

# BreastNav™ MRI

a new horizon  
for Breast Imaging



*Her Health*  
*Our Commitment*

# “BreastNav™ MRI provides a real plus-value to the conventional imaging allowing a multimodal approach, so important in our environment.”



Dr. Camilla Fachinetti – Director of Breast Diagnostic Imaging Unit, Valduce Hospital (Como, IT)

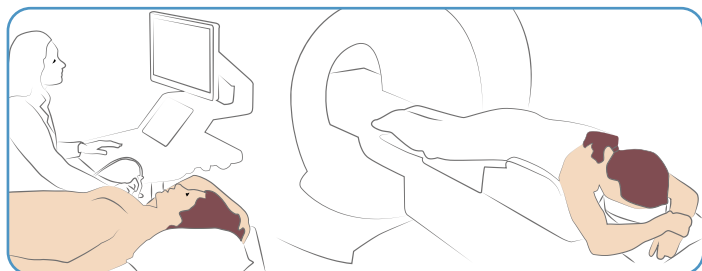
## Background: a multimodality approach for breast cancer screening

Innovation is fundamental in radiology, where research and development of new technologies keep opening new possibilities in diagnostic and therapeutic fields. In particular, for breast cancer care, a multidisciplinary approach is becoming increasingly important, leading to actual Breast Units, in which the patient is followed up along a complete pathway, starting from the diagnosis, to the lesion's follow-up, response to therapy prediction, and therapeutic procedure as an alternative to surgery. The role of the breast radiologist is closely correlated to other important specialists, like surgeons, pathologists, oncologists, radiologists, and specialist nurses. Breast cancer is the most common oncological disease for women worldwide. Increasingly, beside mammography-based screenings, a multimodality imaging approach is being used in the detection and monitoring of early stage cancer disease, with the aim of initiating appropriate treatment in order to decrease mortality.

Several studies have been conducted to optimize breast MRI results that are to date very sensitive but still showing low to moderate specificity and moderate Positive Predictive Values (PVVs) for lesion characterization. In addition, technology evolution over recent years has made breast ultrasound an essential component of the diagnostic scenario.

In current practice, when a breast lesion is identified at MRI, a second look with targeted US is generally performed because it provides additional information to further characterize the target lesion and makes it possible to perform US-guided biopsies, which are less expensive and more comfortable for patients compared with MRI-guided ones.

Nevertheless, there is not always a correspondence between MR findings and targeted US due to several factors, including operator experience and position of patients. Furthermore, 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 positions during clinical examinations, breast location, size and localization of potential internal lesions typically undergo significant variations, with substantial spatial displacement and misalignment. In some cases, these limitations do not allow the diagnosis to be concluded on a second look, and in such circumstances an MRI-guided biopsy could be necessary.



Traditional fusion imaging algorithms are not able to manage such important deformations, and several studies have been performed, requiring additional supine MRI sequences for the navigation with the US examination. Nevertheless there are considerable disadvantages: first of all, supine MRI image quality is lower compared with prone MRI due to respiratory or heartbeat artefacts and to the use of non-dedicated coils; secondly, an additional MRI examination in the supine position is time-consuming, requires additional administration of contrast agent, or may be unavailable. For this reason, a new algorithm, based on 3D adaptive modelling Artificial Intelligence technology, has been developed, BreastNav™ MRI, to overcome such difficulties and to provide the fusion imaging between prone MRI and supine US, thus benefiting from multimodal approach for lesion detection and characterization.

## Technology: the role of BreastNav™ MRI in breast lesion detection and follow-up

BreastNav™ MRI all enables us 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 hardware is based on an electromagnetic tracking system, with a transmitter and a receiver antenna mounted on a reusable bracket positioned on the linear probe (Fig. 1a).

