

ORIGINAL RESEARCH ARTICLE

Clinical evaluation of microwave breast imaging using scattering tomography

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Abstract

Microwave imaging has attracted increasing attention as a breast tumor detection modality because it is non-ionizing and poses minimal risk to the human body. In particular, microwave tomography, which is based on solving the inverse scattering problem, enables visualization of the internal structure of tissues and is therefore expected to have a significant clinical potential. However, the practical implementation of microwave tomography has been hindered by the extremely small scattered-field variations produced by small malignant lesions within lossy breast tissue, as well as unavoidable modeling errors in numerical simulations of the human body and the imaging system. In this study, we introduce a clinically operable microwave breast imaging device that incorporates two key innovations: (i) A highly sensitive dual-polarized antenna array designed to enhance the detectability of weak scattered fields, and (ii) a robust inversion algorithm capable of reconstructing permittivity distributions under substantial modeling and measurement uncertainties. After outlining the relevant electromagnetic properties of breast tissue, we describe how these integrated hardware and software innovations overcome the limitations that have prevented earlier systems from achieving clinical performance. Finally, we summarize clinical results obtained from 24 breast tumor patients. The prototype achieved a sensitivity of 58%, surpassing that of X-ray mammography (40%) in the same cohort, demonstrating the practical potential of our innovation-driven approach to microwave breast imaging.

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1. Introduction

Microwaves can penetrate various dielectric materials and can “see” objects that cannot be detected by optical or acoustic means.¹ In recent years, substantial research and development efforts have been devoted to the application of microwave imaging technology in medical imaging diagnosis.²⁻⁴ The main motivation is that microwave radiation at power levels below 1 W is generally considered safe for the human body, whereas X-ray-based imaging increases the risk of cancer development due to radiation exposure.

In parallel, deep learning-based lesion analysis has also progressed in other medical imaging modalities such as magnetic resonance imaging (MRI).⁵ Recent review articles have highlighted a global trend toward the development of emerging non-ionizing and patient-friendly imaging technologies for breast tumor diagnosis, including optical, photoacoustic, and hyperspectral techniques, reflecting the need for alternatives that can complement conventional mammography and MRI.⁶

Breast cancer is the most common cancer among women, with approximately 95,000 new cases reported annually in Japan.⁷ Early detection and timely treatment are crucial for improving patient outcomes, and X-ray mammography screening is currently recommended for women aged 40 years and older in Japan. At present, X-ray mammography is the only diagnostic device with confirmed evidence of reducing breast cancer mortality. However, several limitations have been identified, including reduced sensitivity in dense breast tissue, X-ray exposure, and pain during screening.⁸ In response to these concerns, the Ministry of Health, Labor and Welfare of Japan published evaluation guidelines in June 2022 for novel diagnostic devices — including microwave imaging — within the framework of the “Evaluation Index for Breast Cancer Diagnostic Support Devices.” Microwave imaging has the potential to complement mammography and ultrasound by providing non-ionizing, contrast-sensitive information that reflects the intrinsic dielectric properties of breast tissue.

The basic principle of microwave imaging is detecting electromagnetic-wave scattering at tissue boundaries. The greater the difference in the relative permittivity or electrical conductivity of the two tissues on either side of the boundary, the stronger the scattered waves. In general, malignant tumors are characterized by increased vascularization, leading to higher relative permittivity and electrical conductivity compared with surrounding normal tissues.^{9–11} Previous studies measured the complex dielectric constant of excised cancerous, glandular, and fatty breast tissue using a probe method¹² and reported a higher dielectric constant and electrical conductivity in cancerous tissue than in normal breast tissue.¹³

Confocal imaging is a method used to depict the intensity distribution of scattered waves. Although its underlying principle is simple, the method is limited because multiple reflections occur in tissues with complex structures, which impedes accurate reconstruction.¹⁴ In contrast, scattering tomography, which is based on solving the inverse scattering problem, can depict the internal structure of complex tissues and is therefore expected to have strong potential for practical diagnostic applications. The inverse scattering problem is inherently nonlinear; however, using the Born approximation, the relationship between the

scattered field b at the observation point and the complex permittivity distribution x in the image reconstruction region can be linearized and expressed as $Ax = b$.^{15,16} The image reconstruction region and the antenna used can be modeled as a collection of small polyhedrons (voxels). Through electromagnetic field analysis, the coefficient matrix A and the scattered field b can be calculated for the situation in which the image reconstruction area is irradiated with radio waves and the scattered field is observed outside the area. Therefore, theoretically, the complex permittivity distribution x can be obtained by replacing the calculated scattered field b with the actually measured scattered field b' . When imaging the biological tissue, the change in the scattered field caused by a small lesion present in the tissue of a lossy medium is small,¹⁷ and a highly sensitive antenna that can stably detect this change is required. In addition, if there is an error in the coefficient matrix A or the measured value b' in the inverse scattering problem, a solution that is significantly different from the true solution will be calculated (this is called an ill-conditioned problem).^{18,19} It is impossible to accurately provide the parameters required for electromagnetic field analysis, such as the shape and electrical properties of the antenna, connector, cable, support mechanism, and biological tissue. Even if the calculation accuracy is improved by making the voxels finer at the expense of calculation cost (memory and calculation time), it is difficult to obtain analysis results that completely match the experimental results. The difficulty of the inverse scattering problem is that a small change in the scattered field must be treated in the presence of analysis error.

In this paper, we first compare the relative permittivity and conductivity of breast tumor and normal breast tissue based on the measurements obtained from 201 cases. We then describe a clinical imaging device equipped with a highly sensitive antenna-based imaging sensor and a calibration technique designed to incorporate the experimental results into the image reconstruction. Finally, we present representative reconstructed images from the imaging results of 24 breast tumor patients and summarize the overall imaging results. This paper includes Appendices A and B at the end, which provide simple explanations of technical terms and formulas for readers without an engineering background.

2. Relative permittivity and conductivity of breast tissue

We have measured the complex permittivity of breast tissues excised during breast tumor surgery to investigate whether the complex permittivity (relative permittivity and conductivity) varies according to the pathological type of tumor. In an earlier study,²⁰ we analyzed complex permittivity of tissue samples from 140 cases of breast

tumor, and showed that the average contrast in the complex permittivity of fibroadenoma (benign tumor) and glandular tissue was small, whereas the average contrast in the complex permittivity of invasive ductal carcinoma and glandular tissue was 17%, and the complex permittivity of normal breast tissue exceeded that of cancerous tissue in 12% of scirrhous carcinoma cases. In the same study,²⁰ these measurements were reported at 1.6 GHz, assuming the use of an imaging sensor based on a folded quasi self-complementary antenna.²¹ In the present paper, we improve data reliability by including 60 additional patients and report measurements at 1.9 GHz, corresponding to the frequency used in the prototype of the clinical imaging device.

2.1. Measurement samples

The pathological distribution of the 201 breast tumor patients is shown in Table 1. The most common type was invasive ductal carcinoma of the scirrhous type, followed by solid ductal carcinoma; together, these two types accounted for approximately three-quarters of all cases. Malignant tumors were observed to develop from the 30s and are distributed across all age groups, with peaks in the 40s and 70s. In contrast, benign tumors developed from the teenager years, and no cases were reported in individuals in their 50s.

2.2. Measurement results

Table 2 shows the relative permittivity and conductivity of breast tissue measured at 1.9 GHz using the probe method. The results are largely consistent with those reported in previous studies.²⁰ Because the tumor originates

from the breast, the contrast in relative permittivity and conductivity between cancerous and normal breast tissue is relatively small, while the contrast with adipose tissue is large. Mucinous cancer and phyllodes tumor exhibit higher relative permittivity and conductivity compared with other tumor types.

Table 3 summarizes the characteristics of glandular and fatty tissue by age group, including measurements of dielectric constant and electrical conductivity. Mammary gland density was determined from X-ray mammography images. High-density mammary glands are common up to 40 years of age, after which glandular tissue becomes increasingly scattered. Consequently, the dielectric constant and electrical conductivity of mammary glands decrease with age. In contrast, the dielectric constant and electrical conductivity of adipose tissue are not affected by age and are considerably lower than those of cancerous and glandular tissues. These dielectric parameters are essential for constructing realistic simulation models and for defining the contrast distribution $\tau(r')$ used in the reconstruction algorithm described in Section 3.

3. Reconstruction of permittivity and conductivity distributions by scattering tomography

3.1. Principles and issues of scattering tomography

As shown in Figure 1, when an electromagnetic wave is incident on an object, the scattered electric field $E(r)$ observed at position r can be expressed as:

Table 1. Pathological classification and distribution of 201 breast tumor patients

Age	10	20	30	40	50	60	70	80	90	Total
Number of persons	2	2	11	48	27	32	55	20	4	201
Pathology type										
Invasive ductal carcinoma, scirrhous carcinoma	–	–	7	19	13	13	27	7	2	88
Invasive ductal carcinoma, solid tubular carcinoma	–	–	1	12	10	10	20	8	2	63
Invasive ductal carcinoma, mucinous carcinoma	–	–	–	4	2	3	1	3	–	13
Invasive ductal carcinoma, tubule forming	–	–	1	2	1	2	3	1	–	10
Malignant phyllodes tumor	–	–	–	2	1	2	–	–	–	5
Invasive lobular carcinoma	–	–	–	2	–	1	1	1	–	5
DCIS	–	–	–	1	–	–	1	–	–	2
Invasive ductal carcinoma, papillotubular carcinoma	–	–	–	–	–	1	–	–	–	1
Invasive ductal carcinoma, medullary features	–	–	–	–	–	–	1	–	–	1
No residual cancer, post-chemotherapeutic status	–	–	1	–	–	–	1	–	–	2
Fibroadenoma	2	2	1	2	–	–	–	–	–	7
Benign phyllodes tumor	–	–	–	2	–	–	–	–	–	2
ADH	–	–	–	1	–	–	–	–	–	1

Abbreviations: ADH: Atypical ductal hyperplasia; DCIS: Ductal carcinoma *in situ*.

Table 2. Relative permittivity and conductivity of breast tissue at 1.9 GHz

Pathology	Tumor				Mammary gland				Fat						
	Number of samples	Permittivity		Conductivity		Number of samples	Permittivity		Conductivity		Number of samples	Permittivity		Conductivity	
		Average	Standard deviation	Average	Standard deviation		Average	Standard deviation	Average	Standard deviation		Average	Standard deviation	Average	Standard deviation
Invasive ductal carcinoma, scirrhous carcinoma	76	58.84	5.998	1.624	0.1823	57	52.115	12.035	1.445	0.343	76	9.686	4.481	0.2438	0.1399
	54	58.66	6.246	1.604	0.1806	30	50.217	14.498	1.399	0.4106	53	9.618	4.069	0.2485	0.1296
	12	64.8	5.32	1.759	0.1056	8	48.463	15.32	1.363	0.4685	11	8.313	3.54	0.2043	0.1104
Invasive ductal carcinoma, mucinous carcinoma	9	59.46	4.003	1.584	0.1724	6	46.37	9.718	1.26	0.2869	10	9.036	5.465	0.2222	0.1804
Invasive lobular carcinoma	5	60	3.909	1.68	0.0979	5	46.812	17.517	1.31	0.4908	5	11.7	4.346	0.3296	0.1342
Malignant phyllodes tumor	4	65.64	7.349	1.747	0.2403	1	61.8138	–	1.707	–	3	11.09	4.466	0.2725	0.1224
Invasive ductal carcinoma, medullary features	1	58.798	–	1.6342	–	1	39.093	–	1.106	–	1	22.903	–	0.68637	–
Invasive ductal carcinoma, papillotubular carcinoma	1	45.57	–	1.3355	–	1	14.867	–	0.41777	–	1	2.6671	–	0.028504	–
Invasive ductal carcinoma with osteoclast-like giant cells	1	58.62	–	1.668	–	1	56.481	–	1.6163	–	1	12.076	–	0.31241	–
Fibroadenoma	7	61.59	4.33	1.659	0.1235	4	60.42	5.27	1.71	0.1401	3	10.737	6.436	0.2528	0.1876
Benign phyllodes tumor	2	67.845	2.564	1.8325	0.2118	1	60.9598	–	1.4864	–	1	5.3258	–	0.0564	–
Invasive ductal carcinoma post-chemotherapeutic status	1	55.748	–	1.5685	–	0	–	–	–	–	1	27.248	–	0.81085	–

Table 3. Relative permittivity and conductivity of breast tissue at 1.9 GHz

Age	10	20	30	40	50	60	70	80	90	Total
Number of persons	2	2	11	48	27	32	55	20	4	201
Mammary gland										
Dense	–	2	11	41	14	7	9	–	–	84
Scattered	–	–	–	5	11	23	39	15	3	96
Fatty	–	–	–	–	–	2	3	4	–	9
No X-ray mammography	2			2	3		4	1	1	13
Number of glandular tissue	1	1	8	39	11	18	33	8	1	120
Permittivity										
Average	68.4658	60.9029	56.425	53.05	55.34	45.88	50.234	36.45	62.6	50.04
Standard deviation	–	–	4.12	12.82	9.18	14.6	12.29	14.91	–	13.3
Conductivity										
Average	1.9302	1.63	1.51625	1.472	1.542	1.267	1.402	1.009	1.73	1.414
Standard deviation	–	–	0.188	0.379	0.269	0.408	0.344	0.403	–	0.381
Number of fatty tissue	1	1	9	42	25	28	48	15	3	172
Permittivity										
Average	19.3205	9.0671	10.86	10.048	8.712	9.829	10.167	8.897	7.369	9.795
Standard deviation	–	–	4.452	4.802	3.004	4.831	5.486	3.647	3.194	4.755
Conductivity										
Average	0.5056	0.1966	0.2713	0.2568	0.2191	0.2542	0.2619	0.2154	0.171	0.249
Standard deviation	–	–	0.1419	0.149	0.0926	0.1538	0.1766	0.1192	0.0037	0.1504

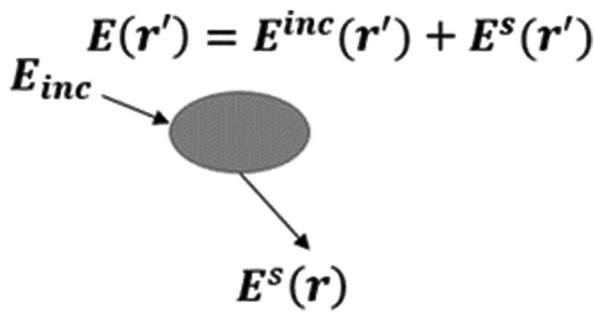


Figure 1. Incident, scattering, and total field

$$E^s(r) = \int_V \tau(r') E(r') G(r, r') dr' \quad (1)$$

$E(r')$ is the total field (the sum of the incident field $E^{inc}(r')$ and the scattered field $E^s(r')$) at the position r' in the region V , and $G(r, r')$ is the Green's function. $\tau(r')$ represents the contrast distribution within the region V . $\tau(r')$ function is defined as:

$$\tau(r') = (\epsilon_r(r') - \epsilon_r^b) \epsilon_0 + \frac{(\sigma(r') - \sigma^b)}{j\omega} \quad (2)$$

Where $\epsilon_r(r')$ and $\sigma(r')$ are the relative permittivity and conductivity distribution, respectively; ϵ_r^b and σ^b are the relative permittivity and conductivity of the image reconstruction region excluding the object, respectively; ϵ_0 is the permittivity of vacuum, and ω is the angular frequency.²²

Equation (1) represents a nonlinear problem because $E(r)$ appears both inside and outside the integral equation, making an analytical solution difficult. To address this, the Born approximation is applied,¹⁷ which assumes $E^s(r') \ll E^{inc}(r')$ and replaces $E(r')$ with $E^{inc}(r')$. Since the product $E^{inc}(r') G(r, r')$ can be acquired by computer simulation and $E^s(r)$ can be obtained by measurement or computer simulation, the contrast distribution $\tau(r')$ of the region can, in principle, be calculated from the observed scattered field $E^s(r)$. Accordingly, Equation (1) can be generally expressed in the form of:

$$b(r) = \int_V A(r, r') x(r') dr' \quad (3)$$

Where $x(r')$ represents the unknown complex permittivity distribution to be reconstructed, $A(r, r')$

models the electromagnetic interaction between each voxel and the antennas, and $b(r)$ denotes the measured scattered-field data. In an imaging system that uses the inverse scattering problem, both the object-containing region and the imaging system are modeled computationally, and Equation (3) is replaced with the following linear equation:

$$Ax = b \quad (4)$$

The matrix–vector representations are given by:

$$A = \begin{bmatrix} a_{11} & \cdots & a_{1N} \\ \vdots & \ddots & \vdots \\ a_{M1} & \cdots & a_{MN} \end{bmatrix}, x = \begin{bmatrix} x_1 \\ \vdots \\ x_N \end{bmatrix}, b = \begin{bmatrix} b_1 \\ \vdots \\ b_M \end{bmatrix}$$

An object is modeled as a set of N small polyhedrons. For example, if a breast with a volume of 150 cc is modeled as a hexahedron with a side length of 4 mm, the breast is composed of $N = \frac{150}{0.4^3} = 2344$ voxels. Each voxel has two unknown parameters, the permittivity and the conductivity, resulting in a total of 4688 unknowns. If the number of observation positions P is assumed to be 28, then the number of combinations of transmission and reception is $M = {}_{28}C_2 = 378$, which means that the number of unknowns is greater than the number of equations. In this case, we use prior knowledge, such as the possible range of x , to solve the problem using the least squares method.

In general, the Born approximation is invalid for living organisms. Therefore, an iterative update method is employed.¹⁶ That is, we differentiate Equation (4) with respect to x and transform it into

$$A'(x_{n+1} - x_n) = (b^{meas} - b_n) \quad (5)$$

Where when $n=0$, an initial estimate x_0 as the initial value is assigned, and b_0 is calculated from Equation (4). b^{meas} is the scattering response of the unknown object, and A' is the derivative of the coefficient matrix A with respect to x . From $\Delta x = x_{n+1} - x_n$ obtained from Equation (5), we update x as follows:

$$x_{n+1} = x_n + \Delta x \quad (6)$$

and use x_{n+1} to recalculate A and b and solve it repeatedly.

In inverse problems, if there is a non-negligible error in A or b , x will be a solution that deviates significantly from the true solution. Therefore, it is necessary to accurately reproduce the real-world phenomenon on a computer and accurately describe A and b . However, with current technology, it is not possible to accurately describe A without error, and the measured value b^{meas} also has measurement errors. Moreover, biological tissue is a highly lossy medium, and even the presence of small lesions produces subtle changes in the scattered field b and

b^{meas} , making it difficult to accurately detect the change by separating it from modeling and measurement errors.

Based on the above discussion, the technical requirements for realizing an imaging system that solves the inverse scattering problem can be summarized as follows:²³

- (i) Realizing a highly sensitive antenna that can detect slight changes in the observed electric field due to changes in the complex dielectric constant set for the voxel group within the image reconstruction area.
- (ii) Establishment of a reliable calibration method for measured data that takes into account the effects of antenna and breast models and measurement errors.

3.2. Solutions to the problems

Scattering tomography has the potential to reconstruct internal tissue structures in living bodies. However, the two problems in Section 3.1 remain unresolved, and consequently, only a limited number of studies have reported practical applications in academic journals.²⁴ To address these issues, we developed a technology for visualizing intramammary tissue structures.

To assist non-specialist readers, the main technical advantages of the proposed system are briefly summarized below. The dual-polarized dielectric-loaded horn antenna achieves more than ten times higher sensitivity than a conventional dipole, allowing the detection of the extremely small scattering variations produced by breast lesions. In addition, the reconstruction method incorporates multiple mechanisms to maintain robustness against modeling and measurement errors, including circuit-theory conversion of simulated S-parameters, the use of dual polarization to increase data diversity, and a two-phantom calibration to reduce systematic discrepancies between simulations and measurements.

3.3. Summary of technical innovations

- (i) Development of an image reconstruction program based on FEMTET–MATLAB integration
An image reconstruction program²⁵ was developed that links the commercial electromagnetic field analysis simulator FEMTET²⁶ with the numerical calculation software Matrix Laboratory (MATLAB).²⁷ This integration reduces modeling errors while ensuring the reliability of electromagnetic field analysis and improving the accuracy of the electromagnetic field analysis (A and b). Kuwahara²⁵ proposes a method to convert the S-parameters obtained from FEMTET analysis into b using circuit theory.²⁸ FEMTET supports data exchange with other software through Excel macros. In Kuwahara *et al.*,²⁵ the main program was written in MATLAB, and the macros were read

out via Visual Basic Scripting Edition. However, since Windows 10, this approach has become impractical because macros cannot be opened when accessed directly from MATLAB. The solution to this problem is described in Section 4.2.

(ii) Use of dual polarization²⁹

Accurate solution of Equation (4) requires sufficient diversity in the coefficient matrix. In general, closed-space antennas produce minor variations in the received response, which limits the diversity of the coefficient matrix. The change in the receiving response can be enhanced by increasing the antenna spacing. However, considering the decrease in the electric field at the receiving point and the increase in calculation costs due to the increase in the size of the imaging system, increasing the antenna spacing is not a practical solution. In order to obtain diverse responses when the antennas are placed close to each other, it is effective to change the polarization of the antennas and arrange them in different directions. Even with the antenna array of the same size, the number of conditions required to evaluate the diversity of the coefficient matrix is reduced by two orders of magnitude using two polarized waves, horizontal and vertical, and the diversity of the coefficient matrix is increased.

(iii) Discovery and application of a linear relationship between the dielectric constant and conductivity of breast tissue.³⁰

Measurements of the dielectric constant and conductivity of breast tumor, glandular, and fatty tissues excised during breast tumor surgery revealed a linear relationship between dielectric constant ϵ and conductivity σ of these tissues in the 1.5–2 GHz frequency band:

$$\sigma \sim 0.03\epsilon \quad (7)$$

$\sigma(r')$ is corrected based on the result of $\epsilon_r(r')$ so that $\epsilon_r(r')$ and $\sigma(r')$ constituting the updated x_{n+1} that remains consistent with Equation (7). Specifically, if $\sigma(r')$ falls outside the range from $0.02\epsilon_r(r')$ to $0.04\epsilon_r(r')$, it is corrected as

$$\sigma(r') = 0.03\epsilon_r(r') \quad (8)$$

(iv) Development of an imaging sensor using a dual-polarized dielectric-loaded horn antenna³¹

Compared with a half-wavelength dipole antenna, this design provides an order-of-magnitude improvement in sensitivity, thereby enhancing the accuracy of b^{meas} .

(v) Calibration of measurement data using two uniform phantoms³²

The specific procedure for calibration is described in Section 4.3.

4. Prototype

4.1. Hardware

Figure 2 shows an overview of the hardware for microwave imaging.¹⁴ Multiple antennas are placed around the imaging target. One antenna is selected to transmit microwaves toward the imaging target. The scattered microwaves are received by the remaining antennas. When a vector network analyzer (VNA) with one transmission and one reception port is used as a transmitter and receiver, transmission and reception are switched in a time series, and scattered signals are collected for all possible transmit–receive combinations. Images of the imaging target are reconstructed using the collected scattered signals.

The configuration of the prototype hardware is shown in Figure 3, and a photograph of the system is presented

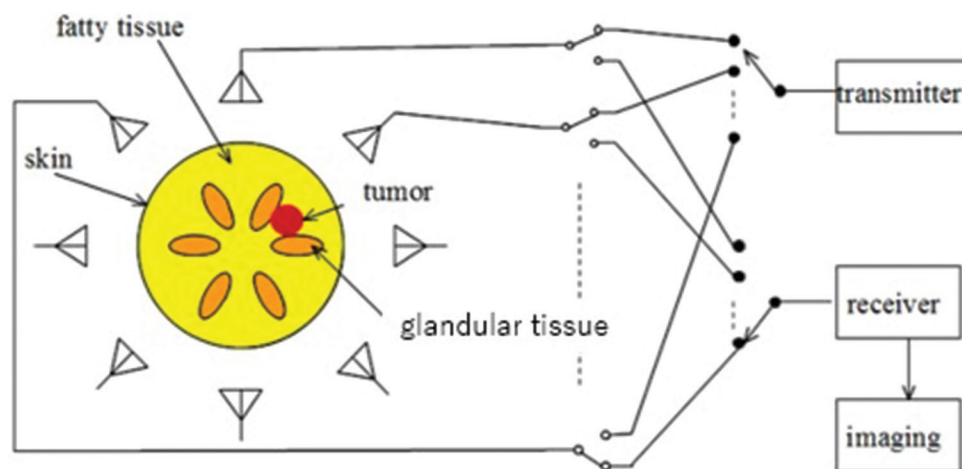


Figure 2. Principle of microwave imaging

in Figure 4. This device consists of a ceramic container that accommodates the breast, 16 antennas attached to the ceramic container (the ceramic container and antennas are collectively referred to as the imaging sensor), an antenna switch that sets the combination of transmitting and receiving antennas, a VNA (Keysight E5071C) for measuring the transmission characteristics (S-parameters) between the transmitting and receiving antennas, a laptop

computer with a measurement program installed, a control unit that properly connects the laptop computer with the antenna switch, and an aspirator to suction and fix the breast within the ceramic container. The imaging sensor and the antenna switch are housed inside the main body of the device. Since 12 of the antennas operate as dual-polarized antennas, the actual number of antennas is 28. The main body is placed next to the examination bed,

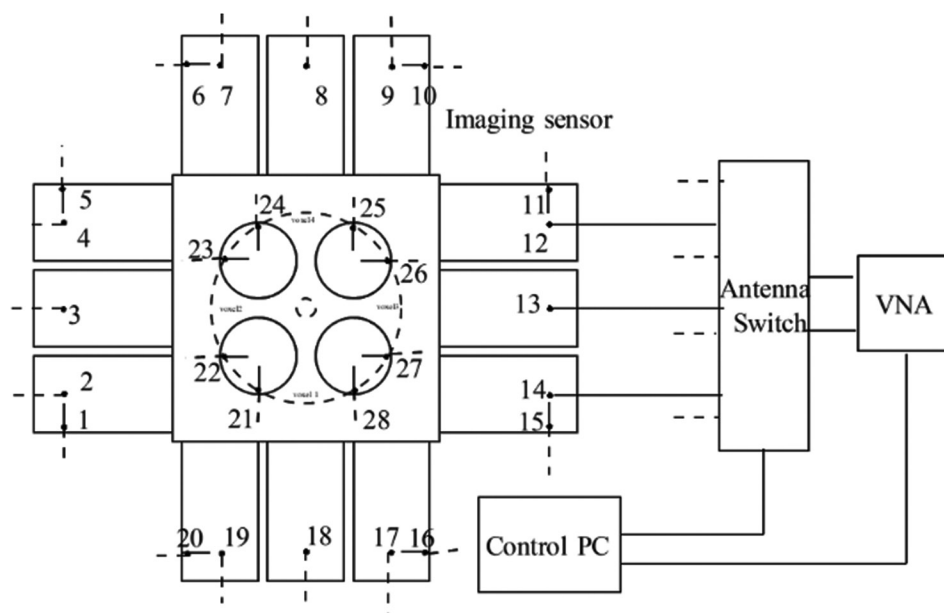


Figure 3. System configuration of the prototype
Abbreviations: PC: Personal computer; VNA: Vector network analyzer.

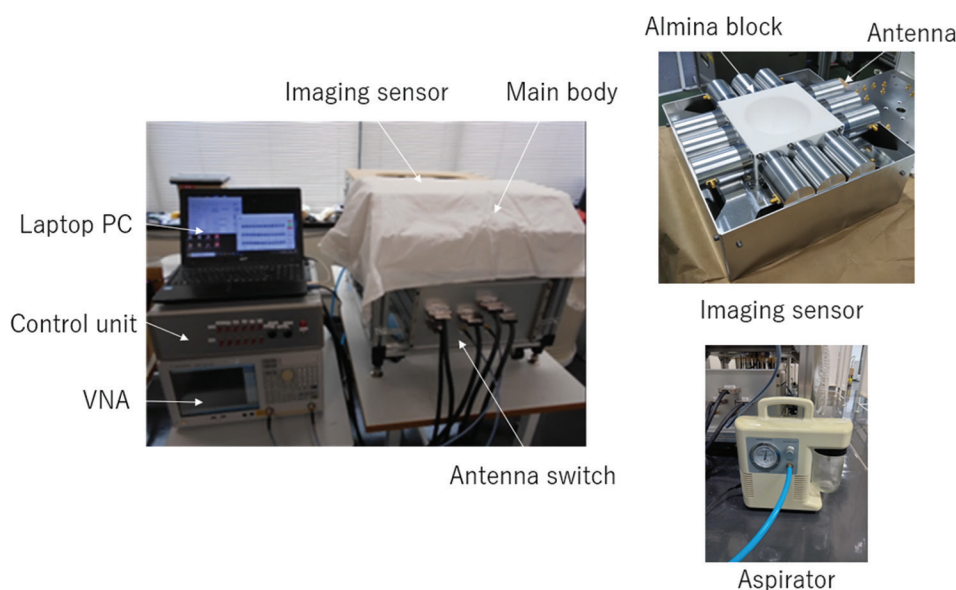


Figure 4. Photos of the prototype
Abbreviations: PC: Personal computer; VNA: Vector network analyzer.

and the patient lies face down and places her breast in the imaging sensor, as shown in Figure 5. To prevent imaging failure due to body movement, the breast is suctioned and fixed by an aspirator.³³ The transmitting antenna is selected, and microwaves with a frequency of 1.9 GHz and an output power of -5 dBm are emitted toward the breast. The S-parameters are measured by the VNA while switching between transmitting and receiving antennas, and the results are recorded on a laptop computer. This operation is repeated for all transmit–receive combinations, requiring approximately 12 min to measure one breast.

4.2. Software

Image reconstruction is performed on a separate workstation using the measurement files recorded on the laptop computer. The image reconstruction program is written in Excel Visual Basic for Applications and, as shown in Figure 6, operates in conjunction with FEMTET and MATLAB. The time required to reconstruct an image of one breast is about 7 h on a workstation equipped with a Core i7 14700K processor and 96 GB of RAM.

FEMTET is a finite element method-based electromagnetic field analysis software.³⁴ It is cost-effective, and when the analysis is performed at a single frequency, the calculation time is expected to decrease. It is also economical because it does not require a graphics processing unit. To avoid conflicts between Excel and MATLAB, the program shown in Figure 7³⁵ was developed. The processing steps are summarized as follows:

- (i) The initial complex permittivity distribution of the image reconstruction area and the measured scattering

parameters are written in advance to an Excel sheet for MATLAB.

- (ii) The complex permittivity distribution from Step (i) is transferred to an Excel macro for FEMTET, and electromagnetic field analysis is performed using FEMTET. The calculated scattering parameters and the electromagnetic field distribution within the image reconstruction area are written to an Excel macro for FEMTET.
- (iii) The scattering parameters and the electromagnetic field distribution of the image reconstruction area in Step (ii) are transferred to an Excel sheet for MATLAB.
- (iv) The image reconstruction MATLAB program is launched from an Excel macro.
- (v) The MATLAB program reads the data from the Excel sheet for MATLAB and computes the update vector.
- (vi) The complex permittivity distribution of the image reconstruction is written to an Excel sheet for MATLAB.
- (vii) Steps (ii) to (vi) are repeated for a predefined number of iterations.

4.3. Calibration procedure using two phantoms

A photo of the phantoms used is shown in Figure 8. The breast-shaped phantom (manufactured by Tanac Co., Ltd.) is made of urethane resin with an ion-conductive agent, graphite, and conductive filler. The relative permittivity and dielectric loss tangent of phantom 1 are 4.6275 and 0.2775 at 1.9 GHz, respectively, while those of phantom 2 are 6.4835 and 0.4383 at 1.9 GHz, respectively. To obtain calibration data with the prototype, a plate-shaped phantom (manufactured by AET) resembling a chest wall is placed on top of the imaging sensor containing the breast phantom, as shown in Figure 9. The relative permittivity and dielectric loss tangent of the plate-shaped phantom are

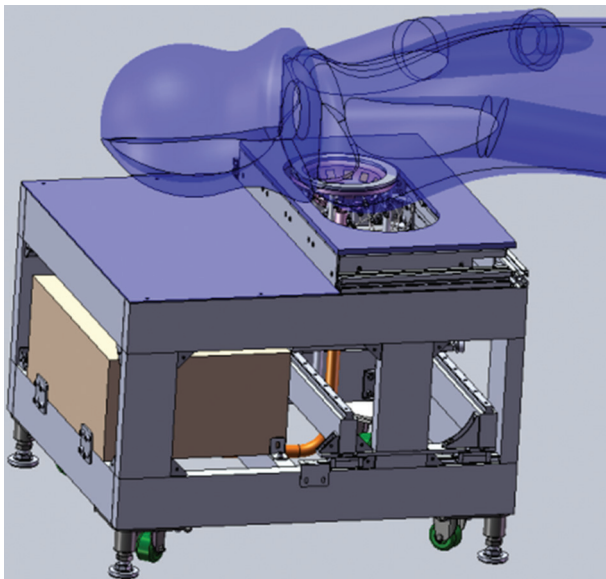


Figure 5. Imaging posture

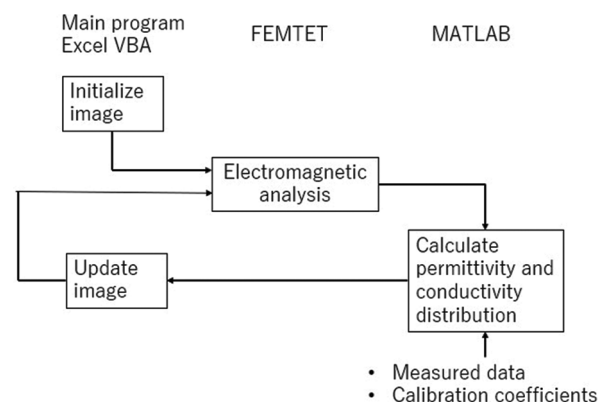
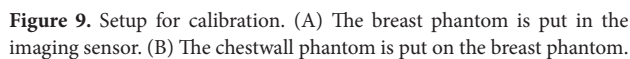


Figure 6. Image reconstruction flowchart

Abbreviations: MATLAB: Matrix laboratory; VBA: Visual Basic for Applications.



For image reconstruction, the relative permittivity and dielectric loss tangent of phantom 1 are set to the voxel group constituting the reconstruction region of the FEMTET model, as shown in Figure 10, and S_{ij}^{cal1} is calculated. Next, the relative permittivity and dielectric loss tangent of phantom 2 are set to the voxel group, and S_{ij}^{cal2} is calculated. The breast measurements S_{ij}^{meas} are corrected to $S_{i,j}$ using the following formula:³⁶

The correction coefficients are defined as:

and the values of S_{ij}^{exp2} at the specified frequency for all transmit–receive combinations are saved as calibration data files for use in the image reconstruction program.

The previous calibration method,²³ which used multiple semi-ellipsoidal breast-shaped phantoms, required selecting calibration coefficients from a database and was sensitive to measurement errors. The superiority of the two-phantom calibration method was verified through numerical simulations. As shown in Figure 11, the correlation between the calibrated scattering parameters and the expected values obtained from the numerical breast phantom becomes significantly higher (approaching 1), indicating a clear reduction in calibration error compared with the previous method using semi-ellipsoidal phantoms.²³ Because the two phantoms have uniform structures but different permittivity and conductivity, the proposed method allows accurate calibration with a simple procedure and provides excellent reproducibility.

The clinical imaging method is briefly explained with reference to [Figure 12](#), which shows the clinical imaging procedure.

- (i) A room large enough to accommodate the imaging equipment and bed is prepared. It is recommended

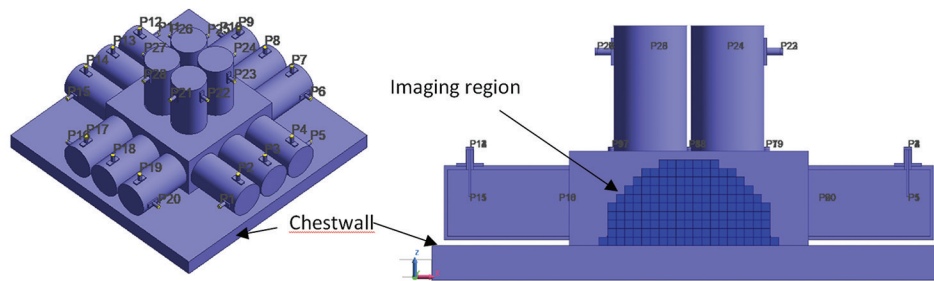


Figure 10. FEMTET model for imaging sensor and chestwall

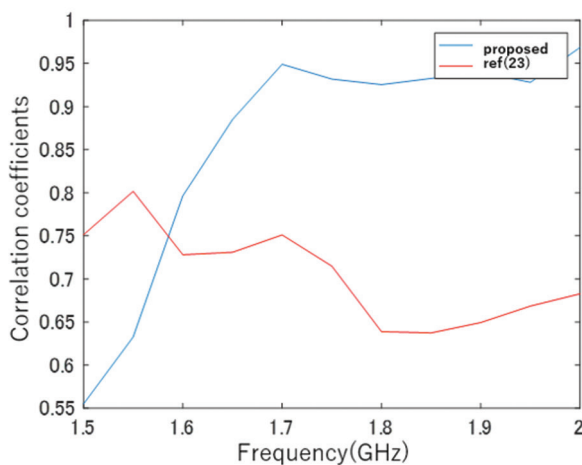


Figure 11. Advantages of the proposed calibration method

to use curtains or partitions around the bed to ensure patient privacy. The wiring between the main unit, VNA, controller, and laptop computer is connected. Then, the power is turned on.

- (ii) The measurement program on the laptop computer is started, and necessary parameters, such as the measurement frequency, frequency point, and response wait time, are entered.
- (iii) The patient lies face down on the bed. The patient's clothing is adjusted so that one breast can be placed in the imaging sensor, ensuring that no clothing is present within the sensor.
- (iv) The aspirator is turned on, and the breast is aspirated. The aspirator's reduced pressure is adjusted from 0.04 to 0.06 MPa.
- (v) If adequate negative pressure is not achieved, the subject's position is adjusted to obtain stable suction. If the breast is small, a gap may form between the sensor and the breast, preventing microwaves from entering the breast and making image reconstruction impossible. In this case, the imaging procedure is terminated.
- (vi) The measurement program is run. Once the measurement is complete, the results are saved on the laptop computer.

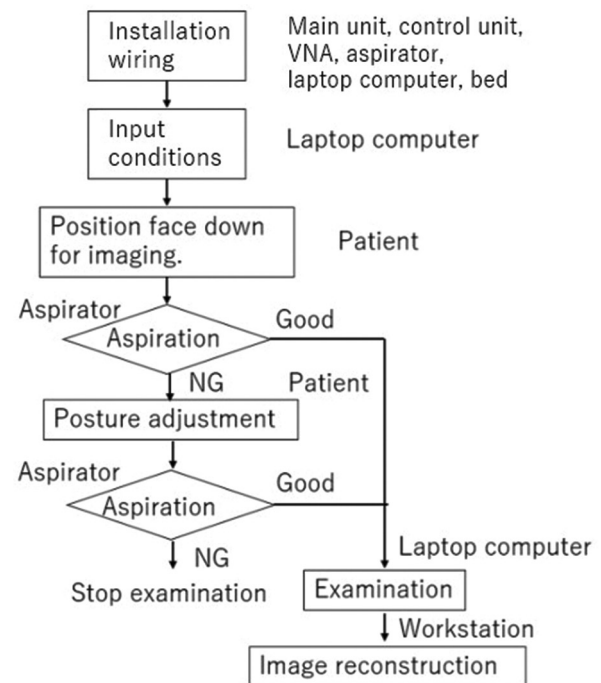


Figure 12. Procedures of clinical imaging

Abbreviations: NG: Not good; VNA: Vector network analyzer.

- (vii) The image is reconstructed on the workstation using the measurement results obtained in Step (vi).

5. Results and discussion

The imaging results for three subjects are presented here. Because MRI was not available for case A, the corresponding X-ray mammography image was used to confirm the tumor location. For cases in which MRI was available, the MRI image served as the clinical ground truth. The measurement conditions are shown in Table 4.

The first patient was a 78-year-old woman with a 34×21 mm cancer located at the 2 o'clock position of her left breast. The breast composition was predominantly fatty. Figure 13 shows the X-ray mammogram and the imaging results obtained with the prototype. The left side of

the reconstructed images shows the distribution of relative permittivity, while the right side represents conductivity. Areas of high permittivity and conductivity were observed in the left breast with cancer. However, no such areas of high permittivity or conductivity were observed in the right breast without cancer.

The second patient was a 36-year-old woman with a high-density breast and well-developed mammary glands.

Table 4. Conditions of the clinical imaging

Frequency	1.9 GHz
VNA IF bandwidth	1 kHz
VNA averaging	None
Sample waiting time	200 ms

Abbreviations: IF: Intermediate frequency; VNA: Vector network analyzer.

She had an early-stage cancer measuring 9×7.5 mm at the 6 o'clock position of her left breast. [Figure 14](#) shows the X-ray mammogram, contrast MRI images, and the imaging results obtained with the prototype. The presence of cancer was confirmed by contrast MRI; however, the detection of cancer by X-ray mammogram is challenging. In the reconstructed images from the prototype, areas of high permittivity and conductivity were observed in the left breast with cancer, while the cancer-free right breast showed no areas with significantly high permittivity or conductivity.

The third patient was a 77-year-old woman, and reconstructed images were obtained before and after preoperative chemotherapy. Before chemotherapy, she had a 22×16 mm cancer at the 2 o'clock position of her left breast. The mammary glands were scattered.

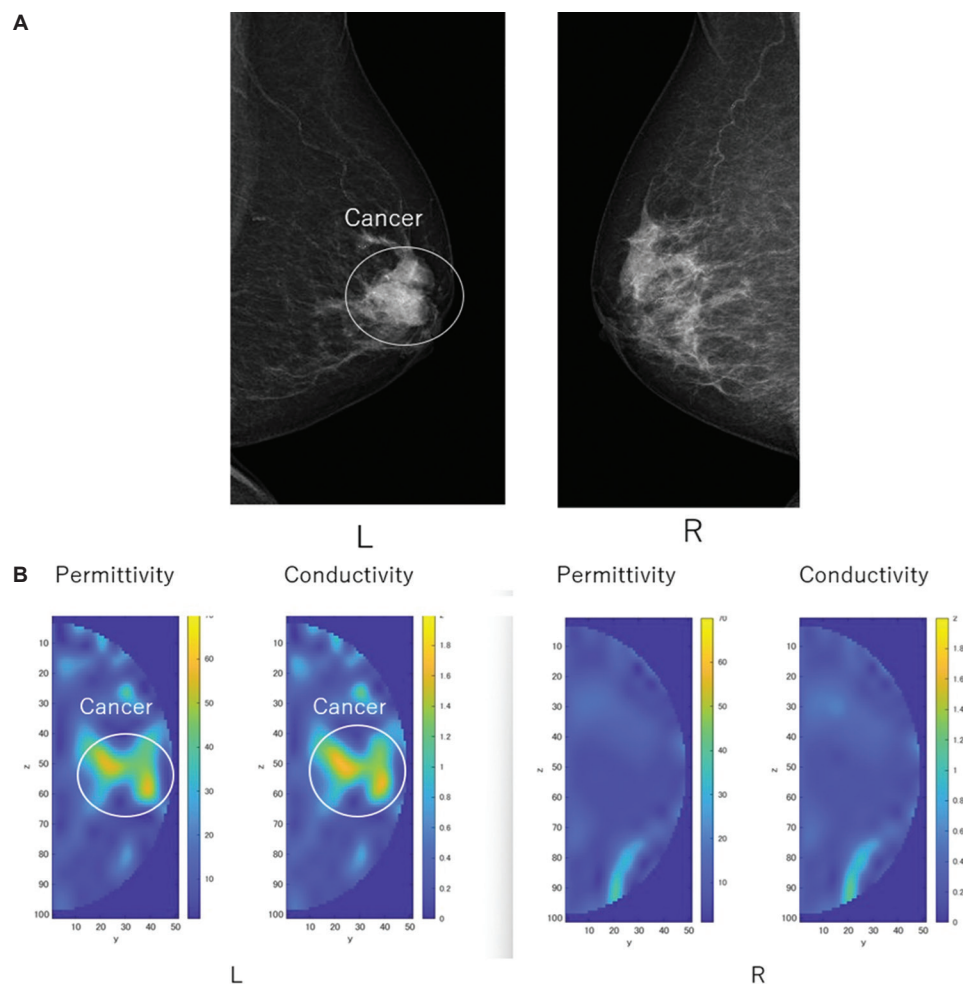


Figure 13. Imaging results of patient 1. (A) X-ray mammogram. Magnetic resonance imaging was not available for this patient; therefore, the tumor location was confirmed using X-ray mammography. (B) Imaging results obtained with the prototype. Abbreviations: L: Left; R: Right.

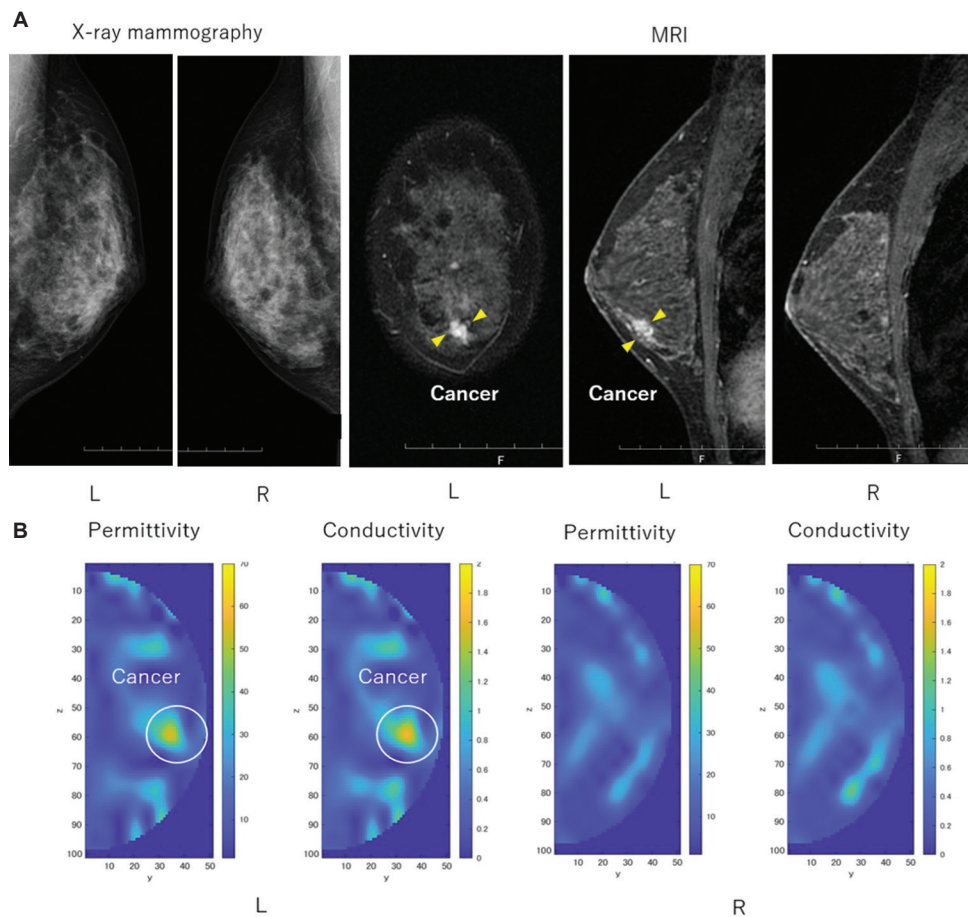


Figure 14. Imaging results of patient 2. (A) Imaging results obtained using X-ray mammograph and MRI. MRI was available and served as the clinical ground truth for tumor localization. (B) Imaging results obtained with the prototype. Abbreviations: L: Left; MRI: Magnetic resonance imaging; R: Right.

Figure 15 shows the contrast MRI image and the imaging results obtained using the prototype. Before preoperative chemotherapy, the presence of cancer near the nipple was confirmed on MRI. After preoperative chemotherapy, the cancer had disappeared on MRI. Similarly, the reconstructed images obtained using the prototype showed the disappearance of the high-permittivity and high-conductivity region, indicating that the tumor had resolved following preoperative chemotherapy.

Table 5 summarizes the imaging results of 24 patients. In the pathological classification shown in the table, M indicates mucinous carcinoma, F indicates fibroma (benign tumor), and D indicates invasive ductal carcinoma. Regarding glandular condition, D denotes dense breast, S denotes scattered glandular tissue, and F denotes fatty breast. Score A indicates a case in which a clear area of high permittivity and conductivity is observed around the tumor location estimated by MRI or X-ray mammogram, yielding a reconstructed image useful for diagnosis. Score B

indicates a case where a high permittivity and conductivity area is observed around tumor location. However, the contrast was weak and insufficient for confident tumor recognition. Score C indicates a case in which no area of high permittivity and conductivity was observed around the tumor location.

As shown in Table 5, the data are sorted in ascending order of tumor size. Smaller tumors are more difficult to diagnose correctly. The size of the scattered waves from breast tumors smaller than 5 mm that can be detected outside the body is extremely small, making detection difficult. In addition, the time required for image reconstruction increases exponentially as the resolution increases. For this reason, the resolution of the reconstructed image of this device is set to 5 mm. When the tumor size is smaller than 5 mm, the contrast in the reconstructed image becomes weak, making diagnosis challenging. Table 5 also lists diagnostic results for the 10 cases with X-ray mammography images. X-ray

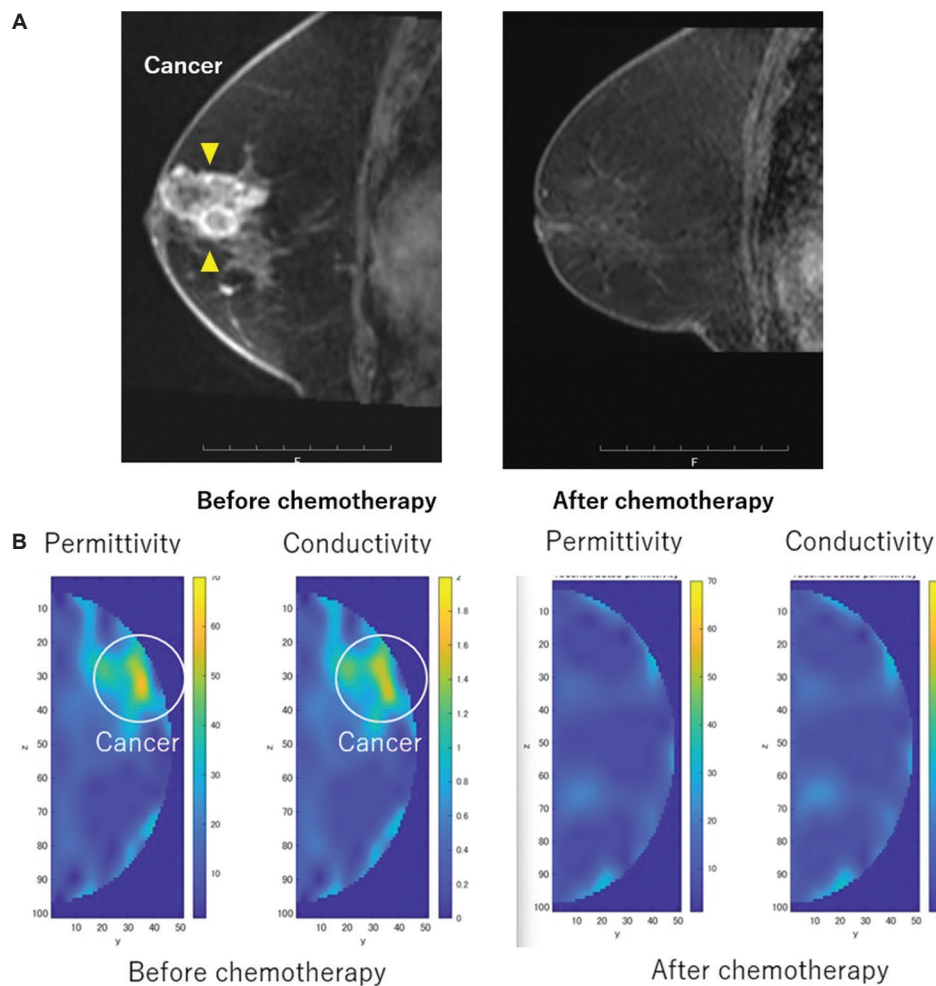


Figure 15. Imaging results of patient 3. (A) Imaging results obtained using MRI before and after chemotherapy. MRI was available and served as the clinical ground truth for tumor localization. (B) Imaging results obtained with the prototype before and after chemotherapy. Abbreviation: MRI: Magnetic resonance imaging.

mammography correctly detected tumors in four cases (true positives [TPs]) and failed to detect tumors in six cases (false negatives [FNs]), resulting in a sensitivity of 40%. Because only tumor-positive breasts were included in this study, specificity and other receiver operating characteristic (ROC)-based metrics could not be evaluated. The prototype demonstrated a diagnostic probability of 88% for tumors approximately 1 cm in diameter (0.5 cc in volume).

While MRI scans are acquired with the breast in a drooping position, this system deforms the breast into a hemisphere to fit the imaging sensor. As a result, there may be discrepancies between the location of the tumor in the MRI image and that in the reconstructed image by this system. The example shown in Figure 14 shows a cancer in high-density breast tissue. Because the lesion was close

to the skin and was a mucinous carcinoma with relatively high permittivity and conductivity, even a small early-stage cancer was successfully reconstructed. Thus, the diagnostic accuracy of this system appears to depend more strongly on tumor size than on breast density.

Because this preliminary clinical study included only tumor-positive breasts, a complete confusion matrix (TP, false positive, true negative, FN) and ROC curve could not be generated. In addition, false-positive regions within the reconstructed images were not systematically identified; therefore, positive predictive value, negative predictive value, and specificity could not be assessed. A future study including both tumor-positive and tumor-negative breasts will enable a full diagnostic performance evaluation and allow direct comparison with MRI and mammography using ROC analysis.

Table 5. Imaging results

No.	Age	Side	Clock position	Distance from chestwall (mm)	Tumor volume (cc)	Pathology	Breast density	Score	X-ray
9	56	R	2	28	0.03	D	S	C	
18	51	R	9		0.03	D	S	B	
15	69	R	7	16	0.04	D	F	B	
16	42	L	3		0.13	D	F	B	TP
4	60	R	8	63	0.2	D	S	B	FN
13	57	R	9	20	0.2	D	S	B	
1	36	L	6	23	0.3	M	D	A	FN
17	40	L	6	2	0.3	D	D	A	FN
24	77	R	9	32	0.3	D	F	B	
6	65	L	1	23	0.4	D	S	C	
19	44	R	11	6	0.5	D	D	A	
21	55	R	3	21	0.5	D	S	B	TP
3	52	L	12	49	1.1	D	D	A	
8	46	R	1	21	1.4	D	D	B	FN
14	44	L	10		1.5	F	D	A	FN
7	47	L	1	9	1.7	D	D	A	
11	72	L	5	19	1.8	D	S	A	
10	76	R	11	63	2.5	D	S	A	
12	77	L	2	32	2.8	D	S	A	
20	53	L	11		3	D	F	A	TP
5	69	R	10		4.6	D	D	A	FN
23	60	L	4	14	5	D	S	A	
22	53	L	10	5	9.2	D	S	A	
2	78	L	2		12	D	F	A	TP

Notes: Score A indicates clear high-permittivity and high-conductivity region at the tumor site (diagnostically useful). Score B indicates high-permittivity and high-conductivity region present at the tumor site but weak contrast (difficult to confirm). Score C indicates no high-permittivity or high-conductivity region observed at the tumor site.

Abbreviations: D (breast density): Dense breast; D (pathology): Invasive ductal carcinoma; F (breast density): Fatty breast; FN: False negative; F (pathology): Fibroma; L: Left; M: Mucinous carcinoma; R: Right; S: Scattered glandular tissue; TP: True positive.

6. Conclusion

We developed a prototype breast imaging system using scattering tomography. The overall diagnostic accuracy across 24 clinical imaging cases was 58%, which is higher than the reported accuracy of X-ray, mammography, and ultrasound diagnostic devices.³⁷ Clinical imaging is planned to continue until March 2027, with a target of 50 cases. The proposed microwave imaging system offers a non-ionizing, painless, and low-cost alternative with strong potential to complement mammography, ultrasound, and MRI, particularly in patients with dense breast tissue. The primary remaining challenge is to improve diagnostic accuracy. To address this, we intend to improve the calibration method and optimize the antenna arrangement. In addition, by incorporating

phase-adjustment functionality for each antenna and increasing the transmission power, this system could be extended to enable non-invasive radiofrequency ablation therapy.^{38,39} Conventional radiofrequency ablation requires an ultrasound diagnostic device to determine the ablation position. In contrast, because the proposed device has an imaging function, an additional ultrasound diagnostic device would not be necessary. In parallel with improving diagnostic accuracy, we will therefore pursue the development of an image-guided, non-invasive radiofrequency ablation system based on this technology.

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Conflict of interest

The authors declare they have no competing interests.

Author contributions

Conceptualization: Yoshihiko Kuwahara

Formal analysis: All authors

Investigation: Kimihito Fujii

Methodology: Yoshihiko Kuwahara

Writing – original draft: Yoshihiko Kuwahara

Writing – review & editing: Kimihito Fujii

Ethics approval and consent to participate

All clinical procedures were approved by the Institutional Review Board of Aichi Medical University (Certification Number of Specific Clinical Research: CRB4200004). The human subjects received a written explanation of their participation in the study and provided verbal consent.

Consent for publication

The human subjects were informed in writing that the test data would be published in academic conferences, journals, etc., and verbal consent was obtained.

Availability of data

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Further disclosure

Part of the findings was presented at academic meetings (Conformal array antenna with the aspirator for the microwave mammography, 2010 IEEE Antennas and Propagation Society International Symposium, July 11-17, 2010, Toronto, Ontario, Canada; Microwave mammography with a small sensor and a commercial electromagnetic simulator, 2016 46th European Microwave Conference, October 3-7, 2016, London, UK; A Microwave Imaging Sensor Composed of a Dielectric-Loaded Double-Polarized Horn Antenna, 2023 17th European Conference on Antennas and Propagation, March 26-31, 2023, Florence, Italy; Clinical Imaging by the Microwave Mammography, 2025 IEEE MTT-S International Microwave Biomedical Conference, April 15-17, 2025, Kaohsiung, Taiwan). Related conference proceedings papers are available at:

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Appendices

Appendix A. Glossary of technical terms

(For readers without an engineering background)

- (i) Inverse scattering problem
An analytical method used to estimate the internal structure or material properties of an object from electromagnetic waves scattered outside the object. In this study, it refers to reconstructing the distribution of electrical properties within the breast using measured microwave signals.
- (ii) Complex permittivity distribution
A spatial map of how tissue responds to microwaves. It consists of two components: the real part (relative permittivity), which reflects how much energy is stored, and the imaginary part (related to electrical conductivity), which reflects how much energy is absorbed. Different tissues (fat, glandular tissue, cancerous tissue) show different complex permittivity values.
- (iii) Lossy medium
A material in which electromagnetic waves gradually lose energy as they travel. Biological tissues are typical lossy media because they absorb part of the microwave energy. This makes the scattered signals weaker and more difficult to detect.
- (iv) Green's function
A mathematical tool representing the electromagnetic field produced by a point source. It is used to express how waves propagate inside and outside the imaging region.
- (v) Born approximation
A simplification used when the scattered waves are much weaker than the incident waves. It allows the nonlinear inverse scattering equation to be treated as a linear problem. Living tissues often violate this assumption, which is why iterative reconstruction methods are used.
- (vi) Coefficient matrix (A)
A matrix that describes the variations in the tissue electrical properties and the resulting changes in measured microwave signals. It is obtained through electromagnetic simulations of the imaging setup.
- (vii) Two-phantom calibration
A calibration technique that uses two uniform phantoms with known electrical properties. By comparing measured and simulated responses for both phantoms, systematic modeling and measurement errors can be reduced.
- (viii) Dual-polarized antenna
An antenna capable of transmitting and receiving microwaves with two orthogonal polarizations (horizontal and vertical). This increases the diversity of measured data and improves the quality of image reconstruction.

Appendix B. Intuitive explanation and assumption of Equations (1)–(6)

(For readers without an engineering background)

- (i) Equation (1)
Equation (1) intuitively means that the measured scattered field is the sum of the small contributions generated at every point inside the object, where each contribution is determined by
 - (a) The differences in the local tissue properties at that location (τ),
 - (b) The strength of the incident wave illuminating that point (the total field E), and
 - (c) The efficiency with which the resulting disturbance propagates to the observation point, as described by the Green's function.
 This expression assumes a linear scattering model based on the volume integral formulation, a homogeneous background medium, and time-harmonic fields.
- (ii) Equation (2)
Equation (2) indicates that the contrast " τ " simply represents the deviation of the local tissue properties from those of the assumed background in terms of permittivity and conductivity. In other words, τ quantifies the degree of electromagnetic abnormality at each point within the imaging region. This expression assumes a linear material model for biological tissue and a homogeneous background medium.

(iii) Equation (3)

Equation (3) simply represents the linear relationship between the measured data b and the unknown contrast x through the operator A , which summarizes the wave propagation and measurement processes. This formulation assumes weak scattering and relies on linearization based on the Born approximation. Intuitively, the Born approximation treats scattering from the object as a small perturbation, allowing the scattered field to be explained as the response to the incident field alone.

(iv) Equation (4)

Equation (4) represents the discretized version of the integral equation, where x is the unknown contrast distribution, b is the measured scattered field, and A describes how changes within the object affect the measurements. Intuitively, the matrix A contains the sensitivity of each measurement to each voxel in the imaging region. This linear formulation assumes weak scattering based on the Born approximation and a known background medium.

(v) Equations (5) and (6)

Equations (5) and (6) intuitively represent a standard linearization approach. At each step, we estimate how the current image x_n should be modified so that the simulated data more closely match the measured data. This iterative method assumes that each update is sufficiently small for the linear approximation to remain valid and that the background medium is known.