Evaluation of the Rupture of Silicone Breast Implants by Mammography

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Evaluation of the Rupture of Silicone Breast Implants by Mammography, Ultrasonography and Magnetic Resonance Imaging of Asymptomatic Patients: Correlation with Surgical Findings

Abstract:
OBJECTIVE: The purpose of this study was to compare the efficacies of mammography, sonography and MR imaging in the detection of breast implant rupture of an asymptomatic population.

MATERIALS AND METHODS: We prospectively evaluated 83 breast implants in 44 asymptomatic patients who subsequently had implants removed by a surgeon to determine sensitivity and specificity of mammography, ultrasonography and magnetic resonance imaging, using predetermined diagnostic criteria of implant rupture. Eighty-three implants were evaluated by both film-screen mammography and high-resolution sonography and 77 implants were evaluated by MRI. All radiological signs were discussed and false positive and false negative were retrospectively evaluated to identify the pitfalls of the investigations.

RESULTS: The sensitivity and specificity of mammography were 20% and 89%, respectively; of sonography, 30% and 81%, respectively; and of MRI, 64% and 77%, respectively. The difference between patients with breast implants for cosmetological and oncological reasons were discussed.

CONCLUSION: Our experience suggests that MRI seems to be the best isolated imaging method for evaluation of rupture among asymptomatic patients and further recommendations were made.

INTRODUCTION:
It is estimated that more than one million and a half to two million women have undergone implant surgery, which are made out silicone gel in their great majority. These implants are used to reconstruct breasts after mastectomy, to correct congenital or traumatic deformities and to increase or to remodel the breast shape for cosmetological reasons. The psychological benefits of this procedure are widely acknowledged; however, silicone breast implants can lead to a range of important complications, such as hardening and rupture.

The pre-operative diagnosis of rupture is very difficult to be made by a physical exam because symptoms and signs are vague most of the time. In the case of deflation of a saline implant there is a decrease in the breast volume, which can be easily noticed during an examination. On the other hand, the rupture of a silicone breast implant is less obvious and thus more difficult to notice, mainly if it is enclosed by the fibrous capsule.

Different imaging methods can identify the integrity of the breast implants and also the extension of a possible silicone leakage going to the glands and adjacent tissues. Mammography (MG), Ultrasonography (US), Computerized Tomography (CT) and Magnetic Resonance Imaging (MRI) were used to evaluate the integrity of breast implants in symptomatic patients for rupture. Each method has its own characteristics, which will determine whether or not the particular method is appropriate for the study of a patient case.

Three different modalities of diagnostic imaging methods were analyzed believing that these methods could help the detection of silicone breast implant rupture. A group of clinically asymptomatic patients were taken as a group sample. These patients wanted to remove or change their breast implants based on psychological or cosmetological reasons. The following methods were analyzed:

1. Mammography: First, because this is the choice exam in the breast cancer screening program. Second, because the sample used had high chances of needing reconstruction surgery and because this service was notably known for accomplishing oncological surgery.

2. Ultrasonography: Because it is a relatively inexpensive exam and also because it does not use ionizing radiation.

3. Magnetic Resonance Imaging: Because, despite being expensive, it allows images in multiple plans with a global vision of the implant in the breast and of the breast into the
METHODS:

This study was approved by the Institutional Review Board of Federal University of So Paulo – UNIFESP / EPM. 44 patients with silicone gel breast implants were taken to the Department of Diagnostic Imaging of the Federal University of So Paulo (So Paulo School of Medicine) for evaluation through Mammography (MG), Ultrasonography (US) and Magnetic Resonance Imaging (MRI) during the period of December 1993 to November 1996. There was a total of 83 analyzed implants. Magnetic Resonance Imaging was performed in 10 patients. Laboratório Fleury’s equipment was used in these exams due to a technical flaw in EPM equipment.

The patients examined were unhappy with the aesthetic aspect or the hardening of their breasts. They did not present a breast lump during the physical exam or a decrease in the volume of the implants in the pre-operative evaluation for surgical correction of the alteration. They were, thus, considered asymptomatic for implant rupture in the clinical point of view. Patients who presented a change of implant history were excluded from this study.

Clinical information collected included the time of implant inclusion (age of material) position (subpectoral or prepectoral), reason of the inclusion (cosmetological or oncological) and implant type (silicone whole gel or single lumen).

Mammography and sonography were performed without any sedation or anesthetic. All 44 patients were submitted to MG and US without problems. It was not possible to accomplish MRI in 3 patients because they could not manage to stay inside the gantry due to claustrophobia.

The mammography of the 83 analyzed implants was performed with state-of-the-art equipment (General Electric Medical Systems, Milwaukee,WI, 600 T, machine 0.3 mm) in the oblique mediolateral and craniocaudal views. Manual technique adjustment was used with exhibition factors among 26 at 30 kV and 100 to 200 MA, with a fraction of time of 5/8 of seconds and distance focus film of 65 cm. The implant displacement views were not done in patients who presented breast reconstruction with TRAM and in those whose implants had intense degree of capsular contraction not allowing, thus, the mobilization of the implant. The sonography of the 83 analyzed implants was done with an ATL (Advanced Technology Laboratories, Bothell, Washington) equipment, Ultramark -9 HDI model, with linear multifrequential 7.5-10 MHz real time transducers.

