Radiation-Induced Effects in Multiprogrammable Pacemakers and Implantable Defibrillators

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RODRIGUEZ, F., ET AL.: Radiation-Induced Effects in Multiprogrammable Pacemakers and Implantable Defibrillators. *Twenty-three multiprogrammable pacemakers and four implantable cardioverter defibrillators (ICDs) containing either complementary metal-oxide semiconductor (CMOS) or CMOS/Bipolar integrated circuit (IC) technology were exposed to 6-MV photon and 18-MeV electron radiation at various dose levels. Of the 17 pacemakers exposed to photon radiation eight failed before 50 Gy, whereas four of the six pacemakers exposed to electron radiation failed before 70 Gy. Photon scatter doses were well tolerated. For the ICDs detection and charging time increased with accumulated radiation dose, the charging time increased catastrophically at < 50 total pulses delivered when compared with the charging time of six implanted ICDs. Sensitivity and output energy delivered by the ICD pulse were constant during the test. It was found that devices using the shorter channel length IC technology (i.e., 3 μm CMOS) were per se harder to ionizing radiation than the devices using larger channel length IC technologies (i.e., either 8 μm CMOS or combined 5 μM CMOS/20 V Bipolar). In fact, none of the devices based on 3 μm CMOS IC technology failed before 76 Gy, which is above the highest dose level (70 Gy) normally used in radiation oncology treatments. (PACE, Vol. 14, December 1991)*

pacemakers, implantable defibrillators, radiation effects, oncology, semiconductors

Introduction

Projections based on clinical experience suggest that four to five patients out of a thousand have implanted devices at the time of radiation therapy treatment. Information about the effects of ionizing radiation on pacemakers is limited. Moreover, no work has been done on the effects of ionizing radiation on the implantable cardioverter defibrillator (ICD) since its introduction in 1980.

Table I summarizes the results of the effects of ionizing radiation on pacemakers in published reports dating from 1975 to 1986. If one includes the 23 pacemakers of this report with the above reports, it makes a total sample of 123 pacemakers over a period of 15 years. The sensitivity of pacemakers to ionizing radiation is highly dependent on integrated circuit (IC) technology. The first generation of pacemakers (before 1978), based on bipolar technology, were hardened to the different types of radiation and therapy machines used. Subsequent evolution incorporated complementary metal-oxide semiconductor (CMOS) and combined CMOS/Bipolar IC technologies which, in turn, showed a decrease in hardness to radiation when compared to the ones using bipolar technology. Moreover, some of the above works[8,10] predicted further decrease in hardness to radiation for the newest state-of-the-art models.

Therefore, the objective of the present research is to update the information available to

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Table I.

Chronological Study of Pacemaker's Failure

Reference	Year	Technology	No. of Pacers	Type of Radiation	Dose (Gy)	Comments
1	1975	Bipolar	5 fix-rate	Cobalt, LINAC, Betatron (e + p)	300 4–42 MeV	No malfunction at all
2	1978	CMOS	24 D	Cobalt, LINAC, Betatron (e + p)	120 6–25 MeV	Less failure with LINAC
3	1981	CMOS	25 D,P	LINAC (e + p)	10–70 10 MeV	Programmable more sensitive
4–7	1982	CMOS	4 P	Cobalt	20–36 4–6 MeV	Case report failure
8	1984	CMOS	8 D,P	Cobalt	90–900	Programmable more sensitive
9	1984	CMOS/Bipolar	19 D,P	LINAC (p)	39–69 4 MeV	Hybrid more sensitive
10	1986	CMOS	15 P	Cobalt	13–750	Very sensitive

Dose = accumulated radiation dose at which a failure occurred; D = demand; P = programmable; p = photon radiation; e = electron radiation.

the medical community regarding the response to ionizing radiation of any new electronics technology introduced into pacemakers and ICDs during the last 4 years and to determine if the projections made by the above investigators are applicable to the new state-of-the-art devices.