Fig. 1a: BreastNav™ MRI fusion imaging hardware components



The algorithm requires minimal user input and interaction and performs automatically a mathematical transformation of the MRI target spatial coordinates from prone to supine patient position, thanks to breast 3D shape modeling. (Fig. 1b)

Fig. 1b: BreastNav™ MRI fusion imaging between US and MR, in real-time investigation



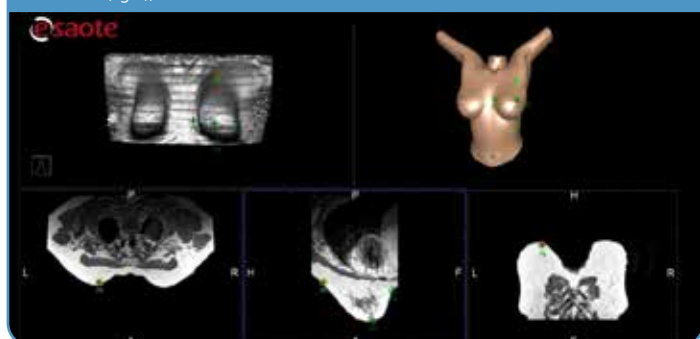
“In breast imaging research and innovation are fundamental. We’re collaborating with Esaote in the development of BreastNav™ MRI and other interesting projects which can help our patients and improve our daily workflow.”



Dr. Daniela Bernardi – Director of Breast Radiology department, Humanitas (Milan – IT)

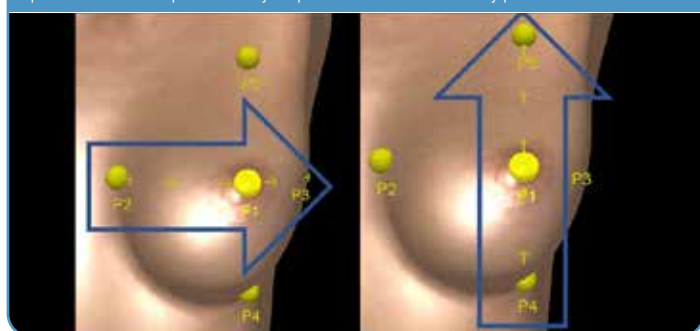
The registration procedure between the two modalities prone MRI and supine US imaging is based on a 3D adjustable breast model. In a first phase, the user needs to set 5 predefined anatomical superficial points on the MRI examination, uploaded via DICOM through USB/CD or PACS. The points will be registered and translated into breast model coordinates: P1 nipple, P2-P3 median and lateral margins, P4 inframammary fold, P5 parasternal line (Fig. 2).

Fig. 2: Registration between 5 anatomical superficial points on prone MRI (left) and the 3D model (right);



In a second step user perform 2 acquisition sweeps to trace the profile of the reference patient’s breast, without any pressure, one horizontal from P2 to P3 and one vertical from P4 to P5 (Fig. 3). This information, together with the points previously acquired will allow the algorithm to correlate prone MRI with supine US.

Fig. 3: Direction of horizontal (left) and vertical (right) sweeps registration procedure, performed with US probe directly on patient’s breast without any pressure



## Clinical benefits and drawbacks

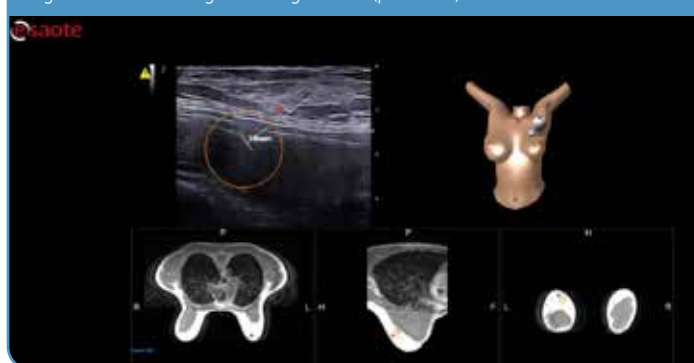
Identified lesions on MRI, which require a second-look US examination, were analyzed: highly suspicious wide area of microcalcification on external quadrants of left breast; neoplastic mass on upper quadrants of right breast; US follow-up of architectural distortion with correlated MRI contrast enhancement; breast prosthesis and parenchymal mastopathy area on left breast with correlated MRI enhancement.

BreastNav™ MRI technology was able to make prone MRI-US supine fusion imaging, properly identifying the lesion during US, previously marked in MRI, with an average mismatch of 7 mm, in a range from a perfect match to a maximum error of 18 mm, corresponding to the prosthesis case, caused by a different behavior compared to the real organ during the patient’s position changing (Fig. 4-5).

