Improved defibrillation thresholds with large contoured epicardial electrodes and biphasic waveforms

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ABSTRACT  A reduction in the shock strength required for defibrillation would allow use of a smaller automatic implantable cardioverter-defibrillator and would reduce the possibility of myocardial damage by the shock. Most internal defibrillation electrodes require 5 to 25 J for successful defibrillation in human beings and in dogs. In an attempt to lower the shock strength needed for defibrillation, we designed two large titanium defibrillation patch electrodes that were contoured to fit over the right and left ventricles of the dog heart, covering areas of approximately 33 and 39 cm², respectively. In six anesthetized open-chest dogs, the electrodes were secured directly to the epicardium and ventricular fibillation was induced by 60 Hz alternating current. Truncated exponential monophasic and biphasic shocks were given 10 sec later and defibrillation thresholds (DFTs) were determined. The DFT was 159 ± 48 V, 3.2 ± 1.9 J (mean ± SD) for 10 msec monophasic shocks and 106 ± 22 V, 1.3 ± 0.4 J, for biphasic shocks with both phase durations equal to 5 msec (5-5 msec). The experiment was repeated in another six dogs in which the electrodes were secured to the pericardium. The mean DFT was not significantly higher than that for the electrodes on the epicardium: 165 ± 27 V, 3.1 ± 1.2 J for 10 msec monophasic shocks and 116 ± 19 V, 1.6 ± 0.5 J for 5-5 msec biphasic shocks. Low DFTs were also obtained with biphasic shocks in which the duration of the first phase was longer than that of the second. In a third group of six dogs, DFTs were determined for the large contoured electrodes as well as for 10 cm² flat patch electrodes on the right and left ventricular epicardium. The mean DFT was significantly lower for the 5-5 msec biphasic waveform than for the 10 msec monophasic waveform for both types of electrodes, and the mean DFT for the large contoured electrodes was significantly lower than that for the flat patch electrodes for both types of waveforms. We conclude that the shock strength required for defibrillation can be markedly lowered by means of biphasic shocks and large contoured patch electrodes.


A CLINICAL advantage would be gained if the shock strength required for direct defibrillation with the automatic implantable cardioverter-defibrillator (AICD) could be reduced. Since the size of the unit is largely determined by the sizes of the battery and capacitor, a reduction in required shock strength would permit the implantable device to be smaller.1, 2 A decrease in defibrillation shock strength might also reduce the myocardial damage1, 3, 4 and cardiac arrhythmias5–7 caused by high-intensity defibrillation shocks. Increasing the size of AICD electrodes has been shown to decrease the defibrillation threshold (DFT).8–11 We designed a pair of large titanium defibrillation patch electrodes that were contoured to fit the right and left ventricles of the canine heart. The purpose of this study was to determine whether the DFT was low for these large electrodes. Since recent studies have indicated that biphasic waveforms decrease required defibrillation shock strengths and reduce cardiac arrhythmias,12–16 we tested the effects of several biphasic and monophasic waveforms on the DFT. We also studied the incidence and types of cardiac arrhythmias that occurred with high-voltage shocks for different types of waveforms.

Methods

Defibrillation electrodes. The defibrillation electrodes were large titanium mesh patches insulated on their outer surfaces.
with silicone rubber. The patches were contoured to fit over the epicardial or pericardial surfaces of the right and left ventricles of the dog heart. The approximate surface areas covered by the right and left ventricular electrodes were 33 and 39 cm², respectively. Ideal placement of the electrodes is shown in figure 1. The electrodes were placed so that (1) the adjacent edges of the two electrodes were equidistant except for the electrode borders along the atroventricular groove and (2) all ventricular myocardium was contained with the imaginary surface formed by connecting the borders of the adjacent electrodes, including the borders along the atroventricular groove. Electrodes were placed on 20 dogs. Adequate electrode placement was achieved in 18; the anatomy of two of the largest hearts was such that the electrodes could not be placed to achieve the above two criteria. The experiment was performed in three parts.