For the evaluation of the implant posterior walls and for very large breasts the sector probe with 3.5 - 3.75 MHz frequency was used to allow a deeper penetration of the sound wave. Ten millimeters (10mm) acoustic pads (Kitecko, 3M company, St. Paul Minnesota) were used in some cases to improve the visualization of the superficial tissues and of the nipple area.

Magnetic Resonance Imaging (MRI) studies were performed with either a Philips 1.5 T Gyroscan MR scanner (Philips Medical Systems Best Netherlands); 57 implants, or with a GE 0.5 T Signa Advantage, V.5.4 software MR scanner (General Electric Medical Systems, Milwaukee, WI); 20 implants. Different coils were used: body coil in the 1.5T equipment, and dedicated breast coil in the 0.5T equipment. In the beginning of the project when anatomic supports were not available, pillows or Styrofoam cushions were used under shoulder and abdomen to lift the thorax and to keep the breasts on the table without pressure.

The prone position was used to produce good quality images with less respiratory breathing movements and also due to the surface coil configuration adapted for this position. The patients were put in a swimmer position: with an arm raised above the head and with the other arm placed alongside the body when they had unilateral implants. Both breasts were analyzed at the same time when the patients had bilateral implants: with the arms abducted above the head.

The scan protocol in the 1.5 T MR scanner consisted of: T2 weighted spin-echo axial and sagittal images (repetition time, 2000; echo time, 80 msc) and T1- weighted fast spin-echo axial (repetition time 750; echo time 20 msc.); 5 to 6 mm slice thickness; 256x180 acquisition matrix.

The following parameters were used for the 0.5T magnet: T2 weighted fast spin-echo, axial and sagittal (TR 4000 msc /TE 170 msc); 256x256 acquisition matrix. 3.6 mm slice thickness. The field of view ranged from 180 to 280 mm in unilateral implants and from 320 to 360 mm in bilateral implants in a total of 18-20 images in the axial plan and approximately 15 in the sagittal plan. No intravascular contrast agent was used, and neither were cardiac or respiratory gating due to their increasing of the acquisition time.

Mammography, sonography and magnetic resonance imaging exams were independently analyzed by only one investigator (A.M.S.) without previous knowledge of each modality results. For each
analyzed implant the classification systems in three categories was used: normal, suspicious for rupture, diagnostic for rupture (Table 1).

All patients had their breast implants removed by only one surgeon (A.F.M.) and the alterations found were classified in:

Normal implants: When the elastomeric envelope was complete, without perforations, but presented a silicone gel layer at the moment of the implant removal due to the bleeding of the gel. These implants were considered not ruptured after the elastomer careful evaluation by the surgeon in charge of rupture research.

Ruptured implants: When there was an elastomer discontinuity and consequently a spread of silicone into the surrounding tissues. This category includes both the extracapsular ruptures as well as the intracapsular ones; due to interest in determining rupture and non-rupture in the sample analyzed. The time elapsed between the image exams and the surgery did not exceed one week. The breast imaging exams were all done in the same day in the majority. The mammogram or the sonogram were done first then the MRI, in a few cases, but the time between the exams did not exceed 5 days. The statistical analysis was the result of each meaningful finding defined as normal, suspicious and diagnostic by the Chi Square Test and Fisher Exact Test. All of this was compared to the surgery results. Afterwards, the totals of the results found were individually compared, according to each exam type, to the surgical finding considered as gold pattern after the McNemar test application. The same procedure was used with the MRI partial results. Each image method was also compared with the surgical finding sub-dividing the sample according to the reason for the implant: cosmetological or oncological. After having the sample results true positive, false positive, true negative and false negative the sensitivity (ability to detect rupture implants) and specificity (ability to detect non-ruptured implants) of each image method used were obtained. The sensitivity of each method was figured through the relation between the true positive values (ruptured implants correctly diagnosed by the image method as ruptured) and the total of the true positive and the false negative values (total number of ruptured implants).

The specificity was figured out by the result between the true negative values (non-ruptured implants correctly diagnosed as such by the image method) and the sum (total of non-ruptured implants in the sample) between the true negative and false positive.

The nullity hypothesis rejection level was set in 0.05 or 5% (p £ 0.05) for all tests. The significant values were marked with an asterisk.

RESULTS:
The results are summarized in Table 2 and Table 3. 39 patients presented bilateral implants and 5 patients presented unilateral ones. 21 patients (50.6%) had implants for cosmetological reasons and 23 (49.4%) for oncological reasons due to breast reconstruction after mastectomy. The implant positions in relation to the pectoral muscles were the following: 65 (78.3%) were located in subglandular position or prepectoral and 18 (21.7%) of them were located in rectropectoral position. Among the 83 implants studied, 30 of them were found ruptured during surgery and 53 non-ruptured. In addition, 27 (32.5%) of these implants already presented bleeding and 26 (31.3%) were intact. The average age of the ruptured implants was 11.9 years. On the other hand, the average age of the bleeding ones was 11.7 years compared to 11 years of the intact ones. The rupture rate was 0% between 1 to 5 years of the inclusion; 35.29% between 6 to 10 years, 36.36% between 11 to 15 years and finally 66.66% between 16 to 18 years.

