Is there an Optimal Shape of the Defibrillation Shock: Constant Current vs. Pulsed Biphasic Waveforms?

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Abstract: *Three waveforms for transthoracic defibrillation are assessed and compared: the Pulsed Biphasic Waveform (PBW), the Rectilinear Biphasic Waveform (RBW), and the "lossless" constant current (LLCC) pulses. Two indices are introduced: 1)* $k_f = W/W_0$ *– the ratio between the delivered energy W and the energy* W_0 *of a rectangular pulse with the same duration and electric charge; 2)* $\eta_C = W/W_{C0}$ *– the level of utilizing the initially loaded capacitor energy* W_{C0}*. The envisioned comparative study shows that* η_C *index is favorable for both PBW and LLCC, while* k_f *of both RBW and LLCC demonstrates advantage over the PBW in the range of small inter-electrode thoracic impedances below 80 Ω. Some design considerations are also discussed. The attractive LLCC concept needs large and heavy inductive coil to support the constant current amplitude, besides it is capable to induce strong electromagnetic influences due to the complex current control. The RBW technology controls the delivery of current through a series of internal resistors which are, however, a source of high heat losses. The PBW implements controlled duty cycle of high-frequency chopped pulses to adapt the energy delivery in respect of the patient impedance measured at the beginning of the shock. PBW technology makes use of small capacitors which allows the construction of light weight and small-size portable devices for transthoracic defibrillation.*

Obviously, there is no outstanding optimal defibrillation waveform, however, the PBW technology reveals some advantages.

Keywords: *Defibrillation, Pulsed biphasic waveform (PBW), Rectilinear biphasic waveform (RBW), Lossless constant current pulses, Energy, Current.*

Introduction

Most of the sudden cardiac arrests begin with ventricular fibrillation [1-2]. In such cases an immediate defibrillation is recommended since each delay reduces the probability of patient survival [3].

About two decades ago, the public access defibrillation has been introduced as the only effective technique for immediate treatment of out-of-hospital cardiac arrest (OHCA) incidents [4]. Death from sudden cardiac arrest is preventable if bystander quickly retrieves and applies an automated external defibrillator (AED) before the arrival of the emergency medical services. Early defibrillation via AEDs can significantly improve the patient outcomes, including the rate of successful defibrillation, return of spontaneous circulation, survival to hospital discharge and the neurological recovery. The easy access and the use of AEDs by nonmedical first responders or lay bystanders, the portability of AEDs, as well as the AED's efficacy and safety are the major considerations in the International Resuscitation Guidelines [5-7].

The mechanisms by which an electric shock terminates cardiac tachyarrhythmias have not been conclusively demonstrated. Various hypotheses have been proposed, the most popular being “the critical mass”, “the upper limit of vulnerability”, “the extension of refractoriness”, “the virtual electrode polarization” [8]. These hypotheses are not necessarily mutually exclusive – some or all of them may be applicable at any one time. It has not been demonstrated conclusively in randomized clinical studies that biphasic defibrillators save more lives than monophasic, however, Guidelines state that biphasic defibrillators achieve higher first-shock success rates [7]. The greater efficacy is explained by the ability of the second phase to reduce the activation threshold on the side of myocites hyperpolarized by the first phase [9]. The benefit of biphasic pulses is also explained by the so called “charge-burping” theory pursued for a simple cell-response model, which states that the first phase depolarizes most of the myocytes while the second phase removes the residual charge on the cell membranes, thus preventing the launch of new wavefronts which are probable to cause immediate refibrillation after the shock [10-11]. Later, Fishler [12] extends this lumped-component model to external defibrillation, supported by adequate mathematical formulations which transfer some theoretical predictions regarding the cardiac cell-response to various monophasic and biphasic waveshapes. The optimization of biphasic waveforms concerns two criteria: the optimal first phase, which delivers a minimal amount of energy when a preset amount of charge is deposited to the cell membrane, and the optimal second phase waveform, which again with minimal energy forces the transmembrane potential to return back to its resting state within a preset time interval. However, the modeling study [12] investigates only four types of waveshapes, i.e. ascending exponential, ascending ramp, rectangular and descending exponential (listed here in decreasing order of energy efficiency). With small adjustments, the underlying mathematical formulations can be applied as a powerful generic tool for designing alternative waveshapes, or predicting the performance of existing ones. The essential weak point, however, remains the experimental verification of the constituting theory. The absence of contradictions with available experimental studies [13] was considered as important support, there could be added more direct confirmation by investigating the possible reconciliation of theory and practice [14]. An extended animal study of Yamanouchi et al. [15] investigates truncated exponential waveforms in respect of the stored energy, the patient impedance, the leading-edge voltage of both phases, the peak current and the pulse width of the first phase, as well as the tilt of the second phase. Sullivan et al. [16] compares the defibrillation thresholds of a variety of truncated exponential vs. chopping modulated waveforms on a pig model with average transthoracic impedance of 29+4 Ω. Although they report higher defibrillation energy for chopping modulated waveforms, the results can not be fitted to performance in cardiac arrest patients with higher thoracic impedance and different myocardial cell-membrane response.

