Stepped defibrillation waveform is substantially more efficient than the 50/50% tilt biphasic

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BACKGROUND Even with biphasic waveforms, patients with high defibrillation thresholds (DFTs) still are seen; thus, improved defibrillation waveforms may be of clinical utility. The stepped waveform has three parts: the first portion is positive with two capacitors in parallel, the second is positive with the capacitors in series, and the last portion is negative, also with the capacitors in series.

OBJECTIVES The purpose of this study was to assess the clinical utility of improved defibrillation waveforms.

METHODS We measured the delivered energy DFT in 20 patients in a dual-site study using the stepped waveform and a 50/50% tilt biphasic truncated exponential as the control. All shocks were delivered using an arbitrary waveform defibrillator, which was programmed to mimic two 220-μF capacitors (110 μF in series and 440 μF in parallel).

RESULTS The peak voltage at DFT was reduced in 19 of the 20 patients. The median peak voltage was reduced by 32.0%, from 472 V to 321 V ($P < .001$). The median energy DFT was reduced by 33%, from 11.7 J to 7.8 J ($P = .008$). The mean voltage and energy were reduced by 25.3% and 20.2%, respectively. On average, the stepped waveform was able to defibrillate as well as the 50/50% tilt biphasic, with 33% more energy. The benefit was more pronounced in patients with either a lower ejection fraction or a superior vena cava coil. The benefit of the stepped waveform had an inverse quadratic correlation with the resistance ($r^2 = 0.47$), suggesting that the capacitance values chosen for the stepped waveform were close to optimal for a 35-Ω resistance.

CONCLUSION The stepped waveform reduced the DFT compared to the 50/50% tilt waveform in this preliminary study.

KEYWORDS Defibrillation threshold; Stepped Waveform; Biphasic waveform; Implantable cardioverter-defibrillator

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Introduction

Patients with a high defibrillation threshold (DFT) present an atypical but vexing problem to implantable cardioverter-defibrillator (ICD) therapy. Such patients constitute approximately 6% to 11% of the implant population.[1,2] Their implant procedures are lengthy, resulting in more risk of complications.[3–6] In addition to acute problems, they often have secondary complications because of the extra leads implanted, including the subcutaneous array.[7,8] Finally, these patients eventually may have a reduced safety margin,[9] which may compromise their survival, although this has never been clearly demonstrated.[10,11]

The advent of the biphasic waveform has significantly reduced DFTs and allowed the routine use of transvenous leads. However, most biphasic waveforms still are not optimized according to the present scientific understanding of their mechanism of action.

The burping theory of the biphasic shock holds that the function of the first phase is to extinguish as many wavefronts as possible by "capturing" a majority of the cells in the broad sense. This is largely achieved by activating recovered cells and prolonging the action potential of stimulated cells. (Complex spatial effects and postshock active processes also are involved but go beyond the scope of this introduction.[12–14]) The function of the second phase is to counter the three side effects of the first phase. These side effects are marginal stimulation, electroporation, and launching of new wavefronts by virtual cathodes[15,16] (created by the complex distribution of intracellular and extracellular current flow). The term "burping" came from the analogy to the removal of excess gas from a baby.[17] All major predictions of the burping theory have been verified in animal[18–21] and human[22,23] studies.

The tilt denomination for the duration of defibrillation waveforms arose from the invention of the truncated capacitive discharge waveform by Schuder et al.[24] They used a single time constant for truncation that gave a residual voltage fraction of $0.37 = 1 - e^{-1}$ (which one would now refer to as a "63% tilt"). This gave a duration for the

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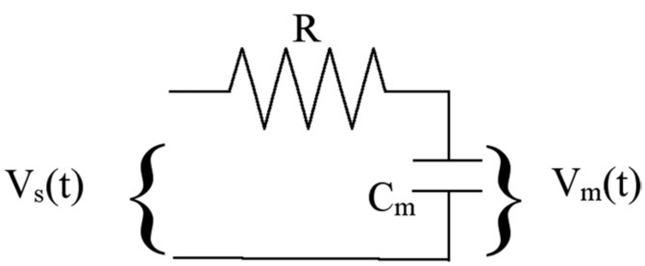

Figure 1 Resistor-capacitor membrane model for cardiac tissue. The shock voltage is $V_s(t)$ and the membrane response is given as $V_m(t)$. C_m represents the membrane capacitance, and R represents the Thevenin equivalent combination of the intercellular and transmembrane resistance.

