The test phantom for implantable medical device to estimate the impact from RF EMF

Kohjiroh Ohshita[1], Yoshiaki Tarusawa[1], Shinji Uebayashi[1], Toshio Nojima[2]
[1]Wireless Laboratories, NTT DoCoMo, Inc., Japan
[2]Division of Electronics and infomation Engineering, Hokkaido University, Japan
E-mail: ohshita@mlab.yrp.nttdocomo.co.jp

Abstract: This paper compares head-shaped phantom to a flat phantom that is used in electromagnetic interference tests for implantable medical devices. A cochlear implant which is used as the implantable medical device in the test, is implanted near the skin of a head subcutaneously in the ear. In an RF EMI test of the cochlear implant, we can use the flat phantom instead of the head-shaped phantom. The results of actual EMI testing of the cochlear implant show that there is no difference in the maximum interference distance. The measurement and calculation results show that there is no difference in the E-field strength near the skin when comparing the flat and head-shaped phantoms. This paper presents the validity of using the flat phantom in EMI tests of implantable medical devices, which are implanted near the skin subcutaneously.

Key words: phantom, implantable medical device, electromagnetic interference test, cochlear implant

1. Background

In December 1995, an electric medical equipment study group was established in Japan to consider the impact of EMI from cellular phones on pacemakers. The group subsequently tested 228 different types of pacemaker used in Japan. Based on the results gathered, the study group issued, in March 1997, guidelines on the use of cellular phones by pacemaker patients [1], [2]. A cochlear implant, an implantable medical device, is similar to a cardiac pacemaker in that it is subcutaneously implanted. In daily life, a patient with a cochlear implant may come in close proximity to cellular phones. Therefore, the estimation of cochlear implant RF EMI is needed, as well as that for implantable cardiac pacemakers. A phantom shaped in the realistic body or head is considered in the construction of the EMI test system. However, using a simple-form phantom is more desirable than using a realistic-form phantom in the EMI test, in order to increase the repeatability of the results. In this paper, a flat phantom is compared to a head-shaped phantom based on EMI testing of a cochlear implant, and measurement and calculation of the E-filed strength in the phantoms. Based on these results, the validity of using a flat phantom as simple-form phantom in the EMI test for the cochlear implant is verified.

2. Experiment

2.1 EMI test of cochlear implant

The EMI test on the cochlear implant is performed using flat and head-shaped phantoms. These phantoms consist of two kinds of tanks filled with the physiological saline. The cochlear implant consists of three parts: the Cochlear Implant (CI), the Sound Processor (SP), and the Head Piece (HP). Figure 1 is a picture of the cochlear implant. Figure 2 is the EMI test system for the cochlear implant. An CI is placed into each phantom and fixed to the external HP by a magnet. External sounds are received by the SP through the CI. Generated signals from the CI are received by a digital oscilloscope through an electrode placed inside of the phantom. Signal waveforms are observed using the digital oscilloscope and the existence of interference is observed. Four kinds of transmitting signal (pattern A, B, C, and D) are used in this test. Table 1 shows the parameters for each transmitting signal. A $\lambda/2$ dipole antenna is used as the exposure source. Initially, the dipole antenna is set a distance away from the phantom and is gradually brought closer to the phantom. In this

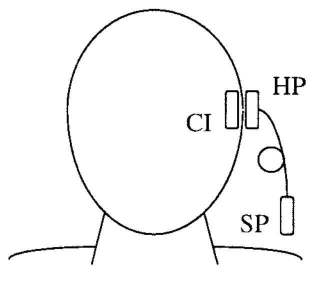


Fig. 1 Cochlear implant

Table 1. Transmitting Signal Parameters

	Pattern A	Pattern B	Pattern C	Pattern D
Frequency band	800 MHz	1.5 GHz	1.9 GHz	2.0 GHz
Antenna power	2.0 W	2.0 W	4.0 W	250 mW
Modulation	π /4 shift QPSK	π /4 shift QPSK	π /4 shift QPSK	Direct spread

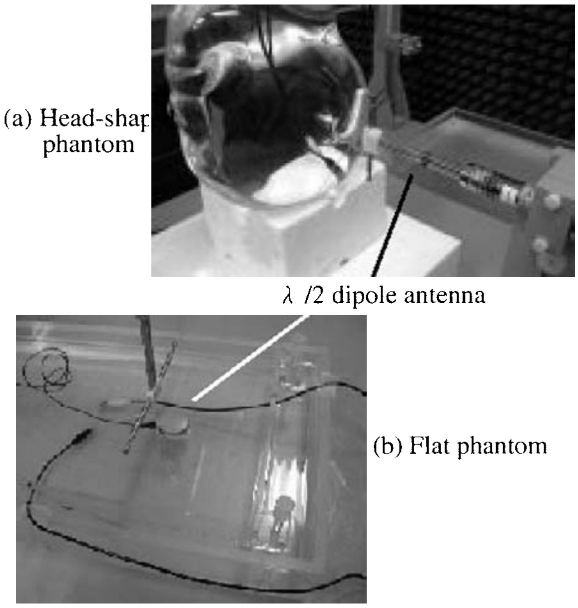


Fig. 2 EMI test system of cochlear implant

way, the distance at which interference is detected can be measured. The farthest point from the cochlear implant at which interference is detected is called the maximum interference distance. The maximum interference distance for each pattern is given in a table 2. There is no difference in the maximum interference distance based on the two phantoms.