Through mammography 71 implants were considered normal and 12 altered (suspicious and diagnostic). Through ultrasonography, 49 implants were considered normal and 28 altered (suspicious and diagnostic). Through MR imaging, 49 implants were considered normal and 28 altered (suspicious and diagnostic).

Through 1.5 T (n=57) MR imaging, 40 implants were considered normal and 17 altered (suspicious and diagnostic). Finally, through 0.5T magnetic resonance imaging with breast coil (n=20) 10 implants were considered normal and 10 altered (suspicious and diagnostic).

The sensitivity found for mammography was 20% (6 in 30), for ultrasonography was 64% (16 in 25) and for the MR imaging was 64% (16 in 25). Furthermore, the 1.5 T and 0.5 T magnetic resonance sensitivities were respectively 50% (8 in 16) and 80% (8 in 10). The differences found among the different methods were statistically significant (p<0.05) for the MG and US data while not significant for the MRI.

The specificity found was 88.7% (47 in 53) for the mammography; 76.9% (40 in 52) for the ultrasonography and 76.9% (40 in 52) for the magnetic resonance imaging. In addition, the specificity found for the 1.5 and 0.5T magnetic resonance imaging was respectively 78% (32 in 41)
and 80% (8 in 10). Once again there was not a statistically significant difference for the MRI data, however; the difference was significant for the MG and US data. The positive and negative predictive values are summarized in Table 4. It is important to point that even though there were not statistic differences, the 0.5T MRI with breast coil presented better sensitivity and specificity results. These data were also analyzed to determine if there would be any benefit from the interaction of these methods when combined two to two or two to three. For this we used the rule that says that the implant could only be considered altered if the two or three methods had the same result. It can be analyzed in table 4 that the combination of these methods caused a decrease of sensitivity in MRI when any combination was used with little improvement of specificity.

**DISCUSSION:**

It is important for the surgeon when making the surgery planning to determine if there is indeed an implant rupture and also to find out where the silicone is located: whether it is retained by the capsule or permeated in the axilla or breast. Leibman (7) says that mammography, sonography and magnetic resonance imaging can detect complications that are clinically occult. The confirmation of the breast implant integrity is a new role for the end of the century radiologist. This research was started based on the certainty that imaging methods can help detect clinically, undetected ruptures. A group of clinically asymptomatic patients for rupture with a long inclusion time were taken as sample in this study. The long inclusion time justify the exams to determine the integrity or non-integrity of these implants. In addition, the exams were justified to determine the need of surgery since the patients wanted to remove their implants for psychological and cosmetological reasons.

Due to the large number of implants included in the 80's in Brazil it can be said that doctors are facing a critical period when the number of implant rupture will certainly increase. Gorczyca et al. (8) stated that 80 to 90% of implant ruptures are of the intracapsular type (rupture of the implant envelope which is surrounded by silicone gel inside an intact fibrous capsule). In this study the implants are grouped as non-ruptured the normal and the bleeding implants and as ruptured the implants with intra or extracapsular rupture (rupture of both the implant envelope and the fibrous capsule with silicone leakage into the tissue).

Mammography is a very precise method in the extracapsular rupture diagnosis, mainly if the silicone gel migrated through the glandular parenchyma (2,7,9,10,11). On the other hand, the intracapsular rupture diagnosis is not possible to be done through mammography (5), because this method cannot determine what is happening inside the radiodense portion of the implant, that is, the silicone gel. In this case mammography evaluates only the external shape.

The main limitation of mammography in the diagnosis is in the evaluation of the implant posterior wall. This is not visualized in several occasions, especially if it is a rectropectoral implant.

The most important mammography pattern in implant alteration is the contours: small lobulations in the contour that are relatively common and generally are not of clinical importance (7). Large bulges may represent implant rupture focal areas or a focal herniation of an intact implant, through a defect in the capsule originated after a closed capsulotomy or direct trauma (6).

In this research bulges were found in practically the same proportion between non-ruptured implants and ruptured ones. The silicone detection ability makes the mammography highly specific in the extracapsular rupture diagnosis. Andersen et al. (11) stated that mammograms are good screening tests for rupture of breast implants because the false positive incidence is low. A low sensitivity was obtained through mammography with a 20% rate; thus confirming that this modality is not considered as a choice for intracapsular rupture diagnosis. In this study only 3 out of 30 ruptures were extracapsular and the implant alterations with bulges and ill-defined contours were misdiagnosed as both suspicious and diagnostic.

