

Best Practice Guideline – DEGUM Recommendations on Breast Ultrasound

PART II Additive and Optional Application Modalities in Breast Ultrasound, Quality Assurance

Best Practice Guideline – Empfehlungen der DEGUM zur Durchführung und Beurteilung der Mammasonografie

TEIL II – Additive und fakultative Anwendungsmodalitäten, Qualitätssicherung

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ABSTRACT

Alongside mammography, breast ultrasound is an important and well-established method in assessment of breast lesions. With the “Best Practice Guideline”, the DEGUM Breast Ultrasound (in German, “Mammasonografie”) working group, intends to describe the additional and optional application modalities for the diagnostic confirmation of breast findings

and to express DEGUM recommendations in this Part II, in addition to the current dignity criteria and assessment categories published in Part I, in order to facilitate the differential diagnosis of ambiguous lesions.

The present “Best Practice Guideline” has set itself the goal of meeting the requirements for quality assurance and ensuring quality-controlled performance of breast ultrasound. The most important aspects of quality assurance are explained in this Part II of the Best Practice Guideline.

ZUSAMMENFASSUNG

Die Mammasonografie hat sich seit vielen Jahren neben der Mammografie als wichtige Methode zur Abklärung von Brustbefunden etabliert.

Der Arbeitskreis Mammasonografie der DEGUM beabsichtigt mit der „Best Practice Guideline“ den senologisch tätigen Kolleginnen und Kollegen neben dem in Teil I publizierten aktuellen Dignitätskriterien- und Befundungskatalog in dem vorliegenden Teil II die additiven und fakultativen Anwendungsmodalitäten zur Abklärung von Brustbefunden zu beschreiben und dazu DEGUM-Empfehlungen zu äußern, um die Differenzialdiagnose von unklaren Läsionen zu erleichtern.

Die vorliegende „Best Practice Guideline“ hat sich zum Ziel gesetzt, den Anforderungen zur Qualitätssicherung und der Gewährleistung einer qualitätskontrollierten Durchführung der Mammasonografie nachzukommen. Die wichtigsten Aspekte der Qualitätssicherung werden in diesem Teil II der Best Practice Guideline erläutert.

Introduction

The differential diagnosis of inconclusive or suspicious breast lesion findings is carried out using multimodal imaging [1]. Depending on the indication, lesions are examined using conventional breast imaging, mammography, sonography and, if necessary, contrast-enhanced MRI. From this complementary information, the indication for histological examination can be set, in most cases with a minimally invasive procedure.

Chapter A of Part II of this Best Practice Guideline (BPG) describes the additional breast ultrasound methods that are available, in routine practice, alongside the B-scan. The focus here is on Doppler sonography, elastography, and minimally invasive interventions.

Chapter B addresses optional modalities such as 3D ultrasound, the fusion of different diagnostic methods, and the integration of artificial intelligence. In addition, Chapter C of Part II of the BPG deals with the important aspects of quality assurance.

The primary objective is to use additional diagnostic modalities beyond the pure B-scan image analysis, to achieve the most accurate assessment of the dignity of a lesion and also keep the rate of invasive diagnostic methods as low as possible.

A. Additive application modalities

1 Doppler sonography

1.1 Basic biological principles

The growth of solid tumors requires the formation of new blood vessels (neoangiogenesis). From a tumor volume of 3 mm³, and the associated extension of the diffusion distance between blood vessel and tumor cell, tumor cells become hypoxic, thereby secreting more angiogenic than antiangiogenic factors, and thus inducing a disordered formation of new tumor vessels. These tumor vessels have characteristics that distinguish them from other blood vessels, and as a result, the blood flow characteristics in breast carcinoma differ from those of healthy tissue [2, 3]. These differences in blood flow, which are measured with Doppler or Power Doppler technology, can be used for the differential diagnosis of lesions identified by ultrasound B-scan.

1.2 Basic technical principles

Doppler sonography measures the change in frequency (frequency shift or Doppler shift) of sound waves that hit a moving medium which reflects sound waves, such as blood. The extent of this frequency shift depends on the angle at which the sound waves hit the blood vessel (Doppler angle), the flow rate of the blood, and

the ultrasound frequency. This frequency shift can be represented quantitatively in numbers (e. g., in cm/s) with a pulsed Doppler or in color (color-coded pulsed Doppler = color Doppler, CD) [4, 5].

In contrast to CD in the amplitude-coded Doppler (also referred to as CPA or power Doppler), the local amplitudes of the Doppler frequency are recorded and superimposed on the B-scan in the form of colored dots, which are coded based on the location. The brightness of each color pixel primarily reflects the number of flowing red blood cells and not their speed. Unlike the conventional, speed-dependent Doppler, the color points are only weakly influenced by the angle of incidence. In some breast carcinomas, CD and CPA can be used to detect increased blood flow and thus display the blood vessel density (► **Fig. 1**). Semi-quantitative classifications for this were already described in the 1990 s. Today, the highly reproducible “vascular index” can be used as a semi-quantitative classification (proportion of Doppler pixels to the total number of pixels within the focal ultrasound lesion) [6].

Since not all tumor vessels are supplied with blood to the same extent and the increased hydrostatic pressure in the tumor can restrict blood flow, this increased blood flow – despite the increased blood vessel density in the tumor – cannot be detected in all breast carcinomas. Moreover, breast carcinomas are biologically very heterogeneous (e. g., in terms of their differentiation, their blood vessel density, and their hydrostatic pressure). For these reasons, semi-quantitative ultrasound imaging of blood flow within tumor vessels cannot be the only method that differentiates benign from malignant focal lesions [7].

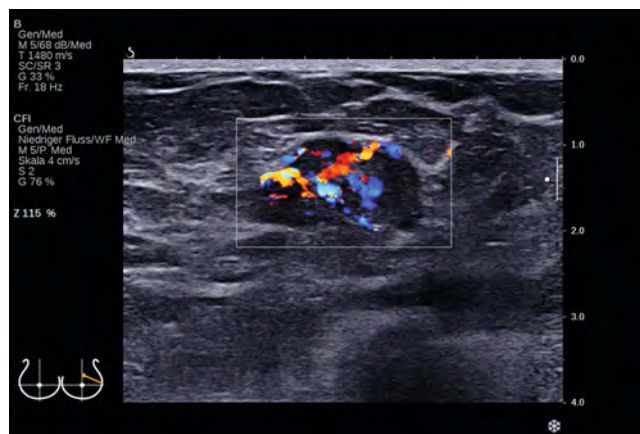
Morphological vascular characteristics, such as blood vessel density, also do not correlate with conventional and contrast-enhanced, ultrasound measured perfusion [3].

1.3 Ultrasound contrast media

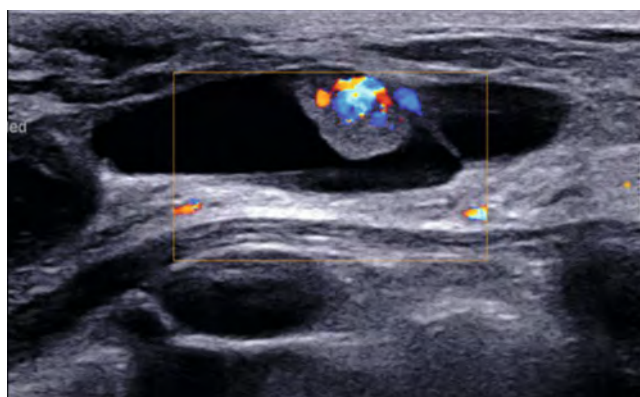
Due to the slow flow rates (relevant for the CD) and the low number of red blood cells flowing through the small-diameter breast carcinoma vessels (relevant for the CPA), the idea of optimizing blood flow imaging, e. g., with ultrasound contrast agent, was further evaluated. These contrast media have increased echogenicity, i. e., they reflect sound waves better than blood and remain in the tumor vessels for a longer period of time. However, as described above, contrast-enhanced sonography of blood flow has not been able to achieve significantly better results than the B-scan in the differential diagnosis of breast lesions – but it can be helpful. This is why the technique has not become established in everyday clinical practice [8, 9].