For a long time, the energy is thought to be the most important setting of defibrillation. Recently, the current flow through the myocardium has been suggested as a major factor for successful defibrillation [17]. Keeping the current constant over the entire pulse duration makes it possible to obtain maximum average current with minimum current peak [18].

Several different biphasic waveforms are presently used in commercially available defibrillators, i.e. Biphasic Truncated Exponential (BTE) waveform [19], Pulsed Biphasic Waveform (PBW) [20-21], Rectilinear Biphasic Waveform (RBW) [22], but no human studies have directly compared these waveforms or compared them at different energy levels related to defibrillation success or survival [7]. There are several knowledge gaps, including the minimal acceptable first-shock success rate; the characteristics of the optimal biphasic waveform; the optimal energy levels for specific waveforms; and the best energy protocol.

Therefore, the title question about the existence of optimal pulse defibrillation shape is rhetoric.

This study aims at comparison of the BPW versus two effective constant current pulses: the RBW and the “lossless” constant current generator [23] by considering different design features and indices for effective energy delivery.

Materials and methods

The efficiency of the pulses is qualitatively assessed by some design features, such as control mode, size and weight of the devices, power and heat losses, risk of high voltage breakdown, electromagnetic influence, etc.

Two quantitative indices for effective energy delivery are introduced:

1) $k_f = W/W_0$ – the ratio between the delivered energy W and the energy W_0 of a rectangular pulse with the same duration and electric charge. It is always true that $k_f > 1$ and an optimal defibrillation shape is assumed to have this ratio near to unity.

2) $\eta_C = W/W_{C0}$ – the level of utilizing the initially loaded capacitor energy W_{C0}. Here $W_{C0} = 0.5CU_{C0}^2$, where U_{C0} is the initial capacitor voltage. The index η_C is indicative when the charging source has a limited energy output.

Attention is paid to the option for adaptive adjustment of the pulse characteristics by measurement of the real patient transthoracic impedance (TTI) during the shock. The distribution of the TTI values depends on the specific paddle/pad size/orientation and position [7]. Referring to our previous study [24], the observed TTI distributions for self-adhesive defibrillation pads placed in 2 standard positions on the chest of 86 adult patients are: 96.6±19.2 Ω (63.1-151.8 Ω) for anterior-apex position; 107.2±22.3 Ω (60.2-151.8 Ω) for anterior-posterior position. The values are reported as mean±standard deviation (min-max range). Visual presentation of the TTI distributions is shown in Fig. 1.

