Comparison of Automated Whole Breast Ultrasound and Handheld Ultrasound

- Time Related Differences and Clinical Thoughts

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Bachelor of Science Thesis in Medical Engineering
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This bachelor thesis project was performed in collaboration with
Siemens AB
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Comparison of Automated Whole Breast Ultrasound and Handheld Ultrasound – Time Related Differences and Clinical Thoughts

Jämförelse av automatiserat helbröst ultraljud och handhållet ultraljud – Tidsrelaterade skillnader och kliniska åsikter

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Abstract

Early detection and treatment of breast cancer mostly decides a diagnosis’ outcome. Mammography is not always able to classify tumours and sometimes is a complementary examination with a handheld ultrasound necessary. Handheld ultrasound may be time consuming and needs a specialist as operator. Recently, an ultrasound transducer that automatically scans the breast has been developed to overcome the problems with handheld transducers. The aim of this study was to evaluate the new transducer in a clinical view and three research questions were set up:

- Which of the modalities mammography, handheld ultrasound (HHUS), automated whole breast ultrasound (AWBUS) and elastography (UE) contributes to best made diagnoses of breast cancer in dense breasts?
- Are there any time related differences in using an AWBUS transducer compared to a HHUS transducer when searching for breast cancer?
- What are users’ opinions to AWBUS transducers?

A literature study compared four different modalities used for diagnosing breast cancer. Measurements of examination times and interviews were held at Västerviks sjukhus (Västervik) and Södersjukhuset (Stockholm). Sahlgrenska Universitetssjukhus (Gothenburg) participated in phone interviews. Previous studies showed that AWBUS found more lesions and UE was more specific in the diagnoses. Requirement of specialists’ time can according to this study be decreased by using AWBUS, but more nurse time was needed. The main advantage with the AWBUS is that specialists do not have to reserve their time for patients.
Sammanfattning


- Vilken av modaliteterna mammografi, handhållt ultraljud (HHUS), automatiserad helbröst ultraljud (AWBUS) och elastografi (UE) medför bäst bröstcancerdiagnoser på täta bröstar?
- Finns det några tidsmässiga skillnader mellan att använda en AWBUS-transducer och en HHUS-transducer när man letar efter bröstcancer?
- Vilka är användarnas åsikter om AWBUS-transducers?

Preface

This Bachelor Thesis in Medical Engineering, 15 ETCS, was performed in collaboration with Siemens AB the spring of 2014. It is recommended that the reader of the thesis has basic knowledge in anatomy and medical imaging systems.

There are many people that have been supportive to me during this project. First of all, I would like to thank Thomas Lindström, my supervisor at Siemens, for taking your time to supervise me. I would also like to thank Oskar Strand, Siemens, for supporting me during the thesis work. Thanks to Lena Persson, Siemens, for establishing the contact between me and Thomas and thank you all employees at Siemens AB department of Ultrasound.

I would also like to thank my examiner at KTH, Lars Gösta Hellström, and my supervisor at KTH, Erik Widman.

Finally, thanks to all healthcare professionals at Västerviks sjukhus and Södersjukhuset, for letting me visit your mammography departments. Also thanks to Sahlgrenska Universitetssjukhus for participating in interviews.

Sandra Kraft
May 27, 2014
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Glossary

**ABUS** Automated Breast Ultrasound System (GE, U-System), a model of AWBUS manufactured by GE.

**ABVS** Automated Breast Volume Scanner (Siemens, Acuson), a model of AWBUS manufactured by Siemens.

**Accuracy** Rate of true results of a test

\[
\frac{\text{True positives} + \text{True negatives}}{\text{Number of tested values}} \quad (1)
\]

**Average time**

\[
\frac{\sum_{i=1}^{n} \text{time}_i}{n} \quad (2)
\]

**AWBUS** Automated Whole Breast Ultrasound, a technology that automatically scans the breast with ultrasound.

**BI-RADS** Breast Imaging Reporting And Data System, a standardised model developed by the American College of Radiology (ARC), which is used for reporting findings in mammograms and breast density. The categories are in this thesis only used for describing findings.

**Coronal plane** Divides the body in vertical slices in direction front to back.

**Dense breasts** Breasts that mainly consist of fibrous and glandular tissues, more than 50% of the breast consists of non-fat tissues.

**HHUS** Handheld Ultrasound, a technology that uses a transducer held in the operator’s hand. The term is in this thesis used as a generalisation of all handheld transducers, independent of manufacturer.

**Mammography** An application of X-rays designed for examinations of breasts.

**Outpatient service** Where patients are followed up and rehabilitated upon completed treatment.

**PACS** Picture Archiving and Communication System, a digital system that archives all medical images that have to be saved.

**Screening program** A population without symptoms of a disease is regularly examined to provide early detection of the disease.

**Sensitivity** How many positive objects that are reported as true by the test

\[
\frac{\text{True positives}}{\text{True positives} + \text{False negatives}} \quad (3)
\]
Glossary

Specificity

How many negative objects that are reported as negative by a test

\[
\text{Specificity} = \frac{True \ negatives}{True \ negatives + False \ positives}
\]  

STD

Standard Deviation of a population of tested values

\[
\text{STD} = \sqrt{\sum_{x=1}^{n} (value(x) - mean \ value)^2 \over n - 1}
\]  

UE

Ultrasound Elastography, a technology that measures stiffness of a tissue. An expression for a technology, which is independent on manufacturer.
Chapter 1

Introduction

Breast cancer is one of the most common cancer types that affects women and 8000 diagnoses are yearly made in Sweden [1] [2]. Early detection enables early treatment, which usually contributes to better prognoses. Women in the age of 40-74 years have the highest risk to develop breast cancer and they are therefore recommended to regularly undergo examinations with mammography. Mammography is an application of X-ray used for breast imaging and is sometimes complemented by an examination with ultrasound. The overall recall rate for patients that have undergone mammography is 8% [3]. A study has shown that mammography does not recognise all lesions in dense breasts [4], which appears in 10% of the female population [5].

Examinations with conventionally used Hand Held Ultrasound Transducers (HHUS) are operator dependent and sometimes time consuming. For this reason, an Automated Whole Breast Ultrasound (AWBUS) transducer has been developed, which aims to reduce the issues with HHUS [6] [7]. The AWBUS technology has an automated sweeping system and examinations are performed by nurses instead of radiologists, which is the case for HHUS. As a consequence, diagnoses can be made by the radiologist after the patient has left the hospital. In these cases, new examinations can only be performed by calling the patient back to the clinic. Technologies with this workflow must be specific and sensitive in order to minimize the rate of false positively and false negatively made diagnoses. Today, two versions of the AWBUS exist. One is manufactured by Siemens Acuson and is called Automated Breast Volume Scanner (ABVS). The other version is manufactured by GE U-system and called Automated Breast Ultrasound System (ABUS).

When women are examined with ultrasound, they usually also undergo a mammography examination. Until recently, the only time requirement identified was for the woman’s entire visit at the hospital, which in these cases included examination with mammography and ultrasound. To be able to use AWBUS in a wider context, examination times for the technology had to be determined. The technology may in the future be used in the national screening programs, but that would require it to be efficient with regards to time and workflow.

The AWBUS systems had to be implemented in clinics before it could be decided on which kind of patients an examination would give the highest utility. As a result, important information and knowledge was assumed to exist in the clinics and was to be identified. The collected information aimed to be shared with other clinics interested in the new systems.

- New workflow; AWBUS allows images to be analysed after the patient has left the clinic and thus diagnoses must be made correctly.
Chapter 1 Introduction

- Time requirement for examinations in the clinical workflow were unknown and to use the technology more widely the examination time had to be determined.
- Users’ opinions had not been evaluated; knowledge about the clinical advantages and disadvantages had not been collected.

1.1 Goals and Objectives

The aim of this bachelor thesis was to investigate if there were any differences regarding time and clinical value between AWBUS and HHUS. Two goals were set up, which were to be reached by answering three research questions.

The main goal of the thesis was to investigate if there were any time related differences between AWBUS and HHUS when used on women that could have breast cancer. Outcomes served to motivate for future extended usage of the transducers. The second goal of the thesis was to analyse users’ opinions about the two transducers. The analysis aimed to simplify future implementations and to support those who already use the technology but are uncomfortable with it.

To reach the goals, the following research questions were set up

- Which of the modalities mammography, HHUS, AWBUS and UE contributes to the most correctly made diagnoses of breast cancer in women with dense breasts?
- Are there any time related differences between AWBUS and HHUS when searching for breast cancer?
- What are users’ opinions to AWBUS compared to HHUS?

1.2 Demarcations

An introducing literature study was limited to a comparison of four technologies used for diagnosing breast cancer. Measurements of time requirement for patient examinations were limited to a maximum of 20 patients for HHUS and respectively AWBUS. Time measurements and users’ opinions were collected for the AWBUS system manufactured by Siemens.
Chapter 2

Theory

This chapter aims to give the reader a theoretical background to the topic of the thesis. A description of breast cancer and how it is diagnosed is followed by common imaging modalities used when searching for and diagnosing breast cancer.

2.1 Breast Cancer

Breast cancer is the most common type of cancer that affects women [1]; it kills 1500 women in Sweden every year, and according to Bröstcancerförerningarnas Riksorganisation [2] does more than 80 000 Swedish women live with the diagnosis. Less than 4% of the diagnoses are made on persons younger than 40 years and more than 60% of the diagnosed persons are older than 60 years [2]. Breast cancer arises in the same way as all other types of cancer; it is a result of mutations on the genes in the cell nucleus. Due to cell ageing, mutations are commonly processes in all cells and during cell reproduction are new genes produced. When mutations are made abnormally, tumours have abilities to occur. These are divided into two groups; benign tumours, cysts, and malign tumours, which are cancer related [8]. In contrast to benign tumours, a malign tumour has the ability of reproducing itself in an uncontrolled way. It grows fast and usually develops metastases.

Breast cancer is generally developed in the milk producing glands (lobular cancer) or in the ducts that carries milk from the glands to the nipple (ductal cancer). A tumour can be detected during palpation or medical imaging of the breast [9].

