

SMART Biphasic

A Proven, Fixed, Low-Energy Defibrillation Waveform

INTRODUCTION

The 1990s heralded a new era of transthoracic defibrillation in which the rules of conventional practice no longer apply. Seeking waveform designs more efficient than the traditional monophasic defibrillation waveforms, most external defibrillator manufacturers followed the lead of the implantable cardioverter-defibrillator (ICD) industry, which established clear research evidence of superior clinical and engineering performance of low-energy biphasic defibrillation. By 1988, virtually all ICDs employed biphasic defibrillation waveforms, offering manufacturers the ability to design defibrillators that were smaller, more reliable, and provided superior clinical performance using lower energies.

As with ICDs, modern day transthoracic biphasic waveform technologies also allow smaller, more reliable devices, however external waveforms must deal with the

potentially adverse effects of varying patient chest impedance. In 1996, the first external biphasic defibrillation waveform in an automated external defibrillator was deployed by Philips Medical Systems. Philips offers the low-energy, impedance-compensating SMART Biphasic truncated exponential (BTE) waveform across its defibrillator product line, and is unique in the defibrillator industry for its leadership in evidence-based design.

Manufacturers have each taken different approaches to defibrillation and impedance compensation. As a result, the notion of one, standardized energy protocol for all is no longer warranted or appropriate, and each defibrillation waveform design must be evaluated based on available research.

Rules of Evidence: Evaluating the Differences Among Biphasic Waveforms

How does one differentiate the various biphasic designs? Which biphasic is better? The answer is no one knows. While peer-reviewed human research comparing each of the biphasic technologies within one study design is recognized as ideal, the likelihood of establishing performance differences that reach statistical significance using feasible sample sizes is remote. Thus, no manufacturer has undertaken a well-designed, prospective study in humans to answer the question of superiority among biphasic technologies.

The American Heart Association (AHA) has, however, established a clear evidence-based process for evaluating technologies. In 1997, the AHA established a set of recommendations for manufacturers seeking to design "alternative waveforms".¹ These guidelines were followed in 1998 by the first application of the new "evidence-based review" process,² in which the AHA evaluated the research available for defibrillation waveforms and provided recommendations for clinical practice. The process resulted in a Class IIb recommendation ("safe, acceptable, and clinically effective") for nonprogressive 150 J biphasic shocks, of which the Philips SMART Biphasic waveform was the first and only example.

Continuing the theme of evidence-based practice in the 2000 Guidelines document,³ the AHA issued no classification for high-energy defibrillation and a clear recommendation for low-energy biphasic. The following statement appears following a list of studies reflecting performance of the Philips SMART Biphasic waveform:

"Early clinical experience with the 150-J, impedance-compensated BTE waveform for treatment of out-of-hospital long-duration VF was also positive. . . The growing body of evidence is now considered sufficient to support a Class IIa recommendation for this low-energy, BTE waveform." Page I-63. (Class IIa is defined as having "good to very good evidence", a "standard of care", "intervention of choice".)

In addition, the following generic recommendation for low-energy biphasic defibrillation is provided:

"The data indicates that biphasic waveform shocks of relatively low energy (≤ 200 J) are safe and have equivalent or higher efficacy for termination of VF compared with higher-energy

escalating monophasic waveform shocks (Class IIa)" Page I-63.

Finally, the need for comprehensive waveform-specific data is emphasized:

"The safety and efficacy data related to specific biphasic waveforms must be evaluated on an individual basis in both in-hospital. . . and out-of-hospital settings."

As noted earlier, manufacturers of modern day defibrillation waveforms employ different strategies for waveform design. Following the lead of the AHA, it is critical to rigorously review the published waveform performance data before making a product decision. To properly evaluate the differences in waveform designs also requires an understanding of some basic electrical concepts.

Understanding Electricity

A Defibrillator Delivers "Electrical Medicine"

Think of administering medicine to a patient: The objective is to provide a dose of the correct medicine to quickly and effectively treat a condition. The dose must be properly measured and delivered over a prescribed period of time. The dose must be large enough to be therapeutic but not so large as to be harmful. With too little, the dose may be ineffective; with too much there are risks of an overdose. In critical situations, it is important to get the dose right the first time without having to try several experimental doses.

Now think of defibrillation as delivering a dose of electricity, and the waveform as a graphical way of showing how current is delivered to the patient over time. As with traditional medicine, it is crucial to tailor this "electrical medicine", calculating and measuring the correct defibrillation dose the first time, then delivering the dose effectively to optimize chances for success.

