Effects of Irradiation on the Components of Implantable Pacemakers

Shinji Kawamura*, Seiji Ono†, Noriyuki Kuga, Tooru Shiba†, Hiroshi Fujimoto‡, Takeshi Toyoshima‡, Kenji Hyodo‡, Tetsuo Hirose, and Masaru Matoba§

Department of Radiological Technology Miyazaki Medical College Hospital
†) Department of Radiology Miyazaki Medical College Hospital
‡) Medotronic Japan Corporation
§) Department of Applied Quantum Physics and Nuclear Engineering, Graduate School of Engineering, Kyusyu University

The excerpts demand address: 5200, Ooaza kihara, Kiyotake, Miyazaki, 889 – 1692, Japan
Department of Radiological Technology Miyazaki Medical College Hospital
The research division 699
Key words: pacemaker, radiation effect, component, programmer, electrical circuit

Abstract
The purpose of this study was to examine the effects of irradiation on implantable pacemaker components. The pacemaker was divided into three components: lead wire and electrode, battery, and electrical circuit, and each component was irradiated by X-ray and electron beams, respectively. The pacemaker parameters were measured by both telemetry data of the programmer and directly measured data from the output terminal. The following results were obtained. For the lead wire and electrode, there was no effect on the pacemaker function due to irradiation by X-ray and electron beams. In the case of battery irradiation, there was no change in battery voltage or current up to 236Gy X-ray dose. In the electrical circuit, the pacemaker reverted to the regular beating rate (fixed-rate mode) immediately after the start of X-ray irradiation, and it continued in this mode during irradiation. In patients with their own heartbeat rhythm, changing to the fixed-rate mode may cause dangerous conditions such as ventricular fibrillation. When the accumulated irradiation dose is increased, another failure can be seen in the output voltage of the pacemaker. The pacing output voltage

* 宮崎医科大学医学部附属病院 放射線部 [〒889-1692 宮崎県宮崎市清武町大字木原5200] : Department of Radiological Technology Miyazaki Medical College Hospital
e-mail : skawamur@fc.miyazaki-med.ac.jp
dropped rapidly by about 40% at 30-88Gy. Decreasing the output voltage results in pacing disorders, and heart failure may occur. In the telemetry data of the programmer, no change in output voltage could be detected, highlighting the difference between telemetry data and actual pacing data.

Received Dec. 17, 2002; revision accepted Apr. 15, 2003

1. Introduction

Several studies have been made on the effects of irradiation on pacemakers. The American Association of Physicists in Medicine Task Group 34 reported some specific recommendations for radiation oncology patients with implanted cardiac pacemakers in 1994\(^1\). If the total estimated dose to the pacemaker may exceed 2 Gy, it was recommended that the pacemaker function should be checked. Later, a review article on studies of pacemaker irradiation was published\(^2\). Some simple precautions are recommended during the planning and administration of radiotherapy to minimize the risk of harm to patients with pacemakers. However, there are various dose levels of irradiation that effect pacemakers\(^3-7\). The effects of irradiation on pacemakers are still controversial and it is for this reason that pacemakers are constantly being miniaturized and functions enhanced with the evolution of the integrated circuit (IC) design rule. There are also differences in sensitivity to irradiation in individual pacemaker devices\(^8\)-\(^9\). Further research was recommended in the past studies. On one hand, it has been reported that radiation to pacemakers effects electrical circuits such as complementary metal oxide silicon (CMOS)\(^10\). However, other effects seem to occur in the lead wire that senses small signals from the cardiac muscle, and in the battery that supplies low power for a long period, and some reports have suggested these effects\(^11\)-\(^13\). However, very few attempts have been made to study the effects on each component of the pacemakers which is essential. In this study, we examined the demand-type pacemaker produced by Medotronics to the IC design rule of 3 microns. This type seems to be the most commonly implanted at present. The pacemaker is divided into three components, the lead wire and electrode, battery, and electrical circuit. Each component was irradiated by X-ray and electron beams from a linear accelerator. By studying the effects of irradiation on each component, we clarified the technique of field collimation and shielding for pacemakers.

2. Methods and Materials

Nine pacemakers were used in this study; they were Thera-i and Kappa400, both produced by Medotronics, and IC design rule was 3 microns. These demand-type pacemakers had DDD and VVI operating modes of the Inter-Society Commission for Heart Disease Resources (ICHD) code. In all experiments, the sensitivity of the pacemaker was set at 0.5mV minimum value. The X-ray and electron beams were generated by a linac (EXL-20DP, Mitsubishi Electric Company). The pacemaker irradiation was carried out on the three components independently. The performance of the pacemaker was evaluated from communication data through the programmer 9790 and output meas-
ured from the pacemaker output terminal directly.

