Arch Gynecol Obstet (2015) 291:889–895
DOI 10.1007/s00404-014-3509-9

GYNECOLOGIC ONCOLOGY

Evaluation of an automated breast 3D-ultrasound system by comparing it with hand-held ultrasound (HHUS) and mammography

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Received: 11 August 2014 / Accepted: 7 October 2014 / Published online: 14 October 2014

Abstract
Purpose Automated three-dimensional (3D) breast ultrasound (US) systems are meant to overcome the shortcomings of hand-held ultrasound (HHUS). The aim of this study is to analyze and compare clinical performance of an automated 3D-US system by comparing it with HHUS, mammography and the clinical gold standard (defined as the combination of HHUS, mammography and—if indicated—histology).
Methods Nine hundred and eighty three patients (=1,966 breasts) were enrolled in this monocentric, explorative and prospective cohort study. All examinations were analyzed blinded to the patientś history and to the results of the routine imaging. The agreement of automated 3D-US with HHUS, mammography and the gold standard was assessed with kappa statistics. Sensitivity, specificity and positive and negative predictive value were calculated to assess the test performance.
Results Blinded to the results of the gold standard the agreement between automated 3D-US and HHUS or mammography was fair, given by a Kappa coefficient of 0.31 (95 % CI [0.26;0.36], $p < 0.0001$) and 0.25 (95 % CI [0.2;0.3], $p < 0.0001$), respectively. Our results showed a high negative predictive value (NPV) of 98 %, a high specificity of 85 % and a sensitivity of 74 % based on the cases with US-guided biopsy. Including the cases where the lesion was seen in a second-look automated 3D-US the sensitivity improved to 84 % (NPV = 99 %, specificity = 85 %).
Conclusion The results of this study let us suggest, that automated 3D-US might be a helpful new tool in breast imaging, especially in screening.

Keywords Ultrasound · Breast · Automated three-dimensional breast ultrasound · 3D scanning · BI-RADS®

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Introduction

Since its introduction in 1951 [1] hand-held breast ultrasound (HHUS) has become an important instrument in complementary breast imaging and is accepted in assessing suspicious lesions of the breast [2–5]. Concerning breast cancer screening of asymptomatic women, especially in women with dense breast tissue sensitivity of breast imaging may be increased by a HHUS in addition to mammography [6–11].

The challenge is to obtain reproducible and standardized data with an ultrasound examination. Until today hand-held breast ultrasound (HHUS) is highly dependent on the examineŕs experience. There have been multiple attempts to solve these problems with automated breast ultrasound systems during the last decades [12–22].

The new generation of automated breast ultrasound systems combines automation and three-dimensional (3D) scanning [23–33]. The SomoV^{TM} (U-Systems, Inc., Sunnyvale, CA, USA) system allows an automated recording of the whole breast 3D volume by a technician. The

acquired 3D volume data can be evaluated time- and location-independent by different physicians.

The aim of this study was to evaluate and compare clinical performance of the automated SomoV^{TM} system by analyzing 1,966 cases in comparison to the standard breast imaging methods and histology if available.

Materials and methods

Study design and procedures

Nine hundred and eighty three patients were included in this monocentric, explorative, prospective, institutional review board approved cohort study. The indication for examination had a wide range including routine check-up, follow-up, preoperative staging of breast cancer, evaluation of palpable lumps and work-up of abnormalities found in HHUS or mammography. The examination with SomoV^{TM} was integrated in the routine of the breast clinic. Mammography, HHUS and SomoV^{TM} were interpreted and classified according to the current American college of radiologists breast imaging reporting and data system (ACR BI-RADS®) [34]. The decision for further histological work-up (biopsy) was based on the conventional methods for breast imaging (mammography and/or ultrasound BI-RADS® category 4 or 5), not on the results of SomoV^{TM}. Thereby the standard methods (HHUS, mammography and—if indicated—histology) served as gold standard.