2.2 Measurement of E-field strength in phantoms

Each electric field distribution in the two phantoms is measured using an electro- optic field probe. The diameter of the probe head is 10 mm. A dipole antenna is fixed to a point 20 mm from the internal surface of the phantom. The RF exposure wave is a continuous wave, and the employed frequency bands are 900 MHz, 1.5 GHz, 2.0 GHz, and 2.4 GHz. Figure 3 is the measurement system for the flat and head-shaped phantoms. Figure 4 shows the distribution of E-fields in phantoms. The E-field is strong along the long axis of the dipole antenna and the distribution tendencies are similar. Figure 5 shows changes in the E-field strength based on distance across the axis of the antenna. The E-field strength value in the graph is a relative value based on the maximum value in the flat phantom. In the range from 30 to 50 mm, the E-field strengths are almost equal. On the opposite side of the antenna, reflection influenced the E-field strength causing a discrepancy between the two phantoms.

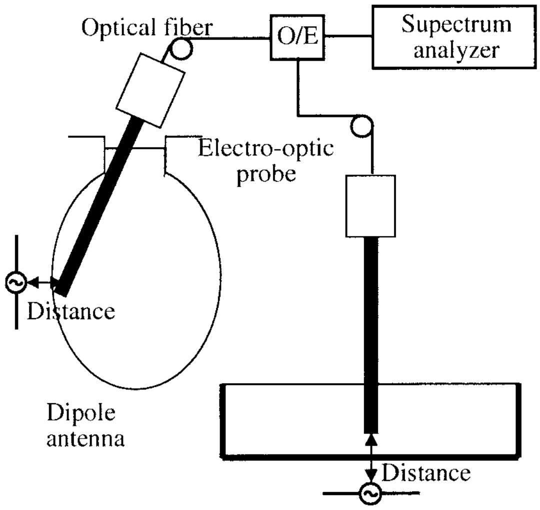


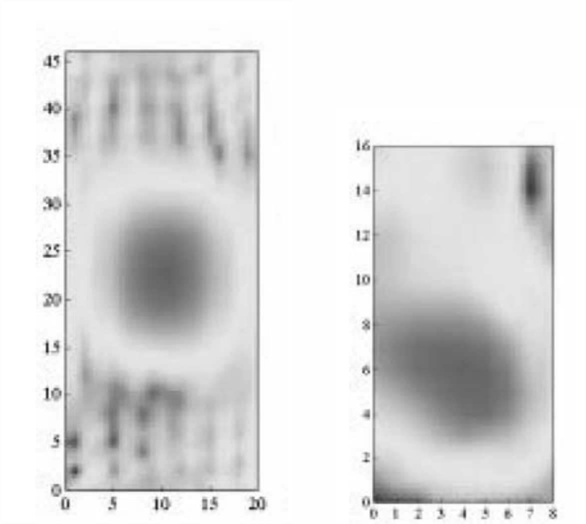
Fig. 3 Measurement system of E-field distribution in phantom

2.3 Calculation of E-field strength in phantoms

The E-field strength of the inside and the outside of the phantoms are calculated using the FDTD method to investigate E-field strength adjacent to the skin. The employed frequency bands are the same as those used above. The cochlear implant is constructed such that there is a subcutaneous part and an external part. Interference may occur not

Table 2. Maximum Interference Distance of Cochlear Implant

	Pattern A	Pattern B	Pattern C	Pattern D
Head-shaped phantom	1 cm	No effect	1 cm	No effect
Flat phantom	1 cm	1 cm	1 cm	No effect



(a) Flat phantom (b) Head-shaped phantom

Fig. 4 E-field distribution for phantom (900MHz-band)

only in regard to the CI, but also to the HP and SP. The E-field from the dipole antenna to the phantom is calculated in order to investigate the influence of the phantom form. Figure 6 shows the difference between the calculated value of the flat phantom and that of the head-shaped phantom. The E-field strength values in the graph are relative values based on the values at the inner surface of the flat phantom. There is no difference between the E-field strength of the flat phantom and that of the head-shaped phantom near the cochlear implant. The tendency of the calculation results is the same as that of the measurement results.