Part I

Surgical procedures and instrumentation. Six mongrel dogs (mean weight ± SD 27.3 ± 3.3 kg) were anesthetized with sodium pentobarbital (30 to 35 mg/kg), intubated with a cuffed endotracheal tube, and ventilated with room air and oxygen through a Harvard respirator (Harvard Apparatus Co., South Natick, MA). A peripheral venous catheter was inserted for continuous infusion of lactated Ringer’s solution supplemented with sodium bicarbonate, potassium chloride, and calcium chloride. A separate intravenous line was inserted for infusion of sodium pentobarbital at a rate of approximately 0.05 mg/kg/min for maintenance of adequate anesthesia. An initial bolus of succinylcholine (1 mg/kg) was given to reduce muscle spasm induced by the defibrillation shocks. Additional boluses of succinylcholine were administered at a dose of 0.5 mg/kg no more than once per hour to maintain muscle relaxation. A femoral arterial line was inserted, and systemic blood pressure was displayed continuously on an oscilloscope. Arterial blood samples were drawn every 30 to 60 min to determine pH, Po₂, Pco₂, base excess, total CO₂ content, and bicarbonate, sodium, potassium, and calcium concentrations. Any abnormal values were corrected as needed. Electrocardiographic leads were applied, and lead II signals were monitored on an oscilloscope.

The chest was opened through a median sternotomy and the heart suspended in a pericardial cradle. The electrodes were secured to the epicardial surface of the right and left ventricles with 3-0 silk sutures (figure 1). For the induction of fibrillation, two solid stainless-steel, Teflon-insulated wires (AWG 30, Cooner Wire Co., Chatsworth, CA) were sutured to the anterior epicardium of either the right or left ventricle.

Defibrillation protocol. Ventricular fibrillation was induced by 60 Hz alternating current delivered through the two stainless-steel wires. After sustained fibrillation lasting 10 sec after termination of the alternating current, defibrillation was attempted by applying shocks through the contoured patches. For the first dog in the series, an initial shock of 100 V leading-edge voltage was given during diastole of normal sinus rhythm and the impedance of the heart was calculated. The defibrillation sequence was then begun with a shock of approximately 4 J for each waveform. In subsequent dogs we used the average DFT of previous dogs as the initial shock voltage for each waveform. The DFT was determined by a method similar to the protocol described by Bourland et al.¹⁷ If defibrillation was successful, the strength of the next test shock was decreased by 20 V. Subsequent shocks were decreased in increments of 20 V until a defibrillation attempt failed. The strength of the shock was then increased by 10 V and the lowest shock that achieved defibrillation was considered to be the DFT.

If the initial test shock failed to defibrillate, a salvage shock was given within 30 sec of the onset of fibrillation. The salvage shock typically was of the same waveform as the test shock and was approximately 50% higher in voltage than the average DFT for this waveform in previously studied dogs. Subsequent test shocks were then increased in increments of 20 V until defibrillation was achieved. The shock strength was then decreased by 10 V and the lowest voltage that successfully defibrillated was designated as the DFT. A recovery period of at least 5 min was allowed between each episode of fibrillation. Fibrillation was not reintiated until heart rate and blood pressure had returned to normal.

DFTs were determined in this part of the experiment for the following five waveforms: (1) monophasic 5 msec duration (5), (2) monophasic 10 msec duration (10), (3) biphasic with both phase durations equal to 5 msec (5-5), (4) biphasic with the first phase delivered for 5 msec at half of the selected voltage and the second for 5 msec at full voltage [5 (%)-5], (5) triphasic with durations of 5 msec, 5 msec, and 2 msec (5-5-2).