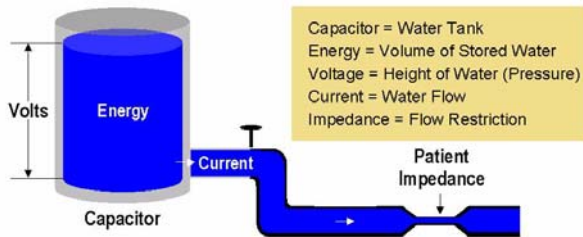
The Defibrillator

A defibrillator generates and delivers electrical therapy. In portable transthoracic defibrillators, the source of electricity is a battery. Although a battery may contain a huge amount of energy, it is not in a form to generate a defibrillation waveform that can be delivered quickly to the patient. To accomplish this, the defibrillator charging circuit extracts energy from the battery and stores it in a capacitor.

To illustrate the various electrical terms associated with this process of efficiently storing and delivering electricity to the patient, think of an analogy using a tank of water (see Figure 1). A water tank stores energy in the form of water raised to a particular height. Similarly, a defibrillator capacitor stores energy in the form of electrons at a particular voltage. The "capacitance" of the capacitor is measured in microfarads (μF). The larger the capacitance, the more energy must be stored to achieve a desired voltage.

Once the capacitor is charged to a desired voltage, it is ready to deliver a defibrillation waveform.

Figure 1 Water Tank Analogy



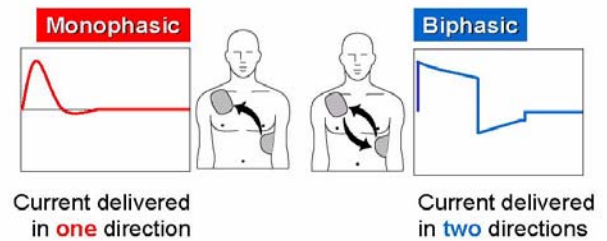
The Defibrillation Waveform

When it is time to defibrillate, switching circuitry within the defibrillator connects the charged capacitor to the patient's chest via paddles or electrode pads. Once connected, the voltage on the capacitor causes current to begin flowing through the patient. Just as the height of water in a tank creates pressure, forcing water through an open pipe, voltage is the driving force for electron flow (current) through a defibrillator circuit. It is current that delivers energy to the patient. Current, however, is resisted by the patient's impedance (measured in "ohms", or Ω) - an effect similar to a restricted water pipe. Contrary to common perceptions, patient impedance is not closely linked to patient size or weight.

The current through the patient's chest must vary during delivery in a specific manner in order to effectively defibrillate. The current delivered to a patient therefore changes during the course of a defibrillation shock. The pattern, or time course, of

this current variation is called a waveform. As shown in Figure 2, the defibrillator current time course flows in one direction with traditional monophasic waveforms whereas current in a biphasic waveform circuit flows in both a positive and negative direction. This biphasic two-directional flow of current within the defibrillator is reflected by current going from pad-to-pad in one direction, then reversing to flow in the opposite direction.

Figure 2 Monophasic vs. Biphasic Waveforms



The amount of current delivered from the capacitor depends upon patient impedance, or resistance to flow. Current flow (I) is equal to the capacitor voltage (V) divided by the patient's chest resistance (the symbol in this case is R); this relationship is known as "Ohm's Law": $I = V/R$.

As defibrillation current flows, it delivers energy to the patient. The longer the current flows, the higher the energy delivered.

Understanding Fixed versus Escalating Energy

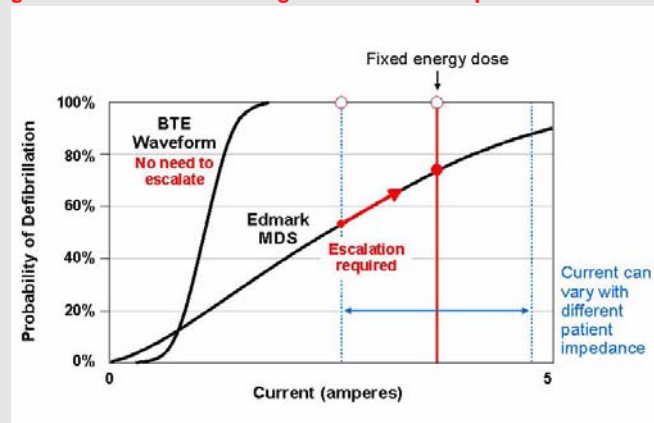
With substantial patent portfolios protecting various waveform designs, each manufacturer has chosen different approaches to manipulating the waveform. As a result, energy protocols are no longer standardized; some manufacturers have chosen a low-energy approach (either fixed or escalating) while others have adopted the escalating energy standard of the past. It is important to note, however, that the historical method of escalating energy was developed because the early monophasic waveforms performed relatively poorly with high impedance patients. Depending on the type of monophasic waveform, average first shock efficacy was only about 40 to 60 percent. Escalating the energy provided a mechanism to increase the current, thus increasing the probability of success despite inherently inefficient technology.

