The differential diagnosis between breast cancer and fibro-micro-cystic dysplasia by full breast ultrasonography - a new approach

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**Purpose**

**Introduction:** The application of the Sonoelastography (SE) in the diagnosis of breast malignancies has controversial evaluations in the literature; indeed, this method has some limitations, by one side inherent to the method itself, but some wrong criticisms are due to the wrong protocol and to the classical, non-anatomical technique of examination. The worst results published about SE were related to its use as an independent method of examination and they were compared with those of 2D Ultrasonography (US) alone. By consequence, it is assumed SE cannot differentiate the scars, the fibro-micro cystic dysplasia (FMCD) and the calcified fibroadenoma from malignant lesions, all of them presenting low elasticity. If we will consider that there are many manufacturers with different methods of acquisition of the Sonoelastograms, more or less performing, and there are different qualitative interpreting scores for the resulted images, some completed with the semi quantitative *strain ratio*, the confusion is partially explained [1; 2].

Thereby we think there are some mistakes of the technique of examination and of the interpreting the Sonoelastograms that are easily to correct by applying the follows:

- *The breast US must be performed in accordance to the particular radial anatomy of the mammary gland*, which is composed by a number (14-20) of lobes surrounding the nipple, separated by more or less developed interlobar fatty tissue; the radial technique, imagined by Teboul and Halliwell in 1995 [3] and named the *Ductal Echography* (DE), promoted by Amy and others [4; 5], is nowadays used in many countries as the unique non-invasive method of investigation of the mammary ducts and lobules, normal or abnormal (*Fig. 1 on page 3, Fig. 2 on page 3*). Using more and more performing machines, the breast US anatomy is visualized with a resolution and magnification comparable with an optical X3, being possible to differentiate the ductal walls of less 0.5mm thickness and to illustrate the pathological changes (*Fig. 3 on page 4, Fig. 4 on page 5, Fig. 5 on page 5, Fig. 6 on page 6, Fig. 7 on page 7*).

- *The US SE must be performed as a complementary technique included in the Full (complete) Breast US (FBU)*, which uses all US technical applications: 2D radial and antiradial US (DE), tissue harmonic imaging (THI), 3D/4D US, Doppler assessment, and SE [6]. FBU is logically, when we intend to precise the most complete and accurate diagnosis by US, similar to the use of the complete protocol of sequences of the Magnetic Resonance Imaging (MRI) or to the use of contrast agents in the protocols of any Computed Tomography; moreover, FBU is recommended as first intention imaging method of breast exam in male and children [7].

- *The US SE must be interpreted using a unique, standardized score*, and the one the most appropriated and almost superposed to the US BI-RADS categories is the Ueno/Tsukuba score, proposed by the promoters of the real-time SE [8; 9; 10]. The qualitative SE is recommended to be sustained
by the semi-quantitative SE represented by the strain ratio, the elasticity of the interest structure being reported to the elasticity of the soft premammary fatty tissue.

**Purpose:** Fibro-micro-cystic dysplasia (FMCD) represents a pseudo-tumoral form of the cystic disease, considered of low risk for developing malignancy (0.3% according to Venta et al [11]) as comparing to the ductal and lobular atypical hyperplasia [12], but presenting similar findings as many breast cancers (BC) on Mammography, classical breast US, SE alone and MRI. We present and illustrate the non-invasive differential diagnosis between BC and FMCD using the Full Breast Ultrasonography (FBU), avoiding unnecessary and frequently uncertain biopsies [13] or unnecessary surgical treatment.

**Images for this section:**

**Fig. 1:** Doppler Ductal Echography: an anatomical scan of a mammary lobe in the left breast at half past one o'clock (L1:30), performed with a long linear probe provided with a water-bag device.
Fig. 2: Radial scan at R10:30 with detailed anatomical rapport inside and outside the mammary lobe, performed with a long-linear probe provided with a water-bag, to respect the breast relief.
Fig. 3: Detail of a Radial scan (Doppler DE) at L12:00 in a dense, young breast, with thick parenchyma (ducts and lobules) and less pre and retro mammary fatty tissue; the "tent" of Cooper ligaments contains the terminal ductal-lobular specific unit (TDLUs). The same aspect in an adult or post-menopausal breast is significant for diffuse hyperplasia.

