High-Current vs. High-Energy Biphasic

Which One Matters Most?

ZOLL MEDICAL CORPORATION 2012

Introduction

There has been a lot of discussion about "low-energy" biphasic defibrillation versus "high-energy" biphasic, and this document is intended to set the record straight. The term "low-energy" has contributed to misunderstanding and has fueled a fear that "low-energy" means less efficacy. In fact, "low energy" actually means "high-current" and "high-efficacy."

The American Heart Association Scientific Guidelines for resuscitation clearly state: "Although the defibrillator operator selects the shock energy (in joules), it is the current flow (in amperes) that actually depolarizes the myocardium. Energy is a non-physiologic descriptor of defibrillation despite its entrenchment in current jargon."[1]

All ZOLL defibrillators deliver a Rectilinear Biphasic waveform that provides more current than the "high-energy" biphasic others use. This capability is particularly important for the difficult-to-defibrillate, high-impedance patient.

This "high-current" RBW is the only biphasic waveform that was developed specifically for external defibrillation. It has been studied extensively in over 7,000 patients and shown to be superior to monophasic. Both high- and low-energy Biphasic Truncated Exponential (BTE) waveforms were adapted from internal defibrillation. The high-current ZOLL biphasic waveform is the only one that the FDA has cleared to claim superiority over monophasic waveforms.*

*The data demonstrate the equivalent efficacy of low-energy (aka, high-current) rectilinear biphasic shocks compared to standard high-energy monophasic shocks for transthoracic defibrillation for all patients at the 95% confidence level. The data also demonstrate the superior efficacy of low-energy rectilinear biphasic shocks compared to standard high-energy monophasic shocks in patients with high tran-sthoracic impedance at the 90% confidence level. There were no unsafe outcomes or adverse events due to the use of Rectilinear Biphasic waveform.

The Scientific Evidence Is Clear

RBW is Superior* to Monophasic

ZOLL is the only company the FDA has cleared to label our biphasic waveform as superior to monophasic for defibrillationof **high-impedance VF** and **cardioversion of AF**[2,3]:

> "The data also demonstrate the superior efficacy of low-energy [ZOLL RBW] biphasic shocks compared to standard high-energy monophasic shocks in patients with high transthoracic impedance."

RBW has been studied in more than 7,000 patients in over 14 separate clinical trials.

RBW Is Superior to BTE Biphasic in Pediatrics

"The ZOLL RLB waveform provided a superior ability to defibrillate a porcine pediatric model in terms of energy dose per body weight (J/Kg) and per heart weight (g) when compared to the Medtronic Physio-Control BTE waveform."[4]

RBW Is Superior in Out-of-Hospital Cardiac Arrest (OHCA)

The ZOLL ORBIT trial represents the largest clinical trial on biphasic waveforms ever conducted for out-of-hospital cardiac arrest. The ORBIT trial is the only OHCA study conducted in an ALS environment, and the only biphasic study that included all presenting rhythms (not just VF or VT).[5]

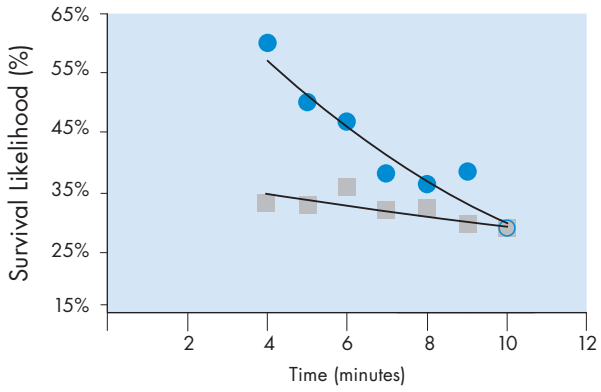
> *The ORBIT results showed ZOLL RBW superiority to monophasic in patients with shockable rhythms: 52% to 33.7%, P= 0.01*

1. AHA Guidelines 2005. *Circulation*. 2005;112 (suppl IV).
2. Mittal, S, Ayati S et al. Comparison of a rectilinear biphasic waveform with a damped sine wave monophasic waveform for transthoracic conversion of ventricular fibrillation. *JACC*, Vol 34, No 5, 1999.
3. Mittal S, Ayati S et al. Transthoracic Cardioversion of Atrial Fibrillation Comparison of Rectilinear Biphasic Versus Damped Sine Wave Monophasic Shocks. *Circulation*. 2000;101:1282-1287.
4. W Tang, J Wang, C Young, Comparison of Rectilinear Biphasic Defibrillation To Biphasic Truncated Exponential Defibrillation For Pediatric Cardiac Life Support In A Porcine Model, Abstract presented at the Cardiostim 2004.
5. Morrison I, Dorian P et al. Out-of-hospital cardiac arrest rectilinear biphasic to monophasic damped sine defibrillation waveforms with advanced life support intervention trial (ORBIT). *Resuscitation*. 2005;66:149–157.

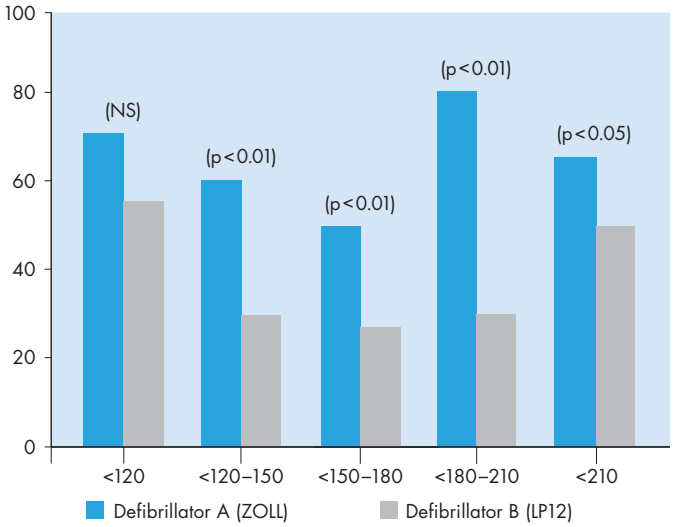
RBW Is Superior for Long Duration VF[6]

The results of the ORBIT study also show that ZOLL biphasic demonstrated even greater improvements over monophasic as downtimes decreased. 24-hour survival is plotted as a function of downtime. The ZOLL biphasic is the upper curve (circles), while the monophasic waveform is the lower curve (squares).

- Nearly double the survival rate at 4 min. downtime
- Relevant especially for AED defibrillation and in-hospital resuscitation



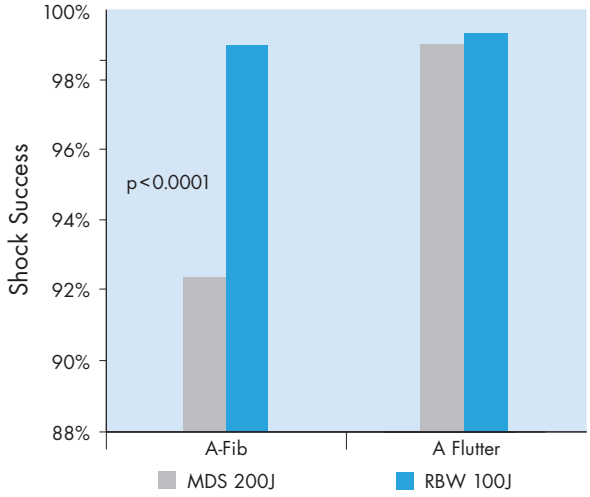
RBW Is Superior for High-Impedance Patients[8]



RBW Is Superior in Obese Patients[9]

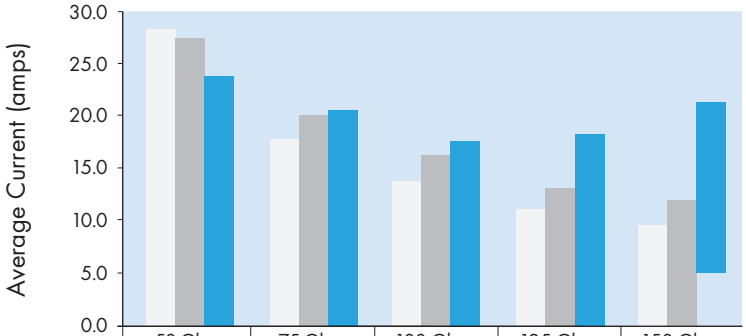
In 140 obese patients weighing more than 135kg (range: 155kg – 194kg), all the patients were successfully cardioverted and the average energy required was also less than 200J.

RBW Is Superior for Cardioversion of Atrial Fibrillation (AF) and Atrial Flutter[7]



RBW Delivers More Current

Average Current at Maximum Energy



	50 Ohms	75 Ohms	100 Ohms	125 Ohms	150 Ohms
Philips 200J	28.2	17.8	13.6	10.7	9.5
Physio 360J	27.5	20.0	15.9	13.5	11.5
ZOLL R 200J	24.0	20.5	17.3	18.0	16

6. *Ibid.*
7. Niebauer MJ, Brewer JE, Chung MK and Tchou PJ. Comparison of Rectilinear Biphasic Waveform with Monophasic Damped Sine Waveform for external cardioversion of Atrial Fibrillation and Flutter. *Am J Cardiol.* 2004;93:1495-1499.
8. Li Y, Ristagno, G et al. A comparison of defibrillation efficacy between different impedance compensation techniques in high impedance porcine model. *Resuscitation.* 2009;80:1312–1317.
9. Niebauer MJ, Brewer JE et al. Rectilinear Biphasic: Defibrillation of Patients with Weight Greater Than 100 Kg. Abstract from the 7thCongress of the ERC, 2004.
10. Stiell IG, Walker RJ et al. Higher Energy Levels for Defibrillation in Out-of-Hospital Cardiac Arrest BIPHASIC Trial. A Randomized Comparison of Fixed Lower Versus Escalating. *Circulation.* 2007:115.
11. Koster RW, Walker RD, van Alem AP. Definition of successful defibrillation. *Crit. Care Med.* 2006 Dec 34 (12 Suppl).
12. Stothert JC, Hatcher TS et al. Rectilinear biphasic waveform defibrillation of out of hospital cardiac arrest *Pre-hospital Emergency Care.* 2004 Oct-Dec;8(4):388-92.
13. Edelson DP. Abella BS, Kramer-Johansen J et al. Effects of compression depth and pre-shock pauses predict defibrillation failure during cardiac arrest *Resuscitation.* 2006;71:137—145.
14. Kramer-Johansen, J, Myklebust H et al. Quality of out-of-hospital cardiopulmonary resuscitation with real time automated feedback: A prospective interventional study *Resuscitation.* 2006;71:283—292.
15. White Rd, Hankins DG et al. Patient Outcomes following defibrillation with a low energy biphasic truncated exponential waveform in out of hospital cardiac arrest. *Resuscitation,* 2001;49(1):9-14.

Some Statements Require a Second Look

No One Type of Waveform Is More Effective than Another up to 200J

ZOLL's Rectilinear Biphasic waveform delivers significantly more current than high-energy biphasic up to 200J. ZOLL delivers more current at 200J than high-energy defibrillators deliver at 360J.

A Biphasic Device that Can Reach 360J Can Increase Rates of VF/VT Termination

The Stiell study, generally cited as proof, compares only suboptimal dosing with a high-energy waveform starting at 150J vs. a high-energy waveform at escalating energy beginning at 200J. The correct adult dose for high-energy biphasic defibrillation is 200J, 300J, 360J.[10]

All this study shows is that if you are going to give multiple shocks with a high-energy defibrillator you ought to be using their protocol of 200J, 300J, and 360J and not reducing the dose below effective levels.

Now that Biphasic Shocks Are More Widely Used, Clinical Data Shows that Biphasic Shocks Are Not as Successful as Previously Reported, with Many Systems Reporting Shock Success of <75%[11]

Studies showing first shock success rates below 75% are ones which combine both in-hospital and OHCA data – that mixes two very different patient populations – or comparison data against monophasic in a single population.[12,13,14]

In addition, studies cited with lower efficacy include patients presenting in asystole and PEA who are returned to a shockable rhythm. Studies showing 92%+ efficacy are all in OHCA patients presenting in VF.[15,16,17]

Repeating the Same Shock Dosage after a First Shock Failed Offers Diminishing Returns While Escalating Increases Success[18,19]

The supporting data, which was not statistically significant, compares only a high-energy waveform at 200J, not a high-current waveform. 200J high-energy waveforms deliver significantly less current than 200J ZOLL high-current RBW.

In VF Defibrillation, the Defibrillation Probability of Success Increases with Each Increase in Energy[20,21]

Defibrillation likelihood increases not because of increased energy, but increased current. 200J high-energy delivers an amount of current similar to 120J ZOLL. As you escalate ZOLL's high-current waveform from 120 to 200J you are stepping up current in the same fashion, and in the end delivering more current.