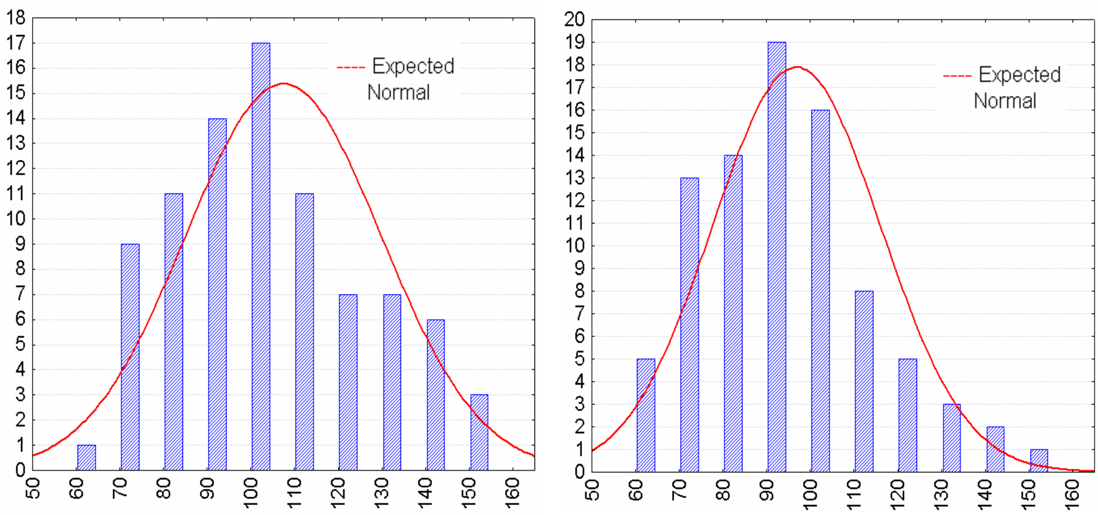

Fig. 1 Distribution of the transthoracic impedance via self-adhesive defibrillation pads

Rectilinear biphasic waveform (RBW)

The RBW technology (ZOLL Medical Corp.) charges maximal voltage at the capacitor and controls the delivery of current through a series of internal resistors, which are stepwise switched in the patient circuit to deliver a relatively 'constant' current during the course of the first phase. We suppose that a bridge circuit (Fig. 2) is used for the RBW pulse generation.

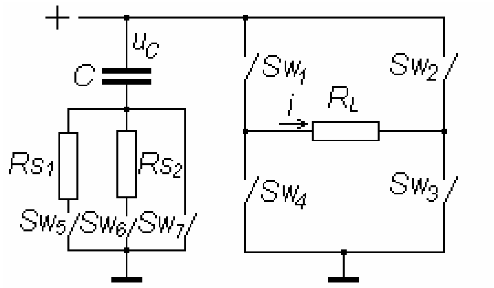

Fig. 2 Bridge circuit for RBW generation

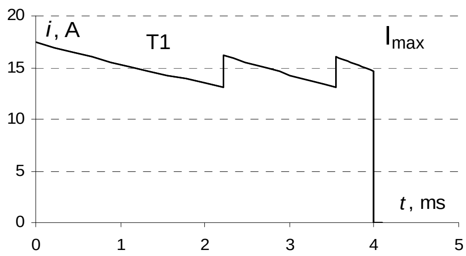

Fig. 3 Patient current controlled by two resistors

A realistic case is considered below, comprising 3 control levels (two resistors R_{s1} and R_{s2} to be independently switched in series to the patient resistance R_L). The current waveform through the patient is shown in Fig. 3. Let us assume that the capacitor C keeps the voltage constant at each transition of the current from $I_{\min}$ to $I_{\max}$:

$$I_{\min}(R_L + R_{s1}) = I_{\max}(R_L + R_{s2}),\ I_{\min}(R_L + R_{s2}) = I_{\max}R_L \tag{1}$$

that allows the calculation of the series resistors R_{s1} and R_{s2}.

