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● *Original Contribution*

COMPARISON OF TWO DIFFERENT ULTRASOUND DEVICES USING STRAIN ELASTOGRAPHY TECHNOLOGY IN THE DIAGNOSIS OF BREAST LESIONS RELATED TO THE HISTOLOGIC RESULTS

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Abstract—This study was conducted to provide evidence that elastograms of two different devices and different manufacturers using the same technical approach provide the same diagnoses. A total of 110 breast lesions were prospectively analysed by two experts in ultrasound, using the strain elastography function from two different manufacturers (Hitachi HI-RTE, Hitachi Medical Systems, Wiesbaden, Germany; and Siemens eSie Touch, Siemens Medical Systems, Erlangen, Germany). Results were compared with the histopathologic results. Applying the Bowker test of symmetry, no statistically significant difference between the two elastography functions of these two devices was found ($p = 0.120$). The Cohen's kappa of k = 0.591 showed moderate strength of agreement between the two elastograms. The two examiners yielded moderate strength of agreement analysing the elastograms (Hitachi HI-RTE, k = 0.478; Siemens eSie Touch, k = 0.441). In conclusion, evidence is provided that elastograms of the same lesion generated by two different ultrasound devices equipped with a strain elastography function do not significantly differ. (E-mail: afarrokh@online.de)

Key Words: **Strain elastography, Breast, Ultrasound, Method comparison.**

INTRODUCTION

Elastography is one of the promising technologies in the field of breast ultrasound and was first introduced in 1990 (Ophir et al. 1991). Since then, this measuring method was steadily developed until the year 2003, when the first commercially available system appeared on the market. One of the oldest examination methods for breast lesions is palpation. This method is based on the fact that malignant tumours are stiffer and less prone to deformation than benign tumours (Samani et al. 2007). Elastography can be understood as an ultrasound-based palpation, measuring the elastic features of a lesions and its surrounding tissue and finally providing these information on the display of the ultrasound device superimposed to the B-mode picture. The current systems are not only able to distinguish benign from malignant breast tumours (Sadigh et al. 2012), but also to find application in the prediction of histologic features (Grajo and Barr 2014; Pu et al. 2017). Furthermore, elastography provides information on whether lesions respond to neoadjuvant chemotherapy and can thus alter therapy planning (Evans et al. 2017; Jing et al. 2016). Elastography is not used as an independent method, but as a lesion-based adjunct to B-mode ultrasound, providing additional information about the lesion, which will influence the final Breast Imaging Reporting and Data System (BI-RADS) assessment (Cosgrove et al. 2013). Adding elastography to conventional B-mode ultrasound increased the specificity of the breast examination (Barr et al. 2015; Wojcinski et al. 2010).

More and more manufacturers incorporate an elastography function in their high-end ultrasound systems. However, the technology used differs among manufacturers and systems. In 2013, the World Federation for Ultrasound in Medicine and Biology (WFUMB) prepared a guideline for the application of elastography. In this, two basically different methods of elastography are distinguished, strain imaging and shear-wave imaging. These two methods also require different methods of conducting examinations to obtain valid elastograms. For strain elastography, the examiner uses the ultrasound

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transducer to exert compression on the breast tissue and the resulting deformation of a lesion can be measured. Shear-wave elastography needs the ultrasound transducer to be held steadily. Then acoustic radiation-force pulses are sent into the tissue. A shear-wave propagates orthogonal to this pulse. The stiffness of a lesion can then be calculated by measuring the propagation speed of that shear wave. The shear-wave propagates more quickly in stiff lesions than in soft lesions (Barr et al. 2015; Shiina et al. 2015). Looking only at the strain imaging group, eight manufacturers are listed in the WFUMB guidelines (Shiina et al. 2015). The basic elastography method is generally named by the manufacturers, but there are no detailed process descriptions that would allow the assertion that the methods of two different manufacturers are identical. Until this study, however, researchers have not evaluated whether the elastograms of different manufacturers using the same physical method are equivalent or divergent. This is of great importance because otherwise the data collected with the device of one manufacturer cannot be transferred to the devices of other manufacturers using the same method.

The aim of this study was thus to compare the strain elastography function of two different manufacturers and to find out whether the elastograms that are created correspond to or differ from each other.

MATERIALS AND METHODS

Patients

This prospective study was conducted according to the protocol of the latest World Medical Association Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Patients and it was approved by our local ethics committee (No. D509). In total, we analysed 110 breast lesions between June 2013 and May 2014. The patients had an average age of 48 y, ranging 14–78 y. They were referred to our breast centre for special diagnostic queries such as palpable masses, pain or suspicious mammograms.

Patients who had a lesion in B-mode ultrasound and were already scheduled for core biopsy or fine-needle aspiration, because of suspicious findings, symptomatic lesions or precautionary reasons (at the patient's request), underwent additional elastographic examination on two ultrasound devices. After we received written informed consent from a patient, we performed either fine-needle aspiration, core biopsy or lesion surgery. The histologic and cytologic findings were compared with the preinterventional rating of the lesion, using the different examination methods. It is important to note that the results of the elastogram did not change the diagnostic approach. All diagnostic steps were conducted according to the German interdisciplinary GoR level III guidelines for the diagnosis, therapy and follow-up care of breast cancer (Kreienberg et al. 2013).

For 10 BI-RADS 2 lesions without symptoms, invasive assessment was not indicated. These cases were monitored with ultrasound for at least 2 y after the first assessment.

Elastogram acquisition

For the present study two ultrasound devices from different manufacturers were used to obtain an elastogram. Both devices use the strain imaging method with manual compression to assess the elastic properties of the lesion of interest. One device was the Hitachi HI VISION Avius (Hitachi Medical Systems, Wiesbaden, Germany) equipped with the Hitachi Real-time Tissue Elastography (HI-RTE) function. The frequency of the probe EUP-L74 M ranged 5–13 MHz, depending on lesion depth. The other device used in this study was the Siemens ACUSON S2000 by (Siemens Medical Systems, Erlangen, Germany) with the eSie Touch elastography feature. The frequency of the transducer 18 L6 ranged 5.5–18 MHz, depending on lesion depth.

We used the same approach on both ultrasound systems to obtain a valid elastogram. Both ultrasound systems were set to the same elastography colour scale, with red indicating soft tissue and blue indicating stiff tissue.

Using strain elastography, the first step to obtain an elastogram is to compress the tissue by means of the ultrasound transducer, which is positioned strictly perpendicular to the skin. To ensure the same amount of precompression in both examinations, the ultrasound transducer is first placed on the breast slightly touching the skin, so that sufficient contact is provided to obtain a good B-mode image. It is then verified whether the subcutaneous fat layer is represented in green and red colours on the elastogram. If the fat layer appears blue, the precompression is too high and is reduced until the fat layer appears in green and red. The excitation by the ultrasound probe leads to a certain degree of displacement within the tissue. The resulting tissue strain is generally lower in stiff lesions and higher in soft lesions. The tissue strain can be calculated by measuring the echo frequency patterns before and after excitation, which is achieved by a cross-correlation method. In addition to the axial movement, the frequency patterns of neighbouring ultrasound waves are compared simultaneously to determine the lateral deviation of the lesion during compression. This is done by both ultrasound devices, using the extended combined autocorrelation method. The strain image is then reconstructed, using the modified 3-D-Finite-Element Method (Frey 2003; Shiina and Yamakawa 2005) and finally colour-coded by the ultrasound device and fused on top of the B-mode picture. Both systems use strain normalization and measure axial strain.