Rectilinear Biphasic Defibrillation: Separating Fact from Fiction

Current—not energy—defibrillates the heart.

ZOLL delivers the most current to high impedance patients.

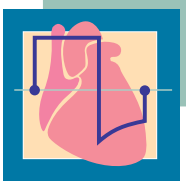
Only ZOLL has proven clinical superiority.*

ZOLL

It's about time.

The ZOLL RBW Difference: Real Performance

ZOLL's Rectilinear Biphasic™ waveform (RBW) was specifically designed for external defibrillation to control for variations in patient impedance. By delivering a constant amount of current, the ZOLL RBW delivers the right "dose" for every patient. At 200 J, the ZOLL RBW delivers more current to high impedance patients than any other biphasic device—even ones that escalate to 360 J.



"The essential requirement for electrical ventricular defibrillation is the attainment of a sufficient current density."
Tacker WA[6]

"... defibrillation success correlates more strongly with average current than with delivered energy."
Higgins et al. for the Physio-Control Biphasic Investigators[7]

Don't Be Fooled by Energy: Current Defibrillates

Energy settings for biphasic waveforms can be confusing. When it comes to defibrillation, it is easy to think 360 J is better than 200 J. However, research has failed to show any clinical benefit from biphasic waveforms delivering more than 200 J of energy.

Why? Because higher energy settings do not necessarily increase current levels; sometimes they merely increase duration. And current—not energy, not duration—is what defibrillates.

So, is 360 J of energy better? Clearly not if it is only an illusion of more capability, created by manipulating waveform durations beyond the clinically-known optimum, without delivering more current.

And subscribing to old-fashioned thinking about energy may decrease effectiveness and increase the risk of myocardial dysfunction and damage.[1-5]

What if there were a better way? A way to provide the optimal amount of current with less energy? A way to adjust the amount of current based on patient impedance? A way to improve efficacy while decreasing risk to the patient?

These improvements are what ZOLL's superior Rectilinear Biphasic waveform is all about. The RBW is an exclusive ZOLL innovation that delivers more current than any other biphasic waveform, improving efficacy while reducing the risks associated with high energy.

The facts about the ZOLL RBW tell a compelling story of superior clinical performance.

Biphasic Defibrillation and the AHA/ILCOR Guidelines 2000[8]

Guidelines 2000, developed by AHA, ERC, and ILCOR, are an evidence-based update to global resuscitation standards.

- A Class IIa recommendation is made for biphasic shocks of 200 J or less.
- Energy levels of biphasic shocks, as they apply to the Guidelines, are 200 J or lower.
- Defibrillation protocols vary with specific biphasic waveform employed.
- Biphasic shocks over 200 J are not addressed.

*See reference #14.

High Energy Does Not Mean More Current

In the diagram on the right, Waveform "B" has more energy than Waveform "A," but actually delivers less current. Here's why: Energy (joules) is simply the work required to get current to the heart; it's the product of three variables:

Joules = Voltage x Current x Time

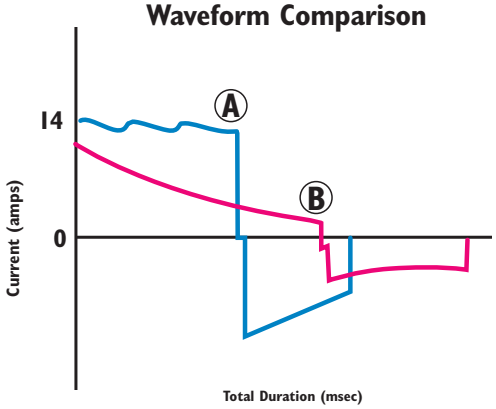
By extending duration (time), as in Waveform "B," you can deliver more energy. But you only create the ***illusion*** of more capability because you have not necessarily delivered more current—or more efficacy.