Let further assume that resistors are switched within time intervals (T_1, T_2 and T_3), and their sum equals the total first phase duration $T = 4$ ms. Then the following combined equations are derived:

$$\begin{aligned} I_{1\min} &= I_{1\max} e^{\frac{-T_1}{(R_L+R_{s1})C}}, \\ I_{2\min} &= I_{2\max} e^{\frac{-T_2}{(R_L+R_{s2})C}}, \\ I_{3\min} &= I_{3\max} e^{\frac{-T_3}{R_L C}}, \\ T_1 + T_2 &+ T_2 = T. \end{aligned} \tag{2}$$

The solution of (2) gives the relation (3):

$$T = \ln\left(\frac{I_{\max}}{I_{\min}}\right) C\left(R_{s1} + R_{s2} + 3R_L\right). \tag{3}$$

The quantity of electricity delivered at the end of the shock is obtained by:

$$\Delta Q = I_{av} T, \tag{4}$$

where

$$I_{\rm av} = \frac{I_{\max} - I_{\min}}{\ln \dfrac{I_{\max}}{I_{\min}}}$$

is the average (quasi constant) defibrillation current.

The ratio $k_f = W/W_0$ is approaching 1.

Considering (4), the initial capacitor voltage is:

$$U_{C0} = I_{av}R_L + I_{av}R_{CT}\text{, where } R_{CT} = T / C. \tag{5}$$

The index η_C can be determined by:

$$\eta_C = \frac{2R_{CT} / R_L}{(1 + R_{CT} / R_L)^2}. \tag{6}$$

An example is shown in Fig. 3 with R_L = 110 Ω, R_{s1} = 56 Ω, R_{s2} = 25 Ω, modulation depth $\nu = (I_{\max} - I_{\min}) / I_{av} = 0.25$, and I_{av} = 15 A.

Lossless constant current (LLCC) generator

LLCC pulses are generated by the patented technology [23] for commutating the patient current through the inductive coil *L*. There is missing detailed information about the technical implementation of such a solution, therefore, we propose two versions for LLCC generation by means of a bridge circuit (Fig. 4a) and a semi-bridge circuit (Fig. 4b). Our preliminary analysis opts for the circuit with the lower commutation voltage. This consideration is important, taking into account the special requirements towards the high-voltage switches, which should commutate biphasic defibrillation pulses with amplitudes of several kilovolts. At a first glance, the circuit with commutation of one charged capacitors is advantageous than the circuit with two charged capacitors ($U_{C1} > U_{C1} + U_{C2}$). The requirement for a lower energy second phase, however, suggests about the option for initial charging of only the capacitor C_1, while capacitor C_2 is automatically charged during the first phase via the inductive coil (Fig. 4b). Therefore, the further analysis is applied for the semi-bridge circuit, with the advantage of only 2 high-voltage switches (instead of 4) at lower commutation voltage (U_{C1}).