Historically, there has never been much evidence to support the practice of escalating energy. In fact, there is early evidence that escalation was associated with adverse consequences.⁴ The problem with this escalating energy approach, be it with monophasic or biphasic technology, is twofold. First, the myocardium remains in a lethal rhythm state while the device ramps up to an effective current dose. This delay in achieving an effective dose is particularly problematic for high impedance patients, for whom delivering adequate current is already more difficult without impedance compensation. Second, a multitude of evidence from both ICD and transthoracic monophasic defibrillators has shown a potential risk of myocardial dysfunction associated with high-energy defibrillation.⁴⁻⁹ To date, no studies have been published to assess the degree of dysfunction which occurs with high-energy biphasic transthoracic shocks applied to ischemic hearts.

For any waveform, the current delivered at a given energy will vary with patient impedance. A well-designed waveform thus accommodates variation in current delivery while maintaining high defibrillation efficacy.

The defibrillation response curves in Figure 3 demonstrate graphically how the probability of defibrillation changes with increasing current.¹⁰ Figure 3 also demonstrates the difference between the defibrillation response curves for a typical biphasic truncated exponential (BTE) waveform and the monophasic damped sine (MDS) waveform (the most commonly used monophasic waveform).

Figure 3 Fixed vs. Escalating Defibrillation Response Curves



With the gradual slope of the MDS waveform, it is apparent that as one increases the current, defibrillation efficacy is also improved. This finding led to the use of escalating energy with the MDS waveform, since peak current is increased with escalating energy, which results in a higher probability of defibrillation. For the monophasic waveform, therefore, increasing the energy can improve defibrillation efficacy. Selecting a fixed energy with the monophasic waveform that would defibrillate all patients could result in dangerously high energy and current levels, another factor supporting the use of escalating energy with traditional monophasic waveforms.

In contrast, the response curve for the biphasic waveform has a steeper slope and the probability of defibrillation changes very little once a certain current level is reached. This means that, if the energy and minimum delivered current levels are chosen appropriately (150 J for defibrillation, in our case), escalating energy is not required to increase efficacy. By selecting a fixed energy dose, the current delivered to the patient can vary as the patient impedance varies (more on this later), and the probability of defibrillation remains high. For the biphasic waveform, increasing the energy does not improve the defibrillation efficacy.

Principles of Effective Waveform Design

Until recently, the way in which electrical therapy was delivered by transthoracic defibrillators was essentially the same for all manufacturers. Most commonly, the defibrillation waveforms used were monophasic. Monophasic technology was constrained by the electronics components available during the era it originated (1960s), remained largely unchanged over time, and never had substantive research to support its performance. Further, the waveforms used energy inefficiently and were not able to adjust effectively to a patient's chest impedance.

Without effective defibrillator impedance compensation, high patient impedance degrades the waveform, a key factor in the relatively poor performance of traditional uncompensated monophasic technologies. Low impedance imposes a different set of potential problems. As will be described in greater detail later, low impedance patients may be more likely to shunt current away from the heart.

Today, modern electronics permit much greater control of therapy generation and delivery, including the ability to compensate for the untoward effects of high and low patient impedance. In the next sections, we examine how a well-designed modern defibrillator addresses crucial dosing factors to deliver safe and effective electrical medicine.

Dosing Factor 1: Seconds Count; Calculate the Correct Dose the First Time

There is ample evidence that speed to an effective first shock matters; even as little as a minute difference in time to first shock affects patient outcome.^{3, 11 - 13} The challenge for the defibrillator, then, is to effectively deliver the right amount of current on the first shock.

