EFFECTS OF HIGH ENERGY RADIATION ON AICDs AND PROGRAMMABLE PACEMAKERS

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ABSTRACT

The response to ionizing radiation of 23 modern programmable pacemakers and 4 Automatic Implantable Cardioverter Defibrillators (AICDs) employing CMOS technology is presented. Photon and electron radiation of various energies and dose levels were used. Eight of the 17 pacemakers exposed to the photon radiation failed before 50 Gy, 4 at doses <17 Gy. Four of the 6 pacemakers exposed to the direct electron beam failed before 70 Gy. Scatter doses, with the units outside the beam, were well tolerated by this group of pacemakers. Three of the 4 AICDs, exposed to photon radiation, showed a major failure before 55 Gy. The charging and detection times increased with radiation dose.

INTRODUCTION

Projections based on our clinical experience suggest that four to five patients per thousand have implanted cardiac devices like pacemakers or AICDs at the time of radiation therapy treatment. It is important to determine beforehand the effects of high energy ionizing radiation, since failures due to the radiation could have immediate catastrophic implications for patients.

This decade has seen an enormous increase in the use of very large scale integration (VLSI) technology in implantable medical devices like pacemakers and AICDs. The complex functions performed by these devices are only possible with the use of highly sophisticated VLSI circuitry. The elements found in this circuitry includes: silicon sensors, bandgap voltage regulators, analog to

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digital converters, switched capacitor amplifiers, memories and microprocessors. High voltage generation and control circuits which deliver high energy outputs also have been implemented with the introduction of the AICD [1]. CMOS with its special combination of low power consumption and high reliability has emerged as the technology of choice for pacemakers and AICDs. However, along with the desirable CMOS features is its undesirable high sensitivity to ionizing radiation.

MECHANISMS OF RADIATION EFFECTS ON MOS DEVICES

High energy particles and electromagnetic radiation contain enough energy to break atomic bonds and create electron-hole pairs in the silicon and silicon dioxide materials. The number of electron-hole pairs created depends on the energy of the incident particle. The ionizing radiation can cause degradation or failure in one or more of the parameters that characterize the normal functionality of MOS devices. Those defects can be either constant or variable with time after the irradiation and depend on the total cumulative dose and dose rate at which the radiation is received.

The silicon dioxide layers are very sensitive parts of an MOS structure. The cumulative radiation damage to these layers has three components: the build-up of trapped charge in the oxide, the increase in the number of interface traps and the increase in the number of bulk oxide traps. The rate at which the ionizing radiation dose is delivered to a device can have a transient effect on it [2]. This effect occurs due to the radiation-induced photocurrents generated by high dose rate and becomes appreciable for dose rates greater than 10^6 rad/sec. In our case we are dealing with lower radiation pulse dose rates ($<10^4$ rad/sec) with no significant dependence on dose rate.

Fundamental characteristics of MOS devices and circuits (C-V and I-V characteristics, mobility, channel conductance and transconductance) change drastically under ionizing radiation. However, those changes are functions of other conditions present during irradiation such as: energy and total dose received; bias applied; type, geometry and method of fabrication of the transistor; dose rate and temperature [3,4]. Changes in the transistor characteristics lead to significant changes in the performance of the "parent" integrated circuits. Among the circuit properties typically affected are: leakage currents, timing, input and switching levels, output drives, functionality, operating voltage and frequency [5].

METHODS AND MATERIALS

To investigate the effects of therapeutic ionizing radiation on modern programmable pacemakers and AICDs, a total of 23 pacemakers and 4 AICDs from 3 different manufacturers were exposed to either high energy photons or electrons from a linear accelerator. Three different protocols were used. 1) A group of 17 pacemakers were exposed to 6-MV scatter photon radiation (adjacent to but outside the direct beam) for 20 treatments, followed by exposure to the direct photon beam, until failure or a maximum dose of 246 Gy. 2) A second group of 6 pacemakers were exposed to a 18-MeV direct beam electron radiation throughout the study, to failure or 300 Gy. 3) A group of 4 AICDs were exposed to a 6-MV direct beam photon radiation to failure or 80 Gy.

The tests were conducted under conditions approximating a standard radiation oncology patient treatment regimen. Initially, daily doses of 3 Gy were given to the devices until an accumulated dose level of 60 Gy, subsequently daily doses were scalated. All the devices were irradiated in tissue equivalent materials to simulate the actual human body conditions (i.e. both the electroconductive and dosimetric characteristics of tissue are simulated). A 500 Ω load was connected to the leads of the pacemakers and the AICDs to simulate the heart. In addition, a 10 to 40 msec half-sine signal with pulse amplitude of 5mV was supplied to the AICDs during radiation.

The pacemakers were both single and dual chamber type with either monopolar or bipolar pacing capability powered by lithium-iodine batteries. Most of the device parameters were set to their critical values. Sensitivity, functional values (pulse amplitude, rate, width and atrium-to-ventricular delay) and battery parameters (voltage and current drain) as well as the telemetry capability were measured for the pacemakers before and immediately after each cycle of radiation. The sensitivity to external signals was tested with a half-sine electrical signal of variable amplitude (0.5-5 mV) and width (10-40 msec). In addition, pulse parameters like rate, amplitude and width were monitored, at least once, during radiation exposure.

For the AICDs, parameters like sensitivity, detection time, charge time, output energy and pulse count were measured before and after each irradiation cycle. For both pacemakers and AICDs the time at which each parameter was measured after radiation was also recorded.

RESULTS AND DISCUSSION

We defined pacemaker or AICD failure as a deviation exceeding the manufacturer's normal specifications from the nominal values or a loss of telemetry. A functional failure was defined as a deviation of 20% from the manufacturer's normal specifications; however, the pacemakers' sensitivity failure was defined according to the manufacturer's manual specifications. As mentioned before all the pacemakers used in this study were multiprogrammable and they could be set to certain values, altered or readout by using their telemetry capability. The loss of real time measurement capability, interrogation or programmability was defined as a telemetry failure. On the other hand, for the AICDs a complete channel failure was defined as the impossibility of the AICD to reacquire a half-sine signal of 0.5 mV. An indication of battery depletion bias was set when the device charging time approached 1.3 times the charging time at the beginning of life.

Table I shows the results of the tests on the 23 pacemakers from manufacturers A, B and C. The first and second failure and the respective radiation dose at which they occurred, the radiation dose level at which the first loss of signal occurred, the maximum radiation dose delivered to the device and its final status are listed. As the table shows there was a first pacemaker failure at doses as low as 14 Gy (A1) and the most common failure was sensitivity (11/23) followed by telemetry (9/23). Four pacemakers (C1, C2, A5, A6) had a total failure (loss of signal) and two of them (C1, C2) didn't recover after the first failure. The total loss of signal was the most common second failure (9/21).

A group of 6 pacemakers (B1, B2, B3, A7, A9, A10) could withstand the total dose, even though they showed either functional or telemetry failures. In a number of cases a partial or a total recovery of the signal or telemetry occurred. For instance, A4 recovered the output signal 26 days after a failure whereas B4 recovered its signal after 14 hours.

Figure 1 shows the pulse width of B4 for an accumulated photon radiation dose of 126 Gy. The pulse width at the base line was 1.55 msec changing to 10 msec after the above radiation level.

Figure 2 presents the sensitivity for dual and single chamber pacemakers as a function of photon radiation dose. For A8-ventricle, A7-atrium and C4-atrium the sensitivity is fairly constant until a certain radiation dose level after which it changes abruptly whereas for B4, A2 and B8-ventricle the sensitivity changes gradually throughout the radiation dose range.