1.4 Clinical use

In individual cases, color-coded Doppler sonography can be used for differential diagnosis, e. g., if blood flow can be detected in a supposedly anechoic focal lesion that was initially assessed to be a cyst. In such a case, the possibility of a solid focal lesion or an intracystic solid mass must be considered, and further diagnostic measures should be performed. Increased blood flow, especially in the area of the lesion compared to the area surrounding the lesion, a radial arrangement of connecting vessels between peripheral and internal vessels, and an aberrant blood flow must be considered suspicious and may suggest potential malignancy [10] (► **Fig. 2**).



► **Fig. 1** Color Doppler – penetrating, irregular blood flow in an invasive breast carcinoma.



► **Fig. 2** Complex cystic-solid lesion with significant perfusion of the solid portion – intracystic micropapillary carcinoma.

In addition to the differential diagnosis of new lesions, the sonographic perfusion diagnostic can also be used in follow-up care to differentiate between a scar and a relapse. Relapses often show an increased blood flow penetrating the lesion, whereas this does not occur in scars [11].

The clinical use of sonographic perfusion as far as the response to neoadjuvant chemotherapy is concerned, is still unclear.

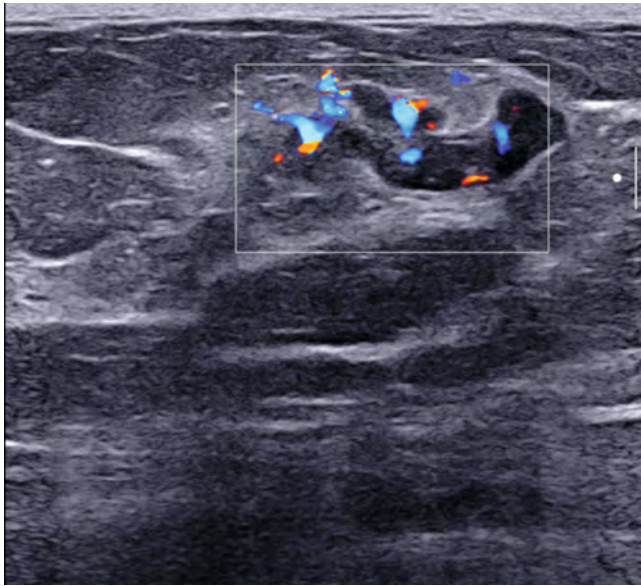
In the context of reconstructive breast surgery, Doppler sonography should be used to check the perforator vessels in the lift region of the transplants [11].

Conclusion

With sonographic perfusion measurements, the precapillary blood flow in the blood vessels (vascular perfusion) can be demonstrated, but not the perfusion of the lesion (tissue perfusion).

Different sonographic Doppler methods cannot clearly discriminate between benign and malignant focal lesions, nor can they provide a histological correlation with tumor biology [10] (► **Fig. 3**).

Doppler sonography can reproducibly identify the vascularization parameter of a lesion, as well as its margins and can therefore



► **Fig. 3** Benign phyllodes tumor with significant intra- and peritumoral perfusion.

be used as an additional criterion in the differential diagnosis of focal lesions [12, 13, 14].

DEGUM recommendations

1. Doppler sonography should be used when assessing the dignity of solid, complex cystic-solid lesions and scars, making it a useful supplement to B-scan diagnostics.
2. In order to visualize the perfusion, the pressure with the transducer should be as low as possible with optimal coupling so as not to compress the blood flow.
3. The entire lesion, including a surrounding area, as large as possible, should be examined for a representative comparison using Doppler sonography.
4. Because of its higher sensitivity in detecting slower flows, power Doppler may be advantageous.
5. Doppler sonography can be of use in the context of biopsies in the area of the axilla since it can display vascular structures.
6. A representative image documentation with color-coded Doppler image should be created for each lesion.

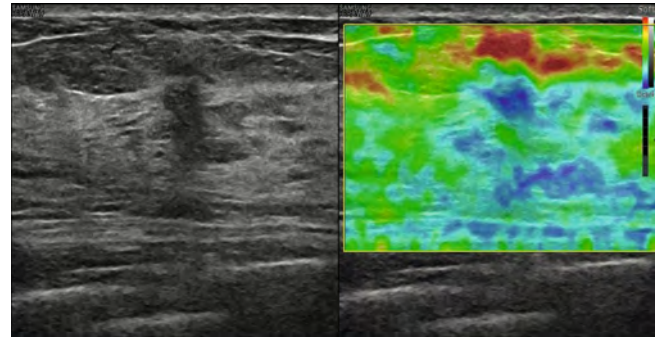
2 Elastography

Elastography is an imaging method that is currently still the subject of clinical research [15]. It is based on the observation that breast carcinoma tissue is less elastic (= higher stiffness) than healthy mammary gland tissue or the surrounding fatty tissue [16].

The term “sonoelastography” is a collective term for different physical methods used to measure tissue elasticity [17]. In general, two methods can be distinguished: strain elastography (SE) and shear wave elastography (SWE).

2.1 Strain elastography

Strain elastography (SE) is a semi-quantitative method that compares the elasticity of a lesion to the surrounding tissue. SE



► **Fig. 4** 2.1 Strain elastography – solid representation of an NST G1 breast carcinoma with blue color coding.

(► **Fig. 4**) detects displacements of the tissue during active compression, which differ in extent depending on the different tissue types; less dense tissue can be compressed to a greater extent than more dense tissue [18]. Various SE methods of measurement were investigated. These include the **Tsukuba Elasticity Score (TES)**, also called **Elasto Score** or **Itoh Score** (► **Fig. 5**) [19], the **Strain Ratio** (also called **fat/lesion ratio**) [20], and the Elastography-to-B-Mode ratio known as **E/B Ratio**[17].

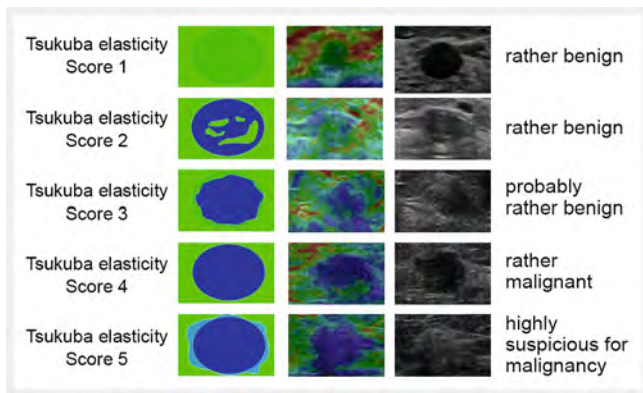
A meta-analysis of 29 studies with over 5,000 cases showed improved specificity of sonoelastography (88 % vs. 70 %) using the **TES** with reduced sensitivity (79 % vs. 96 %) compared to the B-mode ultrasound [21]. After further development of the SWE and further clinical studies, the assessment of elastography using the TES has become less significant.

In a meta-analysis that included 9 studies and a total of 2,087 patients, the **Strain Ratio** (► **Fig. 6**) was able to identify breast tumors with a sensitivity of 88 % and a specificity of 83 % [22, 23]. But individual studies use different cut-off values.