The order in which the five waveforms were tested was rotated for each of the six dogs. For example, the sequence of waveforms in the first dog was 1, 2, 3, 4, and 5 and that in the second dog was 2, 3, 4, 5, 1. The shocks were truncated exponential waveforms delivered from a 175 μF capacitor except for the first phase of the 5 (%)-5 shock, which was delivered from a 350 μF capacitor. For the shocks delivered from the 175 μF capacitor through a 40 Ω impedance, the waveform tilt was 50% for a 5 msec shock and 75% for a 10 msec shock. The left ventricular electrode was anode for the monophasic shocks, cathode then anode for the biphasic shocks, and cathode, anode, cathode for the triphasic shocks. The switch time between phases of multiasic shocks was 0.12 msec. For the full voltage biphasic and triphasic waveforms, the energy of each shock was calculated from the measured leading and trailing edge voltages of the shock and from the impedance at the beginning of the phase for which the left ventricular electrode was the anode. An exponential curve was fit to the leading and trailing edge voltages.

**FIGURE 1.** Diagram of the contoured patch electrodes. The left ventricular electrode covered most of the lateral free wall and apex of the left ventricle. The right ventricular electrode covered most of the outflow tract as well as the base of the anterior right ventricle. The edges of the two electrodes were maintained as equidistant from each other as possible (a). AO = aorta; LA = left atrium; LV = left ventricle; PA = pulmonary artery; RA = right atrium; RV = right ventricle.
and the energy was calculated by dividing the area under the square of this curve by the impedance. For the 5 (½)-5 shock, the exponential voltage curves were calculated from the measured leading edge voltage, the value of the capacitance for each phase, and the impedance measured at the leading edge of the second phase; the energy was determined by dividing the area under the square of these curves by the impedance.

**Part II**

**Surgical procedures and instrumentation.** To allow for the possibility that the large patch electrodes might interfere with wall motion or damage the myocardium, in six mongrel dogs (mean weight 24.8 ± 1.0 kg) the contoured electrodes were affixed directly to the outside of the intact pericardium in positions over the right and left ventricles corresponding to the electrode positions on the epicardium in part I. The two stainless-steel wires used for inducing fibrillation were sutured to the pericardium over the anterior right or left ventricle. The remainder of the surgical procedures were the same as in part I.

**Defibrillation protocol.** As in part I, fibrillation was induced with 60 Hz alternating current and defibrillation shocks were given through the patch electrodes. For the first dog, the initial leading-edge voltage used for each waveform was either the average DFT for that waveform in dogs in part I or, in the case of new waveforms not tested in part I, an initial voltage chosen by our best estimate based on the DFT of similar waveforms. For subsequent dogs, the average DFT of previous dogs was used as the initial shock voltage for each waveform. Defibrillation thresholds were determined by the same procedure as in part I, again with a recovery period of at least 5 min between each episode of fibrillation.

Since the results of part I indicated the efficacy of biphasic waveforms for defibrillation, in part II we determined the effect of changing the relative durations of the two phases while keeping the total duration of the waveform at 10 msec. The durations of the two phases of the biphasic waveforms that were tested were as follows: 2.5 and 7.5 msec (2.5-7.5), 3.5 and 6.5 msec (3.5-6.5), 5 and 5 msec (5-5), 6.5 and 3.5 msec (6.5-3.5), and 7.5 and 2.5 msec (7.5-2.5). A 10 msec monophasic waveform was also tested. As in part I, the order in which the waveforms were tested was rotated for each dog.

**Part III**

**Surgical procedures and instrumentation.** In six mongrel dogs (mean weight 20.8 ± 2.9 kg), the DFT of the large, contoured electrodes was compared with that of an electrode configuration that is used clinically, i.e., two flat titanium mesh patch electrodes, one on each ventricle. Each flat electrode patch was 10 cm² in area. One patch electrode was placed over the anterior basal right ventricular free wall and the other over the posterolateral apical left ventricular free wall. Both sets of electrodes were placed directly on the epicardium in turn and the DFT was determined as in part I. In three dogs, the large contoured electrodes were tested first, followed by the flat patch electrodes, and in the other three dogs the order of electrode placement was reversed. ECGs from leads I, II, and III were recorded as were four epicardial bipolar electrodes, one each from the right atrium, left atrium, right ventricle, and left ventricle.

