

Pacemaker Clinic*

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Pacemaker longevity is a serious problem to overcome. However, our immediate concern is to get as much useful life from a pacemaker as possible. On the average, pacemakers fail in about 23 months. The only pacemaker that lasted much longer was a fixed-rate unit, the Medtronic 5860, which is no longer available. A past suggestion in handling this problem has been to change the pacemaker electively at an arbitrary time, but that time has varied tremendously as the manufacturers once selected 30 months, and more recently 15 months. If a pacemaker is replaced at 15 months, very few of them will actually be near the end of their life span.

For those who like to experiment, there are several kinds of pacemakers available. Presently, we have used 33 different models from eight manufacturers with varying pacing modes. Pacemakers can be fixed rate, atrial synchronous or noncompetitive; bifocal and cyclic; or attached to unipolar or bipolar electrodes. Electrodes have been situated in the myocardium or endocardium, using a variety of testing devices.

Because of the importance of replacing pacemakers as late as possible, the study of the electrical output of the pacemaker has begun in a pacemaker clinic. A pacemaker impulse has certain definable characteristics: its amplitude can be measured at its leading edge, trailing edge, and halfway between; and the electrical impulse has width or pulse duration, measured from the leading edge to the trailing edge, displaying a typical configuration (Fig. 1). A sensitive index of pacemaker function is the repetition rate or pulse interval. Hopefully, if a comparison in pacemaker impulse is made between its appearance at 4 months, which is the best time to establish a base line, and its appearance at 22 months, the following changes may be noted: the amplitude decreases, the pulse width shortens, but the configuration remains about the same (Fig. 2).

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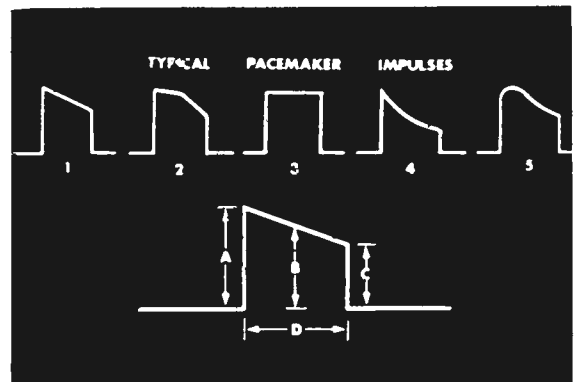


Fig 1—Examples of pulse generator impulses (schematic) as seen on the oscilloscope. Measurements of A, B, C, and D are made and recorded for sequential comparisons. Impulses 1 and 4 seen commonly with Medtronic pacemakers; impulse 3 with Electrodyne; impulses 1, 2, and 5 with Cordis; impulse 4 with American Optical; impulses 2 and 4 with Vitatron; impulse 4 with General Electric.

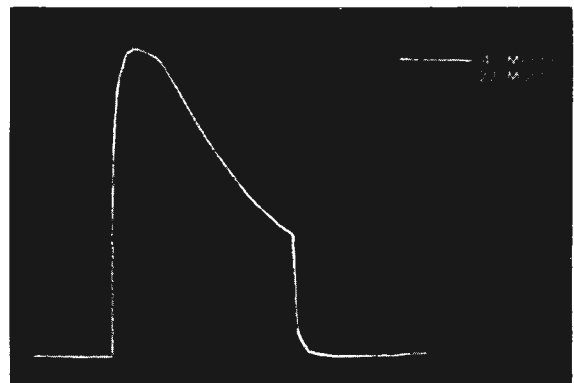


Fig 2—Typical changes in pacemaker impulse over 18-month period.

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Laboratory tests have produced a study of American pacemaker models. Our engineers, working in conjunction with engineers from each company, evaluated the behavior of each pacemaker on the bench as a number of battery cells varied. This study showed that some pacemakers cease to function where one cell fails, but most others cut off after at least two of the five cells have been lost. The drop of pulse generator output is related to the number of functioning cells and varies from unit to unit, and the output of the pulse generator is directly related to the number of cells and also to the resistive load. The amplitude changes with the load and so does the pulse width. Pulse duration also varies with the number of cells. In some pacemakers, the pulse width will widen as the number of cells change; in others, the pulse width will shorten. Pulse width is also affected by the load.

Pacemaker sensing circuits also have a failure threshold. As the number of cells are reduced, the sensing circuits begin to fail. In most pacemakers, the sensing circuit will fail before there is a loss of output from the pulse generator. The sensing circuit of the American Optical pacemaker, however, will continue to function well into late pacemaker life. This parameter can be measured and tested in the clinic.