It is the pattern of current flow, not energy, which enables defibrillation. Voltage, current and the time course of waveform delivery all affect energy delivered to the patient. It is now possible for the defibrillator to manipulate any of these electrical characteristics to deliver an effective current pattern while using energy efficiently.

Escalating energy is no longer required. The solution to problems imposed by patient impedance is, instead, to design a defibrillation waveform that effectively measures and compensates for patient impedance, delivering the correct

dose of current (and energy) on the first shock. One of the challenges to delivering the correct dose of current, however, is to design a waveform that addresses the issue of shunted current, thought to be particularly an issue in low impedance patients.

A defibrillator delivers current across the chest ("transthoracic current"), but it is the proportion of the transthoracic current crossing the heart ("transcardiac current") that is clinically meaningful. Unfortunately, however, only a fraction of the current delivered by the defibrillator flows to the heart.¹⁴ To compensate for this current shunting phenomenon, a well-designed defibrillator provides sufficient transthoracic current even in the presence of shunt current pathways, as demonstrated in Figure 8.

In summary, by manipulating the defibrillator electronics and optimizing the waveform to address issues such as high impedance and shunting, it is now possible to achieve defibrillation on the first dose using a carefully calibrated fixed low-energy waveform design.

In fact, there is extensive and persuasive evidence that the Philips 150 J BTE waveform performs as well as or, in most studies, far better on the first shock than the "gold standard" monophasic defibrillation waveform, without the need to escalate.^{5, 8, 11 - 13, 15 - 18} In one representative study comparing 150 J SMART Biphasic to monophasic defibrillation,¹⁶ the Philips waveform is associated with superior efficacy (96% on the first shock, 98% by the third shock, and 100% patient efficacy), improved return of spontaneous circulation (ROSC), and better neurological outcomes in survivors, despite long call-to-first shock times averaging 8.9 minutes (see Figures 4, 5, and 6). No other defibrillator manufacturer can offer comparable patient outcome and waveform performance data for an ischemic sudden cardiac arrest (SCA) patient population.

Figure 4 Shock Efficacy

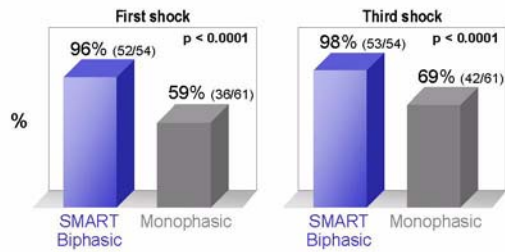


Figure 5 Return of Spontaneous Circulation (ROSC)

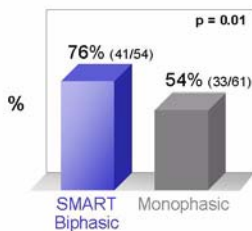
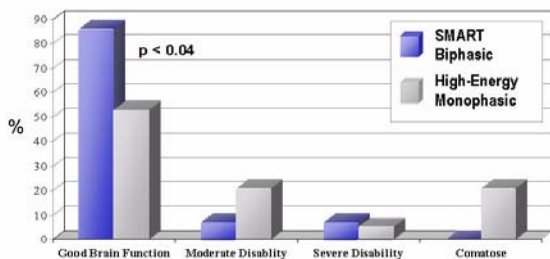


Figure 6 Brain Function in Survivors



Dosing Factor 2: Ensure that the Dose is Measured Accurately and Efficiently, Over the Correct Time Course

Another critical factor in achieving effective defibrillation is to deliver an appropriately measured dose of current for the correct amount of time. The engine of this process is a properly sized defibrillator capacitor. The size of the capacitor, ("capacitance", measured in microfarads, or μF) is crucial to effective and efficient defibrillator design.

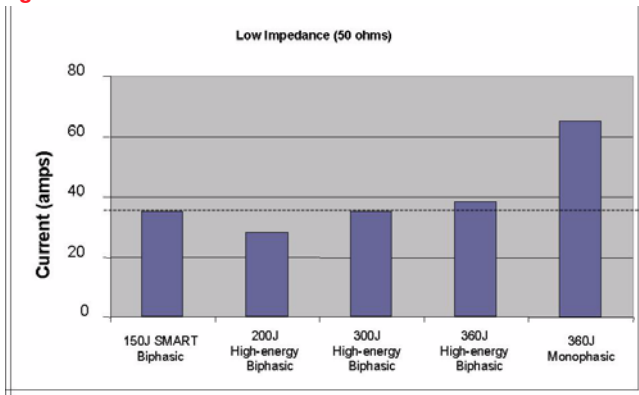
To prepare for a defibrillator shock, a defibrillator's capacitor must be charged to a voltage high enough to drive appropriate current through the resistance of the patient's chest throughout the time course of the shock. Energy is stored in preparation for defibrillation when the capacitor is charged. The larger the capacitor, the larger the amount of energy that must be stored in order to achieve the voltage necessary to initiate an appropriate dose of defibrillation current.

