White Paper

Endocrinology

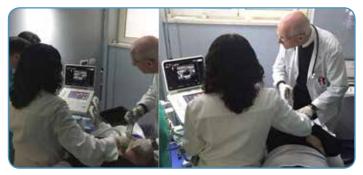


Introduction

In the last decade, there has been a rapid refinement of the diagnosis of neck thyroid lesions, especially in the field of thyroid disease. Ultrasound plays a fundamental role in the management of thyroid nodules and tumors and in the approach to recurring neck problems after thyroidectomy. Specifically, ultrasound examination is the main tool for the indication of fine needle aspiration biopsy (FNA) of thyroid lesions, suspicious cervical lymph nodes and parathyroid glands. Moreover, besides its diagnostic role, ultrasound is currently used as a guidance procedure for ablative treatment of benign and malignant cervical lesions.

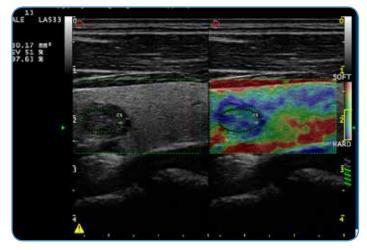
Ergonomics in Everyday Clinical Practice

Ultrasound nowadays has to comply with current diagnostic and interventional approaches that require high levels of performance and dynamism but with very reduced size and weight. An efficient "ready-to-go" solution is required when mobility and time are crucial, but that's not all. A high-resolution monitor that can be rotated 90° to ensure greater comfort and allow the examination to be shared with a colleague when performing FNA procedures, as well control buttons integrated into lightweight appleprobe transducers to remotely control the scanner with rapid actions in sterile conditions, may represent perfect solutions in everyday clinical practice.



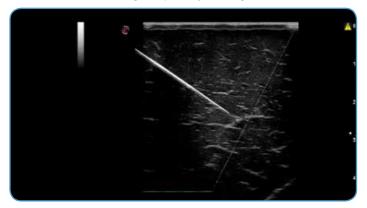
Gold-Standard Lesion Characterization

Tissues have various mechanical properties, and elasticity is one of these. It is well known that tissue elasticity is correlated to pathology and palpation in different areas, and is routinely used as a measure in clinical exams. Thyroid nodules that are hard and firm at physical examination are traditionally considered as suspicious lesions. Currently, however, the majority of thyroid lesions are poorly palpable or are deeply located within the gland. Elasticity allows tissue to change shape under pressure or force and return to its original shape after distortion. Evaluation of elastic properties involves transforming a tissue through the application of an external load. Elastography technology allows the user to perform a tissue elasticity analysis, providing information about the tissue's elasticity by associating different chromatic patterns with the different tissue elasticity responses. Through the addition of real-time evaluation, the sensitivity to malignancy in US findings is markedly increased and the identification of nodules that do not need cytology becomes more reliable. Several clinical studies have demonstrated that a nearly completely stiff pattern is frequently associated with thyroid cancer while a "soft" pattern is in most cases due to benign nodules. Even though its predictive capability for benign or malignant conditions is not complete, the use of elastography provides further useful information with regard to thyroid nodules with ambiguous B-mode sonographic features and may help to dictate the indication for fine needle aspiration biopsy.



Needle Enhancement

The safe and successful performance of ultrasound-guided procedures requires both detailed knowledge of the anatomy and the ability to understand where the needle tip is at all times. The latter is dependent on the needle and transducer manipulation, which can be a challenge, especially for beginners.



"Real-time strain elastography is a valuable tool for detecting malignant thyroid lesions with good sensitivity"

Prof. Enrico Papini President of the American Association of Clinical Endocrinologists (Italian Chapter) Department of Endocrinology and Metabolism - Regina Apostolorum Hospital Visualization of the needle tip requires alignment with the ultrasound beam and sometimes that is not achieved. Even when it is, the physical characteristics of the needle and technological limitations may obstruct visibility.