Methods and Materials

Investigations on the effects of either high energy photons or electrons were carried out on 23 programmable pacemakers and four ICDs from three different manufacturers. First, 17 pacemakers were exposed to 6 MV scatter photon radiation (adjacent to but outside the direct beam) to a total accumulated radiation dose of 70 Gy, followed by exposure to the direct photon beam, until failure or a maximum accumulated dose of 246 Gy. Second, six pacemakers were exposed to an 18 MeV direct beam electron radiation to failure or 300 Gy. Third, four ICDs were irradiated with a 6 MV direct beam photon radiation to a total dose of 250 Gy or failure.

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 was achieved, subsequent daily doses were escalated. All the irradiated devices were embedded in a solid water phantom. This tissue equivalent material simulated the actual human body conditions such as the electroconductive and dosimetric characteristics of tissue. The field size was 20 × 20 cm^2 at a source surface distance of 100 cm. A 500 Ω resistor was connected to the leads of the devices to simulate the heart load.

Single and dual chamber multiprogrammable pacemakers with either monopolar or bipolar pacing capability powered by lithium-iodine batteries were supplied. Some models included additional state-of-the-art capabilities like the rate responsive function. All the devices used telemetry to communicate with their programmers. The IC technology utilized in the manufacture of the devices was broadly diverse. Some devices used 8 μm CMOS metal gate technology, whereas some used 5 μm CMOS and 20 V Bipolar combined technologies.

In conclusion, all the devices shared in some extent a common technology: CMOS.

The device parameters were set to values considered by the manufacturer to be the values most susceptible to radiation exposure (worst case scenario). Sensitivity, functional values (pulse amplitude, rate, width, and atrium ventricular delay), and battery parameters (voltage and current drain) as well as the telemetry capability were measured for the pacemakers before and within 1 hour after each irradiation cycle. When a marginal failure was detected, additional monitoring was performed before the next irradiation cycle.

The capacity to sense 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.

The ICD pulse generators supplied were nonprogrammable with only rate detection circuit capability. Parameters like sensitivity, detection time, charge time, output energy, and pulse count were measured before and within 30 minutes after each irradiation cycle. As with the pacemakers, when a marginal failure was detected, additional monitoring was performed before the next irradiation cycle. To check whether the automatic gain control circuit would remain functional with minimum input signals, a 20 msec width and 800 msec rate half-sine electrical signal of variable amplitude (0.5–5 mV) was applied to the detection leads of the pulse generator. The detection time was checked with the same signal, except that the amplitude was constant at 5 mV and the rate was increased 10 bits per minute above the cutoff frequency of the corresponding device under test. Should a device fail temporarily, additional radiation was delivered once the device recovered from the failure.

Results

Pacemaker failure was defined as a deviation exceeding the manufacturer's normal specifications of the functional values or a loss of telemetry. A functional failure was defined as a deviation of 20% from the manufacturer's normal specifications; however, a sensitivity failure was defined according to the manufacturer's manual tolerance since each manufacturer utilizes different criteria to set the tolerance level of the automatic gain control of its devices.

As mentioned before, all the pacemakers used in this study were multiprogrammable and they could be set to multiple modes, altered or readout by using their telemetry capability. The loss of either real-time measurement capability, interrogation, or programmability was defined as a telemetry failure, which in general meant the loss of communication between the pacemaker and its programmer.

Table II lists the IC technology of the irradiated pacemakers, the type of radiation used, chamber type, the first and second failures 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. 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 total failure (as the first manifestation of radiation-induced damage) and two of them (C1, C2) did not recover after the first failure. The total loss of signal was the most common second failure (9/21) and three of them (B7, C3, C4) did not recover whereas six units (B1, B2, B3, A7, A9, A10) could withstand the total dose, even though they showed either functional or telemetry transient failures. In a number of cases a partial or a total recovery of the signal or telemetry occurred, but they did not occur with sensitivity abnormalities. For instance, A4 recovered the output signal 26 days after the failure whereas B4 recovered its signal after 14 hours.

Figure 1 shows the pulse output at baseline for a typical pacemaker. Figures 2 and 3 show the output signal for A4 after an accumulated photon radiation dose of 25 Gy and the output signal for B4 after an accumulated photon radiation dose of 146 Gy, respectively. It should be noted that the signal amplitude is only 100 mV for A4 and the pulse width for B4 changed from 1.5 msec (baseline value) to around 30 msec after the respective radiation dose level.