SomoV^{TM} examination

Automated ultrasound of the breast was performed by a technician. Both breasts (thoracic wall after mastectomy respectively) were scanned with SomoV^{TM}. Nine hundred and eighty three patients and therefore 1,966 cases (=breasts) were included.

The SomoV^{TM} system consists of a scanning unit and the diagnostic workstation. The scanning unit contains a 10 MHz high-frequency linear transducer. This transducer is able to capture a volume of 17 × 14.5 × 5 cm^3 in a single scan. In the course of a single scan which takes about 60 s the SomoV^{TM} generates 340 two-dimensional slices. The number of required scans to image the whole breast was determined by the patient́s breast size and ranged from one to five scans per breast (Fig. 1a, b).

The acquired volume data were automatically sent from the SomoV^{TM} scanning unit to the diagnostic workstation to process the 3D volume dataset in various multi-planar reconstructions and orientations. For the purpose of this study transverse, coronal and sagittal views were available. Technical details of the SomoV^{TM} method and handling have already been described previously (see Fig. 2, SomoV^{TM} diagnostic workstation) [28, 31, 35].

All scans were interpreted by a physician specialized on breast diagnostics. SomoV^{TM} interpretation took place independent of the patient́s work-up; the reviewer was blinded to the findings on the corresponding mammograms, HHUS and to all clinical information including the medical history of the patient.

Conventional breast imaging

Mammography and HHUS were evaluated in one session by the same breast diagnostics specialist knowing the patient́s medical history and clinical findings. Bilateral HHUS of the whole breast was performed by a physician specialized in breast imaging by using the Acuson Antares ultrasound system (Siemens Medical Solutions, Mountain View, CA, USA) equipped with a linear-array transducer with a bandwidth of 7.5–13.5 MHz.