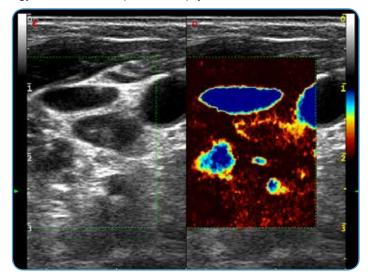
In order to increase the operator's confidence in identifying the needle tip location, Esaote have developed a tool that increases the needle brightness by combining a dedicated image composition of a standard B mode with a properly processed and guided image.

New Technology for Micro-Vascularization Detection

MicroV is the latest technology introduced by Esaote with an astonishing level of sensitivity for small vessels and slow-flow detection. With a top performance in terms of sensitivity and spatial resolution for the study of micro-vascularization, characterized by a very high frame rate, and developed with a motion artifact suppression algorithm, MicroV offers tiny and slow-flow vessel detection without B-Mode interference (no noise related to hyperechoic structures) to represent information related to flows that cannot be detected with standard Doppler techniques.

"microV is rapid, not invasive and definitely inexpensive"

These characteristics allow it to be used as a further diagnostic tool in the routine sonographic examination of thyroid nodules with suspicious ultrasound features or with indeterminate cytology at fine needle aspiration biopsy.



Bi-Dimensional Navigation

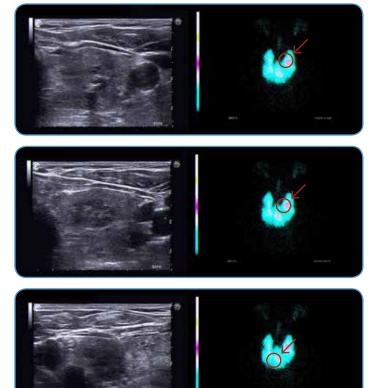
The localization of lesions with real-time ultrasound while taking advantage of secondary 2D technology represents a significant challenge in everyday clinical practice without technological support.

BodyMap is an exclusive technology that enables the real-time



visualization of the probe position on a second system next to any kind of DICOM 2D image, such as Scintiscan, SPECT, MRI,PET, XRay and many more. The co-registration between the ultrasound and the second imaging modality takes less than one minute with a very precise

outcome.



Real-time tracking of the probe on a 2D thyroid scintigraphy image: ultrasound reference according to the different locations and visualization of the probe as a green circle on the second modality.

"Bi-dimensional BodyMap navigation is the guide to biopsy sampling of suspicious lymph nodes in areas difficult to detect at ultrasound examination, as the co-registration may provide a quick and precise definition of the target area and appropriate sampling of tumor recurrence."

Prof. Enrico Papini

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Endocrinology

This innovative technology potentially has a relevant diagnostic use in two main fields: multinodular goiters and neck lesions where cancer recurrence is suspected.

Multinodular goiter is a frequent clinical finding in borderline iodine-deficient regions. Nodular goiters are not infrequently associated with a condition of subclinical hyperthyroidism, due to the autonomous function of one or more hyper-functioning nodules that are not distinguishable from the coexistent hypo-functioning thyroid lesions at ultrasound examination. All the guidelines and consensus documents consistently state that hyper-functioning nodules should not be submitted to fine needle aspiration biopsy due to their negligible prevalence of malignancy and the risk of misleading cytological results. Radioisotope thyroid scans may clearly reveal the "hot" (hyper-functioning) or "cold" (hypo-functioning) nature of thyroid nodules but the topographic localization of the different lesions is usually cumbersome and uncertain. These problems may be easily resolved by the realtime visualization of the transducer position on a second imaging system such as thyroid scintiscan.

A less frequent but extremely important use of the bi-dimensional navigation is as a guide to biopsy sampling of suspicious lymph nodes in areas difficult to detect at ultrasound examination. In a few cases these recurrences may be detected only by crosssectional imaging techniques such as MRI or PET/CT. The co-registration between the ultrasound scan and a functional imaging modality may provide a quick and precise definition of the target area and appropriate sampling of tumor recurrence.

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Technology and features are system/configuration dependent. The use of Contrast Agents in the USA is limited by FDA to the left ventricle opacification and to characterization of focal liver lesions. Specifications subject to change without notice. Information might refer to products or modalities not yet approved in all countries. Product images are for illustrative purposes only. For further details, please contact your Esaote sales representative.