

ADAPTIV™ BIPHASIC TECHNOLOGY

Annotated Bibliography

All Physio-Control defibrillators deliver a full range of biphasic energy up to 360J. No one can identify those patients who are difficult to defibrillate ahead of time, and current science demonstrates that biphasic defibrillation waveforms are equivalent up to 200J. That's why Physio-Control defibrillators offer the broadest range of defibrillation energy available.

The Physio-Control ADAPTIV biphasic waveform shock performance has been evaluated in a wide variety of settings:

- out-of-hospital cardiac arrest
- cardioversion of atrial fibrillation
- open chest surgery
- electrophysiology lab

Its performance has been documented in nearly twice as many cardiac arrest patients as all other major manufacturers combined.

This annotated bibliography summarizes key peer reviewed clinical research where the Physio-Control biphasic waveform was used in patient care.

FULL ENERGY/DOSE ESCALATION

Out-of-Hospital Cardiac Arrest
(Low Fixed Energy Dosing Protocol vs. Escalating to 360J)

Stiell I, Walker R, Nesbitt L. BIPHASIC Trial: a randomized comparison of fixed lower versus escalating higher energy levels for defibrillation in out-of-hospital cardiac arrest. Circulation. 2007;115:1511-17.

The purpose this triple-blinded randomized controlled multi-center trial of out-of-hospital (OOH) cardiac arrest patients was to compare two common biphasic shock energy regimens for defibrillation. A total of 221 patients who received > 1 biphasic automated external defibrillator (AED) shocks were studied. AEDs were randomly programmed to provide fixed lower energy (150J-150J-150J) or escalating higher energy (200J-300J-360J). LIFEPAK® 500 AEDs with ADAPTIV™ biphasic energy were used in the study. The study focused only on the AED portion of care by the basic life support (BLS) providers. In the primary analysis of multishock patients, conversion rates to an organized rhythm were significantly higher for shocks delivered according to the escalating higher energy protocol versus the fixed low energy protocol (36.6% versus 24.7%; $p=0.035$). Ventricular fibrillation termination rates were significantly higher for shocks delivered according to the escalating higher energy protocol compared to the fixed lower energy protocol (82.5% versus 71.2%; $p=0.027$). There were no differences in survival outcomes or adverse events between the two groups, although the study was not designed or powered to evaluate such outcomes. There was a non-significant trend toward more patients with left ventricular ejection fraction of less than 35% in the group treated with fixed lower energy shocks (24.3% versus 10.5%; $p=0.12$).

Out-of-Hospital Cardiac Arrest
(Shock Behavior and Impedance Change)

Walker R, Koster R, Sun C, et al. Defibrillation probability and impedance change between shocks during resuscitation from out-of-hospital cardiac arrest. Resuscitation. 2009;80:773-7.

863 consecutive out of hospital cardiac arrest cases were retrospectively analyzed where Physio-Control ADAPTIV™ biphasic truncated exponential (BTE) AED shocks were given for ventricular fibrillation (VF). Per local protocols all patients received BTE shocks of 200J, 200J, 360J or 200J, 300J, 360J. 467 of the cases contained multiple shocks either because the first shock failed to cardiovert ($n=61$) or because

of recurrence of VF (n=406). Termination rates for VF were high for the first shocks (93%) as well as for all shocks combined (90% overall success or 1919 of 2124 total shocks). The response of a patient to the first shock was indicative of the success/failure of subsequent shocks to that patient. Some patients were difficult to defibrillate: 5% of the patients accounted for 71% of the failed shocks. Defibrillation probability increased with increasing energy levels among the subset of patients who received shocks at each of the three energy levels. Contrary to common belief, impedance changes between consecutive shocks of the same energy was minimal.

Out-of-Hospital Cardiac Arrest
(Shocks Delivered by Advanced Life Support (ALS))

Koster R, Walker R, Chapman F. Recurrent ventricular fibrillation during advanced life support care of patients with prehospital cardiac arrest. Resuscitation. 2008;78:252-7.

