Long-term Follow-up of Pacemakers with an Autocapture Pacing System

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SUMMARY

The aim of this study was to evaluate the safety and performance of the Autocapture pacing system during a 5-year follow-up period.

The study was conducted retrospectively between May 1996 and May 2001. Sixty consecutive patients who had undergone VVI pacemaker implantation using an Autocapture program with leads 1402T (n: 31) and 1452T (n: 29) were included in the study. Intraoperative measurements including a ventricular stimulation threshold test, sensing of intrinsic R wave (mV), and lead impedance (W) were done by a standard pacing system analyzer. Evoked responses (ER, mV) and polarization signals (PS, mV) were measured after the pocket was closed. Pacing thresholds by Autocapture (AC thrd, V) and Vario (Vario thrd, V), battery current (mA), and battery impedance (kW) were also repeated during predischarge and 1, 6, 12, 18, 24, 30, 40, 50, and 60 months after discharge.

According to the ER and PS values an Autocapture algorithm could be activated in 49 patients (88%). The Autocapture algorithm remained active during the follow-up in all of these patients. In patients with inappropriate ER and PS values (11 patients, 12%), pacemakers were programmed to a VVIR pacing mode and Autocapture algorithm was inactivated. ER and PS values did not reach appropriate values to activate the Autocapture algorithm in any of these patients in consecutive follow-ups. Twenty-four-hour Holter monitoring could be conducted in 32 patients (53%). In all recordings, when the loss of capture occurred, it was confirmed that back-up pacing continued. When the first measurements recorded during implantation were compared to approximately the 5th year measurements; ER (9.2 mV vs 9.6 mV), PS signal (1.13±0.30 mV vs 1.15±0.72 mV), AC thrd (0.4 V vs 1.2 V), Vario thrd (0.7 V vs 1.3 V), and lead impedance (502 ohm vs 620 ohm) were not changed significantly. Battery impedance increased 1 kOhm between 30-40 months of the implantation. Seven deaths occurred during follow-up. Three patients had fatal myocardial infarction, one died due to a non-cardiac event, and the remaining three died due to progressive heart failure. Conclusion: ER, R wave amplitude, and PS, which are the main parameters for the continuation of Autocapture function, did not change significantly during long-term follow-up. High output back up pacing provided additional safety for sudden rises in threshold. The Autocapture pacing algorithm was...
found to be effective and reliable during long-term follow-up.  \( \text{(Jpn Heart J 2002; 43: 631-641)} \)

**Key words:** Autocapture, Evoked response, Backup pulse, Polarization signal, Threshold, Holter, Long term follow-up

IN the 1970s, Mugica and Preston proposed a threshold-tracking pacemaker that could reliably and safely pace the heart at a minimal energy requirement and which had the advantage of minimizing battery current drain thereby prolonging pacemaker longevity.\(^1,2\) The pacemaker output has been corrected by continuously observing threshold values while preserving a 0.5 mA safety margin. The Autocapture\(^\text{TM}\) (St. Jude Medical Co., Sylmar, CA, USA) System was first successfully introduced more than 20 years after the original concept was proposed. St. Jude Medical introduced the first successful Autocapture system in the single chamber Microny pacemaker in 1995. This pacemaker constantly and accurately monitors the threshold by recognizing cardiac depolarization and adjusts the effective output close to the stimulation threshold, thus maximizing the efficiency of the pacemaker.\(^3\)

The most important parameters in the Autocapture algorithm are the evoked response (ER) and polarization signals (PS). The ER is the depolarization of the myocardium immediately following an effective pacing pulse. Automatic recognition of the cardiac depolarization by the pulse generator initiated by the delivered stimulus has been hampered by the polarization voltage at the electrode-tissue interface. The polarization, due to the stimulation of pulse, often encroaches into the ER. The polarization artifact has to be minimized in order to reliably sense the evoked response.\(^4\) The manufacturer of the system recommends measuring the ER at the time of implantation, and values higher than 4.5 mV are necessary to turn on the Autocapture algorithm in order to reliably sense the native depolarization.\(^5\) Specially designed leads are also recommended to minimize the polarization signal combined with enhanced sensing ability.