2-1 X-ray and electron irradiation to the lead wire and electrode

The lead wire and electrode detect the potential change in the heart muscle, and transmit a signal, and this is also the component, which stimulates the heart muscle. One pacemaker (Kappa400) was placed in 0.18% salt solution of Irnich's simulation model for the Electro-Magnetic Interference (EMI) measurement. The lead wire and electrode of the pacemaker were irradiated by 6 and 10MV X-rays at 200-400MU/min and by 6, 12 and 20MeV electrons at 600-900 MU/min. Each dose-rate value of the X-ray and electron beams corresponded to 2.05-4.11Gy/min and 5.81-8.87Gy/min, when it was converted into the absorbed dose at the position of the wire and electrode. The irradiation field size was 350 × 350 mm² with the X-ray beam and 250 × 250 mm² with electron beam. During irradiation to the lead wire and electrode, the pacemaker main body, including the electrical circuit and battery, was shielded with 73mm thick lead. The setup is shown in Fig. 1. The effect of irradiation on the lead wire and electrode was evaluated from the change of the intracardiac electrocardiogram through the programmer. The programmer measured the pacemaker parameters of pulse amplitude, pulse width and sensitivity simultaneously.

2-2 X-ray irradiation to the battery

The battery is an important component of the pacemaker for long-term stable operation. Lithium-iodine batteries have high internal resistance, and it is necessary to consume the least amount of current to ensure long life of the pacemaker. Three batteries were removed from pacemakers (Thera-i), and directly irradiated with 10MV X-rays at 200MU/min (2.04Gy/min). The irradiation field size was 50 × 50 mm² at 1000 mm from the target. The 300 kΩ resistance was connected to the output terminal of each battery, and the battery output voltage and current were measured directly. The absorbed radiation dose of the pacemaker was estimated as follows. The pacemaker was placed at 50 mm depth in 300 × 300 × 300 mm³ solid water phantom, and the dose to the pacemaker backside was measured by a shallow chamber PTW23343. This dose value was compared with that of the water phantom in an identical situation. Then the pacemaker was converted into the water equivalent thickness and the dose pacemaker was evaluated at the absorbed dose of half depth of the water equivalent thickness. The relationship between battery output voltage, current and cumulative dose was examined.
2-3 X-ray irradiation to the electrical circuit

A CMOS IC has been used for the electrical circuit of pacemakers since the 1970’s. The CMOS IC is suitable for this use because of its low level of current consumption and high integration. To date many researchers have studied the effects of irradiation on the circuit. To simulate the clinical environment, 510 Ω resistance was attached to the output terminal instead of the lead wire, and the output terminal and battery were shielded with 73 mm thick lead. Thus, only the electrical circuit was irradiated with 10MV X-rays at 200MU/min (2.04Gy/min). The absorbed dose was evaluated as for the battery. In addition, the scatter dose from the shielding block was considered. The pacemaker operation was evaluated from an intracardiac electrocardiogram and pacing output voltage according to the telemetry data through the programmer. The output wave was monitored by an oscilloscope (VC5430) during irradiation. In the case of change, the pacing output voltage was measured directly by a pacing system analyzer (PSA; 5311B). The data from the output voltage were compared between the programmer and direct measurement.

3. Results

3-1 Effect on lead wire and electrode

The intracardiac electrocardiograms before and during irradiation are shown in Figs. 2-a,b. In each case, the lower part of the graph is the intracardiac electro-cardiogram detected by the pacemaker and the middle part shows the operation of the pacemaker function. The pacemaker was set at DDD mode in the ICHD code classification. In the graph before irradiation, the pacemaker senses the sin² wave that replaced the imitation potential change of the heart muscle, pacing was carried out regularly after the sensing point, and pacing appeared in the electrocardiogram. There was no change in pacemaker operation during irradiation. The cumulative absorbed dose including all conditions was estimated at 72.7Gy. The pacemaker did not experience any abnormality, and even though beam, energy and dose rate were changed, the pacemaker parameters of pulse amplitude, pulse width and sensitivity did not change after each irradiation.

3-2 Effect on the battery

The relationships between absorbed dose, battery voltage and current are shown in Figs. 3-a, b.
One battery was irradiated up to 56Gy, and two were irradiated up to 236Gy; none of them showed any change in battery output voltage or current.

