

The detection of impending failure in implanted pacemakers

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As implantable pacemakers last a variable time, it is desirable to be able to foretell when each individual pacemaker is nearing the end of its life. A test which detects a number of different impending electronic failures including battery depletion is described. The test requires only standard laboratory equipment and has been used for four years as a three-monthly procedure in an out-patient clinic. In 17 of 19 consecutive patients the test has enabled a change of pacemaker to be carried out electively, rather than after an arbitrary period or as an emergency when pacing has failed.

Present-day fixed-rate pacemakers have a high standard of reliability, but occasional faults occur. Unexpected failure may well be disastrous in a patient who does not take over.

The test described here, which requires only standard electronic equipment, has been used at our Pacemaker Clinic on all patients attending with implanted pacemakers since August 1964. Patients have usually attended at three-monthly intervals, but they are instructed to come earlier if the pacemaker rate alters more than a few beats a minute or if there are symptoms suggesting intermittent or complete failure of pacing. The pacemakers studied in this way were designed at St. George's Hospital by one of us (J. G. D.)¹ and several years of experience had to be accumulated before the significance of the various readings could be regarded as meaningful. It is now possible to forestall pacing failure by changing the unit when pacing is apparently continuing satisfactorily but the oscilloscope readings indicate impending failure. At St. George's Hospital 17 pacemakers have been changed electively before pacing has failed out of the last 19 changes required for battery depletion or other electronic causes. The technique detects not only battery depletion but, when we were using USCI electrode 'catheters', it enabled us on several occasions to forestall impending wire fractures.

Several other methods of detecting battery depletion of implanted pacemakers have been tried but have proved of little value. Early models designed by us and by others were constructed so

that as the battery voltage fell the rate increased, and it was hoped that speeding a few points would give warning of the necessity of unit change. Experience from various clinics with different makes of pacemaker soon showed the danger of this policy. Increase of voltage drop occurs rather rapidly towards the end of battery life and, coupled with raised impedance of the batteries, causes this speeding to be relatively sudden. The 'runaway' pacemaker stimulating at a high rate soon became recognized as a serious risk (Siddons and Sowton, 1967) and provoked fatal fibrillation in a number of cases. Greatbatch and his colleagues (Chardack, Gage, Federico, Schimert, and Greatbatch, 1964) developed a technique of estimating potential battery life by radiography of the unit in situ, but the technique does not provide a precise indication and requires a radiograph in the exact axis of the batteries, and we have been unable to obtain sufficient film detail.

THE METHOD

The pacemaker stimulus is recorded on a general-purpose measuring oscilloscope, using E.C.G. limb electrodes. The E.C.G. electrodes selected for recording are those in line with the stimulating electrodes, e.g., measurements are taken between the right and left arms if the indifferent electrode is in the axilla for a unipolar system (Davies and Sowton, 1964). This technique gives a maximum reading and it has been found to be relatively unaffected by respiration and posture. The impulse is photographed and the following parameters are recorded: maximum amplitude, amplitude at 0.4 m./sec., and pulse width. The maxi-

¹Devices St. George's pacemakers supplied by P. J. Reynolds Ltd.

imum amplitude varies from patient to patient and is dependent upon the distance apart of the pacing electrodes as well as the recording electrodes. Readings vary from 2 mV with bipolar electrodes to 400 mV with the indifferent electrodes in the right axilla. The arbitrary point 0.4 msec. was chosen for the second amplitude measurement because some pacemakers had pulses as short as 0.45 msec. This parameter is shown by the vertical dotted line (V_1) in Figure 1. The various readings are compared with

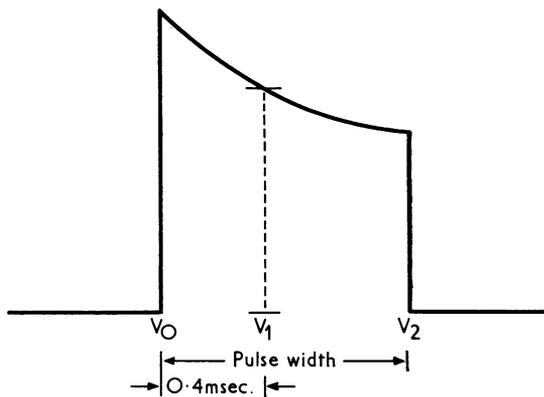


FIG. 1. Diagram of pacemaker impulse recorded from an oscilloscope showing the parameters that are measured.

previous readings from the same patient. The pulse trailing edge (V_2) has not been found to be significant.