Early detection is the main reason to a survival outcome of a breast cancer diagnosis. Previous studies have proven that early detection, thanks to well-functioning screening programs, decreases the mortality of the diagnosis by 20% [10]. The Swedish National Board of Health and Welfare, Socialstyrelsen, recommends all women between 40 and 74 years old to regularly undergo mammographic examinations. Sweden has therefore developed a national screening program in which all women between 40 and 74 years are called to exams every 18:th to 24:th month [11].
Table 2.1: Diagnoses are classified in five categories depending on how far the cancer has spread [12].

<table>
<thead>
<tr>
<th>BI-RADS</th>
<th>Status</th>
<th>Prognosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Cancer has been developed in a few lobules or ducts</td>
<td>Well treated</td>
</tr>
<tr>
<td>1</td>
<td>Cancer has been developed in a few lobules or ducts</td>
<td>Well treated</td>
</tr>
<tr>
<td>2</td>
<td>Tumours to grow and are eventually spread</td>
<td>Well treated</td>
</tr>
<tr>
<td>3</td>
<td>Cancer is spread in large parts of the breast and has also invaded tissues in nearby regions</td>
<td>Aggressive treatment</td>
</tr>
<tr>
<td>4</td>
<td>Cancer is spread to other organs, for example brain, liver or lungs</td>
<td>Aggressive treatment, considered as untreatable</td>
</tr>
</tbody>
</table>

2.2 Mammography

The most common modality used when searching for breast cancer is mammography, which is schematically described in figure 2.1. A mammogram is a reconstructed image of the breasts made with X-rays. Breasts consist of tissues with similar atomic numbers and thus radiation of low energy is used to differentiate different tissues from each other. To attenuate a breast with radiation of low energy, the breast must be compressed to a thickness of approximately 5 cm. The X-ray emitting material consists of Molybdenum, which emits photons with energies of 17.4 or 19.6 keV. The currents used are in the range of 100 mA. To improve image resolution and sharpness, a thinner screen is used in mammography compared to traditional X-ray imaging.

Figure 2.1: Schematic description of a Mammography system. The rotating anode emits X-rays which are produced as a result of a current in the filament. A filter and a collimator decide which of the X-rays that will reach the patient’s breast. The screen is positioned under the breast support [13].
The radiation dose is concentrated to the breast, and therefore only efficient absorbed dose is measured and discussed. A normal absorbed dose for mammography is within the range of 1.5-3.0 mGy per image [14].

### 2.3 Ultrasound

In an examination with ultrasound, a transducer that converts electrical waves into sound waves, and vice versa, is used to send and receive the waves. Frequency of the waves determine image resolution and wave penetration. High frequencies give a high resolution as the penetration depth decreases. By varying the penetration depth, images of high resolution are created for the chosen depths.

To focus the waves into a beam they are sent in pulses, described in figure 2.2. A short pulse length contributes to higher axial resolution, depth, and a short pulse width yields high spatial resolution perpendicular to the wave propagation. The pulse length is defined as the distance that a wave travels in the tissue before it becomes too weak to be used. Pulse width depends on the width of the beam, which is affected by the transducer design [15].

![Figure 2.2: A schematic figure of an ultrasound beam.](image)

Elastography is a handheld transducer that uses the ultrasound waves to analyse the mechanical properties of tissues. These are called shear waves and shown in figure 2.3. Shear waves give information about tissue viscoelasticity and can be imaged using traditional ultrasound [17]. They propagate the tissues by moving its elements and as in traditional ultrasound imaging, shear waves are emitted and received by the same transducer. Elastography can also use physical compressions of tissues affected by for example respiring lungs. Using shear waves to diagnose breast cancer makes it possible to improve the classification of malign respectively benign lesions. Resolution in images can reach 1 mm in the same time as sensitivity is higher than in traditional ultrasound. Because of a speed of the waves, elasticity information can be given for large and moving organs [18].
Chapter 2 Theory

Figure 2.3: The transversal shear waves penetrate the tissue. Their penetration speed depend on the tissue elasticity which is measured by traditional ultrasound beams [17]

2.3.2 Automated Whole Breast Ultrasound

A relatively new application of ultrasound is a mechanically automated transducer (AWBUS), which produces images of breasts without needs of a specialist as operator. A conventional transducer is housed by a plastic box, which is positioned in a chosen angel to scan the breast in the desired view [19]. The housing scanner is not admitted to be moved during the image acquisition and may therefore be locked in the right position by magnets. Sound waves are sent and received by a transmitter in the transducer, and penetration depth varies depending on size of the imaged breast [20]. Scans are generally performed in three different views on each breast and a computer produces volumetric images for each view. After the examination, images are analysed by a specialist and thereafter sent to PACS or another image storage station. One of the differences between HHUS and ABWUS is the operator that sweeps it over the patient. HHUS is used by a specialist, while ABWUS imaging can be performed by a nurse and thereafter analysed by a specialist.