Fig. 4: Radial scan of a lobe reproduced by a composed double-screen image achieved with a usual, short, high frequency transducer; despite the "constructed" image of the lobe, it is useful to assess the dense breast in this menopausal woman of 64-year-old, with non-involuted ducts and lobules, considered as diffuse (lobular) hyperplasia, a risk factor for breast cancer.
**Fig. 5:** DE at R8:00 in a fatty breast illustrates the global atrophy of the lobes, including the parenchyma (ducts and lobules) and the lobar hyperechoic stroma; practically, the lobes appear as thin heterogeneous hyperechoic cords/strings separated by the interlobar replacing fatty tissue. Any eventually mammary lesions will be connected to these strings and to the Cooper’s ligaments that appear elongated.
**Fig. 6:** DE at L12:00 with a long probe illustrates a dense breast, with prolongations of the TDLUs along the Cooper’s ligaments, with posterior shadowing, but without any Doppler signal abnormality; this normal variant can be demonstrated by changing the angulations of the transducer and erasing the shadowing effect of the fibrous Cooper ligaments or by checking the strain on SE.
Fig. 7: R10:00 scan in a fatty breast of a 32-year old patient with ovarian insufficiency, illustrates the mammary lobe with atrophy of the ducts and unapparent lobules, and the Cooper’s ligaments crossing the lobe from the pectoral fascia to the skin. Any pathological aspects of the mammary gland would be connected to these thin ducts.
Methods and Materials

Methods and Materials: We made a prospective study on 819 patients aged 15-year to 88-year-old, examined for screening or symptomatic breasts during January 2008 - July 2011; the US was used as an independent method of diagnosis, sometimes as first intention method and in many cases after mammography, but without prior diagnostic information.

We applied as protocol of examination the last years concept of FBU based on the DE of Teboul, completed with Doppler and SE, which is almost operator independent and guarantee the whole breast examination. We respected the standards of acquisitions with the nipple on the left-upper corner and the notation of the images upon the clock-wise model, resulting reproducible images that could be interpreted by a second reader. A dedicated long-linear transducer of 9cm length with a water-bag device was the first used for the detection of the normal and abnormal breast parenchyma, followed by a conventional shorter, higher frequency transducer of 4.5cm length for Doppler and real-time SE characterization of the breast structures and of the satellite lymph nodes (Fig. 8 on page 10, Fig. 9 on page 10, Fig. 10 on page 11).

The tissue harmonic imaging and the 3D/4D acquisitions were used occasionally, according to the breast structures (Fig. 11 on page 12, Fig. 12 on page 13).

The panoramic views were acquired as complementary information for the use of clinicians or for a better understanding of the disease by the patient, but we not recommend these panoramic images in the breast diagnosis when the long transducer is available (Fig. 13 on page 14), because they are not reproducible, there are inherent artifacts and we can not apply measurements in the horizontal plan.

We used the score of Ueno (Tsukuba) for the SE, and the US BI-RADS categories assessment for the initial diagnosis and the follow-up exams. The qualitative SE was completed when available with the strain ratio, as a semi-quantitative measurement of the elasticity of the region of interest as compared with the premammary fat (FLR=fat-to-lesion ratio), which is the "softest" tissue. For some cases, we compared the FBU diagnosis with different manufacturers’ ultrasound machines, with different linear probes and different techniques for the SE assessment, and the main protocol resulted similar diagnosis.

The final diagnosis of the BI-RADS 3 category was based either on the cytology after fine-needle aspiration or nipple surges samples, or on the relative short-interval follow-up up of 2 to 6 months; for the 4 and 5 categories we based on the pathological report after surgical
treatment or biopsies; for the 1 and 2 categories, the US follow-up and 2 independent ultrasonographers were the most used, and in some cases of large lesions the surgical treatment offered the pathological diagnosis. The core-biopsies were generally avoided, and we reserved them for the cases with large, inoperable tumors with malignant aspect and/or metastases (stages III and IV); the surgical biopsies with extemporaneous exam of the suspect lesions were preferred by the patients and the clinicians in the operable stages.