Once duration extends beyond the optimum, more energy is required to achieve the same efficacy, while risk of post-shock myocardial dysfunction increases.[9-11] That's why the ZOLL RBW has a fixed duration of 10 msec. ZOLL doesn't use longer durations to create the illusion of more energy because it does not result in greater efficacy.

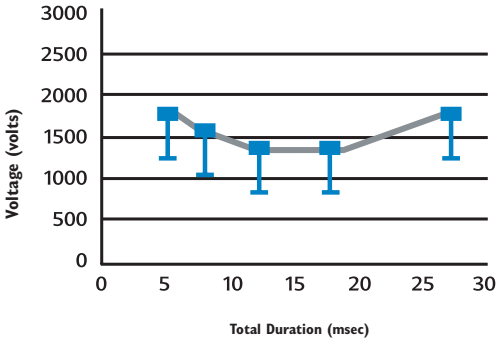
The ZOLL RBW always starts with the most amount of voltage for any given energy setting, and then controls the delivery of current through a series of internal resistors. This means low impedance patients are not overdosed, while high impedance patients get the most possible current.

By delivering the right amount of current over the optimal duration, the ZOLL RBW provides superior performance.

Waveform Comparison



Strength – Duration Curve[13]

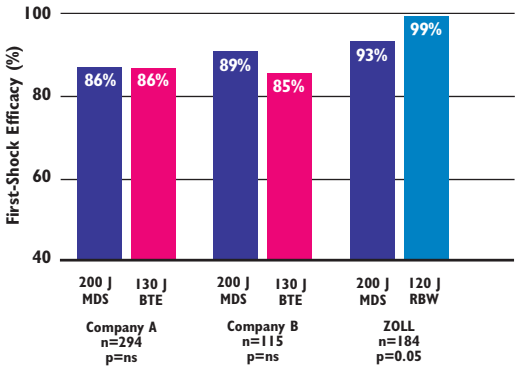


"Higher energy settings artificially created by increasing waveform duration beyond the optimum are not the answer. . . . The approach runs the risk of a decrease in effectiveness, while at the same time increasing the risk of electroporation and myocardial dysfunction."
Platia EV[12]

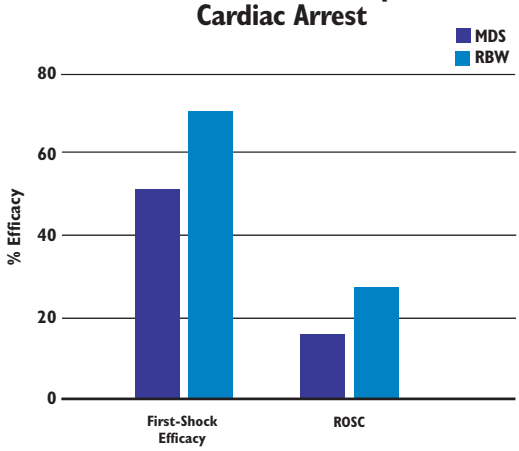
The Most Clinical Evidence—The Only Superior Waveform

All biphasic waveforms are not superior to monophasic waveforms. The fact is, only the ZOLL RBW has demonstrated statistical clinical superiority[14] to monophasic waveforms in peer-reviewed, randomized, controlled trials. And now, with data from more than 2,800 patients, you can feel secure in the strength of the RBW evidence.

First-Shock Efficacy for Ventricular Fibrillation



Better for Out-of-Hospital Cardiac Arrest



Superiority for the Conversion of Ventricular Fibrillation

In multicenter, randomized EP lab studies,[15-17] only the ZOLL RBW showed statistically significant improvement over a Monophasic Damped Sine (MDS) waveform with less energy. Other biphasic waveforms merely showed equivalency.

- 99% of patients were successfully defibrillated at 120 J with the ZOLL RBW on the first shock, as compared with 93% success for monophasic (p=0.05); 100% were defibrillated by a 150 J RBW shock.
- 100% of difficult-to-defibrillate patients (patient impedance > 90Ω) were successfully defibrillated by a 120 J ZOLL RBW shock versus only 63% success with MDS (p=0.02).