Parameters such as sensitivity, detection time, charge time, output energy, and pulse count were recorded as a function of the radiation dose for the ICDs. A complete channel failure was defined as the inability of the ICD to reacquire a half-sine sig-

Table II.
Ionizing Radiation Effects on Pacemakers

Pacer	IC Technology	Type of Radiation	Chamber Type	First/ Second Failure	Dose Level (Gy)	Loss of Signal (Gy)	Maximum Dose (Gy)	Status
A1	Metal/8 μm CMOS	electrons	single	tel	14	—	22	O*
A2	Metal/8 μm CMOS	photons	single	tel + sen/ total	16/26	26	36	N
A3	Metal/8 μm CMOS	photons	single	tel + sen/ total	16/36	36	46	N
A4	Metal/8 μm CMOS	photons	single	tel/total	16/26	26	36	N
A6	Metal/8 μm CMOS	photons	dual	total/total	16/26	16	46	N
B4	5 μmCMOS ~ 20 V Bipolar	photons	single	sen/fun	26/36	146	186	N
B5	5 μm CMOS ~ 20 V Bipolar	photons	single	sen/fun	26/46	166	186	N
A5	Metal/8 μm CMOS	electrons	dual	total/total	30/34	30	46	N
B7	5 μm CMOS ~ 20 V Bipolar	photons	dual	fun + sen/ total	46/56	56	56	N
B8	5 μm CMOS ~ 20 V Bipolar	photons	dual	sen/fun	46/56	66	66	N
B6	5 μm CMOS ~ 20 V Bipolar	electrons	single	sen/fun	60/70	240	300	N
B9	5 μm CMOS ~ 20 V Bipolar	electrons	dual	sen/total	60/90	90	90	N
B1	3 μm CMOS	photons	single	sen/tel	76/206	—	246	O
B2	3 μm CMOS	photons	single	sen/tel	76/226	—	246	O
A9	Poly 3 μm CMOS	photons	dual	tel/fun	106/246	—	246	O
A8	Poly 3 μm CMOS	photons	dual	tel/fun	116/136	146	166	N
C2	n/a	photons	dual	total	116	116	116	N
C1	n/a	electrons	dual	total	130	130	130	N
C3	n/a	photons	dual	fun + tel/ total	136/146	136	146	N
B3	3 μm CMOS	electrons	single	sen	140	—	300	O
C4	n/a	photons	dual	fun/total	146/166	166	166	N
A10	Poly 3 μm CMOS	photons	dual	tel/sen	166/226	—	246	O
A7	Poly 3 μm CMOS	photons	dual	tel	186	—	246	O

sen = sensitivity; fun = functional; tel = telemetry; O = operative; N = nonoperative; n/a = not available. * This particular device had temporal telemetry failures starting at 14 Gy. At the end of the study, a total accumulated dose of 22 Gy was delivered and the device remained operative except for the telemetry capability

nal of 0.5 mV. Detection time failure was defined as a > 7-second interval between the sudden increase in the sensed frequency above the cutoff level and the start of charging of the energy storage capacitors. Battery depletion bias was defined as 1.3 times the charging time at the beginning of life of the device.

Tables III and IV summarizes the results for the four ICDs tested. For example, VC-1 showed a battery depletion bias at a total accumulated dose of 54 Gy and then showed a temporary rate channel failure at a radiation dose of 70 Gy recovering after 15 minutes. Thus, except for VC-1 all the devices had a first major failure before 55 Gy and did not recover after that. Three of the units (VC-1, VC-2, VC-4) were unable to detect the increase in pulse

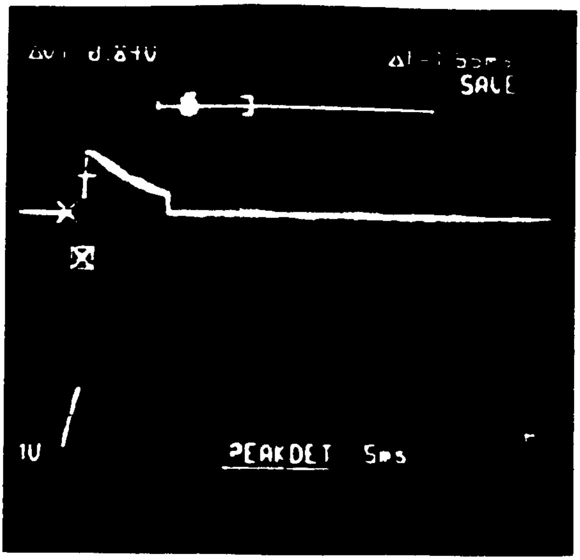

Figure 1. *Pulse output at baseline for a typical pacemaker.*

rate and thereby start to charge their capacitors, one unit (VC-3) could detect but not charge.