**Images for this section:**

![Fig. 8: CM 47-year-old: The first step of FBU with a water-bag long probe demonstrates an infracentimetric nodular lesion in L3:00, periareolary, hypoechoic, well defined, located intralobal and connected to the ductal tree.](image_url)
**Fig. 9:** CM, 47-year-old, the same case: the second step FBU on radial and antiradial 2D Doppler scans with short linear high frequency transducer visualize the mass well defined, with multiple bosselations on the contour (more than 3 lobulations on the contour are suspect for malignancy), without significant posterior effects, taller-less-wide as a benign lesion, but with salient new vasculature with a malignant type of the incident angle. This is a typical case of 2D US images of uncertain malignancy, but Doppler characterization is suspect.
Fig. 10: The same case, the third step of FBU: Real-time SE illustrates a score 4 Ueno and a high FLR, confirming a malignant infracentimetric deep non-palpable lesion, classified as US BI-RADS 5 category. This final pathological diagnosis was micro-invasive ductal carcinoma.
Fig. 11: 4D SE in a fibro-cystic dysplasia demonstrates the multiplicity of the aspects and the complex relationship between the lesions. The future technology must revolve the problem of the 4D acquisitions with a linear probe, or other methods to improve the scans resolution.
Fig. 12: The same case: the use of the threshold and of the various points of illumination is useful for demonstrating the breast pathological architecture; in this case, multiple contiguous or distant cysts are well reconstructed, and the differential diagnosis with a septated cyst is proven by the arcuate contours.
Fig. 13: L4:00 panoramic scan upon the DE technique: the slipping technique with un-standardizable speed offered a good large view of the breast, but the image is less possible to be reproduced identically, the resolution is poor and we can not precise the distance of the cystic lesion to the nipple.
Results

Results: From all 819 patients we found 282 (34.43%) cases with fibro-cystic dysplasia (FCD), of which a quarter represented by 79 (9.6%) cases included FMCD presenting a clinical pseudotumoral more or less painful aspect (Table 1 on page 18).

The US exam visualized unique or multiple lesions type FMCD with multicentric sites (located in different lobes) and/or multifocal (located inside the same lobe), generally sized over 0.5cm up to 3cm. FCD and particularly FMCD was frequently associated with macro cysts, or ductal ectasia, in few cases with intraductal papilloma, benign nodular hyperplasia (fibrodenoma) or diffuse ductal or lobular hyperplasia, but rarely with BC (Table 2 on page 19).

The US aspect of FMCD presented usually a hypoechoic, heterogeneous mass with irregular borders frequently speculated or diffuse, or multilobulated, malignant shapetype with the aspect taller-than-wide, presenting more or less intense posterior acoustic shadowing, the location inside the mammary lobe and a connection with the ductal-lobular tree (Fig. 14 on page 23, Fig. 15 on page 24); sometimes the small lesion were found in the site of the terminal ductal-lobular specific units (TDLU), considered as the initial site for the developing of any mammary lesion, either benign or malignant (Fig. 16 on page 24, Fig. 17 on page 25).

When visible on the Mammography or US (classical or DE) the FMCD lesions are usually classified as 4 or 5 BI-RADS category, but we found no salient new vasculature on Doppler; indeed, with the available transducers of 10-14MHz we were able to visualize the new vasculature in malignant lesions over 3mm diameter (Fig. 18 on page 26), or the functional hyperemia in the lactation breast and dysfunctional hyper prolactinemia. The new malignant vasculature presented an almost incident angle to the surface of the lesion, with centripetal orientation [16], while the benign new vasculature had an oblique to parallel course to the surface of the lesion; sometimes the malignant vessels had a tortuous aspect, disproportional number and size with the surrounding normal breast structures, but proportional increasing of the number of the vascular poles with the lesion size.

On the SE the FMCD was mimicking the score 3 or 4 Ueno, but the correct assessment was the score BGR (blue-green-red) complex/ composed, for the clusters of measurable small cysts (Fig. 19 on page 27) or BGR of summation-type mimicking a unique cyst equal with the lump size (Fig. 20 on page 28). This aspect was not yet correlated in the literature with the micro-cystic dysplasia and could explain the most errors of the assessments of SE. The strain ratio was uncertain, between 2.50 and over
50.0, according to the "hard" region of interest selected inside the lesion; the selection of the whole area of BGR complex or summation-type generally presented a strain ratio (FLR) less 4.70 chosen for the cut-off value [14], a reasoning for the diagnosis of a benign lesion.