The safety and effectiveness of the Autocapture algorithm were confirmed in short and mid-term follow-up studies.\(^3,6-12\) However, long-term follow-up studies examining the safety and effectiveness of the algorithm are also necessary. The aim of this study was to evaluate the five-year performance of the Autocapture algorithm implemented in VVIR pacing systems in 60 consecutive patients.

**Patients and Methods**

**Study design and patient population:** This was a retrospective study performed at the Siyami Ersek Cardiovascular and Thoracic Surgery Center with enrollment
between May 1996 and May 2001. Sixty consecutive patients implanted with a permanent pacemaker using an Autocapture algorithm (Regency SR+, St. Jude Medical, \( n: 44 \); Microny, St. Jude Medical, \( n: 16 \)) were included in the study. The characteristics of the patients and the indications for pacing are given in Table. Two different passive fixation leads with low polarization were implanted: 1) 1402T (St. Jude Medical, \( n: 31 \)), and 2) 1452T (St. Jude Medical, \( n: 29 \)). Exclusion criteria were: 1) life expectancy <1 year, 2) patients who required physiological pacing, and 3) inability to return for scheduled evaluation.

**Pacemaker implantation and measurements:** The pacing system was implanted using standard endocardial implantation techniques. Intraoperative measurements, including the ventricular stimulation threshold, sensing of the intrinsic R wave, and lead impedance were done with a standard pacing system analyzer. ER and PS measurements were performed after the pocket was closed. Data were retrieved at implantation, prior to discharge, and during visits at 1, 6, 12, 18, 24, 30, 40, 50, and 60 months after discharge. During follow-up, ER (mV), R wave amplitude (mV), PS (mV), auto capture (AC thrd, V) and Vario (Vario thrd, V) stimulation threshold, electrode impedance (\( \Omega \)), battery current (\( \eta \)A), and battery impedance (k\( \Omega \)) were recorded.

ER/Sensitivity test measures ER and PS giving a series of paired pulses. During the test, the programmer turns the Autocapture off if it was on. The programmer increases the pulse amplitude to 4.5 V for both pulses in the pair. The pacing rate is increased to 100 bpm during the test. The first pulse in each pair captures the heart and produces ER and PS. The second pulse, delivered 110 ms

| Number of patients | 60 (%)
---|---
Male | 36 (60)
Female | 24 (40)
Mean age (±SD) | 71±16

**Pacemaker indication**
- Sick sinus syndrome with atrial fibrillation | 40 (66)
- Brady-tachy syndrome | 9 (15)
- Complete AV block | 10 (16)
- Intermittent AV block | 1 (1.6)

**Pacemaker type**
- Regency SR+ | 44 (73)
- Microny | 16 (27)

**Leads**
- 1402T | 31 (51)
- 1452T | 29 (49)

**Table.** Indications of Pacemaker Implantation and Demographic Characteristics of the Patients
after the first, occurs when the myocardium is physiologically refractory, which allows for an independent measurement of lead polarization.

The device determines an ER sense margin as close to 100% as possible, but minimally 80%. To accomplish this, the amplitude of the signal resulting from the first pulse is divided by two. Of the available ER sensitivity settings, the closest setting to this value is then compared to the PS. If the amplitude of the PS is greater than 60% of the proposed ER sensitivity, Autocapture is not recommended. The algorithm constantly monitors the ER to ensure capture with each output by confirming the ER 15.0-62.5 ms after a pacing pulse. With each non-capture, a 4.5 V/0.49 ms back-up pulse is delivered 62.5 ms after ineffective primary output. Capture verification of the Autocapture algorithm is confirmed by this way (Figure 1). The second important part of autocapture function is the optimization of capture. The optimization of capture is done by a threshold search in two ways. In the first, the system performs a threshold search every 8 hours. In the second, if non-capture occurs on two consecutive primary output pulses, the pacemaker automatically increases the output of the primary pulse by 0.3 V until there are two consecutive outputs that capture on the primary output. The system then performs a threshold search. During the search, pulse amplitude decreases in

![Figure 1](image_url)

