

First Clinical Results of a New Capture Control Algorithm Implemented in a Dual-Chamber Rate-Adaptive Pacemaker

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Summary

It is crucial to determine the minimum pulse energy required for effective depolarization of cardiac tissue during the implantation procedure and subsequent pacemaker follow-up visits. It is standard clinical practice to program the output of the pacemaker to a value that is twice the measured pacing threshold. Due to various factors, the safety margin may not always ensure effective pacing; on the other hand, an unnecessarily high safety margin will increase energy consumption and shorten the battery life. We have summarized the initial results of a new active capture control (ACC) feature. This feature automatically evaluates signal quality to distinguish the evoked response from polarization artifact, performs continuous beat-to-beat monitoring, discriminates non-capture from fusion beats, responds to non-capture with a safety back-up pulse, periodically measures the pacing threshold, and adjusts the pacing output. The reliability of this algorithm has been evaluated during both acute testing in the EP-lab, as well as in a chronic setting outside the hospital. During acute testing, the sensitivity of capture and non-capture detection was 99.7% and 98.3%, respectively. The pacing threshold measurements were very similar at the implantation procedure: 0.58 ± 0.29 V using a pacing system analyzer, and 0.48 ± 0.28 V using the ACC algorithm. Holter recordings completed in implanted patients showed appropriate algorithm behavior, even with settings programmed to elicit fusion beats.

Key Words

Automatic pacemaker, pacing threshold, safety margin

Introduction

It is important to determine the minimum pulse energy required for effective depolarization of cardiac tissue during the implantation procedure and subsequent pacemaker follow-up visits. This minimum pulse output that depolarizes (captures) the myocardial tissue is referred to as the pacing threshold. It is standard clinical practice to program the pacing amplitude of the pulse generator to a value that is at least twice the measured pacing threshold. The difference between the pacing threshold and the programmed amplitude is

referred to as the safety margin. The purpose of the safety margin is to compensate for any increase in the pacing threshold between follow-up evaluations. Many factors affect the myocardial pacing threshold [1,2]. Lead maturation, changes in medication, lead micro-dislodgment, pathologic changes, or physiologic changes such as exercise may cause variations in pacing threshold. An implantable cardiac pacing system must be able to capture the myocardial tissue independent of these changes. As a result, the pacing

threshold must be measured on a routine basis, and the pacing amplitude must be programmed to a sufficiently large value in order to maintain capture between regular follow-ups. However, the standard 2:1 safety margin may not always ensure effective pacing. On the other hand, an unnecessarily large safety margin will increase energy consumption and shorten the battery life. The ideal solution to address this issue is an automatic feature that discriminates capture from non-capture, periodically measures the pacing threshold, and adjusts pacing output on a beat-to-beat basis. This type of system was proposed nearly 30 years ago [3,4]. In recent years, various algorithms have been developed with different perspectives and goals.

The first dual-chamber pacemaker with this capability was the Logos pacemaker (Biotronik, Germany) [5,6]. The Capture Control algorithm allowed the device to differentiate capture from non-capture and provided continuous monitoring during ventricular pacing by using the ventricular evoked response (VER). As a result, the pacing amplitude could be programmed to a value just above the manually measured pacing threshold. If a non-capture event was detected, the device would automatically increase the pacing amplitude. For that reason, this device was able to ensure effective pacing; however, it lacked the ability to measure the exact beat-to-beat pacing threshold and to adjust the pacing amplitude accordingly.

The Capture Management algorithm (Medtronic, USA) provided an entirely different solution. This algorithm periodically measured the pacing threshold and automatically reprogrammed the ventricular pacing amplitude and pulse width. However, this algorithm lacked the ability to continuously distinguish capture from non-capture between threshold measurements. As a result, this feature could ensure that the programmed output remained at a safe level above the actual pacing threshold, but did not allow the amplitude to be programmed just above the pacing threshold. Therefore, device longevity could not be optimized with the algorithm. Furthermore, this algorithm does not allow the user to evaluate the lead signal to determine if the feature will function appropriately [7]. The Auto Capture algorithm (St. Jude Medical, USA) provided a combination of the benefits of the Capture Control and Capture Management algorithms. This algorithm was initially only available in single-chamber (VVI, VVIR) devices, and allowed for periodic measurements of the pacing threshold as well as con-