This was a prospective study involving 5 large ambulance regions in the Netherlands. The purpose of this study was to analyze the outcomes from defibrillation shocks delivered for recurrent ventricular fibrillation (VF) during advanced life support (ALS) care in a large cohort of patients. Biphasic defibrillators with Physio-Control ADAPTIV™ biphasic technology increasing from 200J to 360J were used to treat 467 enrolled patients. Shocks were delivered according to ERC Guidelines 2000 protocols which required up to three stacked shocks delivered in an attempt to terminate VF before starting the next CPR cycle. The study found diminishing return from repeating the same shock dosage after a first shock failed (92% first shock versus 61% second shock success). Increasing the dosage to 360J for a third shock raised the success rate to 83%. 11% were "difficult-to-defibrillate" and required multiple shocks for recurrent VF. All were eventually defibrillated at 360J.

Out-of-Hospital Cardiac Arrest
(Shocks Delivered by Lay First Responders (BLS))

Whitfield R, Colquhoun M, Chamberlain D, et al. The department of health national defibrillator programme: analysis of downloads from the 250 deployments of public access defibrillators. Resuscitation. 2005;64:269-77.

This paper reports on an audit done on the first 250 uses of the 681 AEDs that were placed in 110 public places by the department of health (England) for use by volunteer first responders. Two models of biphasic AED were used: the Physio-Control LIFEPAK® 500 and the Cardiac Science FirstSave®. Of these 250 deployments, there were 182 confirmed cardiac arrests. Ventricular fibrillation (VF) or rapid ventricular tachycardia (one case) was the first recorded rhythm in 146 cases (82%). 44 of the 177 witnessed cases are known to have survived to hospital discharge (25%). Complete downloads were available for 173 witnessed cases and 140 were shocked. First shock VF termination, was achieved in 132 of 140 cases that were shocked (94%). When data quality permitted, the downloads were analyzed for overall CPR quality. When compressions were being done, the average compression rate was 120 per minute, but because of interruptions, the actual number administered over a full minute from the first CPR prompt was a median of only 38. The speed of response by the lay first responders in AED use was similar to that reported for healthcare professionals

BIPHASIC WAVEFORM COMPARISON

Atrial Fibrillation
(Physio-Control vs. ZOLL)

Alatawi F, Gurevitz O, White R, 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.

The purpose of the study was to determine if there was a difference in two commercially available biphasic waveforms, the Physio-Control ADAPTIV™ biphasic truncated exponential (BTE) and the ZOLL biphasic rectilinear (BRL) waveforms. 188 patients with atrial fibrillation (AF) were randomized to receive transthoracic shocks in a step up protocol with either the BTE (50, 70, 100, 125, 150, 200, 300, 360J) or BRL (50, 75, 100, 120, 150, 200J) waveform. Shock strength was escalated until the maximum dose was achieved. If the maximum shock strength failed patients were crossed over to receive the maximum strength of the opposite waveform. Final analysis consisted of 141 patients. There were no significant differences in efficacy between the Physio-Control biphasic truncated exponential (BTE) and the ZOLL biphasic rectilinear (BRL) waveforms at equal energies up to 200J. However, the BTE shocks cardioverted with less cumulative delivered energy than the BRL shocks (120 versus 157J, $p=0.0009$). 3 out of 5 patients who failed with the ZOLL BRL waveform at its maximum energy of 200J were successfully cardioverted when they crossed over to Physio-Control BTE waveform at 360J, while all ZOLL 200J BRL crossover shocks were unsuccessful (5 total) after Physio-Control 360J BTE shocks failed to cardiovert.

Atrial Fibrillation
(Physio-Control vs. ZOLL)

Kim M, Kim S, Park D, et al. Comparison of rectilinear biphasic waveform energy versus truncated exponential biphasic waveform energy for transthoracic cardioversion of atrial fibrillation. The American Journal of Cardiology. 2004;94:1438-1440.