**Figure 1.** A: Capture verification by detection of ER. After every pacemaker stimulus capture verification is initiated. This requires detection of the ER, which is depolarization of the myocardium resulting from a pacing stimulus. The ER detection window is open from 15 to 62.5 ms after each pacing stimulus. B: Backup pacing in loss of capture. If ER is not sensed within the detection window the pacemaker interprets this as loss of capture, and a backup safety pulse (4.5 V/0.49 ms) is delivered immediately after the detection window to maintain capture.
0.3 V steps while keeping the pulse width constant (Figure 2). Two consecutive capture events must occur at each step for the pulse amplitude decrease to continue. When two successive paced stimuli fail to capture, the pulse amplitude is increased until capture is restored. The permanent pulse amplitude is adjusted to 0.3 V above the actual pacing threshold.

The algorithm device is interrogated using an APSII programmer. ER and PS are measured by telemetry using an automatic diagnostic function. It then calculates the ratio of ER to PS, and if the device recommends the Autocapture function be on, it also proposes a suitable sensitivity setting. If the programmer turns the Autocapture on, an automatic threshold measurement will be taken. Measurements of spontaneous R wave, lead impedance, battery current, and battery impedance are performed by the pacemaker diagnostics. The programmer does the Vario threshold measurement before the Autocapture function is on.

**Pacing electrodes:** The Membrane E 1402 pacing lead is a bipolar, steroid-eluting pacing lead with a 9-mm² electrode surface area. The electrode tip is covered by titanium nitride, and is coated with a semipermeable membrane containing 30 µg of dexamethasone. The Membrane E 1452 T pacing lead is a bipolar, steroid-eluting pacing lead with a 3.5-mm² electrode surface area. The electrode tip is covered by titanium nitride, and is coated with a semi-permeable membrane containing <13 µg of dexamethasone. These two leads are passive fixative leads.

**Holter monitoring:** Twenty-four hour Holter monitoring could be performed in 32 patients in the first 6 months after pacemaker implantation. In these recordings, each complex was examined for capture or noncapture. When noncapture occurred, whether or not there was an appropriate backup pulse was recorded. Backup pulses for R wave undersensing and fusion complexes were also evaluated.

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**Figure 2.** ECG recording during the device conducting an automatic threshold test to verify the appropriate pulse amplitude. Threshold search is performed by decreasing the pacing output until two consecutive ineffective stimuli occur. In this case, the 8th and 9th stimuli with 1.2 V were ineffective and two backup pulses with 4.5 V output were given and then the threshold was increased to 1.5 V. However, backup pulses were needed again with 1.5 V, and the threshold was increased to 1.8 V. Since the pacing should be 0.3 V above the threshold, the output was increased to 2.1 V.
**Follow-up period:** The average length of the follow-up period was 3.9±1.2 years. The shortest follow-up period was 2 months and the longest was 6 years. The follow-up period was longer than 3 years in 56% of patients.

**Statistics:** Data are expressed as mean and standard deviation. Repeated measures by analysis of variance (ANOVA) and regression analysis were performed on the variables throughout the follow-up. *P* values less than 0.05 were considered statistically significant.

**RESULTS**

**Clinical outcomes and adverse events:** Seven patients died during the follow-up period, one due to a noncardiac cause, 3 due to acute myocardial infarction, and 3 due to congestive heart failure. There were 10 reported complications related to the surgical aspect of implantation. The most common complication was a pacemaker pocket hematoma. Other complications were ventricular lead dislodgment, pocket infection, and pneumomothorax.

**Operative and follow-up results:** The average stimulation threshold during implantation was 0.7±0.3 V with a pulse width of 0.5 ms, and 0.73±0.34 V with a pulse width of 0.37 ms prior to hospital discharge. During the follow-up period an insignificant increase in threshold was observed (1.3±0.3 V). The Autocapture stimulation threshold results were similar to the manual measurements of the stimulation threshold. During the follow-up period, the Autocapture stimulation threshold was 1.2±0.24 V (Figure 3).