tinuous beat-to-beat monitoring during ventricular pacing. Unfortunately, this algorithm also required the use of special leads from the same manufacturer as well as programming of unipolar pacing for normal operation. This algorithm requires the user to manually measure the evoked response (ER) and polarization artifact amplitudes [8]. The user also has to manually program the ER sensitivity parameter to function appropriately based on these measurements because the pulse generator includes 2 separate detectors. One is for detecting intrinsic signals and the other is for detecting the ER; these two detectors must be programmed separately [9]. All of these systems have some drawbacks including those identified above. In addition, these features also include some risks that have been previously identified. In some cases, the signal quality changes over time and can result in either undetected non-capture or programming of the pacing amplitude to an unnecessarily high value [7]. Fusion can also be problematic for these devices and can result in unnecessary delivery of back-up pulses, which wastes the same energy that the algorithm was designed to conserve. The design of previous algorithms took into account that nearly 25% of fusion beats resulted in unnecessarily high output back-up pulses [9]. Therefore, the ideal system should be able to:

- automatically and periodically evaluate signal quality to prevent misclassification of pacing effect,
- perform continuous beat-to-beat monitoring and respond to loss of capture with a safety back-up pulse,
- discriminate non-capture from fusing beats, and
- periodically measure the pacing threshold and adjust the pacing output accordingly.

The Active Capture Control (ACC) feature, designed to meet these requirements, was evaluated during and following the implantation of a pacing system [10].

Materials and Methods

Description of the Algorithm

The Philos DR ACC (Biotronik) is a multi-programmable, dual-chamber, rate adaptive pulse generator that is based on the currently available Philos DR with the addition of the ACC feature. This new feature attempts to resolve many of the limitations of the previously developed features. It includes a special algorithm so that the signal following the ventricular pacing pulse is

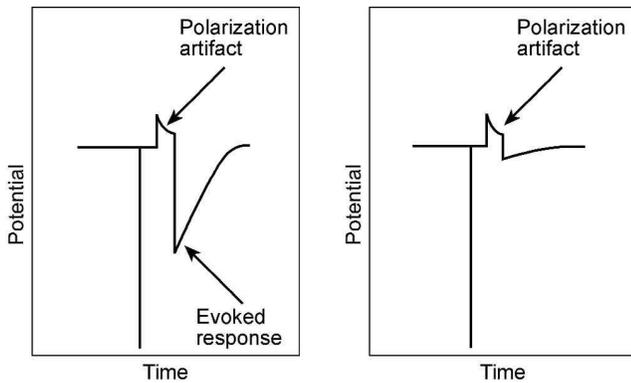


Figure 1. ECG response to a non-captured and a captured pacing pulse.

continuously monitored to verify that a depolarization occurred as a result of the pulse. Differences in the signal morphology between the ER and the polarization artifact are used to distinguish capture events from non-capture events (Figure 1). The ACC feature periodically measures the ventricular capture threshold, automatically adjusts the pacing output, and provides a programmable safety margin. Additionally, the feature assesses ventricular pacing capture on a continuous beat-to-beat basis and responds to loss of capture with a safety back-up pulse. Measurement of the current pacing threshold will occur after loss of capture is detected or at programmable time intervals. The feature includes three primary components:

- Signal Quality Check (SQC),
- Capture Threshold Search (CTS), and
- Continuous Capture Confirmation (CCC).

Signal Quality Check: A polarization artifact that is too large may disturb the signal following the pacing pulse and result in misclassification of the event. Conversely, the ER signal may be too small or may not meet the capture criteria, which again may lead to a misclassification of the event. Therefore, the SQC automatically analyzes the ER and the polarization artifact. A successful SQC must always be completed before the initiation of CTS or CCC. As a result, ACC is fully automatic and does not require a manual assessment of the lead signals or programming of special parameters. This component of the algorithm represents the most significant improvement over previous algorithms and should resolve the risks of such algorithms. The SQC is performed in two separate phases. In both

phases, the AV delay is shortened to ensure ventricular pacing. First, ventricular pacing pulses are delivered at the Maximum ACC Amplitude, which is a programmable maximum voltage setting. If non-capture is detected at the maximum voltage setting, the second phase of the SQC is aborted and the test is classified as unsuccessful. In the next phase, "double" pacing pulses (one pacing pulse followed by another pacing pulse 100 ms later, in the absolute refractory period) are delivered. These pulses are used to verify that the polarization artifact is small enough to distinguish capture from non-capture. If the artifact following the second pacing pulse is higher than a certain limit, the SQC is classified as unsuccessful. If necessary, this test can be repeated at a lower maximum voltage setting. If the result of this automatic test determines that the signal quality is not sufficient, the ACC feature is temporarily suspended or permanently disabled. In either case, the pacing amplitude is reprogrammed to a high output setting to ensure ventricular capture.