In this study 145 patients undergoing cardioversion for atrial fibrillation (AF) were randomly assigned to either a device using the ZOLL biphasic rectilinear (BRL) waveform or a Physio-Control ADAPTIV™ biphasic truncated exponential (BTE) waveform. An initial shock of 50J was used. If unsuccessful, energy was increased progressively to the maximum output of each defibrillator. If cardioversion was unsuccessful with the originally randomized device at its maximum energy level (200J for the ZOLL BRL and 360J for the Physio-Control BTE), the patient was crossed over and received a shock at the maximum energy level of the other device. At identical energies up to 200J, there was no significant difference in success between ADAPTIV BTE and ZOLL BRL technologies. Both patients who failed to cardiovert with the ZOLL BRL waveform at its maximum energy of 200J were successfully cardioverted when crossed over to Physio-Control BTE at 360J. Neither patient who failed to convert with the maximum Physio-Control BTE 360J shock was able to be successfully cardioverted when crossed over to the ZOLL BRL maximum energy shock of 200J.

Atrial Fibrillation
(Physio-Control vs. ZOLL)

Neal S, Ngarmukos T, Lessard D. Comparison of the efficacy and safety of two biphasic defibrillator waveforms for the conversion of atrial fibrillation to sinus rhythm. American Journal of Cardiology. 2003;92: 810-814.

In this prospective trial, 101 patients were randomized to either Physio-Control ADAPTIV™ biphasic truncated exponential (BTE) shocks or ZOLL biphasic rectilinear (BRL) shocks for cardioversion of atrial fibrillation. Shocks were delivered in a step up protocol beginning at 50J, then, 100J, 200J, repeat 200J, and then crossover to 360J. Serum levels of cardiac troponin I levels were measured pre- and post-cardioversion as well as post-procedural skin discomfort and erythema. All but one of the patients (99%) were successfully cardioverted to sinus rhythm. The one patient who failed to cardiovert could not be cardioverted at the maximum energy level of either defibrillator. At identical energies up to 200J, there was no significant difference in success between ADAPTIV BTE and ZOLL BRL technologies. No waveform showed signs of elevated troponin levels and there was no difference in skin redness or irritation between the two waveforms.

BIPHASIC WAVEFORM VS. MONOPHASIC WAVEFORM

Out-of-Hospital Cardiac Arrest

van Alem A, Chapman F, Lank P, et al. A prospective, randomized and blinded comparison of first shock success of monophasic and biphasic waveforms in out-of-hospital cardiac arrest. *Resuscitation*. 2003;58:17-24.

The success of biphasic truncated exponential (BTE) and monophasic damped sine MDS shocks were compared in a prospective, randomized, double blinded trial of out-of-hospital (OOH) cardiac arrest patients. First responders were equipped with either a Physio-Control LIFEPAK® 500 MDS or BTE (ADAPTIV™ biphasic waveform) automated external defibrillator (AED) in a random fashion. Patients in ventricular fibrillation (VF) received BTE or MDS first shocks of 200J. The primary endpoint was return of an organized rhythm within 1 minute after the first shock. The secondary endpoint was termination of VF at 5 seconds post shock. VF was the initial recorded rhythm in 120 patients. 51 patients received BTE and 69 received MDS shocks. The success rates (return of an organized rhythm) of 200J first shocks was significantly higher for BTE than for MDS shocks, 35/51 (69%) and 31/69 (45%), $p=0.01$. The first shock VF termination rates at 5 seconds after the first shock were 63/69 (91%) for the MDS shocks and 50/51 (98%) for the BTE shocks but these results were not statistically significant.

Out-of-Hospital Cardiac Arrest

Kudenchuk P, Cobb L, Copass M, et al. Transthoracic incremental monophasic versus biphasic defibrillation by emergency responders (TIMBER): a randomized comparison of monophasic with biphasic waveform ascending energy defibrillation for the resuscitation of out-of-hospital cardiac arrest due to ventricular fibrillation. *Circulation*. 2006;114:2010-18.