![Graph](image.png)

**Figure 3.** Threshold values during follow-up. The threshold test was conducted with a pulse width of 0.5 ms during implantation, and 0.37-0.49 ms at follow-up visits.
Ventricular sensing was 10.4±6.4 mV at implantation and 15.2±6.3 mV at 24 months. However, the R wave amplitude was 7.8±4 mV at 60 months (Figure 4). The magnitude of the ER increase was small. The mean ER amplitudes at implantation, and 18, 24, and 60 months after were 9.2±4.4 mV, 9.1±3.8 mV, 10.2±3.7 mV, and 9.6±3.9 mV, respectively. PS remained stable and without significant variation over time (Figure 4).

Based on the ER and PS values, the algorithm recommended that the Auto- capture function be turned on in 51 (85%) patients at predischarge. In two patients with functional Autocapture at implantation, the algorithm recommended that the Autocapture be turned on intermittently. In one patient with the Autocapture previously on, the algorithm recommended that the Autocapture be turned off at the first month because of a decrease in the ER value. Therefore, a total of 48 patients (80%) with a functional Autocapture during predischarge continued to have adequate signals throughout the follow-up. In patients with insufficient ER and PS values initially, the algorithm remained nonoperational during follow-up and continued to pace in the VVIR mode.

When comparing both leads in terms of ER, PS, and R waves, the 1452T leads had higher ER (9.9±0.38 vs 9.1±0.41, P: 0.02) and R wave (11.1±0.3 vs 10.2±0.6, P: 0.031), and lower PS (0.9±0.27 vs 1.1±0.2, P: 0.024) than 1402T leads.

Twenty-four-hour Holter monitoring data during the first 6 months after implantation were obtained in 32 of 60 patients (53%). In all recordings, a back-
up pulse followed 100% of the losses of capture of the initial impulse. High-energy back-up pulses also occurred despite spontaneous or fusion beats, as an indication of ER undersensing. The incidence of back-up pulse could not be determined since the Holter system was not suitable for this evaluation.

Mean lead impedance was 502±137 ohm during implantation and 620±140 ohm during the follow-up period. Battery impedance showed a 1 kOhm increase between 30 and 40 months after implantation.

**DISCUSSION**

This study assessed a new generation of pacemakers using an Autocapture algorithm and the long-term follow-up of new leads designed to minimize the polarization signals. The pacemaker has the advantage of prolonging pacemaker longevity by constantly monitoring the stimulation threshold and the effective output adjusted close to the stimulation threshold. Thus, the safety of the patient is maximized as far as prolonging the pacemaker longevity.

The Autocapture system consists of two parts; capture verification and capture optimization. For capture verification, a satisfactory ER amplitude has to be measured after pacing pulse. The changes in the stimulation threshold after pacemaker implantation are similar to those of ER values. In a study assessing the change in ER amplitude, ER remained stable over time in 32% of the patients, increased in 48%, and decreased in 9% of the patients. Despite this significant change in ER amplitude, the ventricular capture threshold was less than 1 V in each group. The most significant change in ER amplitude was seen between the period after discharge and at 3 months. The ER amplitude similar to the stimulation threshold is affected by progressive lead stabilization, physiological conditions such as exercise and progression of the disease, metabolic abnormalities, and pharmacological agents. However, the polarization signals remain more stable. Schuchert, et al recommended the measurement of ER and PS at each follow-up so that the Autocapture algorithm can be activated. The manufacturers recommend the intra-operative measurement of ER and PS. Clarke, et al examined the Autocapture function and 1402T pacing leads in 113 patients. The authors tried to obtain an ER amplitude >4.5 mV at implantation. They were successful in 102 of these 113 patients. The ER signal in several trials ranged between 7-10 mV, whereby Autocapture was on in 80% to 100% of patients. In another study, Schuchert, et al showed that satisfactory ER values could be obtained without intraoperative measuring using 1450/1452 T membrane-electrodes. The Autocapture algorithm could be turned on in 93% of the patients. Clinical data or conventional electrical parameters to predict the patients having low ER values or to optimize ER signal at implantation have not been reported.
However, it was reported that R wave amplitudes measured during temporary cardiac pacing at implantation might be helpful at predicting ER values. In several trials, the polarization signals remained stable over time. PS is primarily dependent on the mechanical characteristics rather than the physiology of the heart.