The specificity obtained was 88.7% isolated and 94.7% when MG and MRI were combined. The mammography sensitivity for breast implant detection varies a great deal. Anderson et. al. (11) reported the highest sensitivity rupture found (67%), due to the fact that they include patients with breast trauma history which other authors (varying from 16.2 to 23%) did not report (4,12).

The more extracapsular type rupture in the sample the higher the sensitivity and the predictable positive result of the mammography method.

No special equipment is needed to do a breast sonogram in patients with implants. The same configuration of linear probes used for scanning in the glandular tissue can be used. As in the mammography, the posterior wall of women with both large breasts or implants is difficult to detail. To improve the sound penetration, a transducer with lower frequency can be used; however its spatial resolution is a lot lower than that of the high frequency probes.
Familiarity with the normal aspect of the "in vivo" implants is acquired through examination experience. The differentiation between envelope folds in the implant anechoic zone can sometimes be obtained through mobilization of the patient or the transducer during examination (13). The reverberation artifacts produced in the superficial layer can be confused with linear echoes of a ruptured elastomer. A type of pad (Kitecko, 3M Company, St. Paul Minnesota) was used to increase the transducer distance from the skin. The pad was associated with up and down movements together with stronger or softer pressure applied, to help in the differentiation between collapsed elastomer horizontal lines that were aligned in artifactual horizontal echoes as in a stepladder sign.

Sonography has been used in the breast implant integrity evaluation for several years. A great variety of sonographic signs suggesting rupture were described (3-7,13-26). The most useful of these signs is the "echodense noise" or snowstorm appearance, which shows diffuse increasing of free silicone echogenicity in the mammary tissues. This causes a sound transmission block or better, creates large differences in speeds of sound across the ultrasound beam when it propagates across tissue impregnated with free silicone. It generates acoustic shadows which darken the structure details located after them (well defined anterior margin of the implant, undefined or ill-defined posterior margin of the implant). It is different to the shadow seen behind stones or gas, because large amount of free silicone gel transmit sound, producing a loss of coherence of the beam by velocity discontinuities, destroying beam focus, and obviously the image (15).

This sign was not found in any non-ruptured implants analyzed in the sample used in this investigation. However, the sign was present in 10% of ruptured implants. This value is statistically significant (p=0.0441*) mainly in the extracapsular rupture visualization found in 100% (3 in 3) of these ruptures (Fig.1). These data are compatible with the literature ones (16,24).

Another sonographic sign that has been described as predictive of ruptures is a series of parallel horizontal or curved echogenic lines in the implant interior that correspond to ruptured elastomer. This sign was called stepladder by DeBurhul et al. (16) and it corresponds to the linguine sign found in MRI.

The stepladder sign (Fig. 2) was detected in 16.66% of the ruptured implants and in 3.77% of the non-ruptured ones (major atypical folds that simulated stepladder sign).This values are statistically significant (p=0.0553*). The main clinical difficulty in its use is due to the fact that all implant types produce an amount of echo reverberation. Chung and et al. (23) related that the stepladder sign has been found in important cases of capsular contracture. These cases produced envelope folds similar to the ones related in this investigation.

Chung et al. (23) also observed that in the absence of other echographic signs for rupture such as the echodense noise, the stepladder sign may not be a diagnostic sign for implant rupture. The stepladder sign is highly specific for rupture. However, there is a divergence of the literature data with the data obtained in this work (16,21,27). This fact shows that the population sample in Chung et al. research is different from the one used in this investigation because in their research predominantly symptomatic patients were used. The patients used by them presented symptoms such as: mastalgia, mammary deformities, myalgias, musculoskeletal pain, capsular contractures or auto-immune illnesses symptoms.

On the other hand, sonography can evaluate the implant integrity, and non-rupture probability, through its anechoic content (28). Anechoic content was found in 60.4% of non-ruptured implants and in 43.33% of ruptured ones.

Even though statistic analysis did not show any significant data, the case of two ruptured and anechoic implants due to elastomer fragmentation was listed here. These had the aspect of not collapsed elastomer according to the surgical description. In addition, a ruptured implant for the same reason mentioned above, was listed. This implant (Fig. 3) was ruptured due to elastomer fragmentation but presented also the teardrop sign through MRI, which is not visualized through US. Furthermore, 6 large implants located in the retropectoral area were listed. These had partial visualization and were proved to be anechoic through the use of a low frequency transducer. Moreover, 3 implants which had discreet artifact of anterior reverberation but which presented anechoic content were listed. The 2 implants mentioned above and which presented capsule calcification were included in this sample. Finally, an anechoic implant with an intracapsular rupture which could not be elucidated was listed.