Fig. 4: Minimum disalignment target-lesion (correct match)



Fig. 5: Maximum disalignment target-lesion (prosthesis)



BreastNav™ MRI technology enables us 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 fusion imaging 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 fusion imaging investigation other breast relevant US technologies such as microvessel imaging, microenhancement imaging and elastography (Strain and/or Shear Wave technology) can be used to support the clinician in the lesion characterization (Fig. 6-9).

Fig. 6: microV technology for the detection of very small flows, associated with BreastNav™



Fig. 7: MicroE technology for hyperechoic spots enhancement, associated with BreastNav™

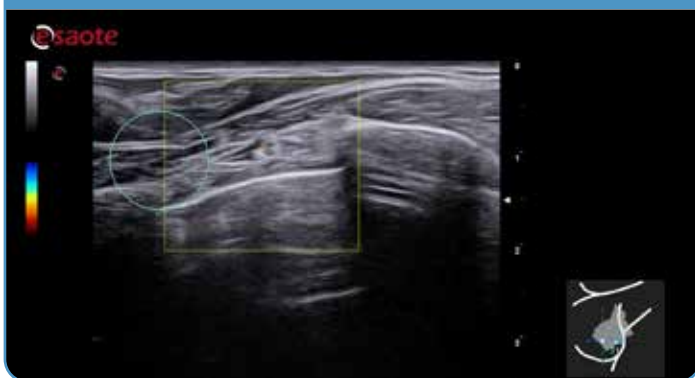


Fig. 8: US Strain Elastography evaluation (ElaXto, Esaote) associated with BreastNav™

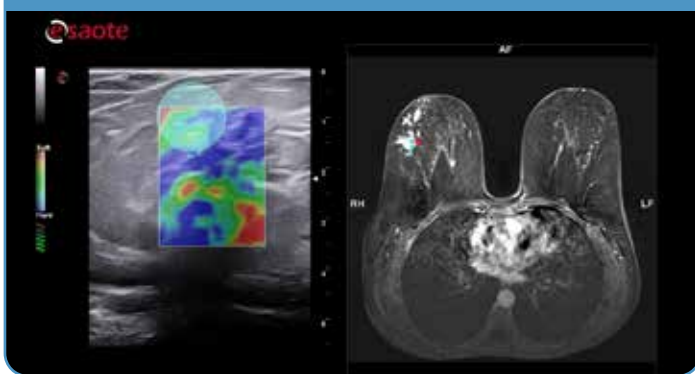
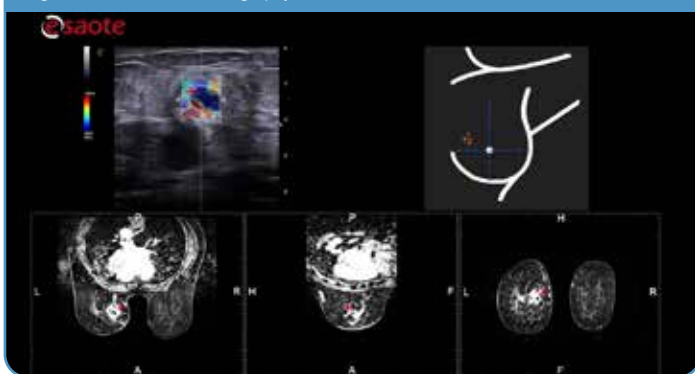


Fig. 9: US Shear Wave Elastography (QElaXto 2D, Esaote) associated with BreastNav™



The algorithm performance provided good results in a preliminary study, but the patient sample is limited; breast size, its tissue composition and the lesion position can affect the final accuracy, due to 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 improve the machine learning procedure by increasing the big data cases in order to provide a more diagnostic confidence.

## Conclusions

Integrated breast multimodal fusion imaging becomes possible, thanks to technology evolution. BreastNav™ MRI aims to manage the deformation induced by different patient positions, and to speed up the detection and characterization of lesions, visible on MRI and on real-time US, thus providing additional information to support the diagnosis, the follow-up of breast lesions and the response to the therapy prediction.

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