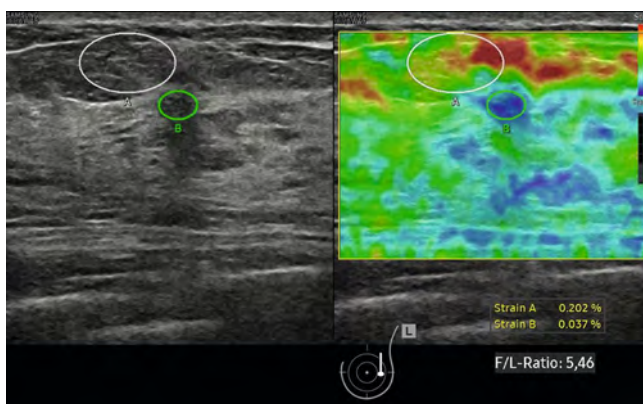
According to current studies, the so-called Elastography-to-B-mode ratio (**E/B ratio**) is of good diagnostic value [24]. For the E/B ratio, a traditional B-mode image and an elastography image are captured from the same plane (preferably in the center of the lesion). The ratio of the maximum lesion length in the elastogram and the maximum lesion length in the B-mode image is then calculated (E/B ratio). This is repeated three times and the highest value is used. An E/B ratio ≥ 1 indicates a malignant lesion and an E/B ratio < 1 indicates a benign lesion. In a multicenter study, the E/B ratio showed a sensitivity of up to 96 % and a specificity of 88 % [24].

2.2 Shear wave elastography

Shear wave elastography (SWE) is a quantitative method that directly shows the elasticity of a lesion in the form of a numeric value (► **Fig. 7**). To determine this value, the device emits remarkably high-pressure sound signals that generate transverse waves (shear waves) within the tissue and propagate at right angles to the original emission direction. These shear waves propagate much faster through more stiff breast tissue than less stiff tissue. The shear wave speed thus provides information about the elasticity of the tissue [18]. Depending on the system used, the elasticity is indicated in meters per second (m/s) or kilo Pascal (kPa) [19, 22, 25, 26, 27, 28, 29, 30, 31]. The breast tissue should only be lightly com-



► **Fig. 5** Interpretation of stain elastography results based on the TES [19].



► **Fig. 6** Measurement of the strain ratio (Fat/Lesion F/L ratio) – suspicious strain ratio in small NST G1 breast carcinoma.



► **Fig. 7** Shear wave elastography – representation of a solid tumor (NST G2) measuring 138.8 kPa (red color coding) compared to the less dense surrounding tissue measuring 31.4 kPa (blue color coding).

pressed during recording the SWE. Excessive contact pressure may yield erroneous results [31]. The measurement is taken in the most dense area of the lesion (maximum) and should be repeated three times. The mean value of the three maxima makes

up the final value. Current research is focused on ascertaining the optimal cut-off value for differentiating benign from malignant lesions or for upgrading or downgrading ultrasound (US) Category 3 or 4 lesions. The multicenter, exploratory BE1 study proposed cut-off values at which US Category 4a lesions can be downgraded (SWE 80 kPa-5.2 m/s or less) as well as values at which US Category 3 lesions should be upgraded (SWE 160 kPa-7.3 m/s), whereby an improvement in specificity with the same sensitivity was observed [32]. These values could not be confirmed in further studies. Different cut-off values (2.2 m/s to 5.2 m/s) and assessment criteria are discussed in the literature [25, 26, 27, 28, 29, 30, 31, 32, 33, 34].

The largest prospective, multicenter, international study to date could not confirm the exploratory cut-off values of previous studies, since the rate of false-positives was indeed reduced, but at the expense of an increased rate of overlooked carcinomas. Secondary analyzes suggest that downgrading US category 4(a) lesions, with a SWE of 2.55 m/s or less, reduces false-positives by 24 % (thereby also reducing unnecessary further biopsies) whilst maintaining a guideline-compliant carcinoma detection rate [35]. When implementing this method, it must be taken into account that the optimal limit value for distinguishing malignant from benign lesions remains to be conclusively established.

2.3 Combination of strain and shear wave elastography

The currently available studies on sonoelastography and its two main methods – SE and SWE – indicate specific advantages and disadvantages of both methods. It has been proposed to combine SE and SWE to overcome the respective limitations of the methods [36]. The analysis of the largest, international, multicenter study in the field of sonoelastography to date showed that the combination of SE and SWE can improve the diagnostic quality in the assessment of breast lesions (especially US Category 4 lesions). Specifically, the downgrading of US Category 4(a) lesions, that had both an SWE value of ≤ 3.7 m/s and an E/B ratio of < 1 , reduced false-positives by 35 % (thereby also reducing unnecessary further biopsies) whilst maintaining a guideline-compliant carcinoma detection rate [36, 37, 38].

Conclusion

Elastography is an increasingly established technology in the field of breast diagnostics, which is specifically used for differentiating US Category 3 from Category 4 lesions. It is an additional criterion to the dignity criteria of the B-scan and can help to reduce unnecessary biopsies and under-diagnoses.

There are limitations when it comes to large lesions (diameter larger than 20 mm), deep-lying lesions (deeper than 30 mm), heterogeneous structures, as well as rare histological entities [19].

DEGUM recommendations

1. The assessment of elasticity is a validated additional criterion for assessing the dignity of focal lesions and can be a useful addition to B-scan diagnostics.

2. Both methods – strain elastography (SE) and shear wave elastography (SWE) – reflect the stiffness of tissue structures, with SWE being the more objective and examiner-independent method.
3. Recent studies show that the combination of SWE and SE can further improve diagnostic accuracy.
4. Examiners should be aware of different color coding and measuring methods.
5. US Category 3 lesions with elasticity findings consistent with the presence of more dense tissue should be upgraded to Category 4.
6. US Category 4 lesions can be downgraded to US Category 3 if the elastography is normal.
7. US Category 5 lesions should not be downgraded despite normal elastography results and should be further confirmed by histology.
8. At least one representative image documentation should be created for each lesion.

3 Minimally invasive US-guided procedures – fine needle aspiration biopsy, core needle biopsy, vacuum assisted biopsy

Category 4 and 5 lesions should be confirmed by histology. Category 3 lesions are followed up after 6 months as defined in the recommendations.

The histological analysis should be minimally invasive and image guided. Open diagnostic excisional biopsies should only be reserved for exceptional cases [1] (e. g., localizations that cannot be reached with minimally invasive methods, high risk of injury to neighboring structures such as axillary vessels or the pleura, suspected false-negative biopsy findings due to discrepancy between diagnostic imaging and histology and, under certain circumstances, in the case of complex cystic-solid lesions).

Compared to mammography-guided interventions, ultrasound-guided interventions do not involve exposure to radiation, and compared to MRI-guided interventions, they do not require the administration of contrast media and are therefore less stressful for the patient and more expedient. Of all the available options, ultrasound-guided interventions are the primary method used if there is a clear lesion correlation.

The procedure is carried out under local anesthetic after the patient receives appropriate written information and gives their consent. It is important to ensure that the local anesthetic is also injected subcutaneously in the vicinity of the injection site and in front of the lesion, and is given sufficient time to take effect. It may be necessary to make a puncture incision in the skin before inserting the needle. The biopsy needle can be positioned to the lesion using a coaxial needle, which makes it easier to reach the target lesion in more dense tissue and avoids repeated penetration of the tissue.