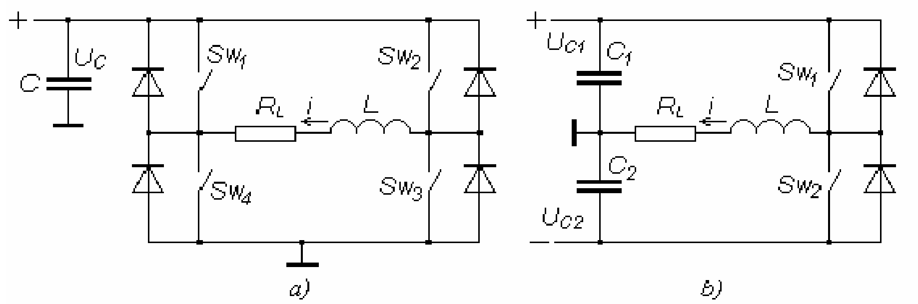

Fig. 4 LLCC generation by: a) bridge circuit; b) semi-bridge circuit

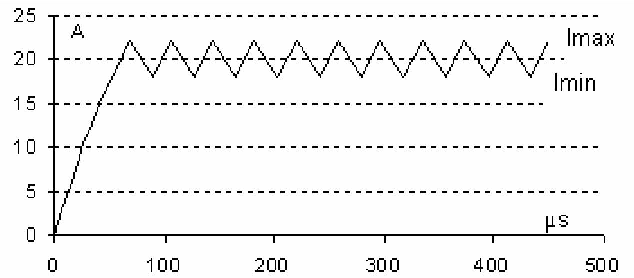

Fig. 5 Patient current during the first phase generated by the semi-bridge circuit

During the discharge of the capacitor C_1, let the switches Sw_1 and Sw_2 (Fig. 4b), which are commutating the current through the inductive coil L to the patient, control the mean current I_{av} within the range from I_{min} to I_{max} (Fig. 5). The current during the second negative phase is supported by C_2 through Sw_2, without any strongly defined requirements towards the pulse shape, but with preset ratio $Q_1/Q_2 = 3$ of the quantity of electricity of first vs. second phases [25].

Since the initial conditions for each commutation cycle are different, a strict circuit analysis can be done only by iterative time-consuming computer-aided calculations. Therefore, we are looking for a fast solution, which would allow the direct determination of the basic circuit parameters with negligible errors, supposing the known variables: R_L, quantity of electricity of the first phase (Q_1) and the modulation depth $\nu = \frac{I_{\max} - I_{\min}}{I_{av}}$.

The total energy, consumed from the capacitor at the end of the phase duration T includes the energy, which is delivered to the patient and the energy provided within the inductance L:

$$\frac{C_1}{2}\left(U_{C0}^2 - U_{CT}^2\right) = I_{eff}^2 R_L T + \frac{L}{2} I_{\max}^2 . \tag{7}$$

Here U_{CT} stands for the capacitor voltage reached at the end of phase duration T. The effective current I_{eff} is proportional to the average current I_{av}: $I_{eff} \approx I_{av}\sqrt{1 + \upsilon^2 / 12}$. The unknown variables L, C_1, U_{C0} for the first phase, and supplementary C_2, U_{CT2} for the second phase are determined having in mind additional considerations [25].

The delivered energy is: $W \approx I_{eff}{}^2 RT$, and therefore the ratio

$$k_f = W / W_o \approx 1 + \upsilon^2 / 12 . \tag{8}$$

The index η_C is calculated by (9), assuming a "flat" control, i.e. $I_{min} = I_{max} = I_{av}$ and $U_{CT} = I_{av} R_L$, neglecting the term $L I_{\max}^2 / 2$:

$$\eta_C = 2 \frac{R_{CT} / R_L}{1 + 2 R_{CT} / R_L} \tag{9}$$

Pulsed biphasic waveform (PBW)

The PBW technology (Schiller Medical S.A.) controls the duty cycle of high-frequency (HF) chopped series of alternated active and inactive pulses in order to deliver unconditionally the preset energy to the patient, without impact from the patient impedance. The bridge circuit with one capacitor and 4 high-voltage switches is used (Fig. 6). The first positive phase of the defibrillation shock, consisting of n chopped pulses with active phase t_1, t_2, …, t_n, separated by inactive pauses t_{10}, t_{20}, …, t_{n0} is shown in Fig. 7.