**Defibrillation protocol.** The DFTs were determined for two of the better biphasic waveforms in part II, 5-5 and 6.5-3.5 msec, and for the 10 msec monophasic waveform. The sequence in which the waveforms were tested was randomized for both types of electrodes. Fibrillation was induced, and DFTs were determined as in part I. For the first dog, the initial leading-edge voltage used for the large contoured electrodes was the average DFT for the same waveform in part II. For the flat patch electrodes in the first dog, an initial voltage was chosen based on the DFT for the same waveform in part II. For subsequent dogs, the average DFT of previous shocks was used as a initial shock voltage for each electrode configuration and shock waveform.

**Statistical analysis.** Comparisons of the threshold voltage and energy among waveforms were made with a one-way analysis of variance. Multiple comparisons between different waveforms and electrode configurations were performed with a Student-Newman-Keuls test. A two-tailed paired t test was performed to compare threshold energy, voltage and impedance for the 10 monophasic and 5-5 biphasic waveform between epicardial and pericardial studies. Significance was defined as p < .05.

**High-voltage studies.** After the defibrillation protocol of part II, we delivered a series of high-voltage shocks to each dog to learn whether postshock arrhythmias would be induced. The high-voltage shocks were given with the biphasic 5-5 and 6.5-3.5 waveforms. The order in which these waveforms were tested was altered for each dog.

The dog was fibrillated as before, and after 10 sec of sustained fibrillation a defibrillation shock with a 200 V leading edge was given with one of the two waveforms. If the shock failed, the dog was fibrillated within 30 sec with a salvage shock of a waveform and strength previously shown to be highly successful. The procedure was repeated with the same waveform using defibrillation shocks of 300, 400, 500, 600, and 700 V in sequence, with a recovery period of at least 5 min between each episode of fibrillation. Arrhythmias were recorded on a Mingograf recorder (Siemens-Elema, Solna, Sweden) from ECG lead II. When fibrillation was induced by the high-voltage shock it was terminated by giving a salvage shock of lower voltage, approximately 50% above the DFT. The entire sequence from 200 to 700 V was then repeated with the other waveform.

After the defibrillation protocol of part III, we delivered high-voltage shocks to determine whether postshock arrhythmias were induced at the same voltage with monophasic and biphasic waveforms. The 10 msec monophasic and 5-5 msec biphasic waveforms were examined. The protocol was the same as that for high voltage shocks in part II. The electrodes placed last on the epicardium for determining the DFT in part III were used to deliver the high-voltage shocks.

**Results**

DFTs. In part I of the study, in which the electrodes were secured to the epicardium, the DFTs expressed as leading-edge voltage were lower for the full-voltage biphasic and triphasic waveforms than for the monophasic or the half-voltage biphasic waveforms (figure 2, table 1). The DFT voltages for the 5-5 and 5-5-2 waveforms were significantly lower than for the 10 msec monophasic waveform, which in turn was significantly lower than the DFTs for the 5 msec monophasic waveform and 5 (½)-5 biphasic waveform. In terms of energy, DFTs for the 5-5 and 5-5-2 waveforms were significantly lower than the DFTs for the other three waveforms. The DFT for the 5-5 waveform was less than 2 J for all six dogs.

In part II, with the electrodes fixed to the outside of the pericardium, the DFTs expressed both in voltage and in energy were significantly lower for the 5-5, 6.5-3.5, and 7.5-2.5 waveforms than for all others (figure 3, table 1). The DFT for the 10 msec monophasic waveform was significantly lower than for the
3.5-6.5 biphasic waveform, which in turn was significantly lower than the DFT for the 2.5-7.5 biphasic waveform. The DFT for the 6.5-3.5 waveform was less than 2 J in all six dogs. An unpaired t-test showed no significant differences between epicardial and pericardial electrodes for the 5-5 biphasic or 10 monophasic waveforms in DFT voltage, energy, or impedance.