In this study, ER and PS were not determined intraoperatively. However, the Autocapture function could be activated in 85% of patients. In one patient with a functional Autocapture during discharge, the Autocapture function was turned off at the first month because of inadequate ER values. In two patients, it was recommended the Autocapture be turned on intermittently at each follow-up measurement. The ER amplitude showed small increases, especially after the 18 month. PS did not show significant changes over time.

In the Autocapture pacing system, it is necessary to use bipolar pacing leads. The polarization of these leads must be low. High polarization leads cause the loss of capture because of false determination of capture. Lau, et al assessed the 1-year follow-up of pacemakers using the Autocapture algorithm. There were no significant differences between leads 1346T and 1388T in terms of ER, PS, chronic R wave sensing, and stimulation thresholds. The Autocapture system could be activated in 92% of the patients in one study using 1402 T pacing leads and in 93% of the patients in another study using 1450/1452T pacing leads. However, the leads were not compared in terms of various electrical parameters. Leads other than the recommended low polarization leads may provide satisfactory ER, but increases in PS prevent turning on of the Autocapture system. Ventricular leads currently available in the market exhibit significant differences in terms of polarization characteristics. Titanium nitride-coated electrodes have significantly lower polarization signals than other electrodes. An electrode tip surface area and the fixation mechanism appear to be less important than coating with titanium nitride in providing the lowest PS. In our trial, low polarization 1402T and 1452T pacing leads were used. When comparing the two leads in terms of ER, PS, and R wave, ER and R wave were higher and PS was lower with 1452T leads. In a study comparing similar variables, in addition to these two variables, R waves were found to be higher with 1452T pacing leads.

In addition to a minimal energy requirement, the Autocapture system is expected to respond to sudden increases in stimulation thresholds, there ensuring patient safety. After pacemaker implantation, an inflammatory reaction to lead positioning may cause early threshold elevation. It has been shown that unexpected threshold elevations in late course occur at a frequency of 10%. The most important response to sudden stimulation threshold elevation in the Autocapture system is back-up pacing to prevent loss of capture. In this study and in another study assessing Autocapture function by Holter monitoring, the effec-
tiveness of back-up pacing has been demonstrated. One of the major causes of delivery of a back-up pulse is the failure to detect the ER due to native fusion complexes. In our study, the pacemaker indication was sick sinus syndrome with atrial fibrillation in 40 of the 60 patients. Pseudofusion beats occur especially in patients with high spontaneous activity as in atrial fibrillation, and in our study frequent back-up pulses following pseudofusion beats might be anticipated. However, the incidence of back-up pulses following pseudofusion beats could not determined since the Holter system was not suitable for this evaluation. Clarke, et al\(^6\) showed that the incidence of pseudofusion beats was 3% and that 22.5% of the pseudofusion beats induced back-up pulses, and these beats accounted for 87% of all back-up pulses. This result suggests that the Autocapture algorithm is unable to detect all pseudofusion beats, and this fact may cause the pacemaker to emit back-up pulses or initiate a threshold search unnecessarily. As a consequence, it may trigger the pacemaker into high output mode, thus reducing energy saving. But in this circumstance one should take into account that during high spontaneous activity the pacemaker will not be active, which decreases the energy consumption.

Since the Autocapture function was originally proposed, the most important advantage of this algorithm is prolongation of the longevity of the pacemaker. Schuller, et al assessed the longevity of Microny pacemakers after 4 years of implantation.\(^{18}\) They calculated a total service duration of 7.8±0.2 years. When compared to a pacemaker with the output traditionally adjusted, the longevity was 65% greater. Other trials showed similar results.\(^{19,20}\) Simeon, et al reported that the advantage obtained with the Autocapture system was the greatest in the highest stimulation threshold group.\(^{20}\)

**Conclusion:** We have described our long-term experience with the Autocapture pacing system. The main parameters for the continuous functioning of the Autocapture algorithm are ER, R waves, and PS. These parameters did not change significantly, thereby not necessitating any change in the Autocapture system during follow-up. High energy back-up pacing provides additional safety in patients with an unexpected high stimulation threshold. The ER amplitude during a 5-year follow-up period was found to be significantly higher in 1452T leads than in 1402T leads. The Autocapture algorithm functioned effectively and safely during a long-term follow-up period.

**REFERENCES**