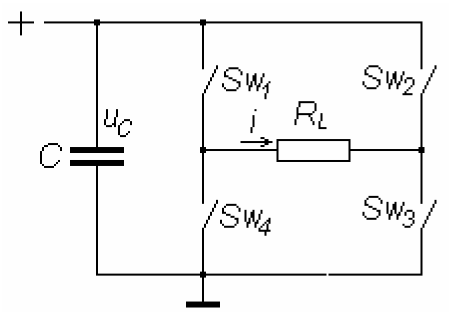

Fig. 6 Bridge circuit for PBW generation

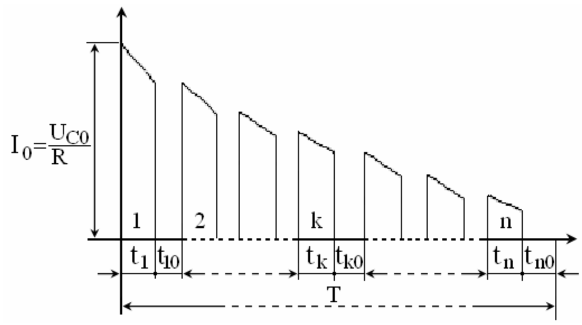

Fig. 7 Patient current during the positive phase

In the HF series, there are no losses during the pauses, so the total current delivered to the patient at the end of the $k^{\text{-th}}$ active pulse t_k is determined by the summary influence of all preceding active pulses:

$$i_k = \frac{U_{C0}}{R} \mathrm{e}^{-\frac{\sum_{j=1}^{k} t_j}{RC}} . \tag{10}$$

The pulses may be merged with common duration of $t_{\Sigma 1} = \sum_{j=1}^{n} t_j$, followed by a common pause that simplifies the calculations of the average I_{av} and effective I_{eff} currents:

$$\begin{aligned} I_{av} &= \frac{U_{C0}}{T} C\left(1 - e^{(-t_{\Sigma 1}/RC)}\right), \\ I_{eff} &= \sqrt{\frac{1}{2T}\frac{U_{C0}^2}{R} C\left(1 - \mathrm{e}^{(-2t_{\Sigma 1}/RC)}\right)}. \end{aligned} \tag{11}$$

The ratio k_f becomes:

$$k_f = \frac{W}{W_0} = \frac{I_{eff}^2}{I_{av}^2} = \frac{T(1+\mathrm{e}^{(-t_{\Sigma 1}/RC)})}{2RC(1-\mathrm{e}^{(-t_{\Sigma 1}/RC)})} . \tag{12}$$

The ratio k_f is always higher than unity but at RC >> $t_{\Sigma 1}$ the pulse tilt is near to rectangular and $W/W_0 \rightarrow T/t_{\Sigma 1}$. This result suggests that it is expediently to charge the capacitor to the lowest possible voltage that can deliver the necessary quantity of electricity.

The index η_C is determined using the border case $t_{\Sigma 1} = T$ for Eq. (11):

$$\eta_C = \frac{W}{W_{C0}} = \frac{2\left(1 - e^{(-R_{CT}/R)}\right)^2}{R_{CT}/R_L}, \tag{13}$$

where the parameter $R_{CT} = T/C$ depends on the capacitor C and pulse duration T.

Results and discussion

The defined two quantitative indices for comparing the effective energy delivery of the three waveforms – RBW, LLCC, PBW, are illustrated in function of the patient impedance – $k_f = W/W_0$ (Fig. 8) and $\eta_C = W/W_{C0}$ (Fig. 9).