In part III, with large contoured electrodes and flat patch electrodes on the epicardium, the contoured electrodes and the biphasic waveforms were both found to lower the DFTs expressed in voltage or energy (figure 4, table 1). The DFTs for each of the three waveforms were significantly lower for the contoured electrodes than for the patch electrodes, indicating the effectiveness of the contoured electrode in lowering DFT voltage and energy. The current was not lowered significantly, however, by the contoured electrode. The DFTs for the two biphasic waveforms were significantly lower than for the monophasic waveform for both the contoured and the patch electrodes, indicating the effectiveness of the biphasic waveform in lowering DFT voltage and energy. The DFTs for both biphasic waveforms with the large contoured electrodes were less than 2 J in all six dogs.

High-voltage shocks. Ventricular tachyarrhythmias were observed after suprathreshold shocks for both monophasic and biphasic waveforms (table 2). There was a tendency for the duration and severity of the arrhythmias to increase with increasing shock voltage. Ventricular fibrillation occurred frequently with shocks of 400 V (10 J) or greater. Both the contoured and patch electrodes applied directly to the epicardium gave rise to postshock arrhythmias.

Tachyarrhythmias were also observed after biphasic shocks administered via the contoured electrodes on the outside of the pericardium (table 3). Although no tachycardias of long duration were observed with the pericardial electrodes, ventricular fibrillation again occurred with strong shocks (500 V, 27 J). Both 5-5 and 6.5-3.5 shocks gave rise to tachycardia and fibrillation.

**Table 1**

<table>
<thead>
<tr>
<th>Electrode</th>
<th>Waveform</th>
<th>Voltage (V)</th>
<th>Energy (J)</th>
<th>Current (A)</th>
<th>Impedance (Ω)</th>
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<tr>
<td>c</td>
<td>5</td>
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<td>3.0 ± 1.6</td>
<td>4.8 ± 1.6</td>
<td>40.7 ± 3.3</td>
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<tr>
<td>c</td>
<td>10</td>
<td>159 ± 48</td>
<td>3.2 ± 1.9</td>
<td>4.1 ± 1.4</td>
<td>39.7 ± 5.2</td>
</tr>
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<td>c</td>
<td>5–5</td>
<td>106 ± 22</td>
<td>1.3 ± 0.4</td>
<td>3.4 ± 0.7</td>
<td>31.8 ± 4.7</td>
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<td>5(½–5)</td>
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<td>3.0 ± 1.5</td>
<td>5.3 ± 1.9</td>
<td>38.3 ± 5.2</td>
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<td>5–5–2</td>
<td>111 ± 28</td>
<td>1.4 ± 0.8</td>
<td>3.7 ± 1.1</td>
<td>30.7 ± 2.0</td>
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<td>165 ± 26.9</td>
<td>3.1 ± 1.2</td>
<td>4.2 ± 0.8</td>
<td>39.3 ± 3.1</td>
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<td>2.5–7.5</td>
<td>281 ± 32.3</td>
<td>8.3 ± 1.8</td>
<td>7.5 ± 0.9</td>
<td>37.7 ± 5.2</td>
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<tr>
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<tr>
<td>c</td>
<td>5–5</td>
<td>116 ± 19.4</td>
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<td>3.6 ± 0.9</td>
<td>32.8 ± 4.7</td>
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<td>1.6 ± 0.5</td>
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<td>30.0 ± 3.9</td>
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<td>Part III</td>
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<td>p</td>
<td>10</td>
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<td>4.1 ± 0.7</td>
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<td>64.5 ± 4.8</td>
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<td>p</td>
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<td>184 ± 28</td>
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<td>1.0 ± 0.5</td>
<td>3.2 ± 0.9</td>
<td>35.0 ± 3.3</td>
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</table>

c = large contoured electrodes; p = flat patch electrodes.
mean values reported are again in the 5 to 25 J range \(^{1, 5, 9, 10, 24-31}\). At the lower end of this range, Mirowski et al., \(^{24}\) obtained DFTs of 4 to 10 J with chronically implanted titanium catheter electrodes and epicardial defibrillation patches in dogs. Kallok et al. \(^{10}\) obtained a mean DFT of less than 3 J in isolated canine hearts using large titanium patch electrodes in conjunction with a defibrillating catheter. A similar electrode configuration required a mean of 7.9 J to defibrillate canine hearts in situ. \(^{32}\) Kugelberg \(^{28}\) also reported low DFTs in the isolated canine heart with multiple monophasic shocks. DFTs may be lower in isolated hearts because the coronary arteries are per-