Capture Threshold Search: This is the component of the ACC feature that measures the ventricular pacing threshold by stepping down the pacing amplitude until non-capture occurs. The CTS occurs over a series of cardiac cycles and begins at the programmed Maximum ACC Amplitude (2.4, 3.6, 4.8, 6.4 V), then decreases until capture is lost. The AV delay is automatically shortened during the test to ensure ventricular pacing. The pacing threshold is measured with a resolution of 0.1 V. The pacing amplitude is then set to the pacing threshold plus a programmable safety margin (Off, 0.1 to 1.2 V). In addition to performing the threshold search after a loss of capture, the search is also conducted at a programmable interval to provide an accurate safety margin even with gradual changes in the pacing threshold.

Continuous Capture Confirmation: This is the component of the ACC feature that provides beat-to-beat capture verification. If ACC determines that capture has been maintained, then the pulse amplitude remains at that current setting and no action is required. If ACC determines that non-capture events occurred, then a safety back-up pacing pulse is delivered at an increased energy after the non-captured pacing pulse (see Figure 2). If a series of ventricular pacing pulses at varying AV delays result in non-capture, the SQC and CTS are initiated to measure the pacing threshold.

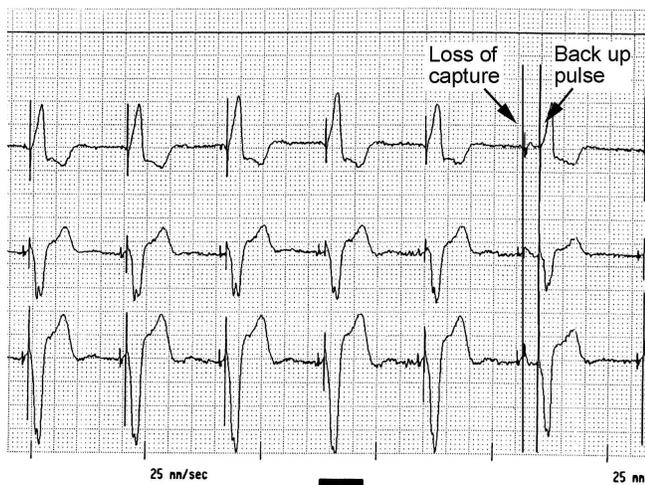


Figure 2. Example of a non-captured pacing pulse followed by the back-up pacing pulse during capture threshold search.

The ACC feature includes an algorithm to respond to fusion beats. In order to discriminate non-capture from fusion, the algorithm varies the AV delay after detection of non-capture in the dual-chamber pacing modes. First, the AV delay is extended to encourage intrinsic conduction without fusion. If a second consecutive non-capture is detected, the AV delay is returned to the normal programmed AV delay. If a third consecutive non-capture is detected, loss of capture is confirmed and the SQC and CTS are initiated. If the first event was truly fusion, the extended AV delay could allow intrinsic conduction. The AV delay will not return to the normal programmed value until ventricular pacing is required. In case the capture confirmation does not result in 3 consecutive non-capture detections, the algorithm shortens the AV delay (to 50 ms after an atrial paced event, and to 15 ms after an atrial sensed event) to confirm the occurrence of non-capture.

Diagnostics: The Philos DR ACC pulse generator includes various diagnostics that were designed to evaluate the behavior of the ACC feature. Event counters provide information about the number of non-capture events, the number of loss-of-capture events, as well as the number and outcome of each SQC and CTS. The Ventricular Output histogram provides the distribution of the pacing amplitudes over time. The ACC Threshold Trend provides a graph of the threshold measurements, and the printout provides a table with threshold measurements including a time stamp and the reason for the threshold search. Other, more

advanced diagnostics are also available to evaluate the performance and behavior of the ACC algorithm.