Table 1 Durations of the three sections of the stepped waveform

Resistance (Ω)	D_1 (ms)	D_2 (ms)	D_3 (ms)
30	3.2	2.2	3.6
35	3.3	2.5	3.6
40	3.3	2.7	3.2
45	3.4	2.9	3.1
50	3.4	3.1	3.0
55	3.5	3.3	2.9
60	3.5	3.5	2.9
65	3.5	3.6	2.8
70	3.5	3.8	2.8

monophasic shock close to optimum for the low-resistance epicardial patches then in use.

The passive cardiac membrane model (Figure 1) suggests that stepping the first phase of the biphasic waveform, thereby approximating a ramping waveform, should give more efficient charging of the cell membranes, which in turn should allow for "capture" of the myocardial cells with lower voltages and energies.[25]

A stepped waveform can be created by separating the high-voltage capacitor pair in an ICD and using them initially in parallel and then in series for the positive phase, and finally leaving them in series for the negative phase. The durations of the phases are chosen based on the myocardial membrane time constant, which is equal to the product of C_m and R in Figure 1.

The stepped waveform and associated membrane charging are shown in Figure 2. The DFT improvement, for the stepped waveform, can be estimated from the increased relative amplitude achieved by the cardiac membrane for a given amplitude defibrillation shock.

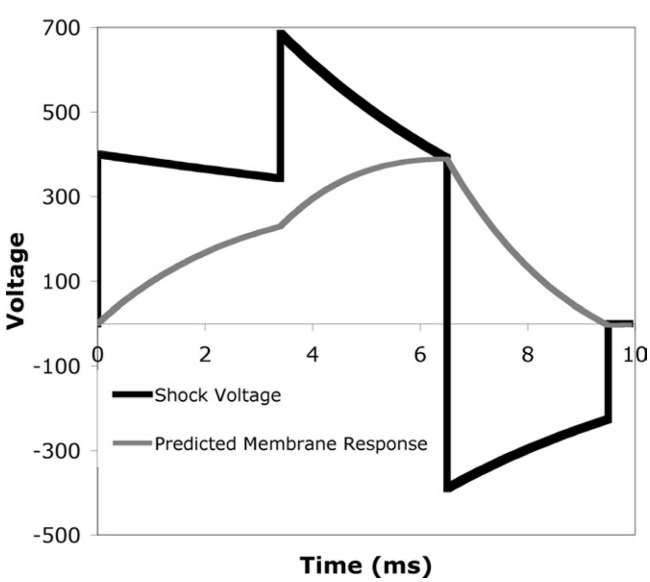

Figure 2 Stepped waveform and predicted membrane response. The shock voltage represents a typical high-energy shock, and the units are actual. However, the membrane response typically is on the order of 20 to 100 mV, and thus the scale on the left does not apply. The positive membrane response shown is a stylized depiction of the typical response near the shock cathodes. The membrane response will be the reverse of this (negative) near the shock anode.

Methods

Criteria for inclusion in the study were as follows: patients must have been approved to receive a *de novo* ICD or an ICD replacement, be stable, and provide written informed consent. Patients with an epicardial lead, age younger than 18 years, pregnant, or—in the physician's clinical judgment—unable to safely tolerate eight inductions were excluded from the study. There were no upper or lower limits on the ejection fraction. The study protocol was approved by the ethics committee of each institution. All norms for conducting clinical research, including the Declaration of Helsinki, were followed properly. The study was sponsored by St. Jude Medical, Inc.

Patients were randomized to receive either the stepped or the control waveform first. The control waveform was a 50/50% tilt biphasic truncated simulated 110-μF capacitive discharge, as this is the most commonly implanted waveform today.[26]

The durations for each of the three sections of the stepped waveform as a function of the interelectrode resistance are given in Table 1. D_1 is the duration of the first section where the capacitors are in parallel (equivalent capacitance 440 μF) and the voltage is positive. D_2 is the duration of the second section where the capacitors are in series (equivalent capacitance 110 μF) and the voltage is still positive. D_3 is the duration of the third section where the capacitors are still in series (equivalent capacitance 110 μF) but the voltage is now negative. Note that D_1 increases very slightly with resistance, whereas D_2 increases almost proportionally. Finally, D_3 decreases with increasing resistance. This is in stark contrast with tilt-based waveforms in which all phases increase in direct proportion to the resistance.

Testing was performed using a custom arbitrary waveform defibrillator with the patient under general anesthesia. The arbitrary waveform defibrillator is a special purpose device that is not intended for commercial distribution but has received a CE safety certificate for research. The arbitrary waveform defibrillator automatically calculates the shock impedance as the ratio of voltage to current and also directly calculates the delivered energy using the delivered voltages and the impedance. All testing was performed with