3. Conclusions

This paper verified the use of a flat phantom in a car-

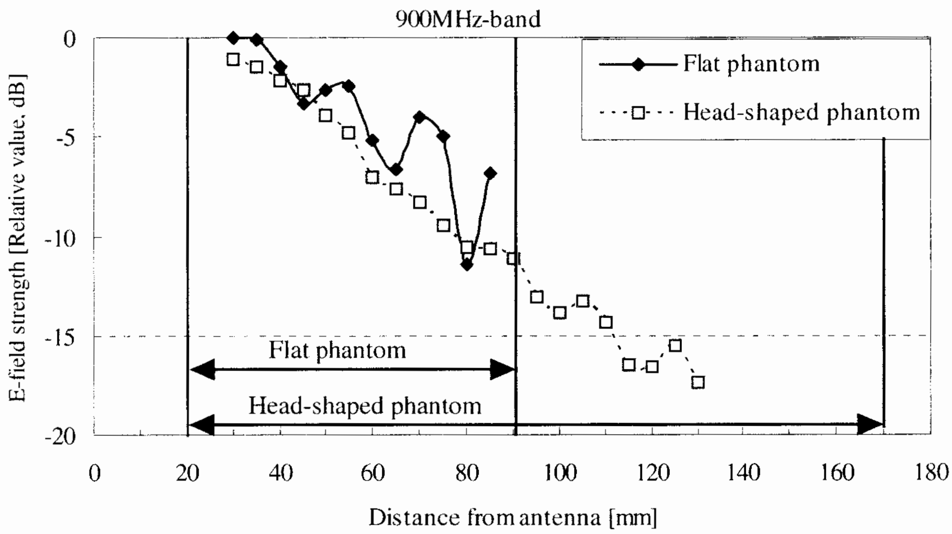


Fig. 5 Comparison of E-field strength in phantoms (Measured value)

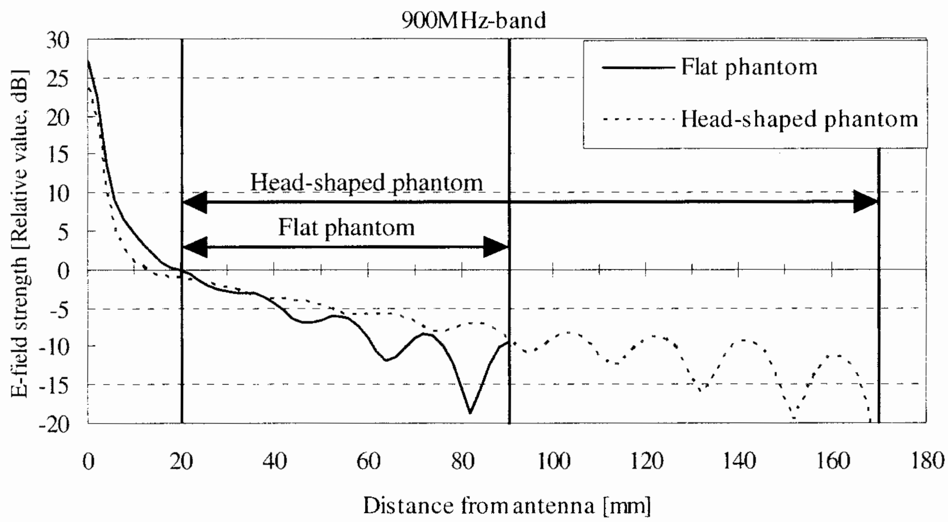


Fig. 6 Comparison of E-field strength in phantoms (Calculated value)

diac pacemaker interference test using other implantable medical devices. The cochlear implant was used as the implantable medical devices in the EMI test using two phantoms: a flat phantom and head-shaped phantom. The maximum interference distances using each phantom were almost equal. No difference was found between the measured and calculated results for the E-field strength near the cochlear implant. At a distance from the cochlear implant, the difference in E-field strength between the measured value and calculated value becomes large since the thicknesses of the phantoms were different. Based on these results, it is possible to use a flat phantom in the EMI test of various implantable medical devices, which are subcutaneously implanted.

Acknowledgement

The authors thank Mr. Kaoru Shibamoto (GETZ BROS. CO., LTD) for his support on the cochlear implant

References

[1]EMC Conference Japan, Electromagnetic Medical Equipment Study Group, "Guidelines on the Use of Radio Communication Equipment such as cellular Telephones-Safeguards for Electronic Medical Equipment", 1997.

[2]K. Toyoshima, M. Tumura, T. Nojima, Y. Tarusawa, "Electromagnetic interference of implantable cardiac pacemaker by portable telephones," Jpn J Cardiac Pacing Electrophysiol, 1996, 12, p. 488-497