Acute Testing

The study was completed between December 1999 and May 2000. Thirty-three patients were included (23 males, 10 females; age 76 ± 9 years, range 45 – 90 years). The study was conducted according to the Declaration of Helsinki for ethical treatment of research subjects and required both ethical committee approval and patient informed consent prior to enrollment. Thirteen patients were tested in DDD mode and 20 in VVI mode. Table 1 shows the ventricular leads used. Using a single ventricular lead model (Polyrox, Biotronik) for the first 18 patients was beneficial because it removed one possible confounding factor (lead type) as a variable. A sufficient variety of lead types were used in the remaining 15 patients (see Table 1). The ability to differentiate capture from non-capture is the most important part of any algorithm. Paced ventricular events have to be classified as either capture or non-capture. This part of the feature could be referred to as the event classifier. The objective of the acute clinical study was to evaluate the effectiveness of the ACC event classifier and the CTS feature. The study was specifically designed to examine the ability of the algorithm to:

- correctly classify capture and non-capture,
- classify lead/patient combinations that will allow the algorithm to function appropriately, and
- correctly determine the ventricular pacing threshold.

During the pacemaker implantation procedure, an external pacemaker comprised of typical pacing and

Lead	No.
Polyrox (BIOTRONIK, Germany)	20
Synox (BIOTRONIK, Germany)	2
Retrox (BIOTRONIK, Germany)	1
Membrane (St Jude, USA)	2
4092 (Medtronic, USA)	3
4058M (Medtronic, USA)	1
5028 (Medtronic, USA)	2
4261 (CPI, USA)	1
Unknown unipolar (Intermedics, USA)	1

Table 1. Type and number of ventricular pacing leads used.

sensing hardware was connected to the implanted leads and used to test the ACC algorithm. The hardware was controlled and could be reprogrammed using special software (Embedded System Platform, ESP, Biotronik) installed on a laptop PC. The PC simulated the function of the pacemaker's microprocessor and ran actual embedded software code related to the ACC algorithm. The ESP software was also used to record electrograms and pacemaker events for later analysis. A ventricular lead was placed via guided fluoroscopy using standard pacemaker lead implantation procedures. If indicated, an atrial lead was also implanted. Prior to placing the pulse generator, an indifferent electrode was temporarily placed in the pocket. The pacing/sensing analyzer (PSA, Medtronic) was used to make normal lead measurements (impedance, sensing and pacing thresholds). If adequate lead placement was determined, the pacing leads and indifferent electrode were connected to the ESP hardware. There were 3 separate procedures (implemented automatically using ESP scripts):

- fixed rate pacing or sensing with and without refractory pacing,
- ventricular fusion pacing (patients with atrial lead and $\leq 2^{\text{nd}}$ degree AV block), and
- ACC algorithm running at maximum ACC amplitude equal to 3.6, 4.8, and 6.4 V.

Chronic Testing

The objective of this chronic study was to further validate the performance of the event classifier and other portions of the ACC algorithm. Patients eligible for implantation of a bradycardia pacing system were selected to participate in this study. The implantation of the pacemaker system was consistent with the procedures and guidelines set forth by the American College of Cardiology/American Heart Association (ACC/AHA) guidelines. Additional testing following the implantation was required to adequately evaluate the ACC algorithm. Manual and automatic threshold testing as well as other standard pacemaker tests were performed following the implantation of the Philos DR ACC pulse generator. A total of nine patients (four males, five females; mean age 77.5 years) were enrolled and implanted between July and November 2001. The study followed the same ethical treatment guidelines as the acute study.

Atrial and ventricular leads were implanted using standard implantation procedures and guided fluoroscopy.

Synox and Polyrox (both Biotronik) ventricular leads were used. The PSA pacing/sensing analyzer was used to make typical lead measurements during implantation. Evoked response signals were recorded during implantation with the ESP system connected directly to the ventricular lead. Patients were also required to wear a 24-hour Holter monitor after the implantation procedure to ensure appropriate device performance. The Philos DR ACC was re-programmed prior to the application of the 24-hour Holter recording to allow collection of numerous SQCs and CTSs. The search interval was programmed to 18 min, which allowed for collection of approximately 72 data points per 24-hour Holter recording. The atrial and ventricular polarities were both programmed to unipolar pacing to enhance the visualization of the pacing spike. The AV delay was shortened or lengthened to promote ventricular pacing, and more importantly, to promote fusion behavior. Additional follow-ups were performed at pre-discharge, 1-month, and 3-months post implantation.