Figure 2.4: The white transducer is placed within a transparent plastic box and sweeps forth and back within the box during image acquisition [21]. The grey handles are used for manually positioning the box on the breast.
Chapter 3

Method

3.1 Literature Study

Six previous studies that used different technologies and had different constructions were compared. They all compared a new application of ultrasound, UE or AWBUS, to conventionally HHUS and/or mammography. Four studies used AWBUS and two used UE. The purpose was to investigate which method that could contribute to the most accurate diagnoses of breast cancer. Articles were found by using the medical database Scopus. A comparison between sensitivity and specificity was carried out.

3.2 Time Measurements

Measurements of time requirement for examinations of 8 patients and 2 test persons with an AWBUS of model ABVS were performed at two clinics: Västerviks sjukhus (Västervik) and Södersjukhuset (Stockholm). Time measurements were also performed at the clinics of 20 patients examined with HHUS. These examinations used a Philips or Siemens system and for each measurement, the protocol in Appendix A was filled. The measurements started when the patient was lying unclothed on the examination bed and ended when patient, specialist and nurse left the room. Table 3.1 shows a list of measured tasks in an examination. Mean time and standard deviation of measured times were used to investigate eventual time differences between the two systems.

<table>
<thead>
<tr>
<th>ABVS</th>
<th>ABVS images</th>
<th>HHUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lotion appl.</td>
<td>Open image file</td>
<td>Specialist’s introduction to patient</td>
</tr>
<tr>
<td>machine setup</td>
<td></td>
<td></td>
</tr>
<tr>
<td>One view</td>
<td>Send images to PACS</td>
<td>Lotion application and machine setup</td>
</tr>
<tr>
<td>of one breast</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two views</td>
<td>Analyse one view of</td>
<td>Image one or two breasts</td>
</tr>
<tr>
<td>of one breast</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Image parts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of one breast</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Chapter 3  Method

3.3 Interviews

Structured interviews were held with 6 nurses and two specialists from three clinics in Sweden that use ABVS and HHUS. The interviews were held with healthcare professionals from Västerviks sjukhus (Västervik), Södersjukhuset (Stockholm) and Sahlgrenska Universitetssjukhus (Gothenburg). One additional clinic was asked to participate in interviews but choose to not participate. The interviews consisted of two parts, an introducing quantitative part where the interviewed person answered with a scale ranging from one (very satisfied) to four (not satisfied at all). The other part consisted of qualitative questions where the interviewed person were asked to answer with his/her own words. Interview questions are presented in Appendix B.

To decrease the rate of answers influenced by colleagues, all interviews were held with only the interviewed person and the interviewer in the room. By using the interview results, recommendations of patient groups that can be examined with automated ultrasound were given.
Chapter 4

Results

4.1 Literature Study

A previous study using ABUS had it as a complement to mammography in the screening program in the US when radiologists intended it necessary [6]. Patients were American women with dense breasts, divided in two groups. One group acted as control group and were only examined with mammography, while the other group acts as test group and were examined with both mammography and ABUS. Results from the groups were compared and are presented in Table 4.1 under 'Screening dense breasts'. More specific diagnoses were made when mammography and ABUS were combined [6].

In comparison to the three ABVS studies [4] [7] [20], the ABUS study showed higher specificity and sensitivity. Each ABVS study was performed with different patient groups, but all women had lesions or had been treated for breast cancer. Comparing the studies, it was showed that AWBUS had higher sensitivity, while elastography contributed to a 0.05% higher specificity, see Table 4.2.

Table 4.1: Calculated mean values [%] when different technologies were used to examine different groups of patients (screening dense breasts respectively recognised lesions).

<table>
<thead>
<tr>
<th>Screening dense breasts</th>
<th>Lesions</th>
<th>ABUS + Mammography</th>
<th>Mammography</th>
<th>ABVS</th>
<th>UE</th>
<th>HHUS</th>
<th>Mammography</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specificity</td>
<td></td>
<td>99.7</td>
<td>98.2</td>
<td>91.9</td>
<td>95.7</td>
<td>81.0</td>
<td>88.7</td>
</tr>
<tr>
<td>Sensitivity</td>
<td></td>
<td>97.8</td>
<td>76.0</td>
<td>96.1</td>
<td>70.1</td>
<td>82.2</td>
<td>78.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cancer</th>
<th>Outpatient service</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ABVS</td>
</tr>
<tr>
<td>Specificity</td>
<td>87.5</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>91.3</td>
</tr>
</tbody>
</table>

According to the study made of Wang et al. 2012 using ABVS, 12% of the lesions that were not found in mammograms were detected by ABVS. The lesions were found in dense breasts with BI-RADS 3 or 4. 2% of the lesions were undetected by the ABVS [4]. They could not see any inter observer disagreements between diagnoses based on mammography, HHUS or ABVS. Furthermore confirmed Sung Hun et al. (2013) that A future study concerning the detection rate

9
Chapter 4  Results

of automated whole breast ultrasound is needed with more cases and various reader groups who have different levels of experience with the technique [20].

Table 4.2: Overall mean values for all studies [%]. The AWBUS found more lesions and UE diagnosed them more correctly. Mammography and HHUS were not able to make good diagnoses at dense breasts.