TABLE 2
Incidence of tachyarrhythmias with suprathreshold monophasic and biphasic shocks with epicardial contoured and patch electrodes

<table>
<thead>
<tr>
<th>Voltage</th>
<th>&lt;2</th>
<th>2–5</th>
<th>6–10</th>
<th>11–20</th>
<th>&gt;20</th>
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<td>2</td>
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<td>5–5 biphasic waveform</td>
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</table>

The numbers denote the number of dogs in each category. VF = ventricular fibrillation; VT = ventricular tachycardia.

^A Shocks of this voltage were near the defibrillation threshold in four dogs for the monophasic waveform and in two dogs for the biphasic waveform and so were not included for those dogs.

TABLE 3
Incidence of tachyarrhythmias with suprathreshold 5–5 and 6.5–3.5 biphasic shocks with epicardial contoured and patch electrodes

<table>
<thead>
<tr>
<th>Voltage</th>
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<th>2–5</th>
<th>6–10</th>
<th>11–20</th>
<th>&gt;20</th>
<th>VF</th>
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The numbers denote the number of dogs in each category. Abbreviations as in table 2.
fused during fibrillation and because current flow is confined to the heart, since it is surrounded by air.

The results of this experiment indicate that defibrillation may be reliably achieved in situ at shock energies lower than those commonly required. Our best results were obtained with large contoured electrodes and 5-5, 6.5-3.5, and 7.5-2.5 biphasic waveforms that defibrillated consistently in the 1 to 2 J range. This is well below most reported values and significantly lower than that observed in the same animals (figure 4) with one of the best electrode configurations previously developed.8 Although the DFT has historically been expressed in terms of energy, leading-edge voltage is a more important determinant of the size of an implantable device. As shown in figures 2, 3, and 4, DFTs when expressed as voltages were also lowest for contoured electrodes and biphasic waveforms.

It has been suggested that the percent success rate for different strength shocks is a more meaningful concept than is the DFT.33, 34 Because of the large differences in thresholds, the DFT protocol allowed us to determine in a relatively short period of time that the contoured electrodes have merit and that some biphasic shocks are superior to monophasic shocks. Because of the smaller differences in thresholds, the protocol did not allow us to evaluate which of the biphasic waveforms is best; this question may require determining percent success rates.

Electrodes. The low DFTs obtained in this study were a result of both the electrodes and the waveforms used (figure 4). Although there were large differences in the DFTs for different waveforms, the fact that the DFTs for both monophasic and biphasic waveforms were lower for the large contoured electrodes indicates that some characteristics of these electrodes contributed to the reduction of DFT.

Several criteria were considered in the design of the large, contoured electrodes:

(1) The surface area of the electrodes was large, decreasing impedance and creating a more even current density through the ventricles.

(2) The size and location of the electrodes were designed so that all of the ventricular myocardium was placed over the borders of the two electrodes, yet the borders of the two electrodes were as far apart as possible to decrease current shunting between the electrode edges.

(3) The electrodes were shaped so that when properly placed on the heart, the electrode borders would be nearly equidistant at all points except along the atrioventricular groove. If the borders were not equidistant, current density would probably be greater where the edges were closer together and lower where they were farther apart.

(4) An electrode was placed on each ventricle so that current would flow from the free wall of one ventricle across the septum to the free wall of the other ventricle.32 If the electrodes were placed anteriorly and posteriorly, it is possible that much of the current may have traversed the high-conductivity blood cavities of the ventricles instead of the septum.

(5) To avoid possible vascular injury, the electrodes were not placed over the three major coronary arteries.

The large size of the electrodes probably contributed to the reduction of DFT. Several investigators have reported improved defibrillation with an increase in the size of external paddles35, 36 or internal patch electrodes.8-11 One reason for this improvement may be that the larger electrodes have a lower impedance, thus permitting more current to reach the heart with a shock of any given energy. It has been hypothesized that larger patch electrodes create a more uniform current density, thus reducing the shock strength necessary for defibrillation.9, 37 Since our left ventricular electrode is strongly curved38, 39 and the heart is both inhomogeneous and anisotropic,40 the current density may still be relatively uneven. If distribution of the current density were marked more uniform with the contoured electrodes than with the patch electrodes, then the DFT expressed as current should have been significantly lower for the contoured electrodes, which was not the case (table 1).

Because of the large size of the electrodes, it was necessary to contour them to fit the curvature of the heart to ensure good contact. Contoured electrodes may be more efficacious than flat or only slightly concave ones because a closer contact is possible. Heilman et al.,31 testing different types of epicardial defibrillation electrode systems in dogs, found the lowest energy requirements (0.5 to 5 J) and the highest reliability (82% success) with conformal apical and basal electrodes. They abandoned the use of contoured electrodes in humans, however, because of the difficulty in achieving a good fit.41 Although the variation in the sizes and shapes of the individual hearts prevented a perfect fit in every case, we obtained adequate contact and placement in 18 of 20 dogs with the same pair of electrodes. In two dogs with very large hearts, the fixed size and shape of the electrodes prevented adequate electrode placement. The fixed size of the electrodes was more of a problem than the fixed shape, but this could be overcome by having electrodes of several different sizes available at the time of implantation. The contoured shape of the electrodes was generally sat-
isfactory and was somewhat adjustable with suturing techniques. However, it may not be possible to use large contoured electrodes in the presence of aneurysms or other morphologic irregularities.

Although large electrodes have been found to reduce defibrillation energy requirements, there are possible disadvantages that must be considered before such electrodes may be used clinically. The use of large electrodes may not be possible in patients with an aneurysmectomy or coronary artery bypass grafts to marginal branches of the left circumflex artery or to distal portions of diagonal branches of the left anterior descending artery. Because the electrodes are large and fit closely to the heart, they may interfere with wall motion and ventricular function when fixed to the epicardium. There is also a chance that large electrodes may present more risk than smaller electrodes, since larger electrodes may increase susceptibility to irritation and create a higher incidence of arrhythmias. Indeed, focal bleeding was observed beneath the left ventricular electrode in three of the animals of part I.

To determine whether some of these possible disadvantages could be avoided, in part II we sutured the electrodes to the pericardium rather than directly to the epicardium. Although statistical analysis showed no significant difference between the epicardial and pericardial DFTs for the 10 monophasic or 5-5 biphasic waveform, the number of animals was too small for this negative result to be conclusive. This finding suggests, however, that any differences between thresholds for electrodes on the epicardium and on the pericardium are small, although others have reported large differences. The advantages of pericardial as opposed to epicardial placement are decreased impairment of wall motion, decreased chance of epicardial irritation and bleeding, and elimination of the need to open the pericardium. Disadvantages are possible irritation of the phrenic nerve or pericarditis.

Waveforms. Various waveforms have been used for defibrillation, and there is some disagreement as to which are more effective. In the AICD developed by Mirowski et al., the waveform is a single truncated exponential pulse as described by Schuder et al. Several investigators have demonstrated that multiple monophasic defibrillation shocks may be more efficacious than single monophasic shocks, although others have found no advantage in multiple shocks in terms of energy requirements for defibrillation. The apparent contradiction in these results may be due to the fact that the studies were performed with a variety of electrodes and waveforms.

Recent investigators have shown that biphasic waveforms are superior to monophasic waveforms in many cases. In experiments with 100 kg calves, Schuder et al. were able to defibrillate with symmetric biphasic rectangular waveforms at a lower range of energy and current and to achieve a higher percentage of successful first-shock defibrillations than with monophasic waveforms. Similar good results were obtained by the same investigators with asymmetric biphasic waveforms in which the amplitude of the second phase of the shock was smaller than that of the first phase; the durations of both phases were equal. Jones et al. found that biphasic waveforms with the second phase of lower amplitude than the first decreased postshock dysfunction in cultured myocardial cells. In the present study, biphasic waveforms were tested in which the duration of the two phases was asymmetric. Waveforms in which the duration of the second phase was equal to or smaller than that of the first phase produced the lowest DFTs. Thus phase duration as well as amplitude affects the efficacy of the biphasic waveform.

Jones et al. have proposed a mechanism for the success of biphasic waveforms. They found that biphasic waveforms reduced the excitation threshold of potassium-depolarized chick embryo myocardial cells when compared with the excitation threshold found with monophasic waveforms. This reduction in excitation threshold occurred for biphasic waveforms of 2 to 40 msec total duration but not for shorter durations. The investigators hypothesized that because extracellular potassium is increased during fibrillation and the resting transmembrane potential is reduced to about −60 mV, the first phase of the biphasic waveform may act as a "conditioning" pulse in that it causes hyperpolarization of a portion of the cells. Hyperpolarization would return the resting potential to a more normal value and lower excitation threshold. If such a conditioning mechanism does indeed function, it seems reasonable that the duration of the first phase affects the extent of conditioning. As can be seen from figures 2 and 3, with the exception of the 5 (½)-5 waveform, the biphasic shocks produced lower DFTs than the monophasic shocks when the first phase duration was equal to or greater than half of the total shock duration and higher DFTs when the first phase was of shorter duration. It may be that a short first phase is of insufficient duration to allow the conditioning process to be completed. Since the initial phase of the 5 (½)-5 defibrillation shock was of low voltage, it may not have generated sufficient current flow to condition the cells.

Higher-voltage shocks. It has been demonstrated that cardiac arrhythmias may result from shocks of high
Evidence suggests that biphasic shocks may cause less dysfunction than monophasic shocks\textsuperscript{12, 14} and that the amount of dysfunction may also depend on the relative duration of the two phases of biphasic shocks.\textsuperscript{14} We studied the incidence and types of arrhythmias that occur at higher shock strengths with monophasic waveforms and two of the most efficacious biphasic waveforms, 5-5 and 6.3-3.5 (tables 2 and 3). Ventricular tachycardia was induced by all waveforms at a shock strength of 200 V, and the duration and incidence tended to increase with an increase in voltage. Ventricular fibrillation occurred with all waveforms and both types of electrodes at shock strengths of 400 to 700 V.

Jones and Jones\textsuperscript{7, 14} have introduced the concept of a safety factor for defibrillation that is similar in concept to the toxic-therapeutic ratio of drugs. The smallest of the higher-voltage shocks that induced fibrillation was approximately 17 J for both monophasic and biphasic waveforms, and the mean DFTs were 1.5 to 3.2 J for 10 msec monophasic waveforms and 0.8 to 1.3 J for 5-5 and 6.5-3.5 biphasic waveforms. Thus the energy safety factor is about 10:1 with the monophasic waveform and 20:1 with the two biphasic waveforms.

The range of energies for which ventricular fibrillation occurred encompasses the standard 25 J first shock commonly used in the current AICD. If our defibrillation electrodes are implemented for clinical use, the strength of the standard first shock may need to be reduced. Although results in humans may differ, this study in animals suggests that defibrillation with large contoured electrodes can be achieved with biphasic shocks of much less than 25 J and that shocks of 25 J may induce arrhythmias.

In summary, we have tested a defibrillation system in dogs that has provided promising results for the development of an implantable device for human use. Although further studies must be conducted to determine the most efficacious waveforms and to test the long-term effects of the electrodes on cardiac function, the biphasic waveform in conjunction with large myocardial contoured electrodes may lead to the development of a smaller AICD that defibrillates consistently at lower energy.

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