Preliminary assessment of an Artificial Intelligence algorithm based on MRI breast modelling with US fusion

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Purpose

Evaluation of a new Ultrasound (US) technology, based on Artificial Intelligence (AI) algorithm, that correlates and fuses MRI-prone with US-supine Breast Imaging (BI) examinations. In-vitro and in-vivo tests were performed.

Methods and materials

Breast cancer represents the most common oncological disease for women and a multimodality approach, with a clinical exam and an advanced set of BI examinations, is mandatory as current medical standard.

MRI and Contrast-enhanced MRI (CE-MRI) play a central role in BI, due to their very high sensitivity. In addition, technology evolution over the recent years has made breast US an essential component of the BI evaluation. In current praxis, when lesions detected on MRI are not visible/equivocal on mammogram and/or are not identified by previous US, a second-look US is commonly prescribed, to provide additional lesions information or lesion precise localization. Obviously said, second-look US examination must be correlated with previous MRI findings.

Breast tissues are soft and easily deformable, the organ is movable and breast size varies substantially among women; in addition, Breast MRI is routinely performed with patients in prone position, while US is performed with the patient in supine position. As a result of varying patient's position during clinical examinations, breast location, its size and the localization of potential internal lesions typically undergo significant variations, with substantial spatial displacement and misalignment.

A new Fusion Imaging (FI) algorithm has been developed (BreastNav®, MedCom GmbH) and embedded on MyLab 9 US system (Esaote SpA, Italy), helping to overcome such difficulties and to provide all the diagnostic and clinical advantages of BI MRI-US Multimodal Fusion.

BreastNav® allows to correlate prone MRI to supine US and to localize on the real time US, with patient supine, the spatial position of a reference anatomical target, related to a lesion under investigation, previously identified on prone-position MRI.

The algorithm needs minimal user input and interaction and performs automatically a mathematical transformation of the MRI target spatial coordinates from prone to supine patient's position, based on breast 3D shape modelling. This enables the identification of the same target on MRI and US examination (Fig.1-2).

System Evaluation

In this preliminary study, we evaluate the clinical feasibility of BreastNav® and we assess the technology's accuracy by in-vitro and in-vivo tests.

· In vitro test was performed with a commercially breast phantom (CIRS, model-073) that presents amorphous lesions, mimicking the ultrasonic characteristics of tissues found in an average human breast.

· For in-vivo tests, 2 different investigation scenarios were performed, on a total of 5 patients.

MyLab9 US system (Esaote, Italy) equipped with a novel technology for FI (BreastNav®, MedCom GmbH), based on electromagnetic tracking system a linear probe (L4-15, Esaote, Operating bandwidth: 4-15 MHz), coupled with reusable tracking brackets with sensor mounted were used (Fig. 3).

Procedure

The registration procedure between prone MRI and supine US imaging is based on a 3D Adjustable Breast Model (ABM). The idea is that the breast shape during MRI and US examinations is registered correspondingly to the 3D ABM, whereby then both shapes are inherently registered to each other. Two steps are needed:

a. registration phase between prone MRI imaging dataset and the 3D ABM, based on 5 fixed anatomical superficial points to be set on MRI BI: P1 nipple, P2-P3 median and lateral margins, P4 inframammary fold, P5 parasternal line; the positions of these 5 points are pre-defined on the 3D model (fig.4).

b. registration between the 3D ABM and real-time US on supine patient: 2 sweeps, to describe breast profile, are performed with the US probe directly on patient's breast without any pressure, one horizontal from P2 to P3 points and one vertical from P4 to P5 (Fig. 5). To further improve the registration accuracy, especially in case of hypertrophic breast, it's possible to furtherly combine the single point acquisition (P1 to P5) and the sweep procedure.

Identifying points and/or acquiring sweeps is completed within a few seconds; after performing the two steps above, a finite element method is used to calculate correspondences and deformations based on points, sweeps and surface information.

Images for this section:

Fig. 1: Clinical FI examination on US system with patient in supine position

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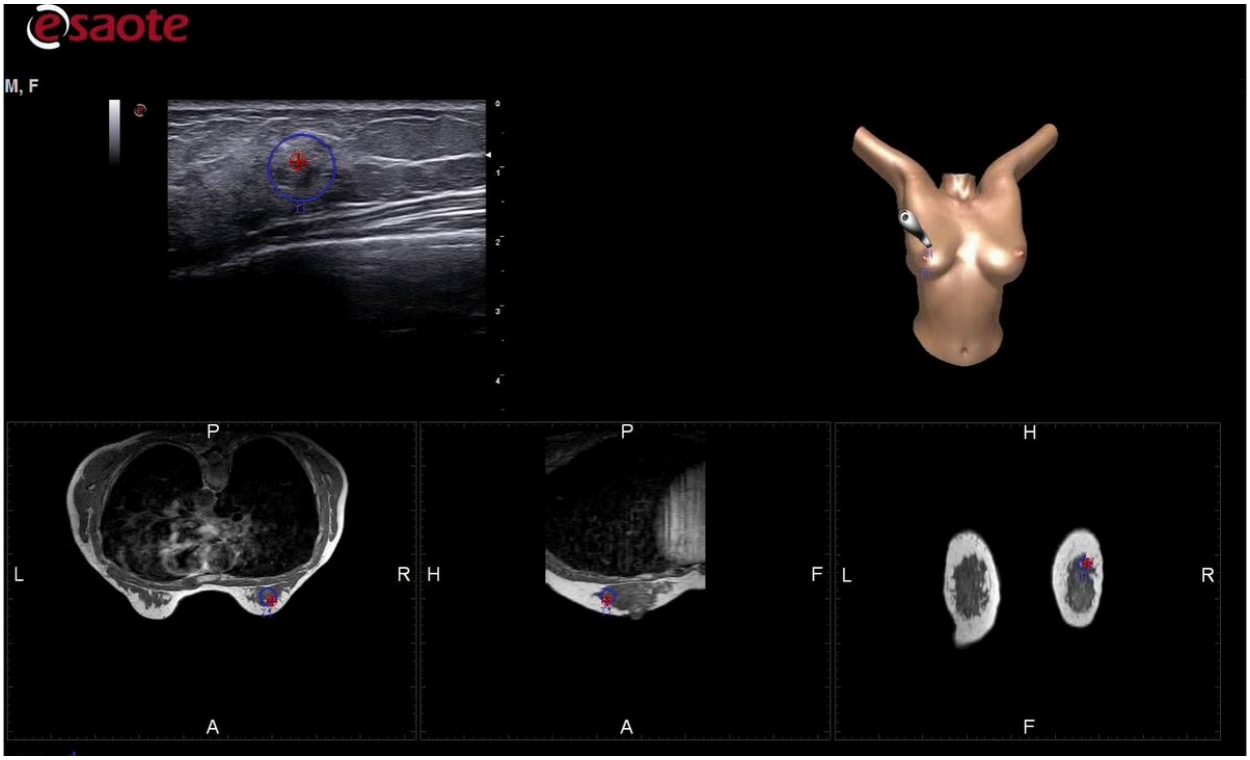

Fig. 2: prone MRI-supine US FI and 3D shape modelling of the breast with identified target (blue sphere and red viewfinder)

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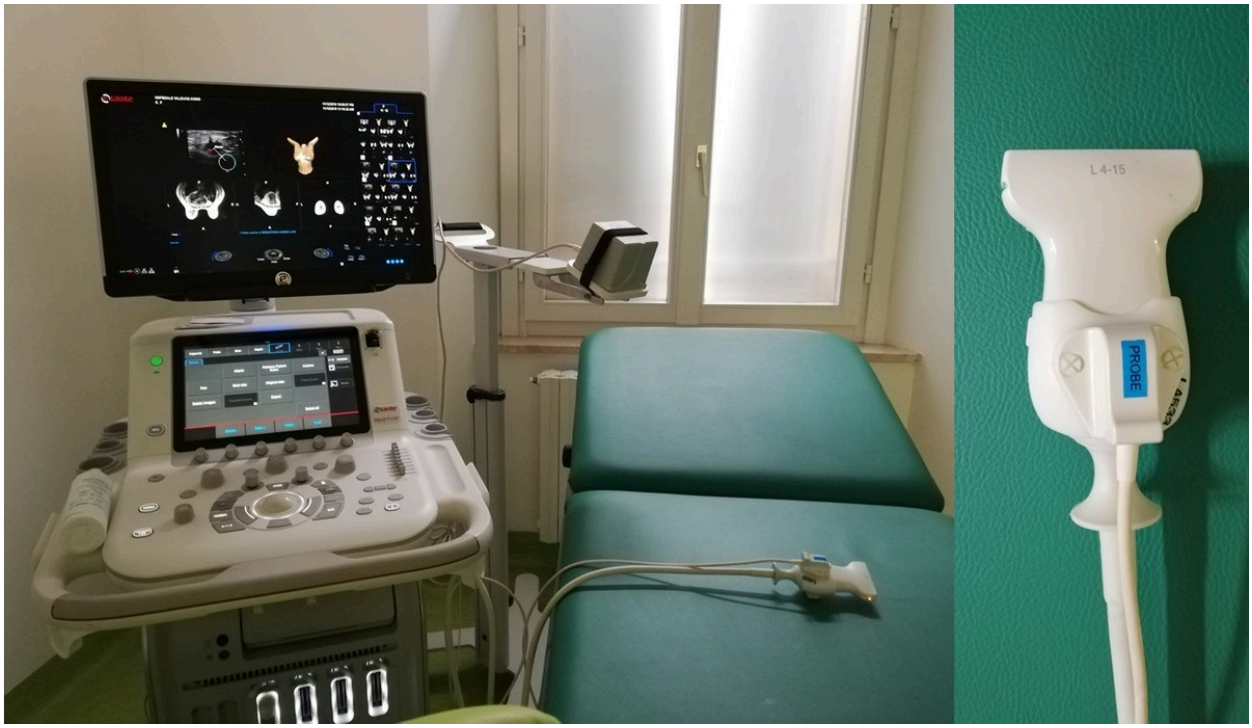