The use of the 3D/4D demonstrated in FMCD the presence of small cysts, invisible on 2D US and sustained the in-vivo diagnosis (Fig. 21 on page 29, Fig. 22 on page 29, Fig. 23 on page 30)in the classical US, the predominantly solid masses with eccentric cystic foci are usually biopsied because of the rised risk of BC, as reported Berg et al [15].

All the 19 (2.3%) patients with proven BC presented a salient new vasculature for lesions over 3mm diameter (Fig. 24 on page 31), a score 5 or 4 Ueno according to the presence or absence of the perilesional halo corresponding to the desmoplastic reaction (Fig. 25 on page 31, Fig. 26 on page 32), while the malignant criteria upon the BI-RADS assessment were not always present in the smallest lesions or in the atypical malignancies, such as mucinous or medullary carcinoma, which have smooth contours and moderate benign posterior effects with acoustic enhancement and marginal shadows (the Kobayashi sign)(Fig. 27 on page 33, Fig. 28 on page 33, Fig. 29 on page 34).

From all patients, the proliferative lesions either benignant (diffuse or segmental ductal or lobular hyperplasia, fibroadenomas, papilloma) or malignant were present in 55.2% cases, while the secretor changes (ductal ectasia (Fig. 30 on page 35) and fibro-cystic dysplasia including FMCD) were found in 66.8% (Table 3 on page 20).

Some BC were associated with the fibro-cystic disease (Table 2 on page 19, Fig. 31 on page 36, Fig. 32 on page 36, Fig. 33 on page 36) considered rather a risk mark than a precancerous condition [17]; more cancers appeared associated with premalignant ductal or lobular hyperplasia, more suspect if detected in the elder patients [18]. In our study, the diffuse ductal or lobular hyperplasia was easily identified and was frequently present in the cases of BC (Table 4 on page 21). The FBU could not yet differentiate the simple Diffuse Hyperplasia (DH) from the Atypical Hyperplasia (AH), but the pathological report presented frequently both forms associated with the breast cancer. However, the benign ductal hyperplasia illustrated thickening of their walls with preserving of the central hyperechoic line corresponding to their virtual lumen, while the presence of segmental ductal /lobular thickening, with salient peripheral vasculature and benign score 2 or 3 Ueno, may be suspect for AH and was classified US BI-RADS 3 Category, with a short-term follow-up exam. This management was useful in the detection of the aggressive evolution, with malignancy development in 2-6 month interval, in a case with multifocal determination, and in some cases with axillary FBU malignant-type lymph nodes rising few months after negative biopsy.
The differential diagnosis in the cases with multiple lesions was based on the duality new vasculature-low elasticity with the score 4 or 5 Ueno and a high strain ratio with the cut-off value of 4.7, as more specific tools, with the highest positive predictive value, complementary to the well-known features admitted by the US BI-RADS classification based on Stavros criteria. This duality was feasible for the multifocal cancers with secondary and tertiary intraductal disseminations inside the same lobe, according to the sick lobe theory of Tibor Tot and col. [19; 20; 21].

FBU used as an independent non-invasive method of diagnosis of BC had in this study a positive predictive value for BC of 86.4%, a negative predictive value of ## 99.7%, with the sensitivity of 95.0% and the specificity of 99.6% (Table 5 on page 22) The results seems to be uninfluenced by the condition of screening or symptomatic breasts, because the most cases presented associations of multiple lesions, which were characterized distinctly, and some BC were either non-palpable, or with multifocal determinations. The 3 cases of false-positive were diagnosed in the beginnings of this study, the FMCD being the final diagnosis after surgical biopsies; the retrospective analysis demonstrated an overdignosis based on DE and on the Stavros criteria, a misinterpreting of the BGR composed/ summation-type score on SE, and a neglecting of the absence of the malignant-type new vasculature on Doppler (Fig. 34 on page 38, Fig. 35 on page 38). The unique case (1/819) of false-negative, proved as invasive ductal carcinoma, in the area of a previous breast contusion, was misinterpreted as chronic multilocular superinfected hematoma, with moderate salient vasculature and BGR complex score on SE. In this case, the cytology was suspect and a correct treatment was applied in the shortest time.