Independent Studies Show the Efficacy of High-Energy Defibrillation in Atrial Fibrillation

None of the studies typically cited shows a statistically significant difference in outcomes – yet there are definite shock protocol differences:

Kim: 4 shocks RBW; 5 shocks BTE on crossover – no reverse cross over data available. Successful cardioversion may only be the next shock away.[22]

Alatawi: 6 shocks RBW – 8 shocks BTE before crossover – difference clearly stated to NOT be significant.[23]

Neal: All patients who receive the RBW converted by the 1st 200J shock – one patient failed 360J (5th shock) and did not convert with 200J. Conversion required simultaneous 200J shocks from both defibrillators.[24]

Khaykin: This study compares the monophasic waveform to the high-energy biphasic waveform – it does not compare it to low-energy biphasic.[25] It demonstrates that to achieve maximum efficacy with a high-energy defibrillator you need to go to 360J.

16. Schneider T, Maartens PR et al. Multicenter, Randomized, Controlled Trial of 150-J Biphasic Shocks Compared With 200- to 360-J Monophasic Shocks in the Resuscitation of Out-of-Hospital Cardiac Arrest Victims. *Circulation*. 2000;102:1780-1787.
17. Koster RW, Walker RG, Chapman FW Recurrent ventricular fibrillation during advanced life support care of patients with prehospital cardiac arrest. *Resuscitation*. 2008;78:252—257.
18. Stiell IG,. Walker RJ et al. Higher Energy Levels for Defibrillation in Out-of-Hospital Cardiac Arrest BIPHASIC Trial. A Randomized Comparison of Fixed Lower Versus Escalating. *Circulation*. 2007;115.
19. Koster RW, Walker RG, Chapman FW Recurrent ventricular fibrillation during advanced life support care of patients with prehospital cardiac arrest. *Resuscitation*. 2008;78:252—257.
20. Walker RG, Koster RW et al .Defibrillation probability and impedance change between shocks during resuscitation from out-of-hospital cardiac arrest. *Resuscitation*. 2009;80:773–777.
21. Koster RW, Walker RG, Chapman FW Recurrent ventricular fibrillation during advanced life support care of patients with prehospital cardiac arrest. *Resuscitation*. 2008;78:252—257.
22. Kim ML, Kim SG et al Comparison of Rectilinear Biphasic Waveform Energy Versus Truncated Exponential Biphasic Waveform Energy for Transthoracic Cardioversion of Atrial Fibrillation *American Journal of Cardiology*, Vol. 94, December 1, 2004.
23. Alatawi F, Gurevitz O et al. Prospective, randomized comparison of two biphasic waveforms for the efficacy and safety of transthoracic biphasic cardioversion of atrial fibrillation. *Heart Rhythm*. 2005;2:382–387.
24. Neal S, Ngarmukos T et al. Comparison of the Efficacy and Safety of Two Biphasic Defibrillator Waveforms for the Conversion of Atrial Fibrillation to Sinus Rhythm. *Am J Cardiol* 2003;92:810–814.
25. Khaykin Y, Newman, D et al. Biphasic versus monophasic cardioversion in shock resistant Atrial Fibrillation. *J Cardovasc Electrophysiology*, Vol. 14, 862-872, 2003.

Which Delivers More?

You buy light bulbs for the light. Traditional 100-watt incandescent bulbs offer 950 lumens of light, while the 23-watt cold compact fluorescents (CCFL) use significantly less energy but offer 1600 lumens of light.

Just because there is a higher number on the outside doesn't always mean you get more.

It's the same with defibrillation. You buy defibrillators for the current, but the larger number of Joules doesn't always mean more current. With high-energy biphasic defibrillators, you need 360 Joules of energy to deliver the maximum current to the heart, approximately 16 Amps in a high-impedance patient. With a high-current/low-energy biphasic defibrillator, like the ZOLL® R Series®, 200 Joules of energy delivers approximately 17 Amps of current.

High-current, low-energy with high efficiency. Just like the more efficient CCFL light bulb.

Shedding more light on biphasic defibrillation.

www.zoll.com/betterbiphasic or call 800-804-4356

ZOLL®

ADVANCING RESUSCITATION. TODAY.®