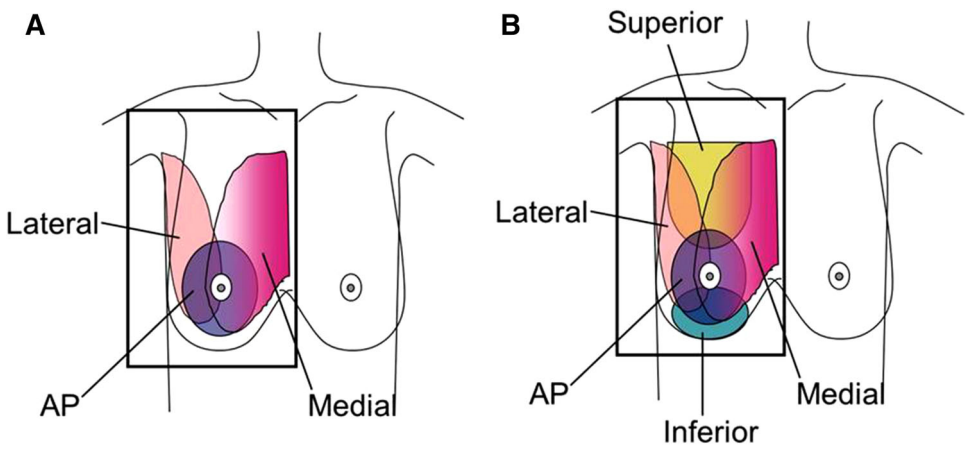

Fig. 1 SomoV^{TM} examination three (**a**) and five (**b**) scans per breast

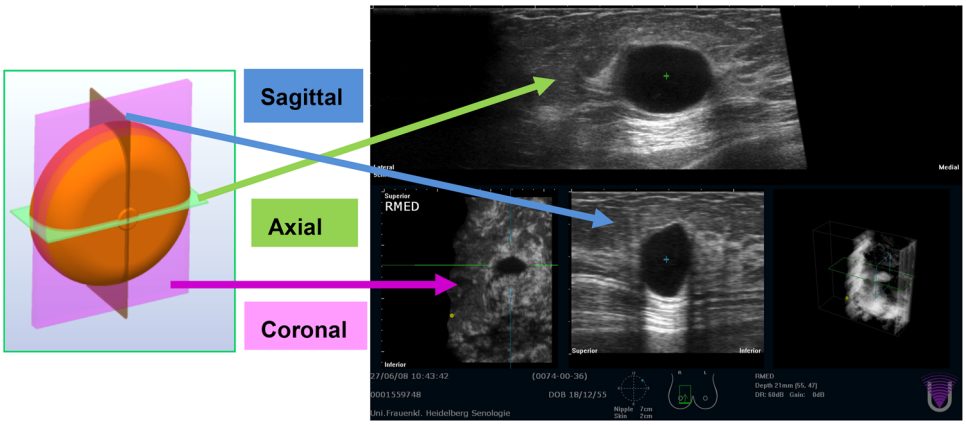

Fig. 2 SomoV™ diagnostic workstation

Digital mammography was conducted by medical technical assistants using the Mammomat Novation DR (Siemens Medical Solutions, Mountain View, CA, USA). Usually the examination consisted of the cranio caudal (CC) and the medio latero oblique (MLO) projections. Whenever necessary based on the decision of a physician, additional positions as the medio lateral (ML) projection, spotfilms or magnification views were performed.

All mammography images were soft copy double-read by experienced physicians in breast diagnostics.

Data evaluation and statistical analysis

As an explorative study, all statistical analyses are descriptive. Reported *p*-values have no confirmatory character. Statistical analyses were performed with SPSS Statistics software Version 21.0.

At first, the study cohort is described by calculating absolute and relative frequencies for categorical variables and means and standard deviations for metric outcomes.

The main objective of this study was to evaluate the diagnostic potential of SomoV™ to truly differentiate cancer and normal/benign breast tissue without the knowledge of other clinical information. Therefore, we compared the BI-RADS® scores given for the SomoV™ examinations with those for HHUS, mammography and the gold standard. In order to do this, the BI-RADS® score results were dichotomized as follow:

For SomoV™, the BI-RADS® 1 and 2 were summarized as benign, the BI-RADS® scores 0, 4 and 5 were combined and rated as unclear/suspicious. BI-RADS® score 3 was not used to characterize findings with SomoV™ in this study simulating a screening situation. BI-RADS® 0 was given in all cases with unclear findings as for example possible scar tissue or artifacts.

For HHUS and mammography the BI-RADS® 1, 2 and 3 were summarized as benign, the BI-RADS® scores 4 and 5 were combined and rated as unclear/suspicious/malignant.

Kappa statistics were applied to measure agreement between the different diagnostic methods [36]. Moreover the corresponding 95 % confidence intervals are provided.

We also calculated sensitivity, specificity and positive and negative predictive values.

Results

Study population

In total, 983 patients were examined with SomoV™ which leads to 1,966 cases (=breasts/thoracic walls) to be evaluated. The mean age was 55.7 years (range 19–92 years). A number of 348 patients (35 %) came for further evaluation of lesions detected in an outpatient clinic, 283 patients (29 %) came for a routine checkup, 274 patients (28 %) attended their follow-up visit after breast cancer and 78 (8 %) came for re-evaluation of lesions that were under observation (further details see Table 1). Table 2 shows the given BI-RADS® scores for SomoV™, HHUS and mammography.

Agreement of SomoV™ interpretation with HHUS and mammography

Table 3 shows the absolute numbers of agreement and disagreement for SomoV™ and HHUS yielding a kappa coefficient of 0.31 (95 % CI [0.26;0.36], $p < 0.0001$). In 1,638 cases (83 %) both methods came to the same interpretation. Mammography and SomoV™ agreed slightly worse (kappa coefficient 0.25 (95 % CI [0.2;0.3], $p < 0.0001$) (see Table 4).