It is possible, however, to design a system in which energy is used efficiently, not requiring as much energy as has been historically the case with traditional monophasic waveforms. Recognizing this, Philips Medical Systems patented an optimal 100 μF capacitor design for its impedance-compensating SMART Biphasic waveform. The Philips capacitor requires little energy during charging, yet achieves the necessary voltage required to create effective defibrillation currents throughout the 150 J shock.

In contrast, some other modern defibrillator designs use larger capacitors (200 μF). These designs require twice as much energy in order to achieve the same patient currents available with the Philips low-energy 100 μF design.

Figure 7 contrasts the 150 J SMART Biphasic waveform, using a 100 μF capacitor, with other high-energy waveform designs. The Philips waveform achieves more current delivering 150 J than a 200 μF design delivering 200 Joules. The current of the high-energy biphasic defibrillator becomes comparable to the Philips waveform only when the energy reaches 300 Joules - on the second shock.

Figure 7 Peak Current Levels



It should also be noted from Figure 7 that modern biphasic waveform designs deliver far less current than some historic monophasic waveform systems. All of the modern biphasic technologies have been designed to be effective at comparatively lower peak currents, thus minimizing potential risks associated with older, high-peak current waveforms.

In short, the Philips system uses a proprietary low-capacitance design to efficiently generate a waveform personalized to patient impedance. This approach yields consistently favorable results even in challenging long down-time patient populations.

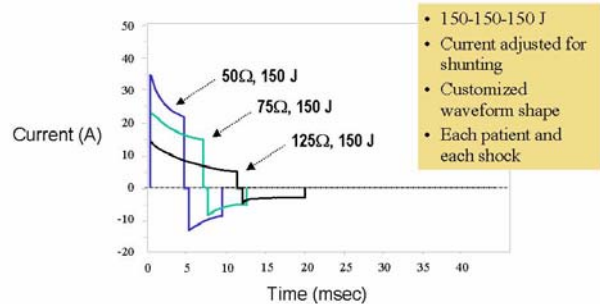
Dosing Factor 3: Deliver the Current (and Energy) Over the Correct Amount of Time for Each Patient Regardless of Impedance - A Personalized Waveform

The last critical dosing factor involves the design of the waveform, which delivers a changing pattern of current to the patient throughout the duration of the shock to accommodate variations in patient impedance. Since this current pattern is sometimes adversely affected by patient impedance, a well-designed waveform must measure patient impedance and adjust the waveform shape and duration accordingly, optimizing waveform performance across the range of anticipated impedance values.

A defibrillator waveform should compensate for both high and low chest impedance. Patient impedance in humans has been shown to vary anywhere from 25 to 180 ohms. According to Ohm's Law ($I = V/R$), a high impedance patient resists the flow

of current and, therefore, the peak current is less; the peak current in a low impedance patient is comparatively higher. This Ohm's Law relationship is illustrated in Figure 8, which shows energy fixed at 150 J and the Philips SMART Biphasic waveform shape and duration adjusting actively based on patient impedance.

Figure 8 SMART Biphasic Impedance Compensation



The shape and duration variations shown in Figure 8 have been carefully designed based on peer-reviewed evidence specific to the Philips waveform.¹⁹ Through this research, the "sweet spot" for waveform shape and duration was determined for the SMART Biphasic waveform using a fixed, 150 J adult defibrillation protocol.

Based on this research, the SMART Biphasic waveform is designed to perform across a wide range of anticipated patient impedance values. In the case of high impedance patients, the waveform lengthens to deliver adequate energy. For low impedance patients, the defibrillator delivers somewhat higher peak currents to compensate for the possible effects of shunting.

The performance of the Philips SMART Biphasic waveform has been tested in numerous peer-reviewed manuscripts, the number and breadth of which far exceeds that of any other manufacturer. These published studies reflect waveform performance both in animals^{7, 19-21} and in humans.