Fig. 3: MyLab 9 US system with BreastNav FI technology and linear probe L4-15 with electromagnetic receiver

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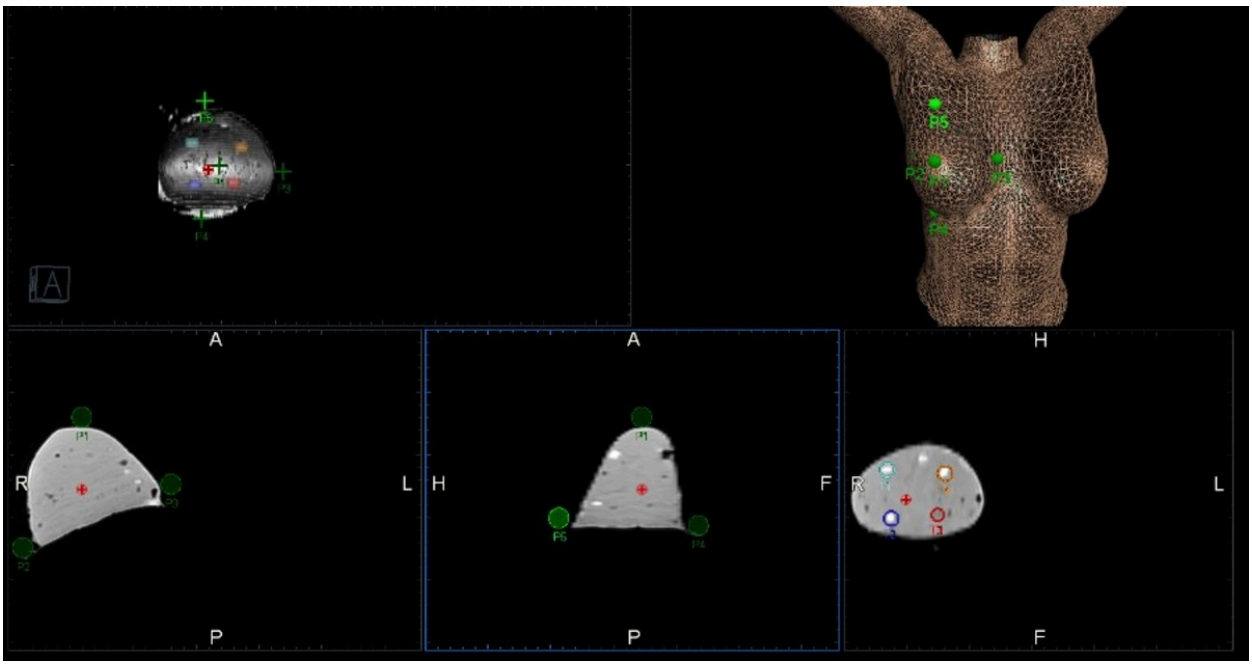

Fig. 4: Registration between 5 anatomical superficial points on prone MRI (left) and the 3D ABM (right); the MRI DICOM Imaging is loaded in US archive by USB, CD/DVD or querying the study to PACS over Ethernet

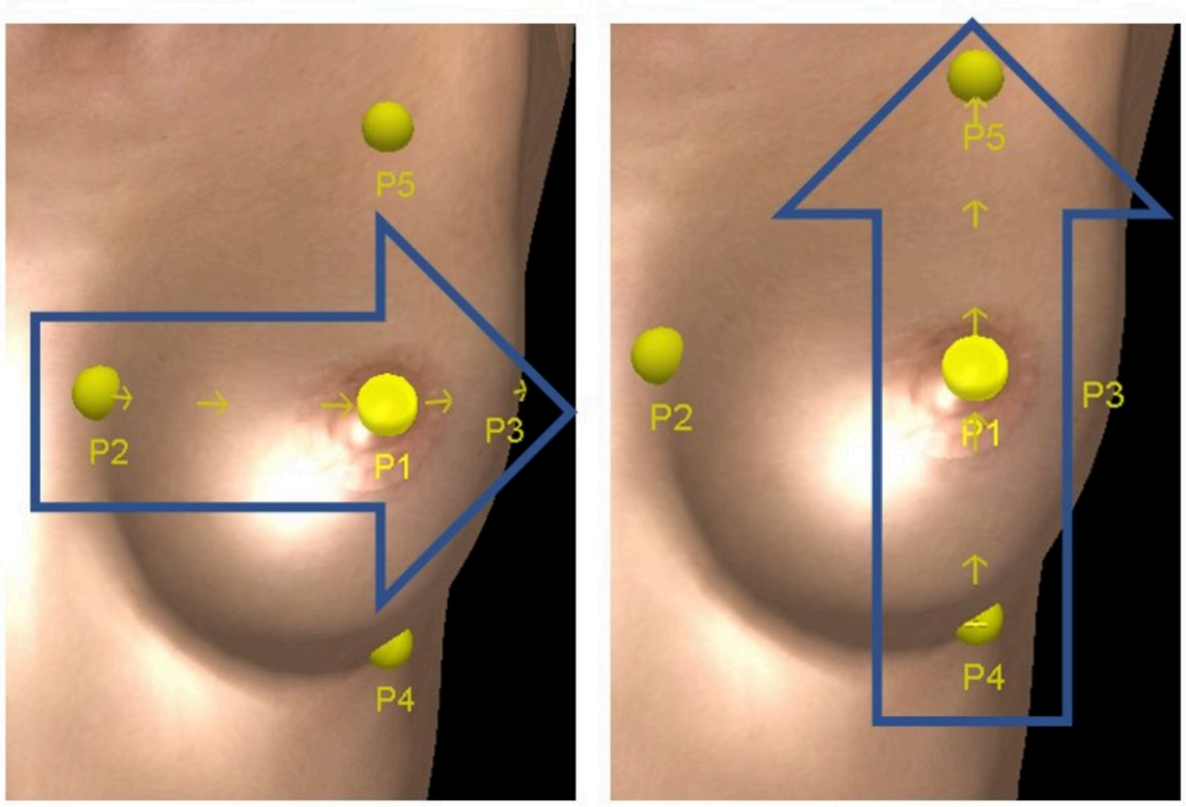

Fig. 5: Direction of horizontal (left) and vertical (right) sweeps registration procedure, performed with US probe directly on patient's breast without any pressure

Results

For in-vitro test, the mismatch on the reference amorphous lesion identified in prone MRI and the one visualized in real-time US, calculated between the real-time US probe position and the MRI set target, was minimal (Fig.6). No further investigations or statistical analysis has been performed, since the phantom deformation is limited, compared to real tissue, therefore phantoms are not an adequate representative of the real breast organ deformation.

For in-vivo tests, 2 different investigation scenarios were performed.

The first investigation was made to evaluate the BreastNav® feasibility and its AI algorithm performance on real patients. In a previous study, the algorithm has been already validated by means of MRI breast examinations, acquired in prone and supine positions.

One healthy volunteer (age:40y) with no lesions and hypertrophic breast has been involved.

Before MRI acquisition, 8 Skin Landmarks (SL) have been positioned on each breast, 5 used for registration purposes (corresponding to P1-P5 points) and 3 as target SL, placed in the position at 3, 6 and 9 o'clock in sub-areola position. These SL better describe the organ deformation and slipping, due to prone-supine change and they are used to compute the error between their position during supine US and the one computed by the AI algorithm, based on MRI acquisitions.

MRI acquisition (1.5T Ingenia-Philips) was performed in prone (4-mm axial T2W-TSE with and without fat suppression,DWI b-values 0-500-1000s/mm2,DCE-Gadobutrol;0,05 mmol/kg;2ml/s) and supine position (4-mm axial T2-SSH with and without fat suppression MultiVaneXD HR) and only the prone DICOM sequence loaded on US system and registered in BreastNav environment; the Euclidean error between the real-time US probe position and the MRI set target, are shown in Table 1.

The second investigation involved 4 patients (medium age: 55y) with MRI reference lesions and no SL positioned.

These patients came from the routine MRI, due to different clinical situations/settings, where a second-look US has been prescribed.

MRI acquisition (GE-1.5T) was performed only in prone position (Axial-T1,STIR,DWI,DCE 1+5-ProHance) and DICOM data loaded on US system; in BreastNav environment the lesions in MRI BI have been identified and target.

The following clinical cases were analyzed: highly suspicious wide area of micro-calcification on external quadrants of left breast; neoplastic mass on upper quadrants of right breast; US follow-up of architectural distortion with correlated MRI contrast enhancement; the last, breast prosthesis and parenchymal mastopathy area on left breast with correlated MRI enhancement.

The lesions in the 4 patients analyzed have a consistent dimension, superior to 1 cm: this choice has been made in order to easily identify the reference target during US and to properly test the feasibility of the technology on real patients.

In all patients, Breast Nav technology has been able to make prone MRI-US supine FI, identifying properly the lesion during US, previously marked in MRI, with a mismatch between a minimum of 4 mm to a maximum of 18 mm, corresponding to the prosthesis case, caused by a different behavior compared to the real organ during patient's position changing (Fig.7-8).

Benefits

Breast Nav technology allows to save all data in the US archive for post-processing analysis and review, to print pictures of the target reference and US probe spatial position with FI and to print reports, also including BI-RADS® categorization (Breast Imaging Reporting and Data System-ATLAS of the American College of Radiology).

During BreastNav MRI-US FI investigation other breast relevant US technologies such as microvessel imaging, microenhancement imaging and elastography (Strain and/or Shear Wave technology) can be also used, making the method a real multimodality BI approach (Fig. 9-11).

Limitations

The algorithm performance provided good results in this preliminary study, but the patients sample is limited; breast size, its tissue composition and the lesion position can affect the final accuracy, due the fact that the deformation and the mammary gland slipping are not homogeneous among different patients and the variability observed among women is huge.

For this reason, further studies are necessary to optimize the system accuracy, improving the machine learning procedure by increasing the big data cases, in order to provide a more diagnostic confidence.

Images for this section:

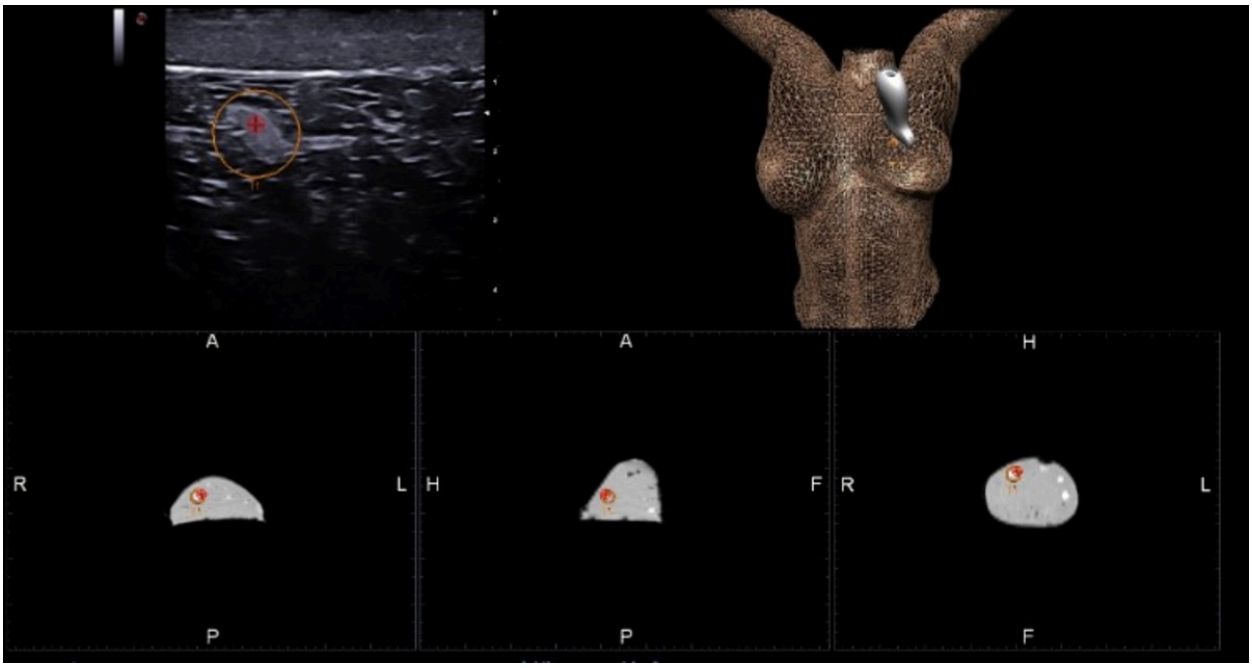

Fig. 6: In vitro test, localization on real-time US of a reference target in the phantom previously set on prone MRI

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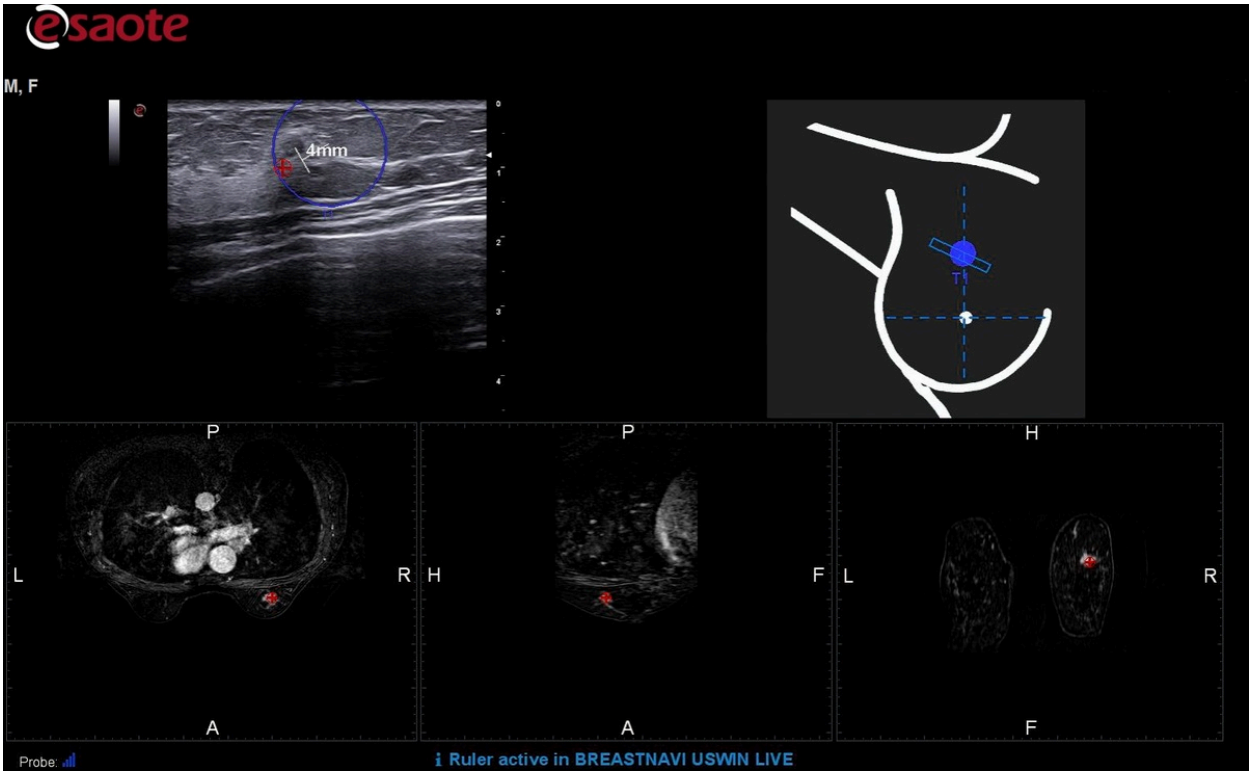

Fig. 7: In vivo test of BreastNav FI technology, minimal mismatch assessed, corresponding to US follow-up of architectural distortion clinical case

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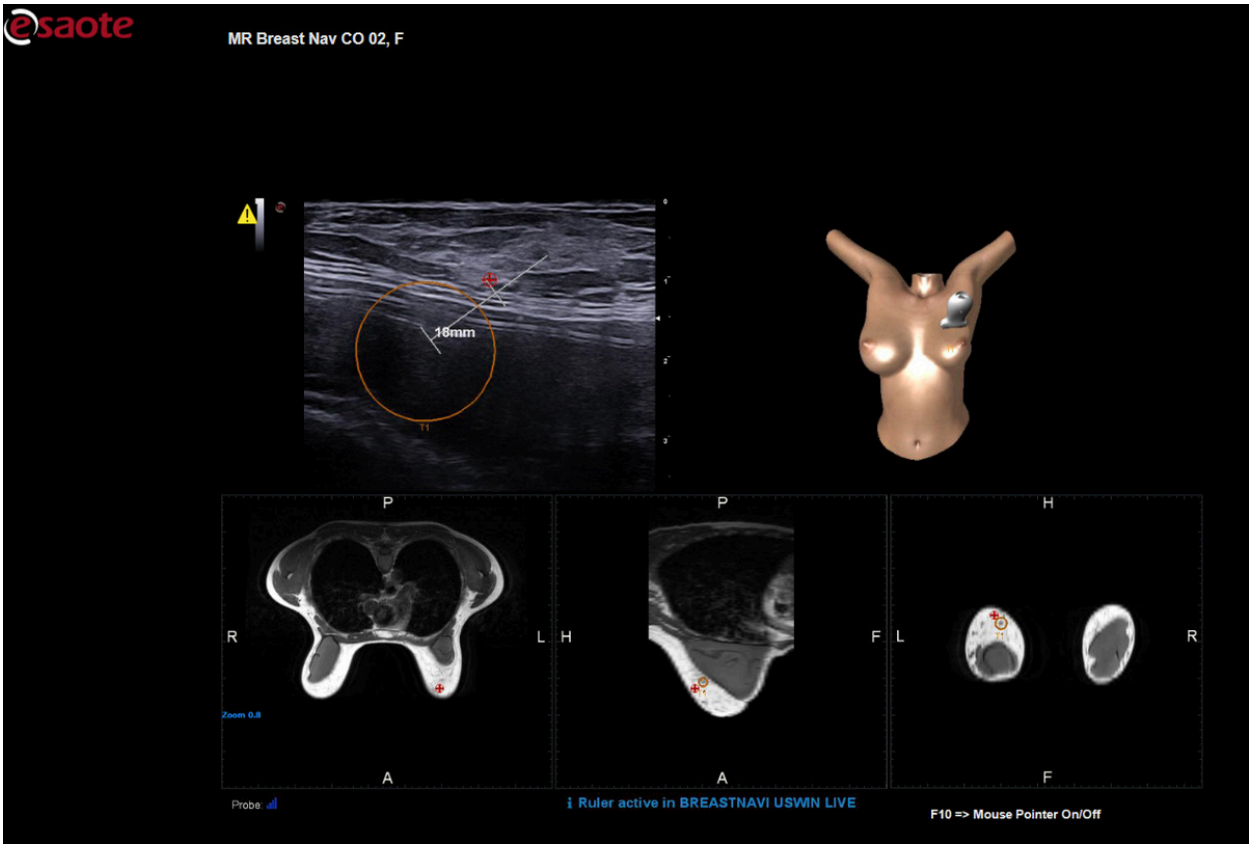

Fig. 8: In vivo test of BreastNav FI technology, maximal mismatch assessed, corresponding to the prosthesis case