<table>
<thead>
<tr>
<th></th>
<th>AWBUS</th>
<th>Mammography</th>
<th>HHUS</th>
<th>UE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specificity</td>
<td>90.6</td>
<td>88.7</td>
<td>80.1</td>
<td>90.6</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>95.1</td>
<td>78.0</td>
<td>82.4</td>
<td>75.8</td>
</tr>
</tbody>
</table>

In the studies were mammography was used, the average miss rate was, according to Table 4.2, more than 20%. When AWBUS was used on these patients, less than 5% of the lesions remained undetected. Additionally could Giuliano et al. 2013 consider that Thanks to earlier detection of malignant lesions, the use of mechanically automated transducers could reduce the cost for each screened woman of dollar 22.75 per year in the US [6]. His calculations assumed that women with dense breasts would have an AWBUS in addition to mammography. Thomas et al. 2006 found that UE decreased the rate of false-positive results on lesions classified by 4 on the BI-RADS [22]. The observers in the study concluded that lesions deeper than 1 cm were undetectable with elastography. In addition to their conclusion, where 30% of the lesions undetected by UE in the study of Zhi et al. 2007 [23]. The lesions missed by elastography were in early stages (BI-RADS 1, 2). 8.7% were missed by UE and 2.7% by HHUS.

Combinations of technologies contributed to more accurate made diagnoses. As shown in Table 4.3, UE contributed to the best specificity. Sensitivity was higher for AWBUS combined with HHUS and mammography. UE in combination with HHUS resulted in higher specificity.

Table 4.3: Many technologies were used in combination in purpose of make better diagnoses. UE contributed to higher specificity and AWBUS had better sensitivity.

<table>
<thead>
<tr>
<th></th>
<th>HHUS + ABWUS + Mammography</th>
<th>UE + HHUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specificity</td>
<td>95.2</td>
<td>95.7</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>97.1</td>
<td>89.7</td>
</tr>
</tbody>
</table>
Table 4.4: The studies with automated transducers used Acuson S2000 ABVS (Automated Breast Volume Scanner, Siemens) and U-System ABUS (Somo-V, U-Systems). The elastography studies used Aixplorer (Super Sonic).

<table>
<thead>
<tr>
<th>Name of study</th>
<th>HHUS</th>
<th>Mammography</th>
<th>AWBUS</th>
<th>UE</th>
<th>No. of patients</th>
<th>Type of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Automated Breast Volume Scanner (ABVS): initial experiences in lesion detection compared with conventional handheld B-mode ultrasound: a pilot study of 50 cases [7]</td>
<td>X</td>
<td>X</td>
<td>ABVS</td>
<td></td>
<td>50</td>
<td>Outpatient service</td>
</tr>
<tr>
<td>Comparison of automated breast volume scanning to hand-held ultrasound and mammography [4]</td>
<td>X</td>
<td>X</td>
<td>ABVS</td>
<td></td>
<td>155</td>
<td>Tumor patients, 72.7 % had dense breasts</td>
</tr>
<tr>
<td>Improved breast cancer detection in asymptomatic women using 3D automated breast ultrasound in mammographic dense breasts [6]</td>
<td>X</td>
<td>X</td>
<td>ABUS</td>
<td></td>
<td>38</td>
<td>Screening dense breasts</td>
</tr>
<tr>
<td>Radiologists’ Performance for Detecting Lesions and the Interobserver Variability of Automated Whole Breast Ultrasound [20]</td>
<td>X</td>
<td></td>
<td>ABVS</td>
<td></td>
<td>38</td>
<td>Breast cancer patients</td>
</tr>
<tr>
<td>Comparison of Ultrasound Elastography, Mammography, and Sonography in the Diagnosis of Solid Breast Lesions [23]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>232 (296 lesions)</td>
<td>Breast cancer patients</td>
<td></td>
</tr>
</tbody>
</table>

4.2 Time Measurements

4.2.1 ABVS

Mean time for a standard scan of one breast consisting of three views was 6:20 minutes (min) and had standard deviation STD = 40 seconds (s). For one scan at one breast, measured mean time was 2:00 min and STD = 10 s. Examination with HHUS as a complement to ABVS had mean time 5:40 ± 1:40 min.

Applying lotion on one dry breast required 1:00 min ± 20 s. One nurse had to apply more lotion for each scan view and refill time was 30 s. Total time for presentation, examination,
cleaning and talking afterwards needed 19:30 min ± 50 s when three views were done at two breasts. When one breast was examined, the examination time was 10:50 ± 1:00 min.

Time for examination with ABVS differed depending on routines at the clinic and not the operator, a usage of unnecessary volumes of lotion doubled the cleaning time. Materials used during examinations were sometimes kept at different places in the room which forced the nurse to walk around to find everything she needed.

Depending on lotion volumes used and cleaning routines, time for cleaning differed between the two clinics. No time relations was found for the cleaning, it varied between 100 and 500 seconds. Lotion application, machine setup and conversation between nurse and patient was independent of number of breasts imaged, which explains why the examination times were less than doubled for examinations of two breasts.

