



Normal Ultrasound Findings and Complications of Breast Implants in Colombia

Hallazgos ecográficos normales y complicaciones de implantes mamarios en Colombia

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Palabras clave (DeCS)

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Summary

Implant augmentation mammoplasty and post-mastectomy breast reconstruction are some of the most frequent surgical procedures in plastic surgery. Breast implants are among the medical devices with the highest amount of reports of adverse events in our country. In suspicion of rupture, removal is the gold standard. However, there is little clarity regarding which strategies and images are adequate for non-invasive evaluation. High resolution ultrasound has shown to be an alternative for the initial evaluation. Due to the variability of the implants it is necessary to recognize their imaging characteristics. This article presents the findings of the ultrasound of the implants, including those that can be generated by tags or marks distinctive of the brand and those of the most common complications associated with them.

Resumen

La mamoplastia de aumento con implantes y la reconstrucción mamaria posmastectomía son algunos de los procedