MammoWave Breast Imaging Device: Prospective Clinical Trial Results and AI Enhancement

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***Abstract*— Microwave imaging is a safe new technology for breast imaging, avoiding ionizing radiation and the patient discomfort due to breast compression. In this paper we present results from the first prospective microwave breast imaging study where both symptomatic and asymptomatic subjects were recruited. For this purpose, a novel microwave imaging device (MammoWave) was examined on 353 women enrolled in the study to allow distinction between breasts with and without radiological findings. We investigated MammoWave’s performance using both features from the reconstructed images (prospective investigation) and through the use of artificial intelligence (AI) models (retrospective investigation). Our results indicate the importance of AI for specificity enhancement, and show a sensitivity greater than 80% for all the investigations. These high sensitivity values are maintained when considering breast cancers only.**

***Keywords—microwave imaging, artificial intelligence, breast cancer detection***

1. INTRODUCTION

Drawbacks of existing established breast screening gold standard x-ray mammography [1], such as the use of ionizing radiation, performance reduction in dense breasts and the limitation in terms of examination age and frequency, have motivated research and development of alternative imaging methodologies such as microwave imaging. Notably, new studies indicate that 30% of breast cancer cases happen in females younger than 50 years old [2]. Consequently, microwave imaging has emerged as an interesting potential alternative, based on its ability to discriminate between healthy tissues and tissues with lesions, through the contrast between their dielectric properties [3].

This paper presents the performance results corresponding to one of these microwave prototypes, named MammoWave, obtained within the very first multicentric, international prospective microwave breast imaging clinical trial, where both asymptomatic and symptomatic women were recruited. The primary objective of this clinical trial was to evaluate the ability of MammoWave in breast lesions detection. MammoWave exam was done on women who had already performed conventional exams’ radiologist review, which was used as reference standard. For each examined breast, our Huygens-based algorithm (embedded in MammoWave) was used to create a set of conductivity weighted microwave images, by varying the conductivity values inputted in the algorithm. In this way, several image features were calculated and used to measure and quantify the images’ non-homogenous behaviour. A selection of these features enables distinction between breasts with no

radiological finding (NF) and those with radiological findings (WF), i.e., with benign or malignant lesions.

A good sensitivity was achieved when using the features (with appropriate thresholds) to classify the breast. Specificity of approximately 50% was achieved, as expected since we used as thresholds the median value obtained after recruiting the first 15 NF women at each hospital. This motivated us further to investigate the use of artificial intelligence (AI) algorithms, which have shown great promise in enhancing accuracy of the results when used in various biomedical applications. Several AI algorithms were tested, with Support Vector Machine (SVM) showing the best performance and hence being used in this paper.

The remainder of this paper is outlined as follows. MammoWave imaging device and the measurement configuration employed are described in Section II. The results obtained from both image features and AI are presented in Section III, while Section IV concludes the paper.

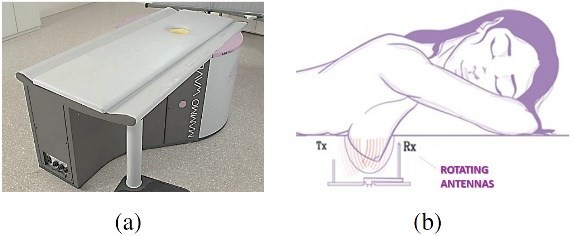
1. MAMMOWAVE DEVICE AND MEASUREMENT PROCEDURE

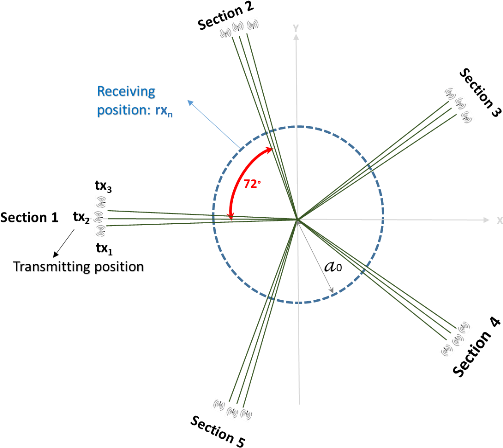
MammoWave, pictured in Fig. 1(a), contains two antennas, one transmitting and one receiving, both positioned at the same height and operating in air within 1-9 GHz frequency range, without the use of matching liquid or medium [4]. The cylindrically shaped hub containing the antennas also includes a cup placed inside a hole, where the patient’s breast fits in a prone position (Fig. 1(b)). Both antennas rotate azimuthally, performing the 8 minutes long scan multi-bistatically in frequency domain. The received signals are post-processed through our Huygens principle- based imaging algorithm, and an image is formed through the reconstruction of internal field [4].

The scanning process covers a total of 15 transmitting positions, for each of which, the receiver rotates 360° around the breast, collecting the signals at 80 positions with a 4.5° step. The 15 transmitter positions are grouped into five triplets, with their centers at 0°, 72°, 144°, 216°, and 288°, respectively. A vector network analyzer is connected to the antennas and measures S21 signals (i.e., the backscattered electromagnetic signal).

MammoWave was recently tested in a prospective clinical trial that was carried out as part of a European Horizon 2020 project (Grant Agreement ID: 830265); after receiving approval from the Ethics Committee, three hospitals (two in Italy and one in Spain) were involved in the

corresponding clinical trials (Clinicaltrials.gov identifier NCT04253366). The clinical data used in this study were collected in the Humanitas Research Hospital, Milan, Italy, IRCCS Ospedale Policlinico San Martino, Genoa, Italy, and University Hospital of Toledo, Spain (former Hospital Virgen de la Salud).





(c)

Fig. 1. (a) MammoWave device’ photo, (b) MammoWave’s scanning configuration sketch depicting the hole and inserted cup, and the position of antennas, (c) antennas’ configuration showing the five transmitting triplets.

1. RESULTS

A dataset of 697 breasts from 353 women (enrolled in 2020-2021) was considered, 376 of which were WF and 321 NF breasts. From the raw S21 output of MammoWave, microwave images can be generated using Huygens’ principle-based algorithm, which represent 2D homogeneity maps of dielectric properties in the azimuthal plane. For each examined breast, through a variation of conductivity values from 0.3 to 0.8 S/m, our algorithm created six conductivity weighted microwave images, which we refer to here as “methods”. Subsequently, several microwave image parameters, i.e., “features” were calculated and used to measure and quantify images’ non-homogenous behavior. Welch’s t-test (two-sample two-tailed unpooled variances t- test) with α= 0.05 performed and the statistical significance was set at p<0.05. A selection of methods and features (with appropriate thresholds) was used to allow distinction between NF and WF breasts; such selection was performed using a feasibility clinical trial (completed in 2019) [5]. The resulting microwave imaging output was then compared to the radiologist study review in a prospective manner in order to calculate the sensitivity, specificity and accuracy of our algorithm [6, 7]; the results are summarized in Table I

Next, in order to investigate the possibility of enhancing the performance of MammoWave, several AI algorithms were tested retrospectively. More in details, we investigated AI algorithms to:

1. allow distinction between NF and WF breasts;
2. allow distinction between healthy (H) and non-healthy (NH) breasts. In this classification, NH breasts indicate those with malignant findings (histologically confirmed) while H breasts include those without any findings or those with benign findings.

Specifically, a large matrix of more than 500,000 electromagnetic field coordinates (S21 data recorded using a vector network analyzer) was produced for each breast. This matrix is denoted as “raw output” of MammoWave; the data contained in it are denoted as “raw data”. The “raw data” AI approaches are so called because we aim to apply machine learning algorithms directly on the raw output (without constructing any microwave image). However, the number of coordinates exceeds the number of samples at disposal by several orders of magnitude; therefore, we could not use raw data as it is, and some pre-processing steps were needed. PCA methods were used to reduce the number of coordinates, fixing the number of components so that at least 95% of data variance is represented. Then, 100 components after PCA analysis were found to meet this requirement; therefore, the total number of electromagnetic coordinates was reduced from 500,000 to 100. Furthermore, class imbalance is considered for H/NH scenario (since non- healthy breasts constitute smaller percentage of the data); in order to deal with this problem, resampling strategies were exploited. Specifically, we combined oversampling and under-sampling methods to obtain at least 40% of the data being represented by non-healthy breasts. Once the classes have been balanced, classical supervised AI algorithms were applied to the data to classify the breasts into H and NH breasts. Several different classical algorithms (SVM, decision trees, random forests, logistic regression, k-nearest neighbors and other similar) were investigated to select the best ones by evaluating their final performances. Specifically, for each of these algorithms, cross validation was performed, the parameters were optimized via grid- search approaches, and relevant statistical metrics (accuracy, precision, specificity, sensitivity, F1- score) were computed. For each cross validation fold a different train-test split is performed on the data, with the test data always being 20% of the total. Among the algorithms, SVM showed the best performance and hence was used in this work to evaluate MammoWave’s performance in terms of sensitivity, specificity, and accuracy [8].

Table I shows a comparison of MammoWave’s performance when prospectively using the features extracted from microwave images (this means that the features thresholds have been fixed prior the execution of the trial), compared to when retrospectively employing AI algorithms [8, 9] (this means that the train-test of AI algorithms was performed using all the data collected in the study). A significant improvement in specificity can be observed.

TABLE I. MAMMOWAVE’S PERFORMANCE COMPARISON THROUGH IMAGE FEATURES VS. AI.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Microwave images’ features (NF/WF)** | **AI (NF/WF)** | **AI (H/NH)** |
| **Sensitivity** | 82% | 90% | 86% |
| **Specificity** | 49% | 92% | 89% |
| **Accuracy** | 73% | 90% | 88% |

1. CONCLUSIONS

This paper presented the first work that shows the results from both prospective investigation via image features and retrospective AI models in the context of a microwave breast clinical trials where both symptomatic and asymptomatic subjects were recruited. The results from 353 women undergoing MammoWave exam indicate a high sensitivity of over 80% using features from the microwave images; sensitivity is further enhanced to approximately 90% when applying AI models. In addition, the use of AI models leads to a specificity of approximately 90%.

Microwave imaging is a promising new technology in breast radiology, avoiding discomfort and use of ionizing radiation. Our work adds another milestone on the road to show that microwave-based technology is a safe and comfortable technique which, augmented by AI, holds great promise for breast screening. The next step involves the investigation of our AI algorithms in a prospective manner, currently under investigation in a larger clinical trial involving 10,000 women [10].

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