Images for this section:
Table 1: The distribution of the cases demonstrated the fibro-micro-cystic dysplasia (FMCD) 4-fold more frequent than the breast cancer (BC), explaining the raised risk for misdiagnosis.
Table 2: The distribution of the secretor changes: E simple= Ductal Ectasia without other abnormalities; FCD= Fibro-cystic dysplasia, including FMCD; P= papilloma; BC= breast cancer.
Table 3: The incidence of the proliferative (benignant and malignant) ductal and lobular changes as well as the secretor lesions (ductal ectasia and FCD) was higher than 50% and different lesions were overlapped. The BC is expected to be more frequent associated with the secretor lesions because their incidence is the highest, but the simple secretor changes are considered for not significant risk factor.
Table 4: The distribution of the association of the proliferative lesions demonstrated the presence of the ductal and lobular hyperplasia (simple or atypical) in association either with benign nodular hyperplasia (fibroadenoma), either with the malignant lesions, but in rare cases coexisted BC and fibroadenoma. H= Hyperplasia, Fa= Fibroadenoma, BC= Breast cancer
Table 5: The global results of the FBU as an independent, non-invasive method used in the diagnosis of BC

<table>
<thead>
<tr>
<th>Test Outcome (FBU)</th>
<th>Test Outcome Positive</th>
<th>Test Outcome Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>True Positive = 19</td>
<td>False Positive (Type I error) = 3</td>
</tr>
<tr>
<td></td>
<td>False negative (Type II error) = 1</td>
<td>True negative = 796</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PPV = 19/22 = 86.36%</td>
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<tr>
<td></td>
<td></td>
<td>NPV = 895/896 = 99.74%</td>
</tr>
<tr>
<td></td>
<td>Sensitivity = 95.00%</td>
<td>Specificity = 99.62%</td>
</tr>
</tbody>
</table>

**Fig. 14:** IR, 36-Year-old: Detail of a radial scan with a short probe illustrates at the R8:00 an intralobar infracentimetric pseudomalignant lesion, with hypoechoic aspect, an irregular shape taller-than-wide, with speculated contour, and with posterior acoustic
shadowing. There are few vessels visible in the area, but none inside the lesion (Doppler negative).

Fig. 15: IR, 36-year-old, the same case: The qualitative SE demonstrates a summation-type BGR score, mimicking a cyst of a same size with the lesion, and the strain ratio with a low FLR between 1.18 (level 5 of quality for compression) and 1.54 (for a level 4 of the quality compression, admitted by the manufacturer).
Fig. 16: MJ, 61-year-old: R4:00 scan reveals on SE a couple of thickened lobules located in TDLUs positions; despite the irregular contour and the hypoechoic suspect aspect, they present benignant posterior enhancement effect and marginal shadows (Kobayashi sign). The correct interpretation of the SE must keep out of the score 3 Ueno, but the correct scoring is summation-BGR, in this case the skew of the enlarged superficial lobules determining the skewness of the BGR levels. The Doppler was negative, and the 6 month repeated follow-up exams revealed no change.
Fig. 17: DI, 27-year-old: R10:00 scan demonstrates on SE a couple of lesions with BGR score: to the left-side there is a typical cyst, both on the 2D display and on the SE, and to the right an ill-defined TDLUs area, with hypoechoic aspect and BGR-summation score corresponding to the fibro-micro-cystic changes.
Fig. 18: DA, 68-year-old: R9:00 double-screen composed radial scan reveals in a fatty breast a less 8mm hypoechoic lesion, connected to the atrophic mammary lobes represented by hyperechoic strings containing tiny hypoechoic ducts. Both the 2D US and Doppler aspects of the lesion are suggesting for malignancy; moreover, a centrifuge duct presents a couple of vessels suggesting the intraductal tiny secondary dissemination.
Fig. 19: CC, 57-year-old: R 9:30 SE illustrates a complex, composed BGR score in the area of a surgical scar with pseudomalignant aspect on mammogram and 2D US; SE aspect is suggesting for micro-cystic changes in a dense, cicatricial tissue. The low FLR is conclusive and a follow-up FBU is reasonable.
**Fig. 20:** FE, 47-year-old: A lump at R9:30 with pseudotumoral aspect, presents a summation-BGR score, mimicking measurable cysts, with low, benignant FLR; the absence of the new vasculature inside the lesion and the SE are sufficient to assess a benign fibro-micro-cystic nodular lesion and to avoid a painful and unnecessary biopsy.