Table I. Ionizing radiation effects on pacemakers

Pacer	Type of radiation	Chamber type	1st/2nd failure	Dose level (Gy)	Loss of signal (Gy)	Max. dose (Gy)	Status
A1	electrons	single	tel	14	-	22	O
A2	photons	single	tel+sen/total	16/26	26	36	N.
A3	photons	single	tel+sen/total	16/36	36	46	N.
A4	photons	single	tel/total	16/26	26	36	N.
A6	photons	dual	total/total	16/26	16	46	N.
B4	photons	single	sen/fun	26/36	146	186	N.
B5	photons	single	sen/fun	26/46	166	186	N.
A5	electrons	dual	total/total	30/34	30	46	N.
B7	photons	dual	fun+sen/total	46/56	56	56	N.
B8	photons	dual	sen/fun	46/56	66	66	N.
B6	electrons	single	sen/fun	60/70	240	300	N.
B9	electrons	dual	sen/total	60/90	90	90	N.
B1	photons	single	sen/tel	76/206	-	246	O
B2	photons	single	sen/tel	76/226	-	246	O
A9	photons	dual	tel/fun	106/246	-	246	O
A8	photons	dual	tel/fun	116/136	146	166	N.
C2	photons	dual	total	116	116	116	N.
C1	electrons	dual	total	130	130	130	N.
C3	photons	dual	fun+tel/total	136/146	136	146	N.
B3	electrons	single	sen	140	-	300	O
C4	photons	dual	fun/total	146/166	166	166	N.
A10	photons	dual	tel/sen	166/226	-	246	O
A7	photons	dual	tel	186	-	246	O

Where: sen: sensitivity fun : functional tel : telemetry
O : operative N. : non-operative

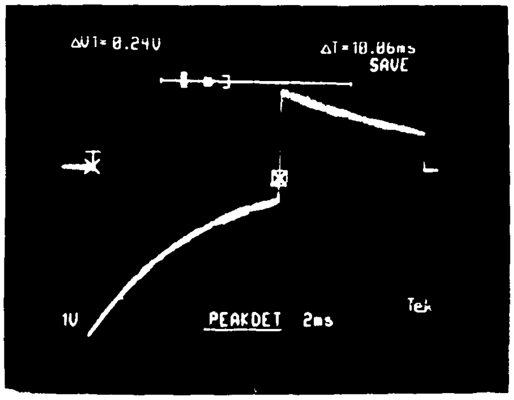

Figure 1. Pulse width after a photon radiation dose of 126 Gy

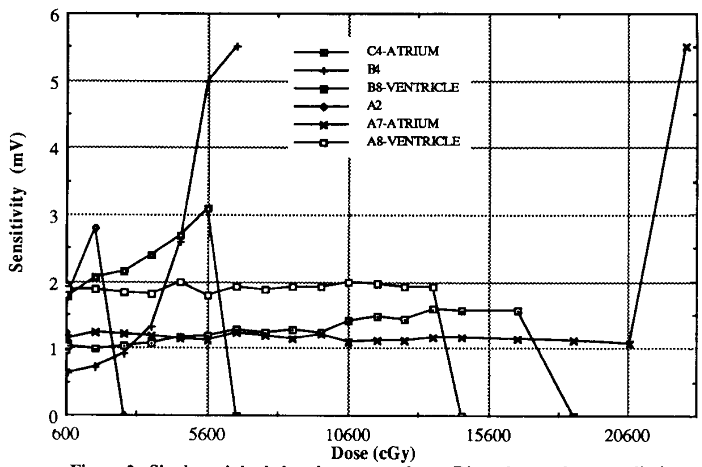

Figure 2. Single and dual chamber pacemakers. Direct beam photon radiation

The results for the 4 AICDs are shown in table II. Except for VC1 all the devices had a first major failure before 55 Gy and didn't recover after that. Three of the AICDs (VC1, VC2, VC4) were unable to either detect the increase in pulse rate or start to charge their capacitors. VC1 had a temporary rate channel failure at a radiation dose of 70 Gy recovering after 15 minutes.