Consecutive adults with nontraumatic ventricular fibrillation (VF) were randomly assigned to defibrillation according to the waveform from LIFEPAK® 500 automated external defibrillators (AED) administered by prehospital medical providers. Providers were blinded to the AED waveform. Of the 168 randomized patients 80 (48%) and 68 (40%) consistently received either monophasic or biphasic waveform shocks, respectively, throughout the resuscitation. First shock VF termination was 82% in the monophasic group and 88% in the biphasic group ($p=.33$). Survival to hospital admission was high in both groups, 73% in the monophasic group and 76% in the biphasic group ($p=0.58$). Although several favorable trends were noted with the biphasic waveform none reached statistical significance. Of note was the trend that 27 of 80 monophasic shock recipients (34%), compared with 28 of 68 biphasic shock recipients (41%), survived ($p=0.35$) to hospital discharge.

Out-of-Hospital Cardiac Arrest

Carpenter J, Rea T, Murray J, et al. Defibrillation waveform and post-shock rhythm in out-of-hospital ventricular fibrillation cardiac arrest. *Resuscitation*. 2003;59:189-196.

The primary objective of the study was to evaluate cardiac rhythms following the first defibrillation shock, comparing biphasic truncated exponential (BTE), monophasic damped sinusoidal (MDS), and monophasic truncated exponential (MTE) waveforms in patients experiencing out-of-hospital ventricular fibrillation cardiac arrest (OHCA). A variety of defibrillators were studied but the biphasic truncated exponential (BTE) devices were either Philips Forerunner® II with a fixed BTE energy of 150J or a Physio-Control LIFEPAK® 12 with ADAPTIV™ BTE waveform with energy settings from 200-360J. The records of 366 patients who suffered OHCA and were treated with defibrillation shocks by first tier emergency responders were reviewed. The main outcome was the cardiac rhythm following the first BLS administered defibrillation shock at 5, 10, 20, 30, and 60 seconds. The MDS and BTE waveforms were associated with significantly higher frequency of defibrillation than the MTE waveform, though only the BTE association persisted to 30 seconds and 60 seconds. No difference in defibrillation rates were detected between MDS and BTE waveform. By 60 seconds, an organized rhythm was present in a greater proportion for BTE (40%) compared with MDS (25.4%, $p=0.01$) or MTE (26.5%, $p=0.07$). Additional investigation is needed to understand the role of waveform and its potential interaction with other clinical factors in order to optimize survival in OHCA.

Atrial Fibrillation

Koster R, Dorian P, Chapman F, et al. A randomized trial comparing monophasic and biphasic waveform shocks for external cardioversion of atrial fibrillation. *Am Heart J*. 2004;147:e20.

The Physio-Control ADAPTIV™ biphasic truncated exponential (BTE) waveform was compared to the conventional monophasic damped sine (MDS) waveform in a multi-center randomized study of 72 patients. The study showed that the biphasic shocks provided higher efficacy for cardioversion of atrial fibrillation requiring fewer shocks, 65% less current and 65% less energy for successful cardioversion than the MDS waveform. With both waveforms escalating energy improved shock success. Patients felt less pain after BTE than MDS shocks at 1 hour and 24 hours after cardioversion.

Atrial Fibrillation

Neumann T, Erdogan A, Reiner C et al. Ambulatory electrocardioversion of atrial fibrillation by means of biphasic versus monophasic shock delivery. A prospective randomized study. *Z Cardiol.* 2004;93:381-7. (German language)

A total of 118 patients with persistent atrial fibrillation (mean duration 8 months) were randomized to receive either monophasic (n=57) or biphasic (n=61) shocks (Physio-Control ADAPTIV™ BTE waveform). A standard step-up protocol (from 100J-360J) was used in either group. The success rate was 100% for the ADAPTIV biphasic group and 73.7% for the monophasic group (p=0.001). 12 out of 15 unsuccessfully treated patients in the monophasic group were converted with biphasic shocks bringing the success rate for all patients up to 97.5%. Patients in the biphasic group required fewer shocks and less cumulative energy.

Atrial Fibrillation

Khaykin Y, Newman D, Kowalewski M, et al. Biphasic versus monophasic cardioversion in shock-resistant atrial fibrillation: a randomized clinical trial. *Journal of Cardiovascular Electrophysiology.* 2003;14:868-72.