4.2.2 Comparison of HHUS and ABVS

Specialists could study six ABVS images in 45:20 min, but only five patients could be examined by HHUS in this time. In some cases were the ABVS images complemented by HHUS and these examinations needed 5:40 min for one breast, instead of 7:30 min as if ABVS had not been done before. A nurse assisted the specialist during examinations with HHUS and time required from the nurse was 16:10 ± 3:50 min when two breasts were fully scanned with HHUS. (Details in Table VIII)

Table 4.5: Time required for examination with ABVS respectively HHUS, from specialists and nurses.

<table>
<thead>
<tr>
<th></th>
<th>1 breast [min:sec]</th>
<th>2 breasts [min:sec]</th>
<th>Nurse/Specialist</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABVS imaging</td>
<td>10:45</td>
<td>19:29</td>
<td>Nurse</td>
</tr>
<tr>
<td>ABVS image analysis</td>
<td>3:07</td>
<td>7:30</td>
<td>Specialist</td>
</tr>
<tr>
<td>HHUS imaging</td>
<td>7:25</td>
<td>9:04</td>
<td>Specialist</td>
</tr>
<tr>
<td>HHUS imaging after ABVS</td>
<td>5.42</td>
<td>–</td>
<td>Specialist</td>
</tr>
</tbody>
</table>

4.3 Interviews

4.3.1 Quantitative Questions

The main advantage with the AWBUS technology it, according to the interviewed persons, that specialists do not have to reserve their time for patients. Nurses thought that the patients’ psychological wellbeing was of highest importance. According to figure 4.1, the four most important things with the scanning technique are

- It is more user independent in comparison to handheld ultrasound
- The imaging is standardised and images are stored in the work station
- The machine is user friendly and overall easy to use
- Carrying out examinations and image samplings was perceived as stimulating
4.3 Interviews

Figure 4.1: Nurses’ and Specialists’ answers to questions which could be answered with 1 – 4 points where higher number corresponds to most satisfied or important, see the questions in appendix. Total score corresponds to the sum of the answers and the mean score represents the total score divided by number of persons that answered the question.

4.3.2 Qualitative Questions

The ABVS was used more frequently on young women due to radiation, and that they more commonly have dense breasts.

Patients that were examined by ABVS:

- Women who could not undergo mammography, for example after surgery or those who were not able to stand up during an examination
- Women who due to heredity or increased risks to develop cancer annually get their breasts examined by mammography and ultrasound. Those who did not have too dense breasts nor had breasts with too high contrasts were examined with ABVS.
- Women who had been treated for breast cancer are annually followed up for a ten year period upon completion of the treatment. One clinic used the ABVS on patients who had tumours found by ultrasound and not mammography.
- Women with supposed but not palpable tumours - generally they were suffered from pain.
- Women younger than 20 years or who were pregnant did not undergo mammography and could instead be examined with the ABVS.

Imaging with ABVS was not performed on:

- Women whose breasts were composed by a combination of fat and dense tissues. The composition induced shadows in the images and as a result, they could not be analysed. On these patients, HHUS was used instead.
- Skinny women with small breasts were examined with ultrasound since mammography did not give satisfying images. According to the nurses, it was complicated to come close to the skin with the ABVS transducer and air could as a consequence disturb the image quality.
Three advantages with the ABVS were mentioned by nurses and specialists, which are presented in figure 4.2a. The nurses agreed about the drawbacks with the ABVS machine and seen in figure 4.2b, these were:

- Difficulties to come close to the patient’s skin and get images of the whole breast
- Imaging is very time consuming
- The transducer and its housing scanner is difficult to clean

![Figure 4.2: The figures show the most recurrent advantages and disadvantages when healthcare professionals were allowed to choose three advantages respectively disadvantages with the technology. The main drawback with the technology is to position the transducer close to the patient’s skin, and the main advantage is the patient’s psychological wellbeing. With a grading scale from one to three, three implies the best/worst for advantage respectively disadvantage.](image)

Change in use frequency

The three clinics had decreased their use of ABVS since it was time consuming and they were in need of more resources. To get familiar with the technology and its workflow they used it more widely the first months.

Expectations and how they were met

Nurses found the new machine interesting and wanted to help the radiologists by releasing their time. Nurses were mostly satisfied with the machine, but did however perceive the cleaning process that followed an examination as time consuming. Resource restrictions affected the frequency of use negatively since the examinations were time ineffective.

Nurses were less positive to the machine at clinics where only a few specialists analysed the images. They found it unnecessary since some patients had to go home and be called back, which for heredity patients could cause fear.

Artefacts

Specialists agreed that imaging with ultrasound, independent on application, is affected by artefacts. Handheld transducers had the ability of avoiding some false shadows by sampling information from different angles. These artefacts could not be avoided with the ABVS. Some clinics had problems with artefacts which they meant occurred from compression of the breast during the
ABVS examination. The mammillary area was always affected by artefacts due to shadows from the mammilla, but by combining different views they could mostly be ignored. When cancer was suspected or was not possible to distinguish from being an artefact, all views were investigated during the image analysis.

Nurses and specialists agreed that women with dense breast would have a utility of undergoing ABVS examinations in addition to mammography. If women with pain were separated from those with palpable findings, specialists considered that those in pain could undergo ABVS scanning while women with findings would undergo HHUS. Wishes about using ABWUS on young women did also exist.