Superiority for Long-Duration Ventricular Fibrillation

In the largest retrospective study conducted on patients treated for out-of-hospital cardiac arrest,[18] the superior performance of the ZOLL RBW was again demonstrated over monophasic waveforms.

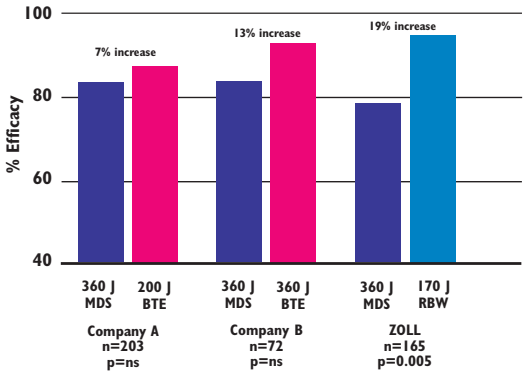
- 40% increase in first-shock efficacy: 67% at 120 J for the RBW, versus 48% at 200 J for MDS (p<0.0025).
- Significant improvement in Return of Spontaneous Circulation (ROSC) with return to normal sinus rhythm: 25% for RBW versus 15% for MDS (p=0.05).

Superiority for Cardioversion of Atrial Fibrillation

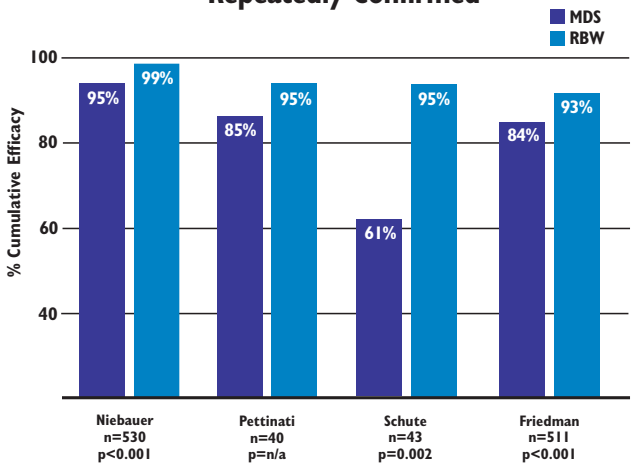
Again, only the ZOLL RBW showed statistically significant improvement over MDS at every incremental energy level and for cumulative efficacy.[19-21]

- 68% of patients were cardioverted at 70 J with the ZOLL RBW on the first shock, as compared to only 21% of those receiving an MDS shock at 100 J (p=0.0001).
- There was a 19% increase in cumulative efficacy over MDS (94% vs. 79%, p=0.005).
- AF superiority has been confirmed in 4 separate clinical trials representing more than 1,200 patients.[22-25]

Cumulative Efficacy for Atrial Fibrillation



Performance Repeatedly Confirmed

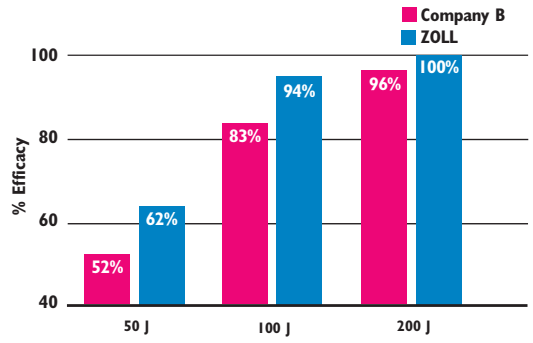


High Energy Offers No Benefit

In the only peer-reviewed randomized trial evaluating biphasic waveforms for AF cardioversion,[26] Neal et al. compared a Biphasic Truncated Exponential (BTE) waveform with a maximum setting of 360 J, to the ZOLL RBW with a maximum setting of 200 J.