3.1 Hygiene recommendations

Based on the available data, a survey by experts from Levels I–III of the DEGUM working group on breast ultrasound, as well as empirical evidence, the following procedure can be recommended

for ultrasound-guided breast biopsies, according to the general KRINKO recommendations [39, 40]:

- Adequate skin disinfection either by means of a spray disinfectant or spray-wipe-spray disinfection using sterile swabs.
- Adequate cleaning and disinfection of the transducer and the biopsy-tool.
- Hygienic hand disinfection and use of gloves.
- The use of sterile contact medium or disinfection spray.
- The use of a sterile transducer cover is not required as a rule, since contact of the transducer with the puncture site or the biopsy needle and an infection caused by this are unlikely, but it can be used.
- A transducer cover should be used to protect the transducer membrane from alcohol-based disinfectants and blood.

3.2 Fine needle aspiration biopsy

A fine needle aspiration should be performed only in exceptional cases for solid and complex cystic-solid lesions of the breast and axilla, since the histological analysis, which is considered the standard, is more advantageous than the cytological analysis.

3.3 Core needle biopsy

Core needle biopsy – automatic

The biopsy needle penetrates the lesion with the pre-selected feed depth and cuts the preparation using a hollow needle. A greater feed rate, produces better tissue cylinders.

The recommended number of cylinders dependent on the needle size is:

- for 14G – collection of at least 2 cylinders [41]
- for 16G – collection of at least 3 cylinders [41].

According to the soon-to-be updated S3 guideline, ≥ 3 samples would still have to be taken for $\leq 14G$ [1].

In order to document the correct position of the biopsy needle, at least 2 images must be taken, one of the needle aligned parallel to the transducer in front of the lesion and the other within the lesion. The image of the needle should be supplemented on a second plane, perpendicular to the first plane (► Fig. 8a, ► Fig. 8b, ► Fig. 8c).

Core needle biopsy – Semi-automatic

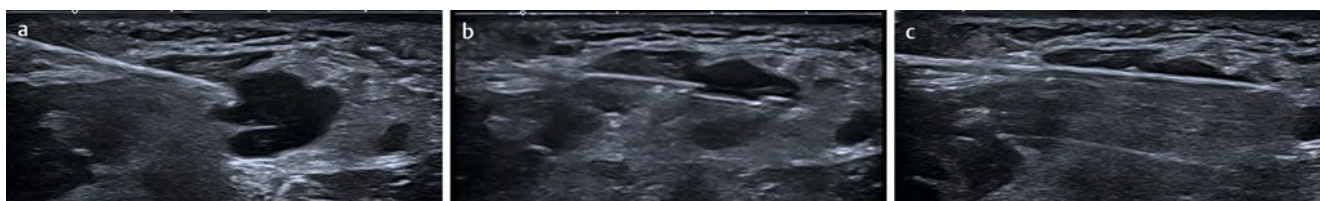
The semi-automatic biopsy system allows more guided tissue collection since the inner needle (with the chamber open) is first inserted from the system into the lesion under visual control. The hollow needle sliding over it then cuts the preparation. Injury to adjacent structures is thus largely avoided. The use of the semi-automatic system can be particularly advantageous in the axilla (► Fig. 9a, ► Fig. 9b, ► Fig. 9c).

3.4 Vacuum-assisted biopsy (VB)

Compared to core needle biopsy vacuum-assisted biopsy allows larger tissue volumes to be removed. Up to 8 cm³ of tissue can be removed [42].



▶ **Fig. 8** Documentation core needle biopsy **a.** Biopsy needle in front of the lesion. **b.** Biopsy needle longitudinal in the lesion. **c.** Orthogonally inserted biopsy needle in the lesion.



▶ **Fig. 9** Biopsy of a pathological lymph node with semi-automatic **a.** Needle with open chamber in front of the lesion. **b.** Manual feed with open chamber into lesion. **c.** Closing the chamber with feed of the cutting sleeve.

The following are possible indications for the use of VB [43]:

- After non-representative core needle biopsy
- Intracystic, intraductal lesions (insert marker!)
- Lesions that appear too small for a representative core needle biopsy (insert marker!)
- Complete removal of symptomatic, benign lesions (e. g., symptomatic fibroadenomas, central papilloma) (insert marker!).

Selecting the needle size

For vacuum-assisted biopsies, one has the option of the following needle sizes: 8, 10, 11 and 13G. The needle size of the VB system is selected depending on the indication and the size of the lesion. It can be said that for purely diagnostic procedures (e. g., intraductal lesions, re-biopsy after non-representative biopsy) an 11G needle is sufficient. Diagnostic-therapeutic removal of symptomatic, benign lesions should be done using large-volume 8G needles.

3.5 Marking the biopsy region

It must be ensured that the biopsy regions can be found again. The person performing the biopsy on the lesion is responsible for finding it again. If the lesion cannot be sure found again, or cannot be re-identified surely a marking must be inserted (e. g., clip, coil, etc.). After inserting the marker, if there is no clear correlation between mammography and sonography and if neoadjuvant chemotherapy is planned, the position of the marker should be documented with a mammography.

3.6 Management under anticoagulants

The use of anticoagulants is common, whereas coagulopathies are rare. A thorough medical history should be ascertained prior to performing a biopsy.

The rate of hematoma formation when anticoagulants are not administered is approx. 3.2% after ultrasound-guided core needle biopsy, approx. 10% after ultrasound-guided vacuum-assisted biopsy, 25% after stereotactic vacuum-assisted biopsy, and 43% after MRI-guided vacuum biopsy [44]. These rates should be considered when deciding on the discontinuation of blood-thinning medication. When considering the discontinuation of blood-thinning medication, the operability in case of bleeding should be considered.

Discontinuation must always be discussed, keeping in mind the indication for taking the medication. An interdisciplinary presentation to assess the risk may be necessary if the blood-thinning preparation is to be discontinued.

The advantage of ultrasound-guided biopsies lies in the possibility of detecting vessels that lead to the lesion or are in the vicinity of the lesion using Doppler sonography. Insertion of the needle to the lesion can be optimized in this way to avoid the formation of a hematoma [44, 45].

The anticoagulant treatment-free intervals to be selected and any laboratory tests that may be required (all time specifications for patients with normal renal function) are listed in the current guideline on regional anesthesia close to the spinal cord and thromboembolic prophylaxis/antithrombotic medication, AWMF register no. 001–005 classification S1) [46]. The following recommendations can be derived from this:

- under ASS 100 treatment, there is no need to discontinue medication before US core needle biopsy;
- in the case of anticoagulant treatment with coumarin derivatives, bridging to heparin should be carried out;
- with heparin treatment in prophylactic doses, no discontinuation is required;
- when taking rivaroxaban (Xarelto 1 × 10 mg/d) a discontinuation of 22–26 hours is recommended;

- when taking apixaban (Eliquis 2 × 2.5 mg/d) a discontinuation of 20–30 hours is recommended;
- when taking dabigatran (Pradaxa 1 × 150–200 mg/d) a discontinuation of 24–36 hours is recommended;
- when taking clopidogrel (Plavix), ticlopidine (Tyklid), or prasugrel (Efient) a discontinuation of 7–10 days is recommended;
- when taking ticagrelor (Brilique) a discontinuation of 5 days is recommended;
- in the case of anticoagulant treatment with edoxaban (Lixiana 1 × 60 mg/d) a discontinuation of 48–70 hours is recommended.

Conclusion

Minimally invasive biopsies are the gold standard for histological analysis of ambiguous lesions in the breast and axillary lymph nodes, as they have a high diagnostic certainty and are available nationwide. A mandatory part of the examination includes the assessment of the representativeness of the tissue samples and the correlation of diagnostic imaging with histopathological findings. Marking breast and axilla lesions with different markers, as well as preoperative marking, are crucial for targeted surgery.