In evaluation of the pulse interval, it seems preferable, although there is no general agreement on this, that a pacemaker should slow down as the number of cells decrease. If the pacemaker stops when it is going slowly, idioventricular rhythm will start fairly soon after the last effective beat. If the pacemaker speeds up as it fails and then stops entirely, there will be a rather prolonged period of asystole before spontaneous cardiac action resumes. Although most new pacemakers are designed to slow down as batteries are exhausted, actual performance varies considerably. The number of cells is not the only thing that will affect the rate; change in resistive load also affects the rate with considerable variation from model to model. All things considered, clinical evaluation of this pacemaker problem is rather complex. There is some doubt as to whether the resistive load has changed from minute fractures in a lead wire or electrode corrosion, or whether the batteries are gradually becoming exhausted.

Within the physical set up of our clinic, there are five examination rooms in which various test devices are connected to the patient by an electrocardiographic cable attached to the limbs. Here lead I of the electrocardiogram is taken, also a "P" lead in which one electrode is on the left arm and the other over the pulse generator. Lead I is used to record a rhythm strip. The P lead is used for evaluation of the amplitude of the electrical impulse. The amplitude of the impulse depends upon the relative position of the stimulating and exploring electrodes. Therefore, it is of great importance to eliminate all factors that will affect the positioning. Hence, this examination must

be performed with the patient in the same position at each visit, using the same exploring electrodes.

In the testing room there is a computer and peripheral equipment. A monitor is used to observe the electrocardiogram during the test process. The output of an amplifier goes to an interval counter and to an oscilloscope where the wave shape is photographed and the amplitude and pulse width are measured. An electrocardiogram is also taken. All this information is then inserted into a computer which types a report, via the peripheral equipment, displaying the rhythm strip, a picture of the wave form, and the doctor's comments. Within seconds, the entire history of the particular pacemaker under test can be seen.

Patients come to the clinic every four months for the first year; every two months for the next six months; and every month after eighteen months. It is quite important that the patient be emotionally reinforced during his visits to the clinic. Great care is taken during the examination to provide the kind of emotional attention and support that he really needs. As a result, the patient likes the clinical atmosphere and will appear for further visits.

For patients who find it difficult to come to the clinic because of infirmity, age, or distance from the hospital, a telephone system has been devised. This system is used to count only pacemaker pulse rate. The patient holds an electrode in his left hand and puts the other electrode against the pacemaker with his right hand. There is a magnet in the electrode which turns the pacemaker to its fixed-rate mode. At the hospital our technician places the phone in a cradle, and then records the rate to within 1/10th of a millisecond accuracy on a digital counter.

There is an advantage of not only counting the electrical impulse, but also counting the physical pulse at the fingertips. A click is heard for the electrical impulse and a musical note for the physical pulse, enabling the physician or technician to tell whether one follows the other. This method has proven to be quite valuable as adjunct to the clinic. Of 89 cases where a satisfactory analysis could be made, interval change occurred as a sign of failure in 67; interval change alone occurred in only 14 cases. In the great majority of cases, the interval changed simultaneously with another parameter. Therefore, the total analysis gives somewhat more information than measuring the pulse interval alone.

This test may seem to be complicated, but the entire procedure takes exactly three minutes to perform; the patient can actually go through the whole process in about five minutes. In New Jersey there is now a network of these clinics, all working in identical fashion. There are also nine affiliated centers, and five or six others waiting to join. At each center the evaluations are done in the same way, including the telephone communication. Each center communicates by telephone

with the computer at the Beth Israel Medical Center and then receives a typed report immediately at their own hospital.

There are many potential advantages to this system. Within one year there will be 1500 pacemaker histories in the computer in New Jersey alone. A physician will be able to know very quickly the actual behavior of a large sample of many different kinds of pacemakers. If a physician decides to use X pacemaker for the first time and something goes wrong with it, the computer system will provide data on the behavior of 30 other X units inserted by other physicians in the state to which the pacemaker in question can be compared. However, the computer is not a doctor and does not replace good clinical acumen. A careful office examination by a doctor, in which the rate is accurately measured and an evaluation of the rhythm strip made correctly, will provide enough information to determine if things are grossly wrong.

Until recently, these were the considerations in replacing a pacemaker. If in one month there was a certain change of rate within 10 milliseconds (not readily detectable by taking a peripheral pulse), or if there was a change in the pulse duration or amplitude (also not detectable at all by examination), the patient would be reevaluated within a few weeks. If any two of these changes occurred simultaneously or if the sensing circuit failed, the pacemaker would be replaced immediately.

In 1970, 318 patients were studied and 126 pacemakers replaced. Forty of these replacements could not be evaluated in the clinic because replacement was for reasons other than battery exhaustion. For example, 7 pacemakers were changed because they were extruding; several pacemakers were replaced because some patients did not want to wait; others were changed because patients did not come to the clinic often enough. Other instances involved pacemakers with high thresholds, runaway rates, plug corrosion, and broken insulation. Of 87 that were suitable for analysis, 76 (87%) were removed electively with only 13% having errors. These errors occurred for several reasons: nine were actually new pacemakers and not much was known about their behavior; three were cases in which the change seen was underestimated; several patients missed crucial visits; three cases were without clues whatsoever. Some of these cases were due to sudden failures of a component that were not detectable.