Fifty-six patients who had previously failed monophasic cardioversion were randomly assigned to receive either a 360J monophasic damped sine shock (MDS) or Physio-Control ADAPTIV™ 200J biphasic truncated exponential (BTE) shocks followed by 200J and then 360J if needed. If either waveform failed to cardiovert, patients were crossed over to the other waveform. In this particularly difficult-to-cardiovert population (sustained AF for 24 days, hypertension, moderate left atrial enlargement, Amiodarone Rx) 61% of patients receiving a BTE shock were cardioverted successfully, compared to 18% of patients who received a 360J MDS shock (p=0.0001). 78% of the patients who crossed over to the BTE waveform after failing MDS shocks were successfully cardioverted with the BTE shock, but only 33% were successfully cardioverted with a MDS shock after crossover from BTE shock (P=0.02). Overall, 69% of patients who received a BTE shock at any point in the protocol were cardioverted successfully, compared to 21% with the monophasic shock (p< 0.0001).

Electrophysiology Lab Study

Higgins S, Herre J, Epstein A, et al. A comparison of biphasic and monophasic shocks for external defibrillation. *Physio-Control biphasic investigators. Prehosp Emerg Care.* 2000;4:305-13.

This prospective, double-blinded, randomized clinical trial compared the first shock efficacies of Physio-Control ADAPTIV™ 200J biphasic truncated exponential (BTE) waveform, 130J BTE and 200J monophasic damped sine shocks (MDS) shocks in the electrophysiology lab. Ventricular fibrillation (VF) was induced in 154 patients. After 19±10 seconds of VF, a randomized transthoracic shock was administered. Mean first shock success rates for the three groups were compared. First shock VF termination rates were 61/68 (90%) for the 200J monophasic, 39/39 (100%) for the 200J biphasic, and 39/47 (83%) for 130J biphasic shocks. The 200J biphasic shocks were superior in first-shock efficacy to both 200J MDS shocks and 130J BTE shocks. There were no significant differences in hemodynamic parameters between the 3 groups after successful shocks. The 200J biphasic shocks were more effective than monophasic and the lower energy biphasic shocks and may allow earlier termination of VF in cardiac arrest patients.

Electrophysiology Lab Study

Higgins S, O'Grady S, Banville I, et al. Efficacy of lower-energy biphasic shocks for transthoracic defibrillation: a follow-up clinical study. *Prehosp Emerg Care.* 2004;3:262-7.

This study prospectively evaluated the first-shock defibrillation efficacy of the Physio-Control ADAPTIV™ 150J BTE shocks in 96 patients with electrically induced ventricular fibrillation (VF) and ventricular tachycardia (VT) and compared it with a historical control group treated with 200J monophasic damped sine shocks (MDS). First shock termination rates for VF were 97.4% for VF patients and 100% for the VT patients. The study demonstrated that the success rate of this 150J BTE waveform was technically equivalent to that of the MDS waveform (89.7% and 94%, success, p= 0.001) while delivering peak current that was about 50% lower than the MDS shocks.

Internal (Open Chest) Defibrillation Study

Schwarz B, Bowdle T, Jett G, et al. Biphasic shocks compared with monophasic damped sine wave shocks for direct ventricular defibrillation during open heart surgery. *Anesthesiology.* 2003;98:1063-9.

This prospective, blinded, randomized clinical study compared the Physio-Control ADAPTIV™ BTE waveform and monophasic damped sine (MDS) shock effectiveness in 91 patients during open chest defibrillation and established a dose-response curve. The biphasic group required lower threshold energy, less cumulative energy and fewer shocks. Dose response curves showed biphasic shocks had higher cumulative success rates at all energies tested. Starting at 5J optimizes for lowest threshold and cumulative energy whereas 10J or 20J optimizes for more rapid defibrillation and fewer shocks.