![Image of ultrasound scan](image)

**Fig. 21:** IR, 41-year-old: A complex mass in L1:30, without new significant vasculature on Doppler (not showed), is composed by some measurable peripheral cysts, and a solid-type well delineated mass mimicking a fibroadenoma. The settings in this SE are specific to a different machine, but according to the Ueno/Tsukuba scoring.
**Fig. 22:** The same case: 4D depicts better the internal architecture of the complex mass, despite the limited resolution that is expected to be improved in the future years.

**Fig. 23:** The same case: 4D freezing acquisitions are proving the presence of the tiny cysts inside the "solid" portion of the complex mass; the contrast is improved and 4D
add a complementary argument to the SE and Doppler (-), sustaining the diagnosis of benignant FMCD.

**Fig. 24:** MD, 49-year-old: L1:00 radial scan composed by double screen slipping acquisition, reveals the peripheral suspect main lesion with a secondary, centripetal dissemination, connected to the same lobar ductal tree. The new vasculature present in the secondary less 5mm lesion is almost pathognomonic for the malignant disease and is proving the sick lobe theory of Tibor Tot et al.
Fig. 25: GR, 57-year-old: L2:00 long probe scan illustrates a multicentric malignant-type lesions connected to the same ducts, with centripetal and centrifugal simultaneous dissemination.
**Fig. 26:** The same case: The SE of the main lesion reveals a very hard lesion in blue with black artifact and a perilesional light blue halo, corresponding to the intense desmoplastic reaction, scored 5 Ueno. The concordance between the 2D US, the Doppler signal (not shown) and the SE is the key of the high accuracy of the FBU.

![Image](image_url)

**Fig. 27:** CC, 74-year-old: Long-probe of 7MHz with water-bag examination demonstrates at L2:00 a solid round-shaped mass, almost isoechoic with posterior enhancement and lateral shadowing (the benign sign Kobayashi), but with internal new vasculature proved even on this resolution.
Fig. 28: CC, 74-year-old, the same case: The high frequency short linear probe increases the scans resolution, demonstrating a complex mass with more than 50% solid portion and internal small cysts; the benignant contour, shape and posterior effects of this large mass are discordant with the Doppler features showing multipolar new vasculature with incident plugging angle, almost pathognomonic for the malignant tumors.
Fig. 29: The same case: SE proved the malignancy, with the score of 4 Ueno and a raised FLR of 5.20; the combined analysis is high suggesting for the rare particular breast cancer of medullary or mucinous type. The US BI-RADS 5 category in this old patient with positive collateral history was concordant with the pathological report of mucinous BC.

Fig. 30: PL, 43-year-old: Zoomed radial scan demonstrates the small lobular cysts connected by tinny ductules to the main lobar duct presenting small ectasia. High resolution US with long linear transducers will improve both the technique of breast
scanning, allowing large availability for the DE, and the understanding the physiological and pathological changes in the real "breast tissue".

**Fig. 31**: CL, 51-year-old: L1:00 radial scan presents a couple of benignant and malignant-type contiguous lesions.
**Fig. 32:** The same case: The high resolution radial and antiradial Doppler scans suggest a cyst in contact with a malignant mass upon the Stavros criteria, concordant with multipolar incident vessels. The intentional low color gain demonstrates the absence of the vasculature inside the well-defined ovalar lesion, suggesting a cyst.
Fig. 33: The same case: The third step of examination demonstrates on the SE the BGR score for the cystic lesion and a score 5 Ueno for the suspect mass, with the very high FLR of 83.41, concordant with the diagnosis of invasive ductal carcinoma. The final US assessment was BI-RADS 5 category.

Fig. 34: SC, 42-year-old: False-positive diagnosis based on the radial and antiradial scans in L4:00, presenting a hypoechoic lesion with malignant features upon the Stavros and US BI-RADS criteria; the unipolar peripheral vasculature without internal penetration is uncommon in malignant lesion and was neglected in the diagnosis.
**Fig. 35:** The same case: The sonoelastogram should be interpreted as a complex, composed BGR score, with low FLR, in concordance with the pseudo-tumoral form of the fibro-cystic disease. The misinterpreting of this aspect, and the over evaluation of the classical features resulted in a false-positive diagnosis, assessed as BI-RADS 4 category.
Conclusion

Conclusion: FMCD represents complex micro-cystic breast masses with solid, usually malignant-type features. Based on the mammogram and the classical US, these masses could not be classified as benign or malignant and proved the raised risk of BC (7/38 cases according to Berg et al [15]), the biopsy is largely recommended.