As shown in Figure 4, the charging time of the irradiated defibrillators increased catastrophically at < 50 total pulses delivered (TPD) when compared with a control group of six patients with implanted ICDs. These implanted ICDs showed no tendency to a catastrophic increase even after 79

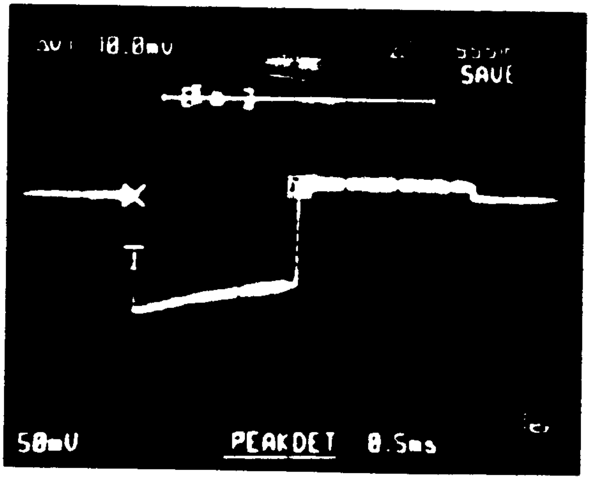

Figure 2. *Pulse output for A4 after 30 Gy photon radiation.*

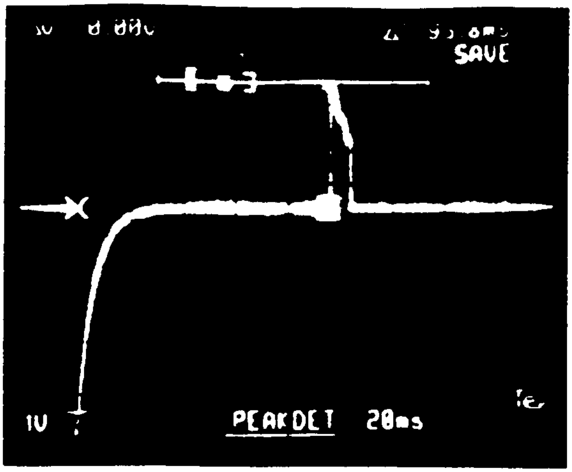

Figure 3. *Pulse output for B4 after 146 Gy photon radiation.*

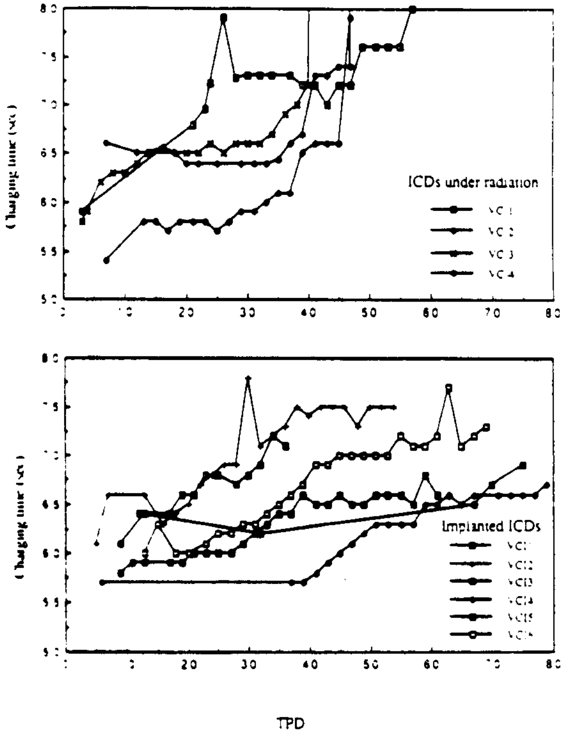

Figure 4. *Charging time versus total pulse delivered (TPD).*

Table III.