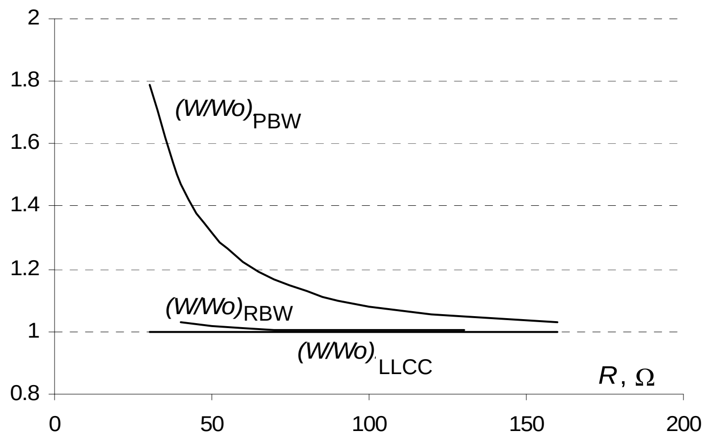

Fig. 8 The ratios k_f (PBW, RBW, LLCC) in function of the mean patient impedance

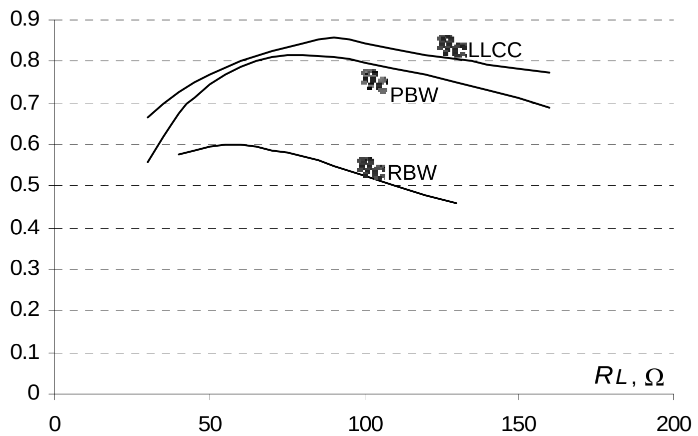

Fig. 9 The ratios η_C (PBW, RBW, LLCC) in function of the mean patient impedance

The squared pulses are beneficial as they provide the minimal ratio W/Q, where the quality of delivered electricity Q has an excitation effect on the myocardial cells, while the delivered energy W is proportional to the damaging heating effect. The coefficient k_f, showing the waveform similarity with the squared pulses is approaching unity for both curves $(W/W_0)_{LLCC}$ and $(W/W_0)_{RBW}$ within the full range of patient impedances. They both demonstrate advantage over $(W/W_0)_{PBW}$, most evidently seen in the lower impedance range below 80 Ω. Within the most commonly encountered impedance range in adult transthoracic defibrillation >80 Ω (see Fig. 1), however, the waveform coefficient $(W/W_0)_{PBW}$ goes down to less than 10% difference from the squared shape.

The level of utilizing the initially loaded capacitor energy η_C is favorable for both types of pulses – LLCC and PBW, which are above 0.75 up to 0.85 for the most commonly seen impedance range between 50 and 140 Ω. In the same impedance range, the RBW pulse is less effective with η_C values of about 0.5-0.6.

The survey of the state of art, as well as the results obtained confirm that an optimal shape can not be strongly evaluated because of the numerous features used for assessment of the defibrillation waveforms. Besides, there is no persuasive clinical evidence indicating that any one type of biphasic waveform is clearly superior to any other [8].

We find difficulties in building constant current devices assessed by the technical solutions we hypothesized in our analysis due to lack of information. The attractive lossless version needs large and heavy inductive coil to support the constant current amplitude, besides it is capable to induce strong electromagnetic influences due to the complex current control. The rectilinear waveforms are generated by large resistors which are a source of high heat losses.

The pulsed technology makes use of small capacitors that allows the construction of light-weight and small-size portable devices for transthoracic defibrillation. One such example is the commercial device FRED easyport (Schiller AG) [26], which is the first pocket-sized semi-automatic AED with weight of only 450 g. Its maximal energy of 130 J has a gentle impact on the heart tissue, with first-shock success rate for termination of ventricular fibrillation (at 5 seconds after shock delivery) of 90% as proved for PBW in a population of 104 OHCA patients [27]. Another OHCA study on 248 patients [28] also supports the high success rate of PBW, which is 86% for 130 J and 77% for 90 J, both considered at 5 seconds postshock. Another benefit of PBW technology is the option for dynamic adaptation of the duty cycle or pulse duration to the inter-electrode transthoracic impedance, which is measured at the beginning of the shock. Thus the preset energy, as well as the mean current through the patient might be kept relatively constant among shocks [21].

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