The divergence of this research data with the literature ones (16,27,28), in the point where an extensive number of ruptured implants with anechoic content was listed, is due to the fact that the anechoic content and/or interior reverberation were put together in the same category. In contrast, other authors used exclusively the anechoic implant classification.
The anterior reverberation phenomenon is seen as close horizontal parallel lines (28). DeBrhul et al. (16) grouped the implants which presented previous reverberation and the ones with anechoic content. They found 75% of this phenomenon in ruptured implants and 67.56% in intact ones. Petro et al. (19) said that the reverberation artifacts produced in implant superficial position were initially found conflicting and were confused with alterations. In this work it was found 43.33% of reverberation in ruptured implants. This sign was generally not isolated and it was not used as normal criteria when the implant presented another sign classified as suspicious or diagnostic. Of the 13 ruptured implants which presented anterior reverberation only 3 (23%) presented this isolated sign (reverberation plus anechoic content). Two of them presented capsular calcification (Fig. 4). 34% of the non-ruptured implants presented echoes in their anterior position. In addition, 66.66% of them presented this sign isolated (reverberation plus anechoic content).

The implant contour through US was not evaluated for its minimum diagnostic value in rupture detection (21).

The following findings were not significant for a definite conclusion between rupture or implant integrity: envelop fold presence or isolated echogenic line, low level echoes, heterogeneous aggregates echoes and echogenic bands.

In spite of the criteria used for implant integrity evaluation through sonography being statistically significant, (p=0.0354*) the data found in this research show that US was not a very sensitive method (30%) in the detection of breast implant ruptures as shown by other authors (varying from 70 to 74%). The false-negative rate though sonography found in this work was 25% and the false-positive one was 12% with a 30% sensitivity and 81.13% specificity.

These rates are related to the high prevalence of non-specific echographic signs in both ruptured and non-ruptured implants. Another factor to be considered is that the population sample used in the literature (16,22,23) was made of symptomatic patients whereas the sample used in this investigation include asymptomatic patients for rupture. When papers which included asymptomatic sample for rupture were considered, it was observed that the sensitivity found by them was inferior to the one found in this work.

The US is considered a fast, easy, cheap and safe method to evaluate patients with mammary implants. It is considered so mainly for patients worried about the integrity of their inclusions. However, this method should be avoided in asymptomatic patients.

The limitations in this work using US (21 false negative implants and 10 false positive ones) indicate that in patients with major folds it is extremely difficult to excluded rupture and that it should be investigated through MRI. The US can be used as the first exam in the breast implant evaluation in asymptomatic patients followed by a mammography. This is because US has a greater ability to detected intracapsular rupture types (clinically hid) and, on top of that, it has the same sensitivity as MRI in detecting extracapsular ruptures.

The magnetic resonance imaging has been proposed as a method for silicone implant evaluation because of its high sensitivity and specificity in both intra and extra capsular (4,5,29) rupture detection.

Initially the images through magnetic resonance imaging were obtained through several pulse sequences, including water and fat suppression (4,29,30,32,33,34). However, the most revealing sequence in this investigation in silicone breast implant evaluation, was the T2 weighted sequence. This sequence was used in this research and was also compatible with several literature reports that came up after the beginning of this work. The use of water suppression in T2 weighted sequences is advantageous because it increases the silicone T2 time as well as its resonance frequency (35). The result of these two parameters is the optimization of the contrast between silicone and tissue associated to high sensitivity.

The Spin Echo or Fast Spin Echo sequences weighted in T1 and T2 were used in this work. Through them it was observed that the silicone had a very low sign in the first sequence and high in the second one when compared with the fat and water signs.

When the water suppression in T2 was done, the water sign became very low compared to the sequence without water suppression. In spite of this, the silicone sign kept high, favoring the identification of alterations inside the gel, that is, in the interior of the implant.

In T1 weighted sequences the low gel sign makes it difficult to visualize the eventual alterations. This sequence is not recommended to investigate alterations in the interior of the implant; however, it is part of the protocol for extracapsular rupture exclusion.

Two coil types were used in this work because two different equipment were used: one with a 0.5 T magnet and another with a 1.5 T. This happened because the 1.5 T machine was under repair and it
was necessary to continue the research. Reynolds et al. (6) and Weizer et al. (3) also used two equipment from different manufacturers, though with similar magnetic field intensity. Initially they used body coils and later superficial coils until a specific breast coil was manufactured. Gorczyca et al. (30) used body coil in a 1.5 T equipment when describing the linguine sign for the first time. Intact implants through MRI, that is, with a homogeneous gel signal intensity and regular contours, were found varying from 52.4% to 72.9% from silicone implant described in the literature series (27,36). The sample used in this research presented 38.9% of implants without alteration sign in the inside of the gel.

This difference was due mainly to the artifacts that darkened the medial position of the implants in the beginning of this work. These artifacts were minimized with the phase change in the equipment. Regarding the signs detected through MRI, the results showed figures statistically significant ($c^2 = 6.634^*$) and in 1.92% (one in 52) of the non-ruptured ones. The linguine sign was not associated to the subcapsular line, to the linguine sign, and to the base of the teardrop sign which are indicative of rupture (37).

Another common finding in normal implants is the presence of isolated radial folds. In the literature, ruptured implants that presented this sign were not frequent (6,37). In the series observed in this investigation the presence of isolated radial folds were significant: they were found in 38.5% of the non-ruptured implants and in 8% of the ruptured ones.