3-3 Effect on the electrical circuit

The intracardiac electrocardiograms at the beginning and end of irradiation are shown in Figs. 4-a, b. In Fig. 4-a, until the start of the irradiation, the pacemaker regularly sensed the $\sin^2$ wave and inhibited the production of a pacing pulse. The operation of the pacemaker changed immediately after the start of irradiation. During irradiation, the pacemaker reverted to a fixed-rate mode. In Fig. 4-b, the pacemaker reverted back to regular sensing immediately after irradiation stopped. These transient phenomena were generated in 5 of 6 pacemakers used in the experiment. The relationship between the absorbed dose and the pacing output voltage was measured directly from the pacemaker output terminal by the PSA as shown in Fig. 5. The pacing output voltage dropped at 30-88Gy, and the pacing output voltage change from the telemetry data through the programmer in the same circuit is shown in Fig. 6. In the programmer data, the pacing output voltage either rose or did not change. It was shown that the pacing output voltage drop in Fig. 5 could not be recognized through the programmer. There was a difference in the data between the actual pacing output voltage and the telemetry through the programmer, suggesting telemetry function defects.

4. Discussion

Some reports of EMI through the lead wire were observed in past research. However,
there was no influence on the operation of the pacemaker in this study, even when 6 and 10MV X-rays at 200-400MU/min (2.05-4.11Gy/min) and 6, 12 and 20MeV electrons at 600-900 MU/min (5.81-8.87Gy/min), respectively, irradiated the lead wire and electrode. Regarding battery irradiation, there was a report that output voltage dropped due to X-ray irradiation to the pacemaker\textsuperscript{13}. However, the whole pacemaker, including the circuit, was irradiated in that report. In the present study, the battery was detached from the pacemaker, and the change in battery output voltage and current was examined using 10MV X-ray irradiation. However, there was no change in the operation of the pacemaker up to the 236Gy accumulated dose. In the case of circuit irradiation, the pacemaker reverted to the fixed-rate mode immediately after the start of irradiation. The pacemaker is equipped with an EMI defense mechanism, and external noise is detected in the pacemaker. There was a slight noise of 23Hz frequency and 12mV amplitude in the intracardiac electrocardiogram under X-ray irradiation, as shown in Figs. 4-a, b. From this noise, it is considered that the EMI defense mechanism worked, although the pacing output voltage dropped at 30-88Gy of 10MV X-ray irradiation. The pacing output energy was calculated on the circuit irradiated up to 90Gy. The pacing output energy equation is given below.

\[
E = \left[ V_{\text{amp}} - \frac{1}{2} \cdot \frac{I_{\text{lead}} \cdot T_{\text{pw}}}{C_{\text{out}}} \right] \cdot I_{\text{lead}} \cdot T_{\text{pw}}
\]

\(E\) : Output Energy (\(\mu J\)),
\(V_{\text{amp}}\) : Pulse Amplitude (V),
\(I_{\text{lead}}\) : Lead Current (mA),
\(T_{\text{pw}}\) : Pulse Width (ms),
\(C_{\text{out}}\) : Condenser Capacity (\(\mu F\))

The pacing pulse waveform is shown in Fig. 7. As a result of the calculation, the output of circuit No.1 fell from 5.8 \(\mu J\) to 2.1 \(\mu J\) at 36% of the output energy setting. The output of circuit No.6 fell from 10.8 \(\mu J\) to 4.6 \(\mu J\) at 42% of the...
output setting. Generally, when a pacemaker is implanted, the detection threshold of the pacing output voltage is set at 2-3 times the myocardial contraction generated by the minimum energy. That is to say, the stimulation to the heart muscle by the pacing output voltage becomes inadequate, and may induce cardiac arrest, when there is no self-pulse. In addition, the output voltage drop was not recognized in the telemetry data by the programmer. The irradiation also seemed to affect the measuring circuit of the pacemaker, and it was shown that the reliability of the telemetry data was lost.

5. Conclusions
a) The lead wire and electrode were irradiated with 6 and 10MV X-rays at 200-400MU/min (2.05-4.11Gy/min) and 6, 12 and 20MeV electrons at 600-900MU/min (5.81-8.87Gy/min). There was no change in the pacemaker function under irradiation.

b) Battery was detached from the pacemaker and irradiated with 10MV X-rays up to 236Gy; however, there was no change in the output voltage or current.

c) The pacemaker operation changed immediately after the start of irradiation in the pacemaker fixed-rate mode, when the circuit was irradiated with X-rays. It returned to normal operation after the irradiation was stopped.

d) The pacing output dropped at 30-88Gy, when the circuit was irradiated with X-rays.

e) There was a difference between the communication data of the programmer and the measured data of the output terminal. It was considered that malfunctions occurred in the telemetry of the pacemaker.

f) It follows from what has been said thus far that irradiation to the circuit leads to damage of the pacemaker. Thus, in radiotherapy treatment of lung and breast, etc. in which irradiation is necessary near the implanted pacemaker, radiation shielding for the electrical circuit should be considered.

Acknowledgements
This research was partially founded by a Miyazaki Medical College consignment study. This work was published in the proceedings of the 82nd conference of Japan Society of Medical Physics, and received an encouragement prize.

References


3) Venselaar JLM: The effects of ionizing radiation on eight cardiac pacemakers and the influence