Summary of ICD's Parameters Change with Radiation

ICD	Detection Time Beginning of Life (seconds)	Parameter Before the First Failure Occurred: Detection Time (seconds)	Sensitivity (mV)	Battery Depletion Bias Factor*	Dose (Gy)
VC-2	3.56	5.32	<0.5	1.14	51
VC-4	4.68	5.48	<0.5	1.36	54
VC-1	3.96	3.92	no signal	2.53	70
VC-3	4.54	5.46	<0.5	3.20	54

* The battery depletion bias factor is defined as the charging time measured at test over the charging time measured at beginning of life of the device.

Table IV.

Ionizing Radiation Effects on ICDs

ICD	Failure	Dose (Gy)	Maximum Dose (Gy)	Final Status
VC-1	Sensitivity + detection	70	80	N
VC-2	Detection	51	51	N
VC-3	Pulse count + charge	54	54	N
VC-4	Detection	54	54	N

N = nonoperative

TPD. On the other hand, the sensitivity and the output energy delivered by the pulse (29 joules) did not change throughout the test (except for VC-1), even immediately before a total failure.

Discussion

This decade has seen an enormous increase in the use of very large scale integration technology (VLSI) in implantable medical devices such as pacemakers and ICDs. The complex functions performed by these devices are only possible by the use of highly sophisticated VLSI circuitry. The elements found in this integrated circuitry include digital and analog components: silicon sensors, bandgap voltage regulators, A/D and D/A converters, switched capacitor amplifiers, comparators, telemetry, ROM and RAM memories, and microprocessors. High voltage generation and control circuits that deliver high energy outputs have also been implemented with the introduction of the ICD.[11]

CMOS with its special combination of low power consumption and high reliability has emerged as the technology of choice for pacemakers and ICDs; however, concomitant with the desirable CMOS features are the undesirable aspects of its high sensitivity to ionizing radiation. The objective of the present study was to experimentally investigate the effects of exposure to levels and types of ionizing radiation used in current radiation therapy protocols on the overall function of state-of-the-art pacemakers and implantable defibrillators as well as the effects on their individual electronic and semiconductor components (i.e., VLSI circuits and chips based on CMOS technology).

Mechanisms of Radiation Effects on MOS Devices

High energy particles such as electrons, protons, neutrons and electromagnetic radiation like gamma rays and X rays possess enough energy to break atomic bonds and create electron-hole pairs in the silicon and silicon dioxide materials. The energy of the incident particle determines the amount of electron-hole pairs created. The normal functionality of MOS devices can be greatly affected by the ionizing radiation. This abnormal functionality depends on the total cumulative dose and dose rate at which the radiation is delivered and can be either constant or variable with time after the irradiation.

Cumulative Dose and Dose Rate Effects

The most sensitive parts of an MOS structure to ionizing radiation are the silicon dioxide layers. The cumulative radiation damage to these layers consist of 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.[12]

Figure 5 shows the process of the ionizing radiation-induced effects in an n-channel transistor. Zones 1, 2, and 3 show the build up of trapped charge in the oxide, whereas 4 shows the radiation induced interface traps at the SiO_2/Si interface. The rate at which an ionizing radiation dose is delivered to a device can have a transient effect on it. This effect occurs due to the radiation-induced photocurrents generated by high dose rate and begins to be appreciable for dose rates $> 10^6$ rad/sec. In our case we are dealing with relatively low radiation pulse dose rates ($< 10^4$ rads/sec) so at these levels there is no significant dependence on dose rate.