The fold presence indicates a certain degree of capsular contraction or tense elastomer. Two ruptured implants where folds were detected (false positive) were found. One case was due to blocked extracapsular rupture without intraparenchymal siliconomes and with ruptured elastomer located radially distant from each other. In the other case it was due to cardiac beat artifacts associated to the subcapsular hypointense sign line in the anterior part of the implant. This sign was misdiagnosed as an implant fold, because this exam was done in November 30, 1993 when the wavy hypointense subcapsular line sign described as a subtle sign for intracapsular rupture had not been described yet (37).

The presence of one contour bulge as the only abnormality detected by the MRI should not be considered predictive for rupture (6). The findings for contour alterations in this investigation were not statistically significant. Of the 8 ruptured implants (32%) which presented contour bulges, 3 presented bleeding (Fig. 5) and one was intact. The only ruptured implant that presented this sign had, at the same time, the linguine sign. However, it is important to know this sign as an alert in the search for incipient signs of intracapsular rupture. Many times this sign is associated to subcapsular line, to the linguine sign, and to the base of the teardrop sign which are indicative of rupture (37).

It was found in this series the linguine sign (Fig. 2.) in 64% of ruptured implants ($c^2 = 17.917^*$) and in 1.92% (one in 52) of the non-ruptured ones. The linguine sign was not detected in bleeding implants. The false-positive was due to atypical fold presence (Fig. 6) which mimicked ruptured wavy elastomer. It is believed that the use of orthogonal plans, with smaller slice
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The sensitivity of this research series was 64% and the specificity of 76.92%. The false-positive flap containing calcified, densely fibrotic necrosis. The finding revealed that this abnormal sign represented remnants of a failed previous pedicled TRAM appearance in the implant inferior border interpreted as intro capsular rupture. This intraoperative tissue simulating real rupture sign. Finally, in the last patient, it was due to the heterogeneous false-positive rate was because of an air bubble inside the implant simulating rupture. In the second false-positive rate was of 3.75% corresponding to 3 out of 80 patients. In the first patient, this had intense capsule calcification with a disintegrated elastomer strongly adhered to the capsule. The false negative rates were of 3.75% and corresponded to 3 patients whose images symptomatic patients presented a 76% detection sensitivity for implants rupture and 97% for rupture through MRI. Capsular calcifications do not have a definite clinical meaning and they are generally incidental radiographic findings in implants included for more than 10 years (41-43).

It was found in the sample used for this work only one 63-year-old patient, with prepectoral bilateral implant included 15 years before for breast reconstruction after cancer. The implant presented thick calcification of the capsule through mammography. These findings were considered normal through all image methods and both implants were ruptured. The data obtained through the applied statistic methods were not pertinent. This was because the sample was small (n=2) but it can be said that the false negative may be related to the fact that the calcification masked the MRI findings keeping the elastomer fixed and not allowing the formation of the linguine sign. This might have happened due to possible pre-capsular adherence which made difficult the penetration of the sonic beam through US. On top of all these reasons there were also reverberation artifacts in the anterior wall. Even though Harris (26) says that the capsular calcification is not generally seen through US, the retrospective analyses of these patients, showed the presence of linear echogenic areas thickened in the implant posterior wall. Reverberation artifacts made difficult the visualization of these structures in the implant anterior wall. Calcification presence in the fibrous capsule are described by MRI in only 4.7 to 20% of the ruptures by different authors (6,27,30,36). The data obtained in this work show the presence of extracapsular silicone in only 10% of surgically proved ruptures. Only 2 of the 3 implants with extracapsular rupture were visualized here. The false negative result was due to the presence of blocked rupture misdiagnosed as irregular contour bulge.

Gorczyca (39) also called the attention to the diagnostic confusion that happens between a small normal pleural effusion and an extracapsular rupture through MRI. In about 20 to 25% of the patients a small pleural liquid quantity may be present posteriorly to the breast in the images through MRI. This happens due to the ventral decubitus position used in most of these procedures. The false positive in this series was related to the presence of hypointense sign in deeper justacostal and justapleural areas. These areas were adjacent to prepectoral bleeding implants which were read as free silicone but which corresponded to inflammatory exudate with neoplastic cells within the pleural space secondary to recurrence of breast cancer.

The series in this work was not representative of the noose or teardrop sign. This sign reflects a case where the implant is ruptured but the elastomer has not yet collapsed and part of the gel is out of it. In this case the gel is entrapped inside a fold producing the aspect of inverted tear. This case was found in 12% of ruptured implants and in none of the bleeding or intact implants. In contrast Berg et al. (29) obtained this noose or teardrop sign in 25% of ruptured implants, in 36% of the bleeding ones and in 6% of the intact ones. It may be possible that the low signal-noise relation is responsible for the little visualization of this sign in this research. When the signal-noise relation was studied for the visualization of the linguine sign and folds characterization, these signs were visible with or without the acquisition with the dedicated breast coil (46). The teardrop sign may not have an adequate spatial resolution because it is more subtle than the linguine sign.