DEGUM recommendations

1. Category 4 and 5 lesions, which can be clearly distinguished by sonography, should primarily be biopsied ultrasound guided under local anesthesia.
2. At least 2 macroscopically representative tissue cylinders with a 14 G needle or 3 macroscopically representative tissue cylinders with a 16 G needle are required.
3. The correlation between the suspected imaging diagnosis and the histological result needs to be reviewed. If there is no correlation, the results should be re-evaluated.
4. The examiner is responsible for re-identifying the location of the lesion and should therefore always insert a marker if the lesion has been completely removed, or if localizing the site of the lesion again may be difficult, or if neoadjuvant chemotherapy is to take place.
5. When making the puncture, the basic hygiene standard according to risk class 1 must be considered.
6. In patients on anticoagulants, the risks of a change in anticoagulation should be weighed against the risks of the puncture, in case of doubt discussed at an interdisciplinary meeting and adjusted if necessary.
7. Image documentation should be provided using at least two, preferably three images, as shown in ► Fig. 8.

B. Optional application modalities

1 3 D ultrasound and ABUS

1.1 3 D ultrasound

3 D/4 D ultrasound is not only successfully deployed in prenatal and gynecology diagnostics, but also in the differential diagnostic for breast lesions [47, 48, 49, 50, 51]. Although 2 D ultrasound

does allow breast tumors to be confirmed [52, 53, 54], 3 D ultrasound offers additional information: multiple display modes, precise control of defined anatomical planes, long-term digital storage of volume data, and the possibility of carrying out ultrasound examinations virtually [51].

Technical requirements

The three-dimensional examination of the breast requires an ultrasound device with 3 D software and, if necessary, a breast volume transducer.

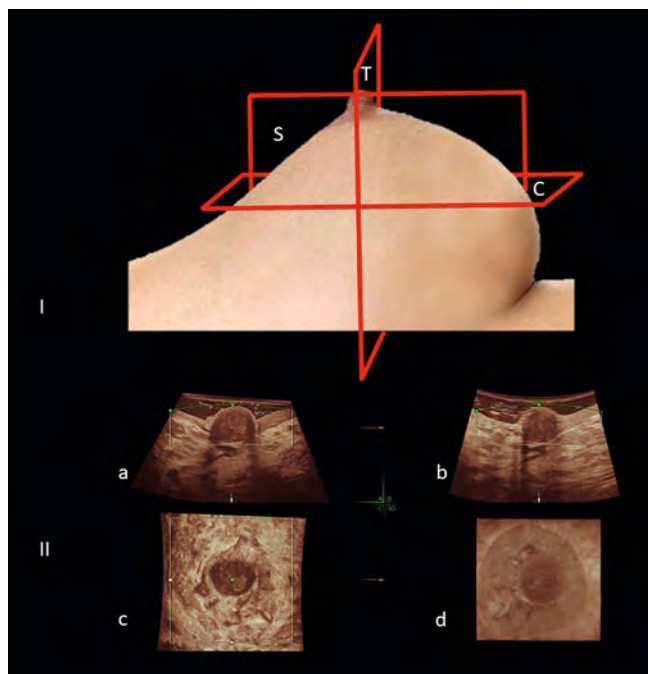
A 3 D ultrasound examination is divided into 4 individual steps: – data acquisition (volume recording), – 3 D visualization, – volume/image processing and – the subsequent storage of these volumes with possibly rendered images/image sequences [55].

a) Data acquisition (volume recording)

The ultrasound examination of the breast begins with the 3 D transducer as a 2 D ultrasound examination, with the transducer being guided in either a meandering or clockwise tangential (anti-radial) motion. If one comes across an abnormal finding, the so-called “region of interest” is marked with the volume box. After selecting the volume angle and the recording speed, the volume recording is activated via the 3 D recording button. To avoid motion artifacts, the transducer must be kept still during volume recording.

b) 3 D visualization

After volume recording, lesions are always displayed in **multiplanar mode**, which depicts a lesion in 3 perpendicular 2 D images, whereby image A always corresponds to the 2 D image recorded. If the breast section was recorded as a longitudinal section, image A corresponds to the sagittal section, image B the transverse section, and image C the coronal section (► Fig. 10). The coronal section in particular provides information (compression or retraction pattern) when assessing the tumor that cannot be obtained in this form with conventional 2 D ultrasound. Other modes include the tomography mode, OmniView mode, VCI mode, surface mode, HD live mode, transparency mode, inversion mode, and glass body mode. In **tomography mode**, parallel 2 D images can be displayed on the monitor. **OmniView** and **VCI mode** allow any plane to be demonstrated as a thin volume image. **Surface mode** is suitable for the three-dimensional display of cyst walls and wall structures, but also for the display of sections in normal and pathological breast tissue. **HD live mode** allows to display skin-colored tissue and to additionally illuminate the tissue with a mobile virtual light source. **Transparency mode** allows see-through images of tissue blocks, whereby, for example, dilated milk ducts can be displayed in detail as hypoechoic structures. In **inversion mode**, such hypoechoic milk ducts are then converted into hyperechoic structures, as a result of which the milk duct system can be viewed clearly as a solid outlet pattern. **Glass body mode** represents a combination of the color Doppler and the gray-value image and allows the spatial assessment of vessel projections within the recorded volumes. In this way, abnormal perfusion patterns within tumors in particular can be specifically identified. 4 D ultrasound also enables the tumor perfusion to be displayed in real time.



► **Fig. 10** I. Schematic drawing of the three perpendicular plane sections in 3D ultrasound: S = sagittal section, T = transverse section, C = coronal section. II. Multiplanar and surface mode, of a lesion in three planes that are perpendicular to one another, whereby image **a.** always corresponds to the 2D image of the initial acquisition. If the breast section was recorded in a sagittal section, then picture **a.** shows the sagittal section (S), image **b.** shows the transverse section (T), image **c.** shows the coronal section (C), and image **d.** shows the coronal section in the surface image (here nipple-areola complex).

c) Volume/image processing

There are various post-processing techniques available for volume and image processing: different color scales, optimization of brightness and contrast, threshold and speckle reduction imaging. In addition, tissue parts or false echoes can be digitally removed with the “electronic scalpel”.

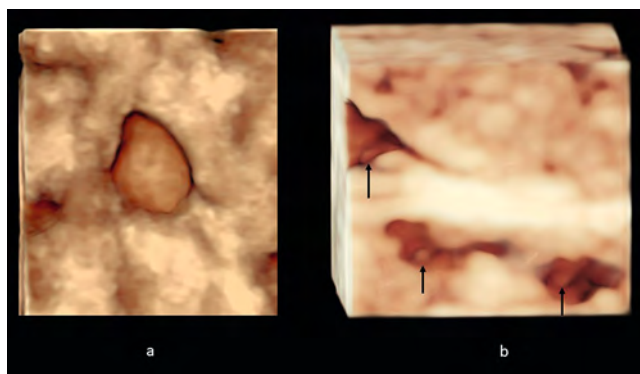
d) Storage of volumes and/or rendered images

Both volumes and rendered images can be saved digitally without loss and can be accessed at any time. Stored volumes thus enable comparative, virtual examinations at a later point in time.

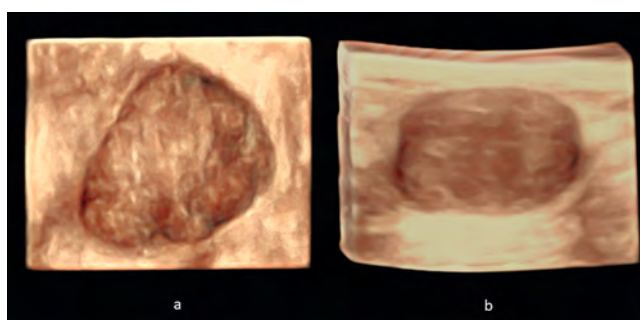
Clinical application of 3D breast ultrasound

An advantage of 3D ultrasound compared to 2-plane sonography is that any 2D plane or surface image can be reconstructed from stored volumes. Surface representations of sagittal sections also allow an assessment of the existing breast density.