Fundamental characteristics of MOS devices and circuits such as capacitance-voltage (C-V) and current-voltage (I-V) characteristics, mobility, channel conductance, and transconductance change drastically under ionizing radiation. However, such changes are functions of other factors present during radiation such as energy and total dose received; bias applied; type, geometry, and method of fabrication of the transistor; and dose rate and temperature.[13]

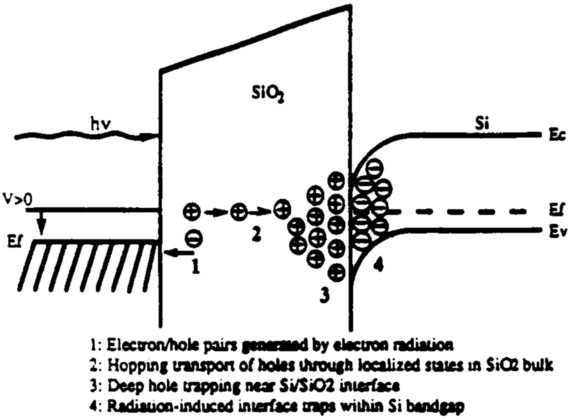

Figure 5. *Schematic of the ionizing-radiation induced effects on an MOS structure under positive gate bias. 1 = electron/hole pairs generated by electron radiation; 2 = hopping transport of holes through localized SiO_2 bulk; 3 = deep hole trapping near Si/SiO_2 interface; 4 = radiation-induced interface traps within Si bandgap.*

Change in the Threshold Voltage

Two factors determine the effects of radiation-induced charge components on the characteristics of MOS transistors. Oxide-trapped charge shifts the I-V curve to the negative direction; whereas interface traps tend to stretch the I-V curve out.

Figure 6 shows the drain current as a function of gate voltage for an n-channel MOS transistor before and after the irradiation. The curve shifts to the negative direction causing the threshold voltage to be more negative meaning that a less positive voltage is required to turn the transistor on. The curve is also less steep, which means that a greater change in applied bias is required to cause the same change in current as before the irradiation.

At first, one might think that the extrapolation of individual transistor response to radiation can be used to elucidate and predict the response to radiation of a full IC subject to the same radiation environment conditions. In practice, doing a qual-

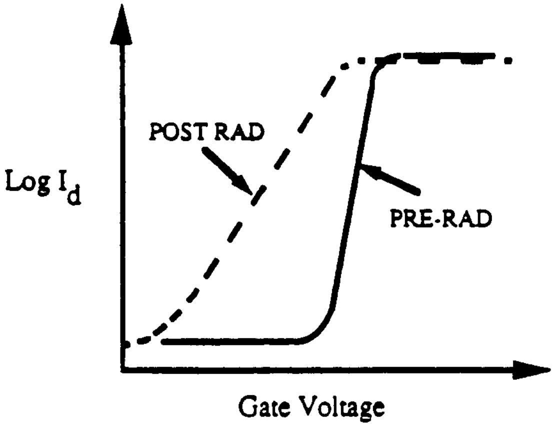

Figure 6. *Logarithm of the drain current as a function of gate voltage before and after radiation on an n-channel MOS transistor.*

itative and a quantitative analysis for all circuit parameters represents a formidable task. In a complex IC the transistor can be biased in a huge number of possible combinations. The shifts in transistor parameters depend on the bias applied during and after radiation: thus the IC response may be different for each of these combinations. A practical useful alternative that has proven to work is to simulate or test critical parameters on timing paths to only worst case conditions,[14] avoiding the 100% simulation or testing of all possible configurations of the circuit.

Current Study

The first radiation-induced abnormalities in the pacemakers were a sensitivity failure in 41% of the devices and a telemetry failure in 33% of the devices. These failures were indifferent to the type of radiation used and the accumulated dose level reached. This suggests that the detection and telemetry circuits are particularly affected by the radiation. In addition, the sensitivity and telemetry failures occurred independently of the IC process technology as can be seen in Table II. The sensitivity and telemetry circuits mainly included analog circuitry, such as: A/D, D/A converters, switch capacitor amplifiers, and multiplexers. Therefore, the above results could be attributed to the fact that analog circuitry is sensitive to radiation.[15] On the other hand, the possibility of failure caused by the ionizing radiation to a digital section of the IC can not be ruled out.

The increase in the pulse width for some of the devices was independent of the type of radiation; however, from Table II one can see that the worst case in pulse-width increase occurred for two particular models using combined 5 μm CMOS/20 V Bipolar technology. For these two models, in order to get constant pulse output throughout the useful life of the device, the manufacturer provided means to compensate the natural depletion of the battery capacity by gradually increasing the pulse width. This result allows one to assume that the above IC process technology could lead to an increase in leakage currents, which would cause the rapid depletion of the batteries.