Of the 13 published human studies, to date, three report on experience with in-hospital induced, short-duration ventricular fibrillation (VF)^{5, 8, 22} and 10 address performance with the challenging long duration VF relevant to out-of-hospital and other delayed defibrillation settings.^{11 - 13, 15 - 18, 23 - 25} These data reflect performance consistently equal or superior to that of high-energy escalating therapies, regardless of factors such as: patient size, age, or impedance, underlying cause of SCA, including myocardial infarction, and pad placement.

Comparing the Transthoracic Biphasic Waveforms

Now that we have highlighted the key elements of effective biphasic waveform design, we turn to a brief overview of other external biphasic waveform technologies on the market. The SMART Biphasic waveform was introduced in 1996 with substantial patent protections. There are also patent restrictions on various other technologies. Consequently, the biphasic technologies are all different as are the associated energy protocols.

Because of these design differences, the energy protocol for each manufacturer's defibrillator should be individualized. The need for product-specific energy protocols is confirmed by ECRI, a non-profit organization whose mandate it is to objectively evaluate biomedical equipment: "...a waveform designed for low-energy defibrillation may result in an overdose if applied at high energies, while another waveform designed for high energy may not defibrillate at lower energies."²⁶

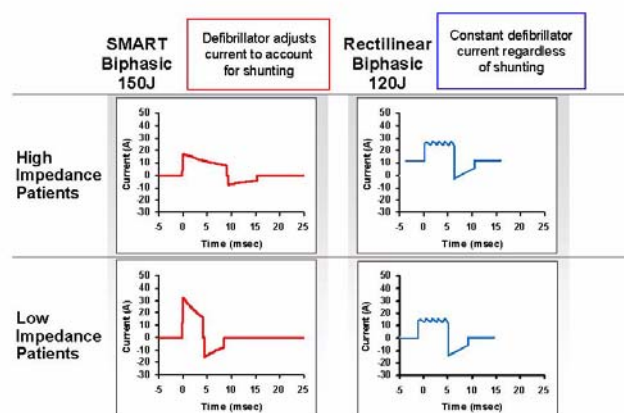
Most importantly, compared to the Philips SMART Biphasic waveform, other manufacturers have relatively few published, peer-reviewed studies to demonstrate the performance of their waveforms. Some manufacturers have no data at all, and others rely heavily upon small sample abstract and animal data to demonstrate waveform performance. Collectively, not only does the number and breadth of published SMART Biphasic manuscripts far exceed that of any other manufacturer's waveform but, to date, only Philips has provided peer-reviewed data from both in- and out-of-hospital patient populations.

The Low-Energy Rectilinear Biphasic Waveform Alternative

The rectilinear biphasic waveform shares with SMART Biphasic a low-energy, low-capacitance design, but there are significant differences. Most importantly, the rectilinear waveform offers only limited peer-reviewed evidence to support its performance. As of this writing, we are aware of no published, peer-reviewed data reflecting performance with the challenging long down-time patient population most difficult to treat effectively.

The rectilinear waveform does little to adjust current in response to the problem of shunt current pathways within the chest. The waveform utilizes what company literature describes as a "constant current" approach in the first phase of the waveform. In contrast to SMART Biphasic, which modifies peak current, waveform shape and duration based on patient impedance, the rectilinear approach is to hold the overall waveform duration and ratio between the two phases constant regardless of patient impedance (see Figure 9).

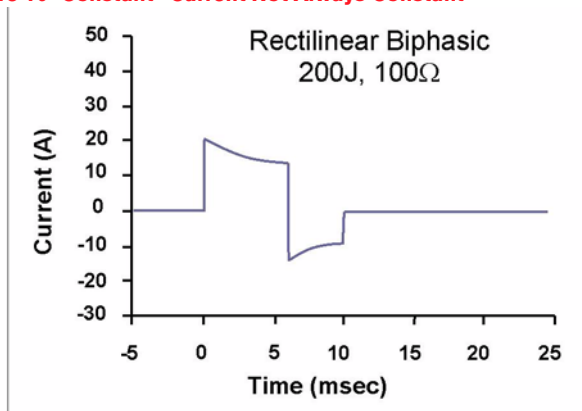
Figure 9 SMART Biphasic vs. Rectilinear Biphasic



The published adult energy protocol for the rectilinear biphasic waveform device starts at 120 J and escalates to 200 Joules. As noted earlier, escalating energy was employed historically to increase peak current with inherently inefficient monophasic waveforms and no longer is required for effective defibrillation with modern technology.

For any selected energy setting, the actual delivered rectilinear waveform energy varies widely across the range of patient impedance. Further, the rectilinear biphasic waveform loses the constant current profile, essentially becoming a BTE waveform very similar to SMART Biphasic (Figure 10), when patient impedance values exceed 100 ohms and 200J of energy is selected.²⁷

Figure 10 "Constant" Current Not Always Constant



In summary, the rectilinear waveform, marketed as a "constant current" waveform, does little to adjust current in response to current shunting in the patient's chest. The manufacturer abandons the hallmark "constant current" approach for some high impedance patients and, perhaps most importantly, has only limited published data on which to measure its waveform's performance, none of which reflects performance with the ischemic SCA patient.

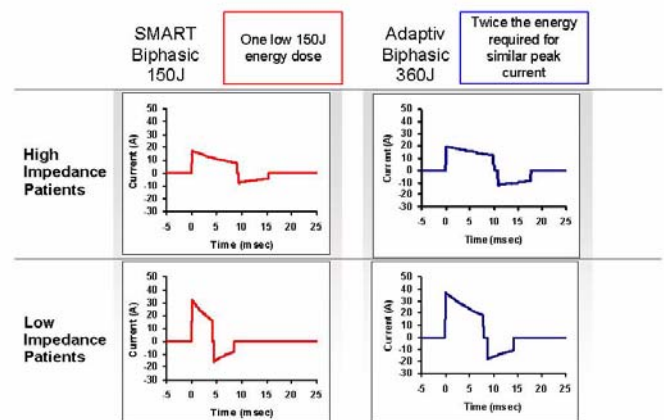
The High-Energy Biphasic Waveform Alternatives

There are several escalating high-energy biphasic waveforms currently on the market. It is beyond the scope of this paper to describe in detail each of the designs. Instead, we offer a high level summary of technology issues to consider with high-energy waveforms as a class.

First and foremost, as of this writing we are aware of no published, peer-reviewed evidence reflecting waveform performance for any of the high-energy biphasic waveforms with the ischemic, long down-time SCA patient population. In some cases, manufacturer's have provided little to no peer-reviewed data of any kind.

The specific methods of impedance compensation vary with the manufacturer. Figure 11 illustrates the SMART Biphasic waveform compared to one of the common high-energy biphasic waveforms on the market. It is evident that the two waveforms modify peak current, waveform shape and duration similarly in response to patient impedance. The big difference is that the high-energy waveforms require high energy to deliver adequate current to the patient because of their large capacitors, while the Philips low-energy BTE waveform delivers adequate current on the first shock without the need to escalate.

Figure 11 SMART Biphasic vs. High-Energy Biphasic



In summary, high-energy biphasic waveforms offer little or no published, peer-reviewed data in comparison to that published for the Philips SMART Biphasic waveform, and none of the data reflect performance with the rigorous long down-time SCA patient population. The high-energy alternatives are energy-inefficient, requiring high energies and, often, multiple shocks to achieve the same current (and voltage) provided on the first shock with the fixed, low-energy SMART Biphasic waveform.

Finally, the AHA has issued no science-based recommendations regarding biphasic defibrillation > 200 Joules.

Conclusion

Traditional monophasic waveform technology, while it saved many lives, had serious design limitations. High patient impedance degraded the waveform, resulting in relatively poor performance. A strategy of escalating energy was employed, without supporting science, in an effort to compensate for monophasic design limitations.

With the advent of modern biphasic waveform technology, however, impedance compensation and other design improvements have led to generally superior clinical and engineering performance characteristics without the need to escalate energy. The variety of external biphasic waveforms in the marketplace has prompted complexity and confusion around clinical practice guidelines. Conventional standards of practice no longer apply and clinicians now must evaluate far more than was historically the case—electrical engineering design principles, waveform-specific energy protocols, and published research.

The AHA has recommended an evidenced-based process for evaluating defibrillation waveforms, reflecting published research in both in- and out-of-hospital settings. To date, Philips Medical Systems is the only manufacturer to offer published data reflecting performance in both in- and out-of-hospital patients, and has established a clear leadership position in evidence-based waveform design. Based on published research, the AHA has provided a IIa recommendation for low-energy biphasic defibrillation (≤ 200 J), a specific IIa recommendation for the type of fixed low-energy biphasic waveform found in the Philips device, and no recommendation for higher energy.

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