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**Diagnostic performance of an automated breast ultrasound system (SomoV®) in comparison with hand - held ultrasound and mammography for histopathologically proven breast lesions**

Promotionsfach: Frauenheilkunde

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The main purpose of this study was to evaluate the diagnostic performance of SomoV® for the detection of benign and malignant breast lesions, and for the classification of BI-RADS® assessment categories. The performance of SomoV® was compared to HHUS and MG on the basis of histopathologically proven breast lesions.

From 25.06.2008 to 17.04.2009, 1262 patients underwent an examination with the automated breast ultrasound SomoV® in the Outpatient Clinic of the Obstetrics and Gynecology Department of the University of Heidelberg. 241 patients with 310 lesions were included in this study. The inclusion criteria for the study were as following:

- 1) Every patient underwent an examination with hand-held ultrasound, mammography and the automated breast ultrasound SomoV®.
- 2) Every patient had evaluation reports of hand-held ultrasound, mammography and the automated breast ultrasound SomoV® scored with Breast Imaging, Reporting and Data System developed by the American College of Radiology.
- 3) Every patient underwent a core needle biopsy guided by ultrasound, mammography or magnetic resonance tomography.
- 4) Every patient had a final histologic result.

The evaluation of the data acquired in this study was done by one experienced physician. The physician was blinded to all patient variables, including patient's medical history and former operations and to all other diagnostic results including clinical findings and mammograms.

The interpretation of the images was according to the BI-RADS® score. BI-RADS® scores and histologic results were recorded in a binary scoring system and the sensitivity, specificity, positive predictive value and negative predictive value, followed by the diagnostic accuracy were calculated for each diagnostic modality. Histologic results were defined as gold standard.

To test if there was a statistically significant difference between paired proportions McNemar's Test was used for each diagnostic method. To measure the agreement between two raters or observers (e.g. SomoV® and histological results, HHUS and histological results) the Cohen's kappa coefficient- often simply called Kappa-  $\kappa$  was calculated.

This study shows that SomoV® is found to be a very pleasant diagnostic modality by patients. There is a relatively short duration of data acquisition and interpretation.

Comprising two separate stations, the Acquisition Station and the Prism Work Station, it is possible to perform examination and to evaluate the images at the same time, providing more time for physicians to interpret the images.

Because of the standardized acquisition process, the work sheet for the evaluation of the images and the manipulation options of the viewing system, there is operator independency and a good reproducibility which are especially relevant for screening situations, and for follow-up and control studies.

The volumetric data sets with the features of the view station could provide potential information for computer-aided detection of breast lesions - as applied in mammography and magnetic resonance tomography- also in automated ultrasound imaging.

Regarding diagnostic performance, SomoV® showed a statistically significant tendency to classify histologically malignant findings as potentially benign and a fair agreement with histologic confirmation.

SomoV® presents a good diagnostic accuracy of 66% compared to the 69 % of HHUS and 71 % of MG. SomoV® can not provide a sufficient high sensitivity (55% - corrected 64%) compared to HHUS and MG to be able to replace any of them, but it provides a complementary function. Considering that SomoV®, -used in conjunction with MG- could increase the sensitivity and NPV of MG similarly to HHUS without markedly reducing the specificity and PPV of MG, SomoV® seems to be a promising supplementary diagnostic tool which could be applied to complement MG for breast cancer screening.