One specialist interviewed had measured the recall rate caused by images with insufficient information and found that it had decreased from 30% in the beginning to 10-15% after 18 months of usage. At this time the clinic had performed 250 examinations with the ABVS.
Chapter 5

Discussion

The goals of this study were to analyse the users’ opinions about ABVS and to investigate whether there exist any time related differences between examinations with HHUS and ABVS. It was concluded that specialists’ but not nurses’ time could be saved by using ABVS. Release of specialists’ time was according to all interviewed persons the main advantage with the technology.

5.1 Errors and Limitations

Possible sources to errors in the study are many. Articles were found using one database, if other databases and more articles had been available, more studies useful for this essay had probably been found. If interviewed persons felt pressure it may have influenced their answers. Questions and answers may have been incorrectly interpreted.

Design of protocols and interview questions were based on technical and not clinical knowledge. Time restrictions limited the number of measurements and interviews that could be done. If the study would be repeated in the future, knowledge about clinical routines is recommended to be collected before designing protocols for time measurements and interview questions. It is also important to be familiar with healthcare professionals’ terminology since it differ from the technologists’. To increase the statistical reliability of the study, time measurements should be performed in a larger extent, at different clinics and with different nurses performing the examinations.

5.2 Literature study

Previous studies have shown that scanning with AWBUS can improve breast cancer diagnoses in dense breasts. Except at the outpatient service centre, AWBUS had the best sensitivity in all studies. UE was more specific than other methods.

Since recall rate for patients that have undergone mammography is 8%, 10% of all women have radiological dense breasts, and more than 20% of the lesions in previous studies were undetected by mammography in dense breasts, the use of AWBUS at dense breasts is justified.

Giuliano et al. 2013 calculated that the US is able to reduce their costs of breast cancer treatments by dollar 22.75 per screened woman if women with dense breasts would be examined by AWBUS. I would, as a result of Giuliano’s and my study, suggest a change of routines for women
Chapter 5  Discussion

with dense breasts in screening programs. Examinations with AWBUS are time consuming for nurses in comparison to mammography, but since diagnoses can be made in earlier stages, costs can be reduced and lives saved.

5.3 Time Measurements

The measurements performed in this study indicated that ABVS is able to save specialists time if no complementary HHUS is necessary. The ABVS did in the same time release specialists’ time since they did not have to analyse the images when the patient was in the clinic, even if it was preferable. Examinations with ABVS were more time consuming than examinations with HHUS and nurses’ time can, based on this study, not be saved by using ABVS.

Examination times varied between clinics and not nurses since they had different workflow routines. To decrease examination times and increase patient flow it is therefore important to review routines for examinations and patient treatment.

5.4 Interviews

For the reason that examinations with ABVS required approximately 10 minutes for one breast and 20 minutes for two breasts, I would recommend clinics is to reserve 25 minutes for a patient when two breasts are imaged and 15 minutes when one breast is imaged by ABVS. Unclothing and time variations are herein included.

In the study where ABUS complemented mammography in the screening program in the US, 0.3% of the tumours were incorrectly diagnosed and 0.24% were missed. In comparison to other articles, these were the best results in the diagnoses. When AWBUS was used on women with dense breasts, diagnoses had better sensitivity and specificity compared to other modalities. It would therefore be recommended to use AWBUS as a complementary method to mammography for women with dense breasts.

Collaboration between nurses and specialists is important in order to improve image quality and to ensure that correct diagnoses are made. Specialists should help each other during the image analysis to increase correctness of the diagnoses they make. They do in the same time have an ability to educate each other. Feedback to nurses is important to enable image improvements.

To get familiar with the technology and its workflow, I would recommend clinics to use the machine as much as possible until image quality is satisfying and diagnoses are correctly and easily made. Inexperienced specialists are recommended to get familiar with handheld ultrasound before they start to analyse ABVS images.

5.5 Future studies

An extensive study should investigate whether scanning with AWBUS on dense breasts in screening programs can contribute to cost savings. This thesis based its conclusions on theory, but a validation with actual facts is necessary before changes can be made in the screening program.

Identification of how artefacts caused by compression arise in images would, by the author’s knowledge, make specialists more secure when they diagnose images affected by artefacts. Com-
implemented by a blind study with specialists uninformed about patients’ diagnoses I believe that large parts of the negative specialists would change their attitudes to AWBUS.

In an ethical view, the sensitivity for all medical devices should be discussed. Modern technologies sometimes have the ability to detect very detailed information and as a consequence, aggressive treatment may be given to patients that possibly would have lived his/hers life without notifying the disease. In these cases, unnecessary money are invested in a treatment that probably caused more pain to the patient than the disease. This discussion is however left to ethical specialists.
Chapter 6

Conclusion

Conclusion to RQ1: To diagnose tumours in dense breast, previously studies have shown that AWBUS in general contributes to most accurate diagnoses. UE had better specificity when tumours were classified to be malignant or benign but had except of specificity worse results than AWBUS.

Conclusion to RQ2: According to the measurements in this study, the total time for personnel could not be decreased by using ABVS. Nonetheless, analysing images from ABVS required less time than examinations with HHUS and specialists’ time can thereby be saved. Examinations required more time with ABVS compared to HHUS and an increased nurse time was necessary. Specialists’ time is more costly than nurses’ and future studies should therefore investigate whether there are any economic advantages in using ABVS.