Figure 2 shows that pacemakers of different voltages produce a correspondingly different millivoltage pick-up on oscilloscopic test from a patient. (This only applies to pacemakers of the 'constant voltage' type, such as the Devices models.) Thus, initial amplitude (V_0) of the impulse bears a direct relationship to the output power; a significant drop from previous readings (30% with a Devices pacemaker) suggests

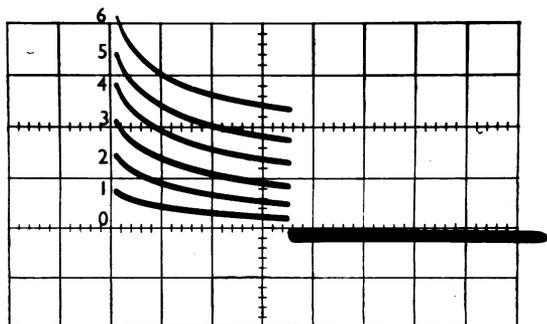


FIG. 2. A recording of the pacemaker impulse from a patient showing the change in amplitude as the pacemaker output (volts) is varied.

that a battery has failed. However, battery depletion is not the only cause in fall of output power; it occurs also with high output impedance resulting from a bad connexion, a transistor change, a high resistance wire, or a break in the insulation of the implanted wire. All these will result in a change in initial amplitude (V_0), but some of the various causes may be distinguished by the means indicated in Table I.

TABLE I
LOCATING FAULT IN A FAILING PACING SYSTEM—EXCLUDING GENERATOR

Fault	Signs
Broken wire ..	Small impulse or none at all—check unit with a radio and listen for clicks
Broken insulation ..	Changed vector and pacemaker impulse
Exit block	Failure to pace but readings constant
Fibrosis	Possible failure to pace—readings constant 0.4 msec. amplitude less than 75%
Sepsis	Possible failure to pace—readings constant except 0.4 msec. amplitude usually 85-90%

Other faults in the pacing system may be shown up by the 0.4 msec. amplitude (V_1). The standard reading using the current electrode system is 62% of the maximum amplitude (V_0). A drop to 85-92% occurs when there is fluid (usually from sepsis) around the indifferent electrode of an endocardial system. Broken or breaking C50 or 3650 (USCI)² endocardial wires also show a characteristic pattern (Fig. 3). Slight increase in pulse width associated with rate decrease,

TABLE II
ROUTINE READINGS: PACING APPARENTLY SATISFACTORY

	Possible Cause	Action
Rate decreased Pulse width increased	Movement of epoxy resin affecting transformer or timing capacitor	If rate change is over 10%, assess re removal of pacemaker
Rate increased Pulse width decreased		
Rate increased 5% Pulse width increased	Increase in battery impedance	Remove pacemaker: it is probable that batteries are nearing exhaustion
Rate decreased 5% Pulse width decreased		
Rate variation without change in pulse width	Timing resistor changed value or diode failure	If over 10%, remove pacemaker
Fall in maximum amplitude (leading edge)	Battery failure, sepsis, wire failure or high impedance of transistor	If 30%, replace

²United States Catheter Corp. Inc.

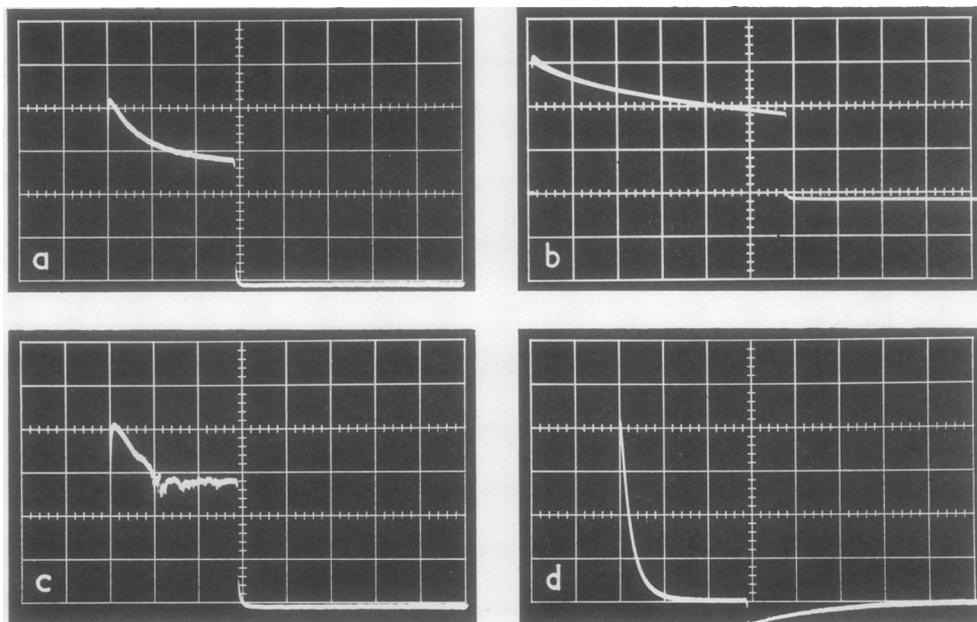


FIG. 3. (a) Normal. (b) An impulse recorded when there was fluid (sepsis) around the indifferent electrode. (c) A fracturing wire giving rise to judder on the impulse. (d) A completely fractured wire with insulation remaining intact.

or vice versa, is usually an indication of stabilizing of the epoxy resin having an effect upon the gap separation of the transformer, and does not call for action. However, if rate and pulse width are both increased or both decreased by more than 10%, this is taken as an indication to remove the pacemaker, as the battery impedance is having an effect on the electronic circuit. A rapidly increasing rate requires urgent removal to avoid pacemaker-induced fibrillation.

These results have been taken only on pacemakers made to our design, and readings on other units may not show the same variations, particularly in pulse height. These tests can be done on bipolar systems, but because respiration and posture affect appreciably electrode alignment, the pulse height measurements

are less meaningful; better results are obtained from unipolar systems. However, it is possible with both systems to measure pulse width and rate, and a check on these two parameters gives a useful indication of pacemaker function.

Table II indicates the interpretation of changes in the readings on routine testing, when pacing is proceeding apparently satisfactorily. Table III sets out the findings in one patient when the oscilloscopic test indicated the necessity of a prophylactic change of a pacemaker which on purely clinical grounds appeared satisfactory.

It is hoped that by means of these tests it will be possible to predict the life of each particular unit. If the method proves reliable with greater

TABLE III

RECORDINGS FROM PATIENT W. N.: 'ABDOMINAL' TYPE PACEMAKER MANUFACTURED MARCH 1966

Date:	22.6.66	21.9.66	21.12.66	22.3.67	21.6.67	13.9.67
Maximum amplitude of pulse (mV)	260	260	240	260	280	130
Amplitude of pulse at 0.4 msec. (mV)	160	160	160	160	180	70
Minimum amplitude of pulse (mV)	130	120	120	140	150	50
Pulse width (msec.)	0.98	0.98	0.98	0.96	0.94	0.85
Rate (per min.)	68	69	68	70	70	76
Amplitude of pulse at 0.4 msec.						
Maximum amplitude of pulse × 100	62	62	67	62	64	54
Recording electrodes	I	I	I	I	I	I

As a result of the readings on 13.9.67, the unit was removed and examination revealed two batteries totally exhausted, primary cause not elucidated.

experience it should enable each implant to be considered individually so that the unit would be changed when the tests indicated that the pacemaker life was nearing its end rather than having to await failure of pacing or make a change after an arbitrary period of implantation.

Early in the life of a pacemaker it is probably unnecessary to test every three months. However, a change in rate of three or four impulses per minute indicates the need for testing. We suggest that intelligent patients should keep an accurate

record of their pulse and report for testing when an alteration of pulse rate is noted rather than at arbitrary intervals.

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