The trial failed to demonstrate any advantage for the 360 J BTE waveform in a series of 101 patients. At all energy levels tested—50 J, 100 J, and 200 J—the ZOLL RBW was shown to have greater efficacy than the BTE waveform.

Biphasic Comparison



Leadership in Defibrillation and Resuscitation

- The performance of ZOLL's RBW has been confirmed in over a dozen clinical trials involving more than 2,800 patients.
- ZOLL's RBW has the highest defibrillating current for patient impedance ≥75 ohms of any biphasic waveform, delivered over the optimal duration.
- Only ZOLL's RBW has the clinical data to support labeling[27] as clinically superior to monophasic waveforms for the cardioversion of AF, and the conversion of VF in high impedance patients.

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824-4105
U.S.A.
800-348-9011
978-421-9655
978-421-0025 Telefax
www.zoll.com

ZOLL Medical
European Operations
Dodewaard, The Netherlands
+31 488 4111 83
+31 488 4111 87 Telefax

ZOLL Medical U.K. Ltd.
Cheshire, England
+44 1925 846 400
+44 1925 846 401 Telefax

ZOLL Medical Germany
Cologne, Germany
+49 221 3989 340
+49 221 3989 336 Telefax

ZOLL Medical Canada
Mississauga, Ontario, Canada
905-629-5005
905-629-0575 Telefax

ZOLL Medical France
Coignières, France
+33 1 30 05 1498
+33 1 30 49 0693 Telefax

ZOLL Medical Australia Pty. Ltd.
New South Wales, Australia
+61 2 9420 8733
+61 2 9420 9834 Telefax

ZOLL Medical Middle East
and Africa Region Office
Athens, Greece
+30 210 6236691
+30 210 6236692 Telefax

ZOLL Medical Japan
Tokyo, Japan
+81 45 905 2864
+81 45 905 2864 Telefax

ZOLL Medical Latin America
Parkland, FL 33067
954-345-4224
954-345-2684 Telefax

References

1 Tang W, Weil MH, Sun S. "Low-energy biphasic waveform defibrillation reduces the severity of postresuscitation myocardial dysfunction." Critical Care Medicine. 2000 Nov;28(11 Suppl):N222-4.

2 Reddy et al. "Biphasic transthoracic defibrillation causes fewer ECG ST-segment changes after shock." Annals of Emergency Medicine. 1997 Aug;30(2):127-34.

3 Kern KB. "Postresuscitation myocardial dysfunction." Cardiology Clinics. 2002 Feb;20(1):89-101.

4 Tang W, Weil MH, Sun S, Povoas HP, Klouche K, Kamohara T, Bisera J. "A comparison of biphasic and monophasic waveform defibrillation after prolonged ventricular defibrillation." Chest. 2001 Sep;120(3):948-54.

5 Tang et al. "The effects of biphasic and conventional monophasic defibrillation on postresuscitation myocardial function." Journal of the American College of Cardiology. 1999 Sep;34(3):815-22.

6 W.A. Tacker. Electrical Defibrillation. (Boca Raton, Florida: CRC Press, Inc.; 1980) p. 14.

7 Higgins et al. "A comparison of biphasic and monophasic shocks for external defibrillation. Physio-Control Biphasic Investigators." Prehospital Emergency Care. 2000 Oct-Dec;4(4):305-13.

8 American Heart Association. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care: International Consensus on Science. Circulation. 2000;102(suppl. I):I-90-I-94.

9 Gliner BE, Lyster TE, Dillion SM, Bardy GH. "Transthoracic defibrillation of swine with monophasic and biphasic waveforms." Circulation. 1995 Sep;92(6):1634-43.

10 Feeser SA, Tang AS, Kavanagh KM, Rollins DL, Smith WM, Wolf PD, Ideker RE. "Strength-duration and probability of success curves for defibrillation with biphasic waveforms." Circulation. 1990 Dec;82(6):2128-41.