In our study, none of the individual characterization criteria of breast lesions was accurate (Stavros criteria developed on the BI-RADS assessment, Doppler, 3D/4D, SE), but the combined analysis was performing [22], and in our experience FBU offered the best results, concordant with the reports of the promoters of DE [23].

The duality Doppler-SE was valuable in the differential diagnosis of BC from the benign pseudo malignant lesions, such as FMCD, scars (Fig. 36 on page 41, Fig. 37 on page 42), calcified /inspissated cysts (Fig. 38 on page 42) or calcified fibroadenomas.

The BGR composed/complex and BGR-summation-type scores proposed by the authors represent a variant of the BGR score, and could be explained by the liquid component of the microscopic lesions grouped in clusters surrounded by an amount of fibrous connective tissue.

The 3D/4D as a complementary tool was useful in the pathological characterization of the small cysts dissimulated by the fibrous stromal reaction or the associated hyperplasia.

The radial technique was valuable because its acquisitions are standardized and able to demonstrate the connection of any abnormal finding to the ductal-lobular tree, essential to the diagnosis; even in the fatty breasts and in the cases with atrophy of breast parenchyma, DE offers the best resolution as compared with more expansive techniques such as breast MRI or Tomosynthesis. Moreover, DE is the unique non-invasive method to analyze the terminal ductal-lobular specific units (TDLUs), considered the main site for the developing either of the benign lesions such as the mammary dysplasia including the fibro-cystic disease, sclerosing adenosis, fibroadenomas, pathological lobules (sclerotic, dilated, hypersecretory, hyperplastic, atypical), or of the malignant lesions beginning with the ductal carcinoma in situ (DCIS) and lobular carcinoma in situ (LCIS) [24].

The radial and the additional antiradial scans were useful for the estimation of the volumes, without losing the connection of the lesion to the branching ductal-lobular tree and the relation with the nipple, the images being easy to interpreting and to localize for treatment reasons upon the clock-wise model; by contrarily, in the automatic breast 3D
scanning the images are presented as reconstruction scans in the sagittal, axial and the horizontal planes (plane C), intersecting randomly the mammary lobes and without any relation with the nipple.

The FBU represents nowadays the only anatomical non-invasive method of breast diagnosis, the only imaging method that can demonstrate the *sick lobe theory* of breast pathology [18; 20]; it can be performed with the best cost/effectiveness ratio and could have good availability; it is repeatable without pathological side-effects, recommended for short-interval follow-up instead of biopsy, MRI or 6 month interval follow-up mammography [25; 26].

The standardization of the technique of examination based on Doppler DE and in the future the standardization of the SE, the improvement of the length of the transducers of high frequency and the use of the reporting data description according to the US BI-RADS categories will offer the possibility to use the complete (full) US in the breast screening, in the new-coming non-mammographic era [27].

Images for this section:
**Fig. 36:** DM, 48-year-old: pseudo-tumoral aspect with malignant-type features upon the Stavros criteria of this scar 6 month after a conservative surgical treatment, but the absence of the new vasculature is discordant.

![Image of ultrasound scan with color-coded strain ratio and B mode image showing a scar mark labeled as SCAR with a central zone marked as A and B with a complex BGR score.]

**Fig. 37:** DM, 48-year-old, the same case: SE is concordant with the Doppler results and suggests a benign scar; the general aspect of the Sonoelastogram could be assessed with the score 2 Ueno, but the central zone reveals a complex BGR score, which could be explained by the reparatory process with interstitial œdema, possible wire granulomas, or by the occurrence of tiny ectasia of the lobar remnant segments of the ductal-lobular tree.
**Fig. 38:** GE, 48-year-old: R8:30 presents a complex hypoechoic mass, taller-than-wide, connected to the mammary ducts, with peripheral calcified cyst, type over 50% solid portion after Berg et al [15], with intense posterior shadowing. This type of lesion is considered of high risk for BC in the classical US and the biopsy is usually recommended; however, the BGR-summation score and the absence of new vasculature (not shown) indicate a BI-RADS 2 category, and the first 6 month-interval follow-up confirmed no further evolutionary change.
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