Table II. Ionizing radiation effects on AICDs.

AICD	Failure	Dose (Gy)	Max. Dose (Gy)	Status
VC-1	sensitivity+detection	70	80	N.
VC-2	detection	51	51	N.
VC-3	magnet test+charge	54	54	N.
VC-4	detection	54	54	N.

Figure 3 shows the detection time as a function of radiation dose for the 4 AICDs. Despite the variations showed and the small sample used, the overall tendency of the detection time was to increase with radiation dose, as shown by the interpolation curves. The charging time of the radiated defibrillators increased catastrophycally at approximately 50 delivered pulses when compared with the charging time of 6 implanted AICDs whose follow-ups are being carried out at the Medical Center.

On the other hand, the sensitivity and the output energy delivered by the pulse (29 Joules) didn't change throughout the test, even immediately before a total failure.

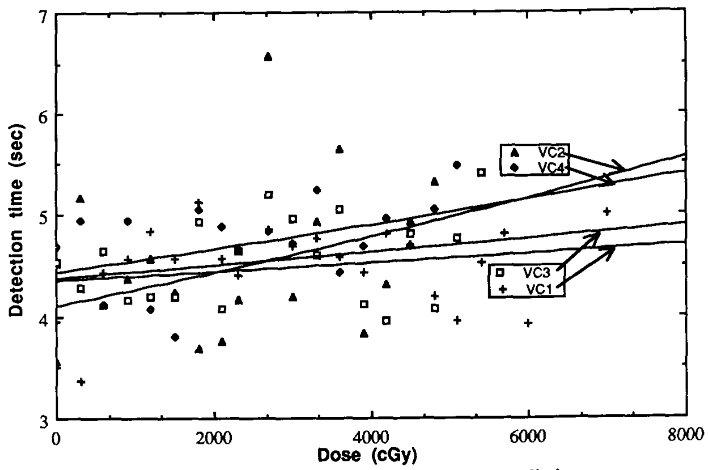

Figure 3. AICDs' detection time as a function of photon radiation

CONCLUSIONS

All the devices used in this study employed CMOS technology in their electronic circuitry. The normal function of programmable pacemakers and AICDs based on CMOS exposed to therapeutic radiation levels (<70 Gy) can be seriously affected, with no difference between photon and electron radiation effects on pacemakers at these dose radiation levels. Failures were produced at cumulative dose levels of more than 14 Gy, most of the first defects in this group of 23 pacemakers and 4 AICDs were sensitivity and telemetry failures. However, at higher dose values, total failure was mostly observed. (See table I). Most of the devices showed increased power consumption probably as a result of leakage currents in faulty CMOS integrated circuitry, leading to a more rapid battery depletion.

In patients dependent on a pacemaker, a total failure is much more serious than a sensitivity, a functional or a telemetry failure. Scatter doses, with the units outside the beam, were tolerated by this group of pacemakers without major problems due to the low transmission factors of the shielding case of the devices for the energy beam levels used. Table I shows the list of failures headed by 5 devices of one manufacturer; it seems reasonable to think the choice of the design structure and components can affect the radiation sensitivity of devices. AICD's charging and detection time increased with radiation dose whereas the sensitivity and the output energy kept constant during the test.

A comparison of our results with Vensenlaar's et al. [6] showed a lower threshold to radiation damage for the current generation of programmable pacemakers. The telemetry capability of this group of modern pacemakers constituted a new parameter to be affected by the ionizing radiation. From the above results and taking a total failure as a catastrophic event we should consider carefully an upper radiation limit for the present generation of pacemakers. AICDs failure can be expected during standard treatment. In any case, direct radiation of devices should be avoided. Transient device malfunction from the linear accelerator electromagnetic field was detected in some devices. The pulse rate was the most sensitive parameter to the electromagnetic radiation. It is apparent that components, circuit designs, and structures of the chip technology should be improved for application in implantable devices, which could be subject to ionizing radiation.

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