Capsular calcifications do not have a definitive clinical meaning and they are generally incidental. It was assumed that these areas correspond to deposits of calcific material. Reverberation artifacts made difficult the visualization of these structures in the implant anterior wall. Calcification presence in the fibrous capsule is seen through MRI as hypointense sign and justapleural areas. These areas were adjacent to prepectoral bleeding implants which were read as free silicone but which corresponded to inflammatory exudate with neoplastic cells within the pleural space secondary to recurrence of breast cancer.

Ahn et al. (35) in a MRI silicone breast implant retrospective study in big series with 100 symptomatic patients presented a 76% detection sensitivity for implants rupture and 97% for specificity. The false negative rates were of 3.75% and corresponded to 3 patients whose images were considered inconclusive for diagnostic of rupture. This was due to the fact that their implants had intense capsule calcification with a disintegrated elastomer strongly adhered to the capsule. The false-positive rate was of 3.75% corresponding to 3 out of 80 patients. In the first patient, this false-positive rate was because of an air bubble inside the implant simulating rupture. In the second one, it was because of a progress history of rupture with silicone residual granuloma in the breast tissue simulating real rupture sign. Finally, in the last patient, it was due to the heterogeneous appearance in the implant inferior border interpreted as intro capsular rupture. This intraoperative finding revealed that this abnormal sign represented remnants of a failed previous pedicled TRAM flap containing calcified, densely fibrotic necrosis.

The sensitivity of this research series was of 64% and the specificity of 76.92%. The false-positive
rate found in this work was of 42.85% and the false-negative one of 18.36%. These results were related mainly to atypical folds interpreted as the linguine sign: non collapsed ruptured elastomer, artifactual images, pleural effusion misdiagnosed by free silicone and finally blocked extracapsular rupture simulating a major bulge aspect.

The divergence of the results found in this work with the literature ones is basically due to the fact that the sample used here corresponds to asymptomatic patients. Other authors who included a number of asymptomatic patients in their study, could not unfortunately, prove their images findings surgically or could only obtain small samples (3,6).

Weizer et al. (3) used MRI equipment with body coil and surface coil dedicated to the breast. They found a sensitivity of 38.9% and of 52.2% respectively and a specificity of 80 and 91.7%. This series correspond to 107 implants examined with breast coil and to 53 implants analyzed with body coil.

When the equipment used was considered, the sensitivity and the specificity through 0.5 T MRI were of 80% and through 1.5 T MRI sensitivity was of 50% and the specificity of 78.04%.

Although the number of patients with exams performed in 0.5 T equipment was almost one-third of the ones with exams performed in the 1.5 T, the number of false-positive and false-negative presented by the 1.5 T is almost four times higher.

In the 0.5 T equipment a breast surface coil was used and in the 1.5 T one a body coil. The statistical evaluation among the exams performed in the 0.5T and 1.5 T equipment did not show significant differences (p>0.05) when compared to the surgical findings. The same happened with the evaluation of the 77 implants not considering the equipment but the imaging method.

The results of this research are similar to those of Weizer et al. (3) when this methodology was used. It is possible that the sensitivity found in this work be higher than these author's with breast coil use. This is because these were the last exams of this series performed and the investigators were already in the second half of the learning curve acquired with this research.

Reynolds et al. (6) results were of 69 and 55% for sensitivity and specificity, respectively, if they considered class II and class III as positive (equivalent to what is considered as suspicious and diagnostic in this work). When these authors used only criteria III (silicone out of the implants including silicone adenopathy) equivalent to part of the diagnostic findings in this work, the sensitivity and specificity changed to 15 and 100%. Obviously this discrepancy is because of the different method used.

One of the limitations of this work is not accomplishing a retrospective data review. Several of the findings could have been modified retrospectively, but it was decided against it. The findings in the surgeon report will be the first impression obtained. Another weak point is the classification system used here, which presented deficiency, if analyzed retrospectively. One example of this weakness is not including subcapsular hypointense lines as a sign considered diagnostic. Another example is not including amorphous areas with hypointense signal in the implant interior as a sign considered suspicious. Finally, the use of different MRI equipment: performing exams in 1.5 T fields with body coil is not the same as performing exams in 0.5 T with surface coil.

When the methods were compared to each other in this work, it was noticed that the agreement of MRI diagnosis with the ones of US is of 76.62% and the agreement of MRI with MG is of 59.74%. These data show that both MRI and US are methods which allow the detection of implant alterations, in relation to MG. In addition, the data show that MRI allows the detection of a higher quantity of alterations considered suspicious or diagnostic by both methods.

The fact that the sample was divided in cosmetological and oncological groups do not show difference in the detection ability of each method, that is, MRI and MG or MG and US. However if MRI and US are considered, it is believed that the oncological group is in disadvantage in the sonographic evaluation. This probably happens because of fibroglandular tissue absence adjacent to the implants or because of the transducer closer contact, as said before, causing a higher number of non-real lesions or damaging the real alteration evaluation due to the artifacts.

The association of the three agreeing methods with each other did not increase the sensitivity (22.2%) in a way that it went over the MRI and MG or MRI and US sensitivities.