11 Jones JL, Milne KB. "Dysfunction and safety factor strength-duration curves for biphasic defibrillator waveforms." American Journal of Physiology. 1994 Jan;266(1 Pt 2):H263-71.

12 Platia EV. "Considering the strength-duration relationship for defibrillation: Physiologic basis and clinical implications." White Paper.

13 Ibid.

14 M Series Operator's Guide, Rectilinear Biphasic Waveform Defibrillator Option Insert, 9650-0209-01:4-5. For defibrillation of VF "... data also demonstrate the superior efficacy of low-energy rectilinear biphasic shocks in patients with high transthoracic impedance at 90%** confidence level.
**Kerber et al. AHA Scientific Statement, Circulation. 1997;95:1677-82. For cardioversion of AF: "...data demonstrate the superior efficacy of low energy rectilinear biphasic shocks compared to high energy monophasic shocks for transthoracic cardioversion of atrial fibrillation."

15 Bardy et al. "Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular fibrillation." Circulation. 1996 Nov 15;94(10):2507-14.

16 Higgins et al. "A comparison of biphasic and monophasic shocks for external defibrillation. Physio-Control Biphasic Investigators." Prehospital Emergency Care. 2000 Oct-Dec;4(4):305-13.

17 Mittal S, Ayati S, Stein KM, Knight BP, Morady F, Schwartzman D, Cavlovich D, Platia EV, Calkins H, Tchou PJ, Miller JM, Wharton JM, Sung RJ, Slotwiner DJ, Markowitz SM, Lerman BB. "Comparison of a novel rectilinear biphasic waveform with a damped sine monophasic waveform for transthoracic ventricular fibrillation. ZOLL investigators." Journal of the American College of Cardiology. 1999 Nov 1;34(5):1595-601.

18 Stothert et al. "Resuscitation of out-of-hospital cardiac arrest using the rectilinear biphasic waveform." Prehospital Emergency Care. 2004 Jan-Feb;8(1):109-10 (abstract).

19 Page et al. "Biphasic versus monophasic shock waveform for conversion of atrial fibrillation: The results of an international randomized, double-blind multicenter trial." Journal of the American College of Cardiology. 2002 Jun 19;39(12):1956-63.

20 Dorian et al. "A prospective, randomized comparison of monophasic and biphasic shocks for external cardioversion of atrial fibrillation: Shock efficacy and post-procedure pain." European Heart Journal. 2001;22:132 (abstract).

21 Mittal S, Ayati S, Stein KM, Schwartzman D, Cavlovich D, Tchou PJ, Markowitz SM, Slotwiner DJ, Scheinder MA, Lerman BB. "Transthoracic cardioversion of atrial fibrillation: Comparison of rectilinear biphasic versus damped sine wave monophasic shocks." Circulation. 2000 Mar 21;101(11):1282-7.

22 Niebauer et al. "Success rate of rectilinear biphasic waveform in atrial cardioversion in a large cohort of patients." 73rd Scientific Session of the American Heart Association. 2000 (abstract).

23 Friedman et al. "Role of ibutilide and biphasic waveforms for cardioversion of atrial fibrillation in routine clinical practice." PACE 2002; 24:634 (abstract).

24 Schute et al. "Rectilinear biphasic rather than monophasic waveforms for transthoracic cardioversion of patients with rheumatic heart disease and longstanding atrial fibrillation after corrective mitral valve procedures." Journal of the American College of Cardiology. 2002 Mar 6;39:429A (abstract).

25 Pettinati et al. "External electrical cardioversion of atrial fibrillation: Rectilinear biphasic vs. monophasic shock." Journal of the American College of Cardiology. 2002 Apr;39:618 (abstract).

26 Neal et al. "Comparison of the efficacy and safety of two biphasic defibrillator waveforms for the conversion of atrial fibrillation to sinus rhythm." The American Journal of Cardiology. 2003;92:810-814.

27 FDA 510K Clearance K990762.

ZOLL
It's about time.