The results from the clinic in comparison to the bench tests revealed, pulse duration the one exception, that bench tests corresponded to what was actually observed in the clinic. Because the bench analysis has proven so helpful, in the future whenever a new model pacemaker is introduced, it will be tested to provide some idea of what the performance will be in its failure mode.

In conclusion, the clinical approach to pacemaker

evaluation is important because it is at least 90% accurate. Hopefully in the near future, with the accumulation of accurate data to rely on, computers will be used to a greater degree in aiding the diagnosis of pacemaker malfunction: the computer will "remember" how things ought to be and will tell when things are wrong, suggesting when the pacemaker should be changed. However, it is hoped to soon have pacemakers that will operate reliably for ten years. Elective replacement at nine years will then be feasible and frequent clinic tests will no longer be required.

PANEL DISCUSSION

Questioner: What would be the indication for using a low voltage pacemaker?

Dr. Parsonnet: Pacemakers are made with a rather sizeable leeway between the anticipated threshold and its output. Presumably, if you can use or have a lower output, you can get the pacemaker to last longer. An alternative would be to use a fewer number of batteries, thus making a smaller pacemaker. The Cordis people have experimented with this idea, and I am sure other companies will do the same. As a matter of fact, the Medtronic company tried to do the same thing by having a potentiometer on it; you just turned your output down and caused a decrease of a drain on the battery. Because of this substantial decrease, we are planning to go back to this method soon.

Questioner: Why haven't they implanted a set of batteries in parallel elsewhere in the body to take over when and if the other batteries fail?

Mr. Berkovits: Because most of the problems in batteries involve short life, the extra set may fail as quickly as the first set. There are many battery failures that are unrelated to exhaustion.

Dr. Drew: Do any of the companies make any financial adjustments if the pacemakers go out prematurely?

Mr. Berkovits: To my knowledge, all manufacturers in the United States are giving some credit for pacemakers returned with premature exhaustion.

Questioner: How accurate is the phone monitor?

Dr. Parsonnet: It is accurate to a tenth of a millisecond for the interval counter, which just measures pulse interval.

Questioner: Have you used the transmission of a rhythm strip to give you the intervals?

Dr. Parsonnet: No, we have not. Although it would give you some information, it would not give you quite enough. You would have to count the rate on an electrocardiograph which has a sizable error in paper speed, 2 to 3 percent, I think. It will tell you whether or not the pacemaker is capturing the heart, but there are other ways to find that out.

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Dr. Drew: Do you predict that other states will have to follow suit as the number of pacemakers grows, in order to have the type of follow-up that you have in New Jersey?

Dr. Parsonnet: Perhaps a modification of it. I am not quite certain what the phone is going to bring. Right now, at least for my purpose, it is an ancillary test procedure which is helpful but not sufficiently diagnostic. I think every patient with a pacemaker should go to some kind of an evaluation clinic. He should be going either to a doctor who sees him regularly or to a center with a group of patients.

Dr. Tarjan: There is a company in Philadelphia that follows these people with pacemakers. I would imagine that their methods of evaluation are somewhat similar. Should a doctor entrust his patients' care to this sort of an organization?

Dr. Parsonnet: I do not know if there is anything wrong with the organization. Personally, I would rather test the rate myself. I don't trust myself half the time, but I do trust myself more than I would a company located elsewhere. The reason we use the system I showed you today is because we have control over it; we can count the rate with our own technicians, and if something doesn't look right, we can run downstairs and see what the matter is. With the Pacer Tracer company, which is the one you referred to, they count the pulse at the fingertip and the rate, and call you on the phone. It is that middle

man that makes me a little uncomfortable. They have a clever system and I don't want to knock them in any way; it may turn out to be a good idea.

Questioner: How do you prepare a patient for surgery with a pacemaker, where cautery is needed?

Dr. Parsonnet: The danger is having the ground plate of the cautery near the pacemaker, and the active end of the cautery directly across from it. If you are going to do a transurethral resection, it is best if your pacemaker is up in the infraclavicular area. Be sure the patient is sitting on the ground plate and that you are monitoring the heart. Because the cautery causes interference, monitor the pulse manually. The only precaution necessary is that you don't have a direct line across the pacemaker. Although other opinions may vary, we do not restrict the surgeon in any other way; we just tell them that we will be around in case they need any help.

Dr. Drew: What restrictions are on the patient if they should decide to go for ultrasound treatment on the back?

Dr. Parsonnet: Tell them to avoid diathermy, ultrasound, and everything else. We have had only two instances of interference in our patients; both in the early days of pacemakers when adequate protection was not provided. Nevertheless, there has to be a delicate balance between warning the patients and scaring them.