Even though the specificity (93.9%) is higher than the MRI and US or US and MG specificities it did not prove more specific than the MRI and MG association. This is due to the fact that the number of agreeing interpretation is low (n=42) and true-positive and false-positive and false-negative values are distributed evenly.

In the examination of a patient with breast implant it is considered primordial the knowledge of the implant type and the inclusion time before the performance of any imaging diagnostic exam. It is believed that mammography should be the choice exam in patients over 40 years of age and asymptomatic for rupture.
This should be the exam done in habitual incidences (oblique mediolateral and craniocaudal) and in cases of posterior displacement of the implants. This is because it is part of the screening of breast cancer. If the implant is considered normal through mammography, it should be kept in mind that extracapsular rupture type is eliminated. If the implant was included in less than 5 years and if it does not show mammography alterations such as irregular contours and silicone presence it will probably not be ruptured. Thus, the investigation for ruptured detection in asymptomatic patients will end.

If there is a major bulge or patient important anxiety, and normal breast parenchyma, the MRI with breast coil should be performed because of its higher sensitivity. If MRI is not available, US is recommended.

However, if there is a major bulge, patient anxiety some breast parenchyma alterations, focal asymmetric density with positive palpation or breast lumps an US should be performed as much for the breast lesion explanation as for the implant integrity evaluation.

In patients under 45 years of age, the US is the choice method for implant integrity evaluation. If there is any positive sonography sign such as the stepladder sign or echogenic noise, there is no need to perform a MRI. In this case the implant will very likely be ruptured if its inclusion time is above 6 to 8 years.

If the implant is anechoic or if it contains fine internal echoes, it is labeled as non-ruptured. If the implant was included in less than 5 years and if it presents echographic alterations such as thick echogenic lines, echogenic bands, associated or non grouped amorphous echoes or the anterior reverberation; it will probably not be ruptured if it is double lumen or textured type. However, the findings are considered suspicious if the implant is of the silicone gel type and thus, should be investigated through MRI.
Fig. 1. Patient 16. (A) Longitudinal sonogram in the upper lateral quadrant region of the right breast shows an echolucent globule adjacent to the snowstorm appearance. (B) Sagittal Fast spin echo magnetic resonance image shows localized rupture of the implant in the right breast. (C) Craniocaudal view mammogram show abnormal implant demonstrating rupture and extravasation of free silicone into the breast.
Fig. 2. Patient 38. Intracapsular rupture with collapsed elastomer shell. (B) Ultrasonography (US) of contained intracapsular ruptured implant showing multiple layers of the collapsed implant shell visible as sets of parallel echogenic lines (stepladder sign). (A) Sagittal magnetic resonance image (MRI) showing the same aspect of the collapsed implant shell (linguine sign).

Fig. 3. Patient 12. Intracapsular rupture without collapse of the elastomer shell. (A) Sonogram of the left breast shows an anechoic implant. (B) Sagittal fast SE T2-weighted MR image shows a small area where a amount of gel is outside the shell (noose sign, arrowheads).
Fig. 4. Patient 43. Breast sonogram showing calcifications foci of the fibrous capsule (arrows).
Fig. 5. Patient 5. Intact silicone prosthesis with heavy gel bleed identified at surgery. Axial fast SE MR image of the right breast shows a small teardrop extending to medial aspect of implant (arrowheads) and a hyperintense water droplet (arrow) in conjunction with subcapsular lines.
Fig. 6. Patient 23. Intact breast silicone implant. Sagittal fast SE T2-weighted MR image shows atypical folds that simulate linguine appearance of a ruptured implant.

<table>
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TABLE 2. Results

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<th>Ultrasound Results</th>
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<td>L</td>
<td>R</td>
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<td>+</td>
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<tr>
<td>2</td>
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<td>P</td>
<td>.</td>
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R = right
L = left
y = years
m = months
C = cosmeticological
R = retropectoral
+ = diagnostic finding
- = normal finding
b = bleeding
* = suspicious finding
i = intact
m = mire
O = oncological
P = propretoral
NR = not realized

R = right
L = left
y = years
m = months
C = cosmeticological
R = retropectoral
+ = diagnostic finding
- = normal finding
b = bleeding
* = suspicious finding
i = intact
m = mire
O = oncological
P = propretoral
NR = not realized
TABLE 3. Results *

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<th>SONOGRAPHY</th>
<th>n</th>
<th>MAGNETIC RESONANCE IMAGING</th>
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<td>Anechoic interior</td>
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*Some implants showed more than one finding. Values in parenthesis represent the number of implants ruptured. n = number of implants demonstrating finding.

TABLE 4. Sensitivities, Specificities, PPV e NPV for MG, US and MRI.

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<th>Method</th>
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<th>Sensitivity (%)</th>
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<th>NPV (%)</th>
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References:


3. WEIZER, G.; MALONE, R.S.; NETSCHER, D.T.; WALKER, L.E.; THORNBY, J - Utility of magnetic...


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http://www.obgyn.net/obgyn-ultrasound/evaluation-rupture-silicone-breast-implants-mammography

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