Table 1 Description of the study cohort

Variable	Specification	Number (%)
Indication ($n = 983$)	Further evaluation	348 (35.4)
	Routine check up	283 (28.8)
	Follow-up after breast cancer	274 (27.9)
	Re-evaluation	78 (7.9)
Age ($n = 983$)	<40	101 (10.3)
	40–50	249 (25.3)
	50–60	280 (28.5)
	60–70	254 (25.8)
	>70	99 (10.1)
Menopausal status ($n = 983$)	Premenopausal	261 (26.6)
	Perimenopausal	39 (4.0)
	Postmenopausal	640 (65.1)
	Missing	43 (4.4)
Breast size ($n = 1{,}966$)	Cup A	254 (12.9)
	Cup B	834 (42.4)
	Cup C	522 (26.5)
	>/=Cup D	290 (14.8)
	Missing	66 (3.3)
SomoV^{TM} scans per breast ($n = 1{,}966$)	1	278 (14.1)
	3	1,403 (71.4)
	5	285 (14.5)
Histology ($n = 242$*)	Benign	98 (40.5)
	Malignant	144 (59.5)

* Based on clinical routine (Mammography and/or US BI-RADS 4 or 5) histology was indicated in 242 cases

Table 2 BIRADS® assessment

Variable	Specification	Number (%)
SomoV^{TM} BI-RADS® ($n = 1{,}966$)	1	944 (48.0)
	2	651 (33.1)
	0	136 (6.9)
	4	192 (9.8)
	5	43 (2.2)
HHUS BI-RADS® ($n = 1{,}966$)	1	544 (27.7)
	2	1,219 (62.0)
	3	32 (1.6)
	4	85 (4.3)
	5	86 (4.4)
Mammography BI-RADS® ($n = 1{,}846$)	1	535 (29.0)
	2	1,084 (58.7)
	3	36 (1.9)
	4	110 (6.0)
	5	81 (4.4)

Table 3 SomoV^{TM} vs. HHUS

	HHUS		
	BI-RADS® 1 + 2 + 3	BI-RADS® 4 + 5	Total
SomoV^{TM}			
BI-RADS® 1/2	1,531	64	1,595
BI-RADS® 0/4/5	264	107	371
Total	1,795	171	1,966

Table 4 SomoV^{TM} vs. Mammography

	Mammography		
	BI-RADS© 1 + 2 + 3	BI-RADS© 4 + 5	Total
SomoV^{TM}			
BI-RADS© 1/2	1,395	94	1,486
BI-RADS© 0/4/5	260	97	357
Total	1,655	191	1,846

Performance of SomoV^{TM} compared with the gold standard

As some lesions were explicitly not seen in HHUS e.g. microcalcification (even not in a second-look US after MRI) the lesions were consequently biopsied under mammographical guidance (53 lesions). These cases are not expected to be seen in SomoV^{TM} and therefore have been excluded from the further analysis.

The absolute numbers of agreement which result in a kappa coefficient of 0.3 and a total agreement rate of 84 % are shown in Table 5. In this group 119 breast cancers were detected. Sensitivity, specificity, positive and negative predictive values (PPV and NVP) are given as 74, 85, 24 and 98 %, respectively.

SomoV^{TM} detected breast cancer correctly in 88 cases (74 % sensitivity). Thirty one breast cancer cases were not detected with SomoV^{TM}. After reevaluating these cases another 12 were seen when rereading the original SomoV^{TM} scans for evaluation (84 % sensitivity, 85 % specificity, 27 % PPV and 99 % NVP). A further eight cases were seen primarily with MRI or mammography and the US-guided biopsy was done after a second-look HHUS. Within the remaining 11 cases not seen by SomoV^{TM}, the cancer was located behind the nipple or very peripheral in five cases so that acquisition technique came to its limits. In two cases an ulcerated carcinoma made the examination difficult and in one case a recurrent focus near the chest

Table 5 SomoV™ vs. Goldstandard

	Goldstandard		
	Benign	Malign	Total
SomoV™			
BI-RADS© 1/2	1,520	31	1,551
BI-RADS© 0/4/5	274	88	362
Total	1,794	119	1,913*

Kappa 0.3 (95 % CI [0.25;0.35], $p < 0.0001$), 84 % total agreement
*Cases with stereotactical biopsies excluded

wall after mastectomy and reconstruction was difficult to interpret without the clinical information. In a clinical situation when informed about the patients history and combining that knowledge with the clinical findings and breast imaging only 11 cancers would not have been found. Respectively 108 of 119 breast cancers would have been detected resulting in a sensitivity of 91 %.

