt 250, after it has been identified that the short circuit fuse 160 was triggered, so that the likelihood of a renewed high voltage flashover is reduced, while it is still possible to deliver sufficient shocking energy 260 for likely success of the therapy. If, in this case, no renewed high voltage flashover occurs, the intended defibrillation energy is delivered, and the tachyarrhythmia can thus be terminated.

FIG. 3 schematically illustrates the above-described switch of the capacitors C1, C2. Initially, the defibrillation shock 410 or electrical current pulse is delivered from a series connection 400 of the two capacitors C1, C2, which in the event of a failure causes the short circuit fuse 160 to be triggered (see above). The subsequent shock is now delivered from the parallel connection 420 of the two capacitors C1, C2, which offers the advantage that the shock peak voltage is cut in half, for example, and at the same time essentially the entire maximum shocking energy can be delivered.

FIG. 4 illustrates another option of reducing the voltage so as to implement a defibrillation shock delivery with a considerably reduced peak voltage, and thereby reduce the likelihood of a high voltage flashover.

The first shock 310 or electrical current pulse for defibrillation is delivered from a series connection 300 of three capacitors C1, C2, C3 here, wherein this results in the short circuit fuse 160 being triggered as a result of an insulation defect.

In the subsequent shock or current pulse 330, the tap for the shock delivery is only set in a series connection 320 of the capacitors C2, C3 by way of electronic switch elements (not shown here), and the peak voltage of the shock 330 is thereby reduced by $1/3$. In this system, the capacitance resulting during the shock delivery increases, and the duration of the shock phases is thus extended, which can result in a higher efficiency of the therapy, yet also a lower shock peak voltage, if the capacitances are suitable designed.

The implantable medical device and the method advantageously increase the likelihood that a life-saving therapy can still be delivered in the event of an electrode defect of the implantable medical device.

Claims

1. An implantable medical device (1) for the defibrillation of a patient's heart, comprising:
 - an energy storage (C1, C2), which comprises at least two capacitors (C1, C2) for providing a voltage;
 - at least one electrode (100) for delivering an electrical current pulse by way of the voltage; and
 - a short circuit fuse (160), which is designed to be triggered in the event of a short circuit of the at least one electrode (100) and to terminate or to prevent a delivery of an electrical current pulse, wherein the implantable medical device (1) is designed to prompt the delivery of a further current pulse from a parallel connection of the at least two capacitors (C1, C2) in the event of the short circuit.
2. The implantable medical device according to claim 1, characterized in that the implantable medical device (1) comprises an identification device (170), which is designed to identify the triggering of the short circuit fuse (160) and to signal this to a control unit (180) of the implantable medical device (1), the control unit (180) being designed to prompt the delivery of the further current pulse if it has been identified that the short circuit fuse (160) was triggered.
3. The implantable medical device according to claim 2, **characterized in that** the control unit (180) is designed to prompt a switch of a series connection (400) of capacitors (C1, C2) to the parallel connection (420) of the at least two capacitors (C1, C2) if it has been identified that the short circuit fuse (160) was triggered.
4. An implantable medical device according to any one of the preceding claims, **characterized in that** the at least one electrode (100) of the implantable medical device (1) is designed to be inserted into a ventricle of the patient via a vein.

5. An implantable medical device according to any one of the preceding claims, **characterized in that** the at least one electrode (100) of the implantable medical device (1) is designed to be subcutaneously implanted.
6. An implantable medical device according to any one of the preceding claims, **characterized in that** the at least one electrode (100) of the implantable medical device (1) is designed to be substernally implanted.
7. A method for controlling an implantable medical device (1), comprising the following steps:
 - providing a voltage by way of at least two capacitors (C1, C2) of the implantable medical device (1) for delivering a current pulse;
 - terminating or preventing a delivery of the electrical current pulse in the event a short circuit of an electrode (100) of the implantable medical device (1) is identified; and
 - delivering a further current pulse from a parallel connection of (420) the at least two capacitors (C1, C2).
8. The method according to claim 7, **wherein** a short circuit fuse (160) of the implantable medical device (1) is triggered in the event of a short circuit of the electrode (100), and a delivery of the electrical current pulse is thereby terminated or prevented.
9. The method according to claim 8, **characterized in that** the triggering of the short circuit fuse (160) is identified by way of an identification device (170), the identification device (170) signaling the triggering of the short circuit fuse (160) to a control unit (180) of the implantable medical device (1), and the control unit (180) prompting the delivery of the further current pulse if it has been identified that the short circuit fuse (160) was triggered.
10. The method according to claim 9, **characterized in that** the control unit (180) prompts a switch of a series connection (400) of capacitors (C1, C2) to the parallel connection

(420) of the at least two capacitors (C1, C2) if it has been identified that the short circuit fuse (160) was triggered.