GUIDELINES 2000 VS. 2005

Jost D, Degrange H, Verret C, et al. *DEFI 2005: a randomized controlled trial of the effect of automated external defibrillator cardiopulmonary resuscitation protocol on outcome from out-of-hospital cardiac arrest. Circulation. 2010;121:1614-22.*

In a randomized controlled trial, patients with out-of-hospital cardiac arrest requiring defibrillation were treated with one of 2 automated external defibrillators. Physio-Control defibrillators with an ADAPTIV™ biphasic truncated exponential waveform (BTE) were used in both arms of the study. The control protocol was based on Guidelines 2000 with sequences up to 3 stacked counter shocks, and with rhythm analyses initially and after the first and second shocks. The study protocol mirrored the 2005 Guidelines and featured 1 minute of CPR before the first shock, shorter CPR interruptions before and after each shock, and no stacked shocks. The primary end point was survival to hospital admission. 1238 patients out of 5107 cardiac arrest patients required defibrillation and 845 were included in the final analysis. Although the study patients had shorter pre and post shock pauses, and received more CPR and fewer shocks than control patients, survival to hospital admission of patients with VF did not improve. First shock VF termination was similar in both groups, averaging 88%.

Berdowski J, ten Haaf M, Tijssen J, et al. *Time in recurrent ventricular fibrillation and survival after out-of-hospital cardiac arrest. Circulation. 2010;122:1101-08.*

The continuous ECG recordings of out-of-hospital cardiac arrests patients were analyzed prospectively from January 2006 to January 2008. Physio-Control AEDs and manual defibrillators were used and the data was merged to form a continuous timeline. 64% of the G2000 patients and 79% of the G2005 patients were treated with a Physio-Control defibrillator with an ADAPTIV™ biphasic truncated exponential waveform. Patients treated according to Guidelines 2000 (G 2000, n=282) or Guidelines 2005 (G 2005, n=240) with VF as an initial rhythm were included. The total time a patient was in recurrent VF was measured. The primary outcome measure was neurologically intact survival to hospital discharge. The median time in recurrent VF was 2.7 minutes under G2000 versus 4.0 minutes under G2005. The use of G2005 was associated with a longer time in recurrent VF. The longer lasting time in recurrent VF was associated with worse outcomes.

BODY WEIGHT AND ENERGY REQUIREMENTS

Atrial Fibrillation

Jain V and Wheelan K. *Successful cardioversion of atrial fibrillation using 360J biphasic shock. American Journal of Cardiology. 2002;90:331-2.*

This article describes 3 patients with recurrent atrial fibrillation (AF) who were successfully cardioverted to sinus rhythm (SR) after 360J biphasic truncated exponential (BTE) shocks (Physio-Control ADAPTIV™ BTE waveform). All 3 patients were obese (BMI=34) or morbidly obese (BMI=43 and 49). No adverse effects were noted and the 3 patients remained in SR at follow-up ranging from 3 months to 1.5 years. The authors concluded that a 360J biphasic shock should be attempted before labeling an obese patient as having refractory AF.

Atrial Fibrillation

Rashba E, Gold M, Crawford F, et al. *Efficacy of transthoracic cardioversion of atrial fibrillation using a biphasic, truncated exponential shock waveform at variable initial shock energies. American Journal of Cardiology. 2004;94:1572-1574.*

120 consecutive patients with persistent atrial fibrillation were treated with Physio-Control ADAPTIV™ biphasic truncated exponential (BTE) shocks. Patients were randomized to 1 of 4 initial shock energies of either 20J, 50J, 100J or 200J. If the first shock was ineffective, a 200J shock was delivered, followed by a maximum output 360J shock if the second shock failed. If the 360J shock failed additional 360J shocks were given. All but one patient eventually cardioverted at 360J, although a few required several 360J shocks. Shock success improved as energy escalated. The observed success rates were 7% at 20J, 23% at 50J, 63% at 100J and 83% at 200J, and 95% at 360J. None of the 5 patients in whom the first 200J shock failed were successfully cardioverted with a second 200J shock. Body weight was a strong predictor of higher shock energy requirements. The authors propose that initial shock energy should be 200J for patients weighing less than 90 kg and 360J for patients weighing more than 90 kg.

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