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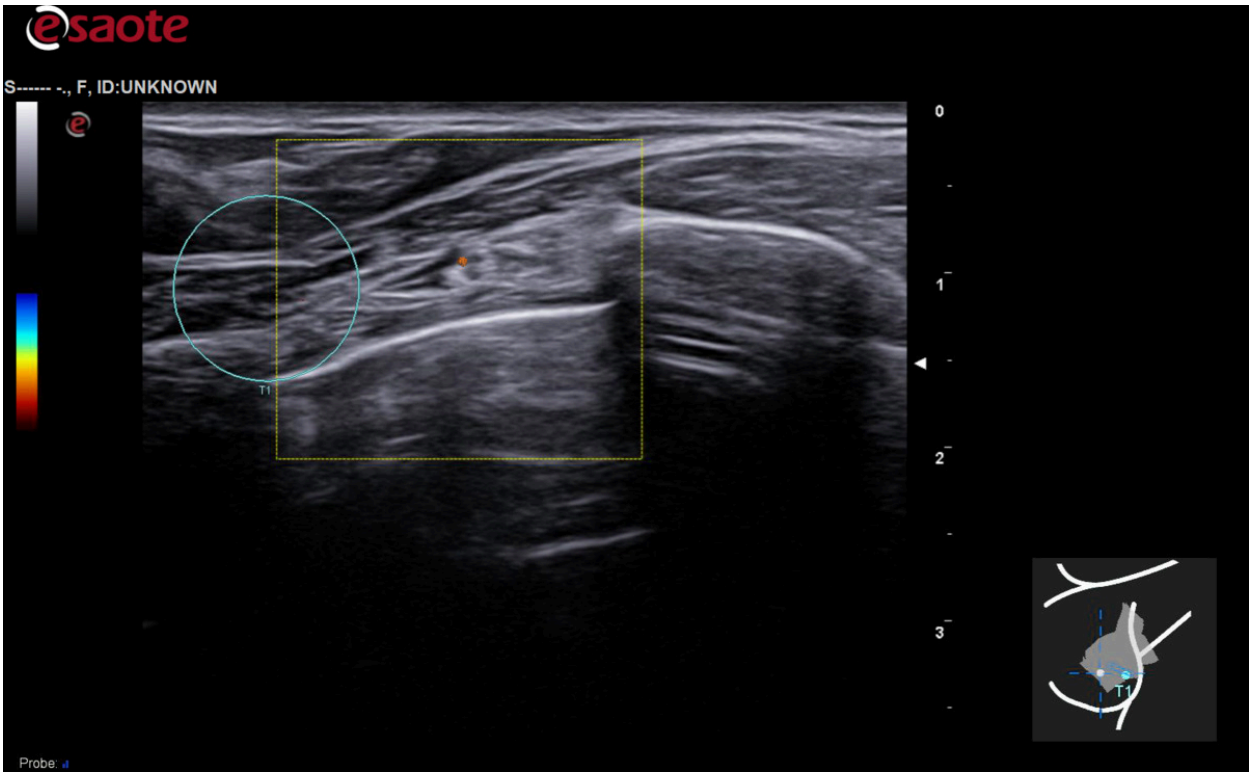

Fig. 9: US microenhancement technology (microE, Esaote) together with BreastNav MRI-US FI investigation on a microcalcification area