Discussion

SomoV™ was at a disadvantage in comparison to HHUS and mammography due to the blinding since the examiners of HHUS and mammography had knowledge about the clinical situation (scars, lumps, history of the patient, etc.). In addition, the results of mammography were available during HHUS examination and interpretation. In contrast the examiners evaluating SomoV™ data were given no further information about the patients' medical history or results from any other examination. We were aware that this would lead to a diagnostic imbalance between the different methods and a disadvantage for SomoV™, but we aimed to analyze the diagnostic test performance in a situation similar to screening. By including diagnostic cases we intended to increase the number of potential findings in the SomoV™ data.

Nevertheless the study revealed kappa coefficients that indicate fair agreement ($k = 0.25$–0.31) with HHUS and mammography. Otherwise total agreement rates for dichotomized (benign vs. malignant) were even above 80 %.

The specificity rates are acceptable, which means that a negative result with SomoV™ is very likely to be truly negative. The sensitivity ranged from 74 to 91 % depending on the fact if second-look US and clinical information were included or not.

Challenges of the scanning technique

Some problems concerning the quality of the acquired data arise from the scanning units construction. As soon as a breast contour is modified (for example after surgery) the contact between transducer and tissue can be inadequate and a lack of data and artifacts can be the consequence.

Strength of the study

The strength of this study is the large series of cases. Contrary to other studies, where nearly every examined breast showed a finding, the examiners in our study had a more heterogeneous group and were blinded to all clinical information. This made evaluation more difficult. Wenkel et al., for example, examined only suspicious breasts with SomoV™ so that there was a finding in nearly every data set [31]. Kotsianos-Hermle et al. included only suspicious findings in their study [37]. In the study of Prosch et al. the examiners did not know the results from HHUS and mammography but they were informed about the patients clinical history so that they knew about scars, etc. [28].

Outline: implementation of SomoV™ as a screening tool

It is very important for the application of a screening method that nearly every patient with a lesion is detected. From the 144 carcinomas confirmed by biopsy, 92 were detected with SomoV™. From the remaining 52 cases 21 cancers could not be seen with HHUS, neither with SomoV™. Excluding all cases where the failure was definitely not due to the SomoV™ technique (see results), only 19 cancers would not have been detected with SomoV™. Moreover the number of undetected lesions would decrease with the examiners gaining experience and a setting where the examiners are given additional information concerning the patients history. Therefore Somo V™ could be a valuable screening tool for either young women in addition to the clinical examination or women between 50 and 70 in combination with mammography. The problem of false positive results is that they cause unnecessary anxiety for patients on the one hand and further diagnostic procedures, as a second-look HHUS and in some cases core cut biopsies on the other hand. This means an emotional drain for the concerned patients. The false positive rate in our study would probably decrease with growing experience and when medical history and the clinical information can be taken into account. The BI-RADS® score 0 was given exceptionally frequently for SomoV™ data. It is likely that being given more information about the patients history and clinical findings and having more experience with SomoV™ examination, the examiners could decide more often whether a lesion is suspicious or not and the number of BI-RADS® score 0 would decrease, which would lead to decreasing false positive rates.

Conclusion

The results of this explorative study let us suggest, that automated 3D ultrasound might be a helpful new tool in breast imaging, especially in screening.

Ethical standards The vote of an independent ethics committee has been received.

Conflict of interest There is no actual or potential conflict of interest.

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