Results

Acute Testing

Raw event classifier results: All ventricular paced events were analyzed for appropriate classification. There was a total of 24,487 ventricular pacing events of which 24,185 (98.8%) were true ventricular captures and 301 (1.2%) were true non-captures as determined by visual analysis. The captures included those depolarizations resulting from fusion or anodal stimulation, as well as asynchronous cycles occurring during magnet application. The non-captures included true ineffective ventricular pacing pulses and pacing pulses during the refractory period of a previous ventricular depolarization. Table 2 describes the raw detection accuracy.

False positives: The 16 false positive (FP) events, the true non-capture events detected as capture, were classified as follows:

- Seven FP events were caused by an intrinsic depolarization occurring during the measurement window. The patient was supported by the intrinsic depolarization.
- Two FP events were due to asynchronous pacing in the refractory period during magnet application. This situation does not occur during synchronous pacing with accurate sensing.

	Detected as non-capture	Detected as capture
True non-capture	285	16
True capture	301	23884

Table 2. Raw detection accuracy.

- Two FP events were a result of ventricular pacing during a baseline shift in the electrogram due to relative high pacing rate. Limiting the rate at which the algorithm actively determines capture/non-capture reduced the possibility of such a misclassification.
- Five FP events were the result of a polarization artifact being misclassified as capture during a stable baseline. These misclassifications occurred with leads not considered low polarization (CPI 4261 and Medtronic 4092) and were due to uncharacteristically large polarization artifacts at low amplitudes.

False negatives: There were a total of 301 false negative (FN) events, true capture detected as non-captures. In these cases, an unnecessary back-up pulse would be delivered and, if the loss-of-capture criterion were met, an unnecessary SQC/CTS sequence would be initiated. The probable causes of FN events were as follows: 97 (ventricular fusion), 33 (anodal stimulation), and 25 (asynchronous pacing during magnet application). The remaining 146 were misclassified without any obvious contributing factor.

Nearly 40% of the misclassifications occurred at pulse amplitudes greater than 5 V (typically at 6.4 V). Because the programmable maximum amplitude for the algorithm is nominally 3.6 V, these misclassifications will not be considered for further analysis.

Adjusted event classifier results: The data collection methods used during acute testing did not allow automatic exclusion of events that were not suitable for analysis. Most of the incorrectly classified events included other factors that affected the classification performance. These factors would need to be taken into account in the final algorithm used during chronic testing. Therefore, events related to these various factors (fusion, anodal stimulation, asynchronous pacing during magnet application, high intrinsic rate causing a disturbance in the baseline signal, and misclassifications due to intrinsic depolarization not caused by but following the ventricular paced event) were removed

	Detected as non-capture	Detected as capture
True non-capture	286	5
True capture	74	23881

Table 3. Adjusted detection accuracy.

from the analysis. With the creation of the acceptance criteria, a decision was made to set the nominal value for the maximum ventricular pulse amplitude for ACC to 3.6 V. Therefore, waveforms greater than 3.6 V that were misclassified were also removed from the analysis. The adjusted event classifier results are provided in Table 3.

In conclusion, the sensitivity of capture detection and the specificity of non-capture detection are 99.7% and 98.3%, respectively. Sixty-eight of the 74 FNs (91.9%) occurred in a single patient with a Polyrox lead. This patient had an unusual unipolar ER waveform that was especially difficult for the event classifier to detect at higher pulse amplitudes. Overall, 29 of 30 patients (96.7%) with true positives had sensitivity greater than 99%, and 25 of 27 patients (92.6%) with true negatives had specificity greater than 99%. In the patient with the CPI 4261 lead only one true non-capture was classified as a capture. However, with only 51 true negatives, this resulted in specificity less than 99%. In the patient with the Medtronic 4092 four of nine true non-captures were misclassified. The poor performance in this patient was a result of an electrical artifact that resembled capture (i.e., sharp negative waveform without an initial positive signal). It is recommended that leads with these types of physical characteristics (highly porous cathode and smooth anode) not be used with the ACC algorithm when programmed to bipolar pacing and sensing.

Ventricular pacing threshold comparison: In general, there was close agreement between the pacing analyzer measured thresholds and the algorithm measured threshold values. Figure 2 provides a CTS example from the evaluation. A paired t-test was performed on the threshold data to determine their similarity. The analyzer threshold was 0.58 ± 0.29 V and the ACC algorithm threshold was 0.48 ± 0.28 V. This mean difference of 0.09 V was not clinically significant, although the result was statistically significant (p-value = 0.022).