Surface images of coronal sections are suitable for differentiating between benign and malignant tumors (► **Fig. 11**, ► **Fig. 12**, ► **Fig. 13**). Simple cysts are characterized by smooth inner walls and sharp margins to the surrounding tissue (► **Fig. 11a**). Cyst conglomerates or complex cystic-solid lesions with wall-associated proliferation can be detected. Small polyps within dilated milk ducts are identified as wall-associated prolif-



► **Fig. 11** **a.** Simple cyst characterized by a smooth inner wall and sharp margins to the surrounding tissue (HD live surface mode). **b.** Shows polyps within dilated milk ducts as wall-associated proliferations (HD live surface mode).

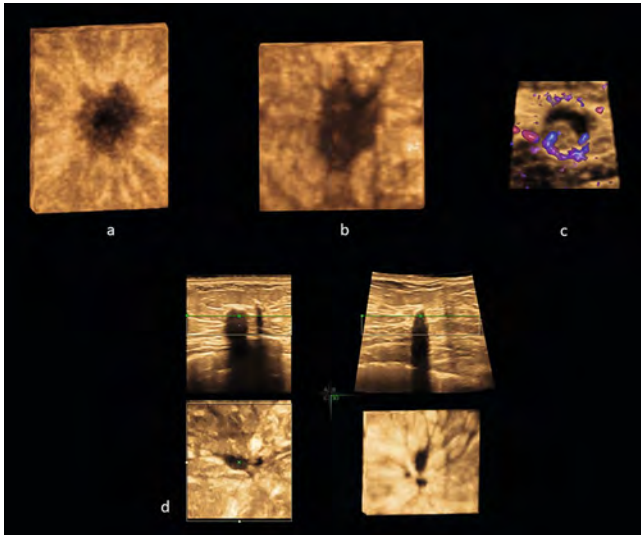


► **Fig. 12** Benign solid lesions present with a compressive growth pattern (= compression pattern) **a.** Coronal surface image of fibroadenoma **b.** Fibroadenoma in transverse surface image.

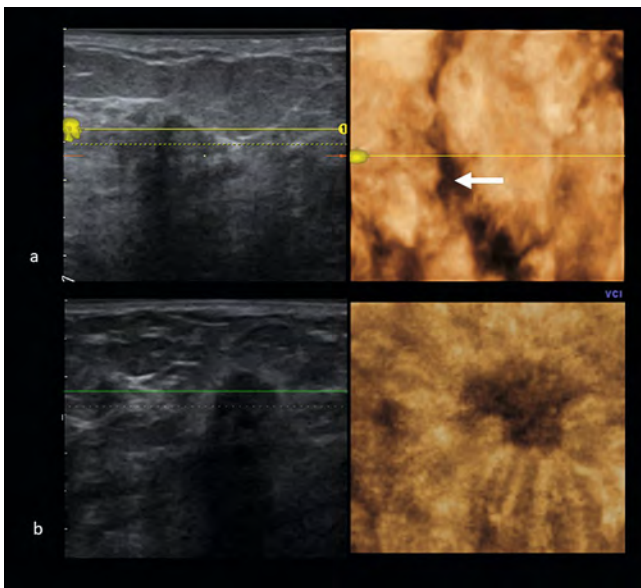
erations (←) (► **Fig. 11b**). Solid lesions can be identified as benign in this so-called third plane by their **compression pattern** (► **Fig. 12**) and/or by a relatively homogeneous tissue structure. In contrast, the majority of malignant breast tumors (80%) [56] show a typical radiating surrounding pattern (= **retraction pattern**) (► **Fig. 13a**) [47, 49]. In the other carcinomas, an indifferent growth pattern with non-homogeneous tumor structure and/or infiltrating growth into the surrounding tissue can be detected (► **Fig. 13b**).

In the case of complex cystic-solid lesions with irregular wall structures, additional information on tumor vascularization can be obtained with the assistance of the glass body mode (► **Fig. 13c**). Postoperative scars often cannot be clearly assessed by 2D sonography. With 3D sonography, both the multiplanar mode which assesses the three superimposed perpendicular sectional planes and the surface mode which displays the coronal plane can be used to better delineate the scars from carcinoma/relapse (► **Fig. 13d**).

In non-homogeneous tissue, it can be difficult to differentiate a structural defect from a solid focal lesion. The so-called **canyon sign** (► **Fig. 14a**), which can be seen in the coronal plane in case of scars and mastopathy tissue in 3D sonography, is an additional differential criterion because it is not observed in true focal lesions (► **Fig. 14b**) [57].

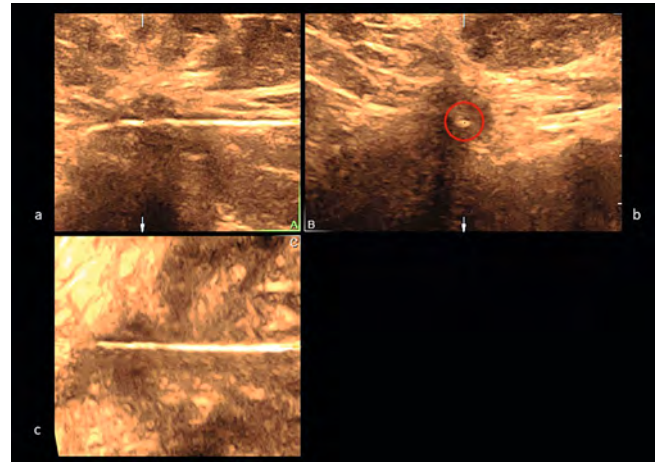


► **Fig. 13 a.** Malignant breast tumors appear up to 80% with a typical radiating surrounding pattern (= retraction pattern) in the coronal surface image **b.** Medullary breast carcinoma without retraction pattern. Instead, the non-homogeneous, hypoechoic focus shows a finger-shaped invasion of the surrounding tissue (coronal surface image) **c.** Sagittal glass-body representation of a complex cystic-solid lesion with wall-associated non-homogeneous proliferations and clear vascularization (1.2 mm papillary breast carcinoma) **d.** For comparison, representation of a scar in multiplanar and surface modes.



► **Fig. 14 a.** Identifying canyon signs in scars and mastopathy tissue by 3D ultrasound in the coronal plane (surface image, OmniView/VCI mode) **b.** For comparison, an invasive breast carcinoma (NST) in the coronal plane (surface image, OmniView/VCI mode).

For diagnostic confirmation of lymph node metastases in the axilla, the multiplanar and surface modes allow an assessment of the non-homogeneous lymph node structure on different planes.



► **Fig. 15** Punch biopsy of an abnormal hypoechoic area. After the puncture has been made, it can be demonstrated in multiplanar mode that the biopsy needle is located centrally in the tumor in all three planes. **a.** Sagittal section **b.** Transverse section (needle in cross section) **c.** Coronal section.

An advantage of 3D ultrasound can be seen in the ultrasound-guided biopsy. When puncturing a tumor in multiplanar mode, the needle can be displayed in all three planes and corrected if necessary. After the puncture is made, the position of the needle in the tissue can be demonstrated and documented in all 3 planes in multiplanar mode (► **Fig. 15**) [58, 59].