Conclusion to RQ3: Nurses found examinations with ABVS time consuming but were satisfied with the interaction with the patient that could be developed. Cleaning the scanner is very time consuming and was the main reason why nurses were unsatisfied with the machine. Specialists found the machine contributing to the patient care but technical problems with the workstation’s software was a common problem. The main advantage with the machine is that specialists do not need to reserve their time for patients.
Chapter 7

References


Chapter 7 References


[19] Siemens Medical Solutions USA Inc. 3D Total Breast Ultrasound, 2014.


Appendix

.1 Appendix A

Table 1: The protocol that was used for measurements of examinations with AWBUS. Mean time and standard deviation (STD) are presented in seconds respectively minutes and seconds.

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Scanning three views of one breast</td>
<td>380</td>
<td>35</td>
<td>6:20</td>
<td>0:35</td>
</tr>
<tr>
<td>Scanning one view of one breast</td>
<td>122</td>
<td>11</td>
<td>2:02</td>
<td>0:11</td>
</tr>
<tr>
<td>Applying lotion and machine setup</td>
<td>60</td>
<td>16</td>
<td>1:12</td>
<td>0:16</td>
</tr>
<tr>
<td>Total time nurse: three views of two breasts</td>
<td>1169</td>
<td>53</td>
<td>19:29</td>
<td>0:53</td>
</tr>
<tr>
<td>Total time nurse: three views of one breast</td>
<td>645</td>
<td>64</td>
<td>10:45</td>
<td>1:04</td>
</tr>
</tbody>
</table>

Table 2: Time requirement for analysis of ABVS images

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Open image file</td>
<td>29</td>
<td>10</td>
<td>0:29</td>
<td>0:10</td>
</tr>
<tr>
<td>Save and send images to PACS</td>
<td>10</td>
<td>4</td>
<td>0:10</td>
<td>0:04</td>
</tr>
<tr>
<td>Analyse one breast</td>
<td>209</td>
<td>47</td>
<td>3:29</td>
<td>0:47</td>
</tr>
</tbody>
</table>

Table 3: Description of times measured when examinations with HHUS were performed by a specialist.
### Appendix

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Palpable finding: HHUS of one breast</td>
<td>163</td>
<td>72</td>
<td>2:43</td>
<td>1:12</td>
</tr>
<tr>
<td>Palpable finding: HHUS of two breasts</td>
<td>227</td>
<td>40</td>
<td>3:47</td>
<td>0:40</td>
</tr>
<tr>
<td>Recalled after mammography screening: HHUS of two breasts</td>
<td>175</td>
<td>40</td>
<td>2:55</td>
<td>0:40</td>
</tr>
<tr>
<td>Gel application and machine setup</td>
<td>19</td>
<td>13</td>
<td>0:19</td>
<td>0:13</td>
</tr>
<tr>
<td>Specialist’s introduction to patient</td>
<td>98</td>
<td>77</td>
<td>1:38</td>
<td>1:17</td>
</tr>
<tr>
<td>Total time specialist: one breast</td>
<td>448</td>
<td>130</td>
<td>7:28</td>
<td>2:10</td>
</tr>
<tr>
<td>Total time specialist: two breasts</td>
<td>578</td>
<td>203</td>
<td>9:38</td>
<td>3:23</td>
</tr>
<tr>
<td>Total time nurse: two breasts</td>
<td>967</td>
<td>230</td>
<td>16:07</td>
<td>3:50</td>
</tr>
</tbody>
</table>
Appendix B

.2 Appendix B

Quantitative questions
Please answer the following questions with 1-3 points, 1 = totally satisfied, 2 = almost satisfied, 3 = not very satisfied, 4 = not satisfied at all.

- What is your opinion of that images easier are sent to PACS and that they are stored in the work station?
- What is your opinion to the standardised imaging?
- Is it important that the imaging with ABVS is more user independent than HHUS?
- Is it good that surgeons are able to investigate images in the coronal view before surgery?
- How high is the recall rate on the clinic due to image quality?
- How high is the recall rate on the clinic due to that something is found in the images?

Nurses
- How friendly is the ABVS to use and take images with?
- Do you find it fun and stimulating to examine patients with ABVS?

Specialists
- How easy is it to analyse the images?
- Do you find it fun and stimulating to analyse the ABVS images?

Qualitative questions
- Which three best benefits do you experience with the ABVS? Please order them 1-3 where 1 is best.
- Which three biggest drawbacks do you experience with the ABVS? Please order them 1-3 where 1 is the worst drawback.
- Which patients are examined with the ABVS on this clinic?
- On which type of patients is ABVS useful?
- On which patients is the ABVS needless to use?
- Has the clinic changed its use frequency after the purchase? How and why?
- What expectations did you have of the machine before it was bought? Why did the clinic by themachine?
- Are your expectations answered?
- Are artefacts a more or less common problem with ABVS compared to HHUS?
- Which patients that do not undergo ABVS today would you like to examine with ABVS if recourses needed were available?