Chronic Testing

Lead measurements at implantation: Standard atrial and ventricular lead measurements were obtained during the implantation procedure. Table 4 summarizes the relevant ventricular lead measurements. There was a small but clinically insignificant difference of 0.08 V between the manual and ACC pacing thresholds at implantation. This small difference demonstrates the ability of the CTS feature to accurately measure the ventricular pacing threshold.

Lead measurements at follow-up: Table 5 summarizes the manual and ACC pacing threshold measurements collected during follow-up. Again, the differences between the measurements are very small and not clinically significant.

Holter recording: A total of six patients were able to complete the 24-hour Holter recording. Because the search interval was programmed to occur every 18 min, there should be approximately 72 SQCs during a 24-hour period. Table 6 presents the ACC related diagnostics for the patients that performed the 24-hour Holter recording.

Discussion

The results demonstrate that the pulse generator is performing as programmed. Almost all of the SQCs resulted in successful outcomes. As one would expect, the number of daily non-captures is low. This result also demonstrates that fusion beats are rarely classified as non-capture by the event classifier. The low number of short AV delays demonstrates that the fusion avoidance algorithm is working appropriately, and that fusion is either appropriately classified as capture and is resolved by slightly lengthening the AV delay. Previous algorithms that provided continuous monitoring had demonstrated significant problems with fusion beats. The fact that the ACC algorithm seems better able to handle fusion is a significant improvement. Using the current algorithm, there were no cases where the ACC was disabled because of non-capture classifications due to fusion beats. Upon removal of the Holter, the ACC algorithm was in a suspended mode of operation for one patient because of non-capture detected at the maximum ACC amplitude. The ACC algorithm suspends itself as a safety mechanism and programs the device to a safer higher output level until

Results	
R-wave	
No. of tests	9
Mean \pm SE (mV)	15.5 \pm 1.2
Range (mV)	9 – 19
Manual pacing threshold	
No. of tests	9
Mean \pm SE (V)	0.45 \pm 0.03
Range (V)	0.4 – 0.6
ACC pacing threshold	
No. of tests	9
Mean \pm SE (V)	0.37 \pm 0.02
Range (V)	0.3 – 0.5
Impedance	
No. of tests	9
Mean \pm SE (Ω)	1059 \pm 126
Range (Ω)	625 – 1667

Table 4. Ventricular lead measurements (at implantation).

Follow-up interval	Manual	ACC
Pre-discharge		
No. of tests	9	9
Mean \pm SE (mV)	0.44 \pm 0.30	0.61 \pm 0.11
Range (mV)	0.5 – 2.6	0.3 – 1.4
1-month		
No. of tests	2	2
Mean \pm SE (mV)	0.95 \pm 0.30	0.90 \pm 0.20
Range (mV)	0.7 – 1.2	0.7 – 0.9
3-months		
No. of tests	3	4
Mean \pm SE (mV)	0.83 \pm 0.10	0.85 \pm 0.10
Range (mV)	0.6 – 1.2	0.7 – 1.2

Table 5. Manual versus Active Capture Control (ACC, Biotronik) ventricular pacing thresholds at different follow-ups.

ACC diagnostic parameters	Results (counts)
Total SQC's performed per patient	
Mean	69
Range	10 – 91
Total	415
SQC success rate	
Mean (%)	98
Range (%)	96 – 100
Total	598
Daily non-captures	
Mean	272
Range	48 – 601
Total	1630
Short AV delay (SAV)	
Mean	26
Range	1 – 68
Total	159

Table 6. Summary of Active Capture Control (ACC, Biotronik) diagnostics.

the next scheduled search interval. There were no instances of a pacing pulse failing to capture due to low output during automatic operation of the ACC feature. Additionally, there were no instances of a back-up pulse failing to capture due to a low output setting. There are obvious benefits that accompany pacemaker algorithms; these can automatically measure the pacing threshold and adjust the pacing output on a periodic basis. Previous studies have demonstrated that even manual optimal programming of the pacing output offers a slight increase in pacemaker longevity [11]. Depending on the implementation, these algorithms have the possibility to increase pacemaker longevity even further [12,13] High impedance leads can also provide a significant increase in pacemaker longevity. Together, the ACC algorithm and high impedance pacemaker leads should provide even more substantial increases in pacemaker longevity. Features that allow the automatic measurement of the pacing threshold and automatic adjustment of the pacing output are currently available. However, many of the previous algorithms still have limitations in their implementation. The ACC algorithm should address some of these limitations and is worthy of further investigation in a larger group of patients with a larger variety of ventricular leads.

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