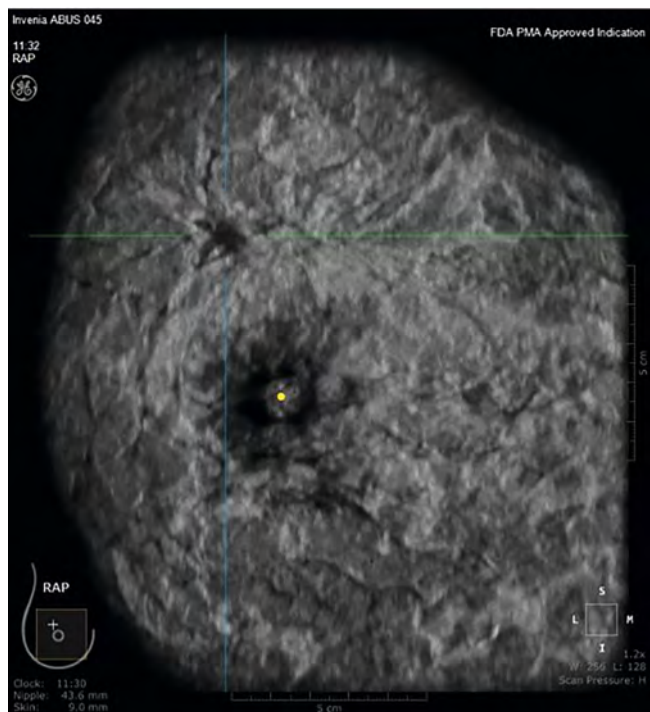
1.2 Automated Breast Ultrasound Screening – ABUS

The term ABUS stands for **A**utomated **B**reast **U**ltrasound **S**creening, an automated breast ultrasound method that enables the acquisition of a 3D dataset covering almost the entire breast volume in 3 planes – sagittal, transverse, and coronal. The coronal plane, which can be shown with the ABUS system in addition to the other planes, is particularly suited to visualizing architectural distortions and retraction patterns as a criterion to assess the dignity of malignant lesions (► **Fig. 16**). This increases the detection rate of malignant changes, especially in dense mammary gland tissue [60]. Compared to mammography alone, ABUS has shown a 55% increase in sensitivity when detecting breast carcinomas in dense mammary gland tissue [60, 61]. The European Asymptomatic Screening Study (EASYS study) managed to demonstrate that combining mammography with ABUS resulted in the relative detection rate increasing by 57%, with the recall rate increasing by only 0.9% [62].

ABUS is also a valuable tool outside of early breast cancer detection, as part of preoperative local staging before breast cancer surgery. The depiction of the coronary plane and the assessment of the tumor's spread in the entire volume of the breast facilitate enhanced surgical planning [63].

ABUS could also be used for treatment monitoring in primary systemic therapy.

An automated ultrasound of the breast is taken for image acquisition, using a “Reverse Curve TM ultrasound transducer” that matches to the anatomy of the breast. The 3D image acquisition is user-independent, standardized, and provides reproducible information. After data acquisition, diagnosis of the images takes



► **Fig. 16** ABUS coronary plane with evidence of a breast carcinoma top right/on the outside.

place at a workstation. Depending on the anatomy, additional optional volume recordings are possible.

Conclusion

3D/4D ultrasound is a valuable addition to 2D ultrasound diagnosis thanks to the volume recording feature and the different display modes. This applies in particular to the assessment of dense mammary gland tissue (parenchymal density category c and d). A major advantage is the ability to represent the breast in the coronal plane, which allows to detect important additional criteria, that are used to identify abnormal lesions. In a US-guided biopsy, the multiplanar display enables the needle to be guided in all three planes.

Special 3D ultrasound devices (ABUS) allow automated 3D volume acquisition of the entire breast tissue.

DEGUM recommendations

1. Special attention should be paid to the coronal section plane in the 3D assessment of the breast. The retraction and compression signs visible in this plane represent important additional criteria for differentiating malignant and benign focal lesions.
2. Mastopathic changes can often be better differentiated from focal lesions in the coronal plane, which means that unnecessary biopsies can be avoided.
3. OmniView mode enables a simple and quick display of lesions in the coronal plane.
4. The limits of 3D ultrasound become apparent when it comes to very fast-growing tumors (e. g., triple-negative breast carcinoma), or in case of irregular scars, where a differential diagnosis can be difficult.

mas), or in case of irregular scars, where a differential diagnosis can be difficult.

5. Digital volume storage enables an examination to take place virtually at a later point in time.
6. At least one representative image documentation should be created for each lesion.

2 Fusion with different diagnostic methods

There is ongoing research underway to optimize the sensitivity, specificity, and quality of breast imaging; among other things, the fusion of several imaging methods promises further development in breast diagnostics [64, 65]. Combining different imaging methods into one single work step, may allow to answer several different questions simultaneously. This can result in better image resolution or spatial representation. Assertions about the metabolic activity of the examined tissue could also be made, as has already been done in clinical diagnostics in terms of combining CT and positron emission tomography [64, 66].

Another advantage of combining different imaging lies in the more precise allocation of the region of interest (ROI) in one imaging modality relative to another modality. The result of the fusion of mammography and sonography can be a clearer spatial assignment of the lesion in the two modalities [67].

Fusion research has advanced the computer-based automation process in complementary breast diagnostics, which, even if it is not yet routinely used, is likely to gain importance in the future [68].

Conclusion

Combined imaging is not yet established in routine diagnostics, the reasons being the currently still experimental approaches and the associated costs. Standardized diagnosis of images is currently not possible [64, 69, 70]. There are many potential uses of these techniques both in screening and in routine diagnostics, and further research may enable combined imaging to become part of routine breast diagnostics [71, 72, 73].

DEGUM recommendations

1. There are currently no valid recommendations for action that can be derived from this technology for routine use, as it is still being developed.
2. There is currently insufficient available data to evaluate the clinical value.

3 Possible applications of artificial intelligence (AI)

Despite the increasing standardization of the examination technique of hand-held ultrasound, this remains an individual examination that requires the operator to have completed good training in order to achieve a high level of diagnostic certainty. A precondition is that the examiner must first visualize a lesion in order to have it subsequently evaluated using trained artificial intelligence (AI). Thus, when it comes to hand-held ultrasound, the areas of application of AI are to support the examiner in the evaluation of a lesion that has already been visualized. Use of AI in the

detection of a lesion would be desirable, but data on this is scarce. For example, Zhang et al. [74] reported on the implementation of AI in a real-time ultrasound device, which enables real-time detection of a lesion while the breast tissue is being examined with the ultrasound transducer. If a lesion, that needs further evaluation, appears on the monitor it is marked with a colored rectangle and thus made visible to the examiner. In the setting described, the lesion is visible up to a frame rate of 24 frames per second with a sensitivity and specificity of 89.25 % and 96.33 %. However, this is a small, single pilot study that does not permit generalization.

It is necessary to evaluate [75] to what extent AI can possibly improve medical care, or whether it could even be a substitute for evident examination experience. It would be desirable to utilize AI in healthcare to achieve higher sensitivity and specificity, as well as improve the negative predictive and positive predictive values, ideally combined with a reduction in the workload on healthcare personnel and a simultaneous reduction in costs.

A possible application of AI, which is deemed very promising for the future, can therefore be seen in the application of automated ultrasound systems.

The performance of AI was improved through the use of deep learning algorithms, which use artificial neural networks to independently evaluate unstructured data, such as ultrasound images consisting of many pixels [76]. This takes place on several levels. The entry level is the level in which, for example, an ultrasound image is presented. The final level is the output level, in which the final assessment of the image is stated by AI (e. g., malignant or benign lesion). There are several other levels in between, in which parts of the data or the image is analyzed independently. The levels are connected to each other via so-called “synapses”, which are always re-weighted during training. If the AI made a correct decision during training, the synapses involved in the decision are more heavily weighted. If the AI makes a wrong decision, the synapses involved are weighted less. The AI learns constantly through repetition, thereby becoming more and more confident in how it evaluates tasks. A high-quality training dataset is fundamental.

Deep-learning techniques for AI algorithms from datasets collected from examinations performed with ABUS are already being clinically explored. There are currently examinations of 20,000 US datasets from ABUS examinations with 3,000 histopathological correlations. A study by van Zelst et al. [77] with the QView CAD - software has already shown a reduction in unnecessary recalls. The study group postulates the potential for AI application for second opinions in ABUS examinations. Wang et al. [78] managed to demonstrate that the evaluation of the ABUS datasets by trained AI can achieve the diagnostic certainty of an experienced diagnostician (Sensitivity: 88.6 % vs. 88.1 %; Specificity: 87.6 % vs. 85.1 %). This data suggest the AI may potentially be suitable for the evaluation of ABUS datasets in a screening setting. However, these studies are small, single studies.

Developers see the opportunity to possibly replace the initial examiner in a screening setting with AI, which could lead to cost reductions as well as a decreased workload for personnel. Dembrower et al. [79] managed to demonstrate in a retrospective simulation study that a trained AI tool can reliably evaluate 60 % of the mammography performed without a carcinoma being overlooked.

Other working groups, such as Cao et al. [80] research “deep learning” techniques – also on an experimental level. Furthermore, possible uses of AI are seen not only in hand-held ultrasound and with ABUS, but also in elastography [81]. The working group of Zhang et al. [82] managed to substantiate that deep learning technology can achieve a high diagnostic accuracy in the evaluation of elastograms in an experimental setting (AUC 0.947, 88.6 % sensitivity, 97.1 % specificity). It should be noted that this was a single small study.

Conclusion

There are currently several promising AI approaches, however, they still require further development and improvement and need to demonstrate their value in prospective studies. The approach of deep learning technology appears promising in the evaluation of image data.

DEGUM recommendations

1. There are currently no valid recommendations that can be derived from this technology for routine use, as it is still being developed.
2. There is currently insufficient available data to evaluate the clinical value.

C. Quality Assurance

The chapter “Quality assurance in early breast cancer screening” in the S3 guideline for early breast cancer detection in Germany published in 2003 [1], already described the structural, process and result quality measures for breast ultrasound in detail. Reference was explicitly made to a fundamental work on quality control from 2003, which is still valid today [83].

Structural quality

This includes the requirements for the sonography devices by carrying out phantom tests as well as the image quality in clinical use as basic and routine repeat tests. One should always strive to carry out regular checks of the ultrasound devices [84].

Additional requirements concern the examiner, who should periodically update his/her expertise through continuing education and training in accordance with the requirements for level I–III of the DEGUM qualification. For this, DEGUM has implemented a quality-oriented, multi-level certification system for ultrasound examiners [85]. The requirements for a standardized examination procedure, for the documentation, the level of training, and the quality of the equipment according to the DEGUM specifications are the basis of levels I–III [14].

Process quality

This includes the indication, assessment of the lesion, classification of dignity, and documentation, as well as the derivation of further action [14]. This also consists of complying the waiting

periods between indication and examination in accordance with the specifications of the DKG-certified breast centers in Germany, and those in the mammography screening program.

Result quality

This includes the quality of the findings and the biopsy results.

In the first update of the aforementioned 2008 guideline, it was required that “structure, process, and result quality for the use of breast ultrasound must be verified as a prerequisite (GCP, recommendation level A)”.

The results of the Schleswig-Holstein QuaMaDi program convincingly demonstrate that these requirements should be met [86, 87]. However, if one considers the results of the quality assurance carried out on the ultrasound devices of the Austrian mammography screening [84] for instance, then one should keep in mind that about one quarter of the devices did not meet the required quality standards after the first check.

1 Quality requirements for the examiner

If one takes the above-mentioned qualification according to DEGUM Level I as a basis, the examiner should have completed 18 months of medical work in the field of gynecology and obstetrics, radiology, or surgery and have examined and documented over 300 independently performed breast ultrasound examinations during this period, with 100 of these representing pathological findings (at least 50 solid tumors, with 20 of these identified as carcinomas). All lesions examined should have been assessed either primary by ultrasound or after the initial mammography or breast MRI examination.

The German ultrasound agreement of the National Association of Statutory Health Insurance Physicians (KBV) gives a detailed statement addressing the question of who should train the examiner [88]. According to § 135 para. 2 SGB V on ultrasound diagnosis, (ultrasound agreement) dated October 31, 2008, in the version valid as of July 1, 2022, trainers in breast ultrasound are defined as follows:

- a) Physicians who already meet the requirements for professional qualification in the respective area of application according to this agreement;
- b) physicians who are fully authorized to carry out further training in the respective area of application according to the further training regulations;
- c) physicians who cumulatively meet the following requirements:
 - Completed further training as a specialist in radiology, gynecology, or surgery;
 - The fulfillment of the professional and technical requirements according to this agreement for the respective area of application;
 - at least 36 months of independent work in the field of ultrasound diagnosis;
 - 10x the number of examinations required for the respective area of application.

Here, KBV requires 200 examinations and, in the case of proof of qualification in the B-mode procedure of another area of application, 150 examinations. There are no requirements pertaining to the proportion of pathological findings.

2 Quality requirements for the devices

With regard to the device guidelines, the Breast Ultrasound (in German “Mamasonografie”) working group refers to the ultrasound agreement of the KBV dated October 31, 2008, in the version valid as of July 1, 2022 [88], and the standards formulated by DEGUM, which are recorded in Part I of the Best Practice Guideline of DEGUM [14]. The EFSUMB guidelines for a regular technical review are the basis of the DEGUM recommendations [89]. The already valid draft standard for constancy testing on ultrasonic devices can be found under DIN 6859-1:2022-01(D) [90]. Regarding the temporal sequence, DEGUM takes the position that the inspection intervals for the various components of a system should be staggered depending on their probability of failure:

- Inspection of the transducers annually;
- Review of console functions every 3 years;
- Review of the monitors every 6 years.

Moreover, the following points should also be checked by the user every year:

1. Hygiene requirements
2. Conformity of the ultrasound gel to the transducer according to the manufacturer’s specifications
3. Power connection and cable connections
4. Printer settings
5. Ultrasound transducers – detection of
 - a) defective transducer elements using an air sample
 - b) visible surface defects of the transducer
 - c) cable defects

In addition, maintenance reports are required from authorized device technicians and/or manufacturers at 3- and 6-year intervals.

3 Quality requirements for the device and image setting

There are basic internationally-applicable rules for the optimization of breast sonograms [85], which have been included in the current DEGUM recommendations in Part 1 of the Best Practice Guideline [14]:

- a) Use of high-frequency transducers, 9–13 MHz max. 18 MHz;
- b) Set image field so that the entire mammary gland is visualized and fills at least 2/3 of the image;
- c) Focus on the region(s) of interest (ROI);
- d) Set the gain and time-gain compensation so that a harmonious image is created that is neither too bright nor too dark. Regulate contrast and brightness on the monitor and printer;
- e) Use of image optimization methods, such as spatial compound or harmonic imaging;
- f) Application of additional ultrasound modalities such as color Doppler and elastography.

Conclusion

Quality-assured breast ultrasound depends on an optimized and repeatedly checked device setting, the examiner’s degree of training, and a standardized examination procedure.

Quality assurance measures for device standards and continuous examiner training and further education are an integral part of quality-assured breast ultrasound, making these indispensable for adequate breast diagnostics.

DEGUM recommendations

1. If a medical facility has breast ultrasound equipment available, the requirements for structure, process, and result quality should be met.
2. In particular, continuous training (ideally DEGUM-certified) as well as the maintenance of device quality and a standardized examination process must be ensured.

Conflict of Interest

The authors declare that they have no conflict of interest.

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