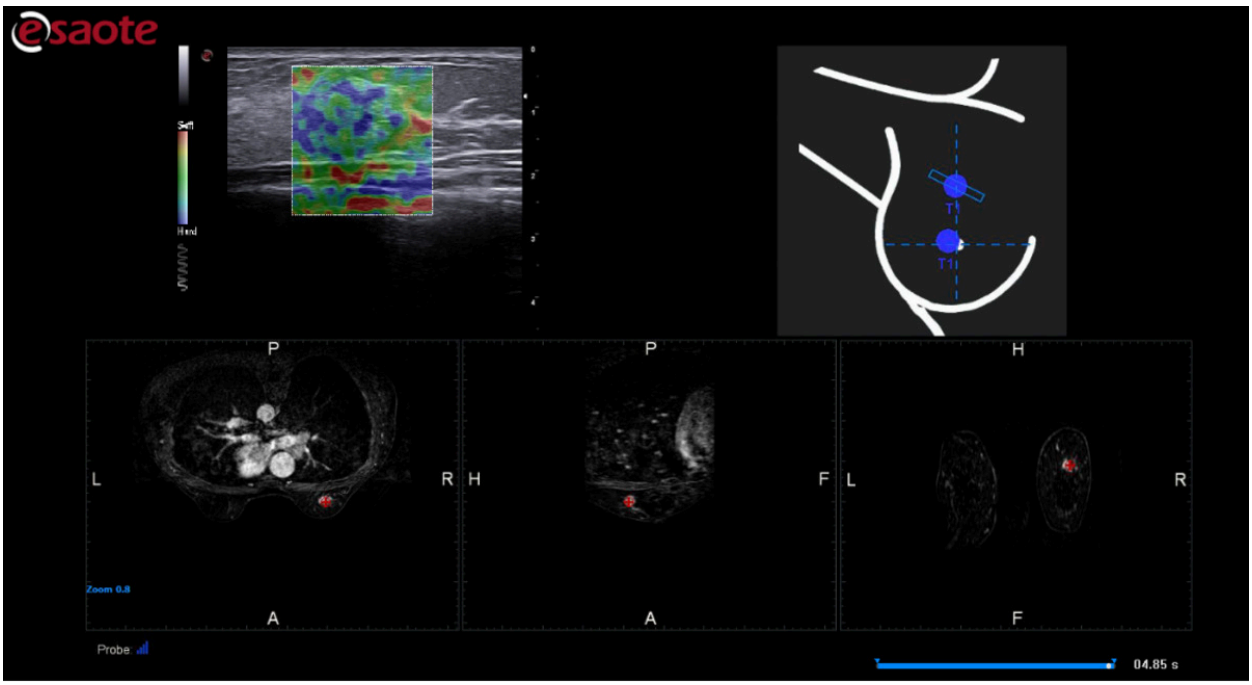

Fig. 10: US Strain Elastography evaluation (ElaXto, Esaote) together with BreastNav MRI-US FI investigation on neoplastic mass

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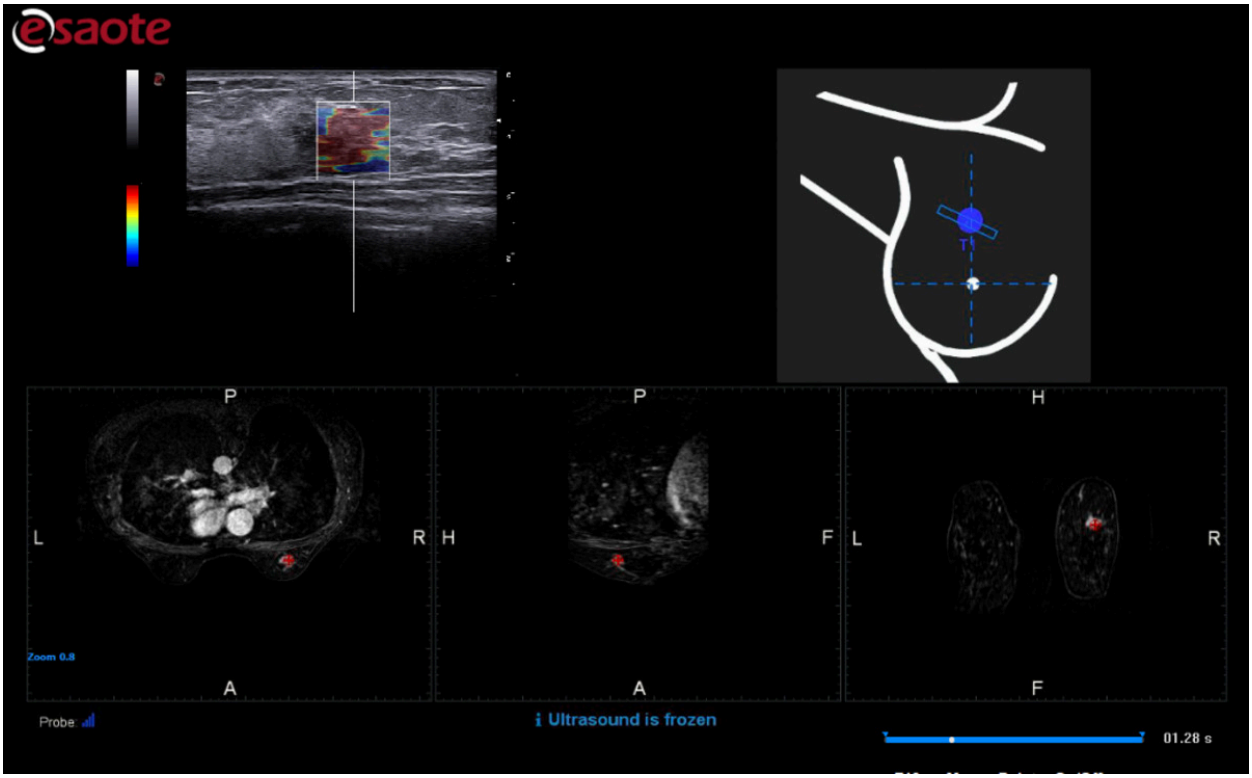

Fig. 11: US Shear Wave Elastography evaluation (QElaXto 2D, Esaote) together with BreastNav MRI-US FI investigation on neoplastic mass

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Reference skin landmarks (SL) position	Euclidean error between SL and MR reference position
Right breast 3 o'clock 	12 mm
Right breast 6 o'clock 	5 mm
Right breast 9 o'clock 	8 mm
Left breast 3 o'clock 	7 mm
Left breast 6 o'clock 	8 mm
Left breast 9 o'clock 	6 mm

Table 1: Euclidean error between Skin Landmarks and MR reference position on healthy patient

Conclusion

Integrated breast multimodal FI is starting to become possible, thanks to technology evolution.

Breast Nav technology is aimed to speed up the detection and characterization of lesions, visible only on MRI, also on real-time US, thanks to the FI between the two different BI modalities and to manage the deformation induced by patient's different positions between US and MRI, within clinically acceptable localization errors.

Personal information and conflict of interest

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