The change in battery voltage and current drain as a function of radiation dose can be closely related to change in consumed-cell capacity. It is interesting to note that for some devices (A9, A10) the battery voltage increased as a function of radiation dose and for others (B2, B5, B6, A5, and A8) the current drain showed a peak value at a certain radiation dose level. Those effects could be related to the annealing effect after irradiation since the leakage current of the individual MOS transistors that form part of the device changes with time after irradiation.[16]

Large channel length technology has thicker gate oxide. Radiation sensitivity of MOS devices is highly dependent on oxide thickness. Therefore, from Table II one can see that the CMOS IC technology with the shorter length channel is harder to radiation than the ones with longer length channels and combined bipolar technology. It should be noted that 43.5% of the devices failed at dose levels < 50 Gy and 17.4% at dose levels between 51 and 100 Gy. Nevertheless, most of the devices that failed at the above radiation dose levels used relatively old IC technologies (i.e., 8 μm CMOS and 5 μm CMOS/20 V Bipolar). Moreover, the IC technology of the six pacemakers that remained operative at the end of the test after a radiation dose of 246 Gy photons or 300 Gy electrons was 3 μm CMOS. The high dependence of radiation sensitivity on oxide thickness of MOS devices accounts for the above results.[17] Finally, for the energy levels used, there was no appreciable difference between the effects caused by either photon or electron radiation.

From Table III one can see that two of the ICDs (VC-2 and VC-4) failed before getting to the battery depletion bias level. Moreover, the fact that the charging time of the four devices increased catastrophically at < 50 TPD when compared with the charging time of the six implanted devices (See Fig. 4) implies that the photon radiation dose had a direct effect over the charging time of the four ICDs.

It is difficult to determine which parameter failed at a given radiation dose due to the simultaneous occurrence of failures at the same radiation dose level, as can be seen in Table IV. Although one could discern between a detection time or a charging time failure, when the device failed to fire the pulse, malfunction in other circuitry could be related to this failure as well (e.g., a failure in the magnet test logic circuit would not enable the high voltage inverter circuit to fire the pulse). Therefore, much of the ICDs circuitry could potentially be implicated in any particular failure.

The ICDs tested were nonprogrammable with only rate detection circuit capability. That means that the sensing circuitry only included the rate analysis and averaging circuit. This circuit includes analog components such as high pass filters, preamplifiers, automatic gain control amplifiers, comparators, and square signal generators. These elements are sensitive to ionizing radiation. Furthermore, the high voltage inverter and control circuits include elements such as low frequency oscillators and high current switching transistors, which also are sensitive to ionizing radiation. The other ICD circuitry like the magnet test logic, parallel to serial converter, and modulator also are sensitive to ionizing radiation.

By comparing the levels of failure of ICDs and pacemakers, it seems that the ICDs used in the test incorporated a relatively old IC technology, perhaps 8 μm CMOS or 5 μm CMOS/20 V Bipolar. This information was not provided by the manufacturer, however.

In conclusion, the rapid increase of charging time with radiation dose implied a rapid decrease of battery capacity. The depletion in battery capacity is caused by increase in current drain. Therefore, it is logical to assume that an increase in leakage current is one of the possible causes, if not the most important, of the radiation induced failure in the ICDs circuitry.

Conclusions

Programmable pacemakers and ICDs can be damaged by typical therapeutic radiation doses (< 70 Gy). All the devices used in this study used CMOS or combined CMOS/Bipolar technology in their integrated circuits. By examining the type of IC technology of each particular device and then correlating it with the radiation dose levels at which a failure occurred, one can draw the conclusion that devices using the newest IC technology (i.e., 3 μm CMOS) are per se harder to ionizing radiation than the ones using relatively old IC technologies (i.e., 5 μm CMOS/20 V Bipolar or 8 μm CMOS). This result can be explained by the fact that shorter channel length implies reduced oxide thickness, which is one of the major factors affecting the sensitivity to radiation of MOS devices. When the above results are compared with historical data, the relationship between the IC technology and the radiation dose failure level can be described by the curve in Figure 7. The difference between the radiation dose level failures for the latest IC technologies predicted by past works and the ones obtained by the present work should be emphasized. Pacemakers with an 8 μm CMOS IC technology showed failures at radiation dose levels < 16 Gy whereas pacemakers with a 3 μm CMOS IC technology did not show any failure before 76 Gy. Moreover, the six devices remaining operative after the test utilized 3 μm CMOS IC technology. There was no evidence of difference between electron and photon radiation for the dose rate and the two energy levels used.

Most of the first failures in the test group of 23 pacemakers were sensitivity and telemetry failures independent of the device's IC technology. The sensitivity and telemetry circuits are mostly composed of analog elements. Therefore, analog circuits were demonstrated to be more sensitive to

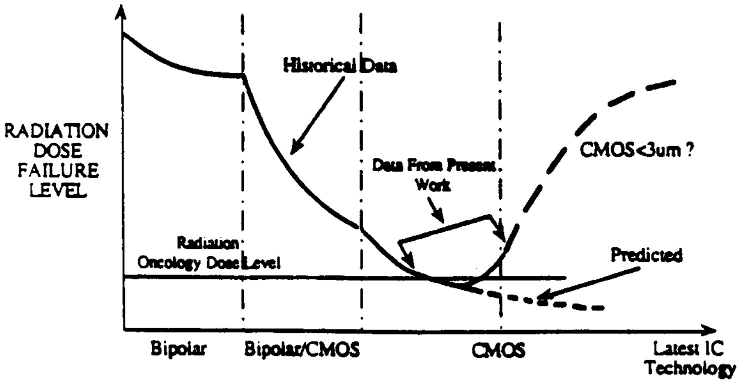

Figure 7. *Relationship between pacemaker IC technology and radiation dose level failure.*

ionizing radiation than their digital counterparts. These failures may be less serious for patients than functional failures.

The increase in power consumption by most of the devices could be related to the increase in leakage currents in faulty CMOS IC. This increase in leakage current led to battery depletion, dependent on the accumulated radiation dose with no difference between photon and electron radiation. The response to ionizing radiation is highly dependent not only on device IC technology but on design structure and components used by the individual manufacturing process of the devices. Despite the high transmission factor of the device's shielding case, scatter doses were well tolerated by this group of pacemakers due to the low cumulative radiation dose levels (< 600 Gy) delivered to the devices.

The most important factor contributing to the radiation-induced failure in the ICDs was the increase in leakage current. The ICD's circuitry is mainly composed of analog elements. As discussed before, there is clear deterioration of analog circuitry response during radiation exposure. Therefore, ICD parameters dependent on analog circuitry such as detection and charging times were clearly affected by the ionizing radiation. However, other parameters such as TPD and output energy were not affected.

A comparison of our results with those of Vensenlaar et al.[10] showed a lower threshold to radiation damage for the current generation of programmable pacemakers based on old CMOS IC technology. However, the devices based on the newest CMOS IC technology showed a higher threshold for radiation damage. In fact, pacemakers using CMOS 3 μm IC technology did not show failure before 76 Gy, which is above the highest dose level (70 Gy) normally used in radiation oncology treatments. On the other hand, the telemetry capability of modern programmable pacemakers constitutes a new parameter that may be affected by the ionizing radiation, independent of IC technology.

Based on the above results, it is clear that an upper radiation dose limit should be carefully considered for the present generation of pacemakers. Ideally, the manufacturer should provide specific dose limits for its devices; however, this is unlikely to be provided due to technical and liability concerns. Factors such as IC technology, design structure, and components should be taken into account when attempting to set such an upper radiation dose limit for a particular device model.

The use of VLSI circuits for pacemaker or ICD applications must be fully customized in order to cope with the special characteristics of the devices itself and the working environment (i.e., the human body). Full custom circuits are designed to minimize current drain by using low frequency operation and minimum operating current analog concepts. Therefore, the manufacturer can easily take into account different procedures and guidelines applied to IC process technology, circuit designs, and components in order to make his devices harder to the ionizing radiation. Further research should be done on the sensitivity of devices using new shorter channel length CMOS IC technology (< 3 μm) to the ionizing radiation in order to conclude that the devices with the shorter channel length CMOS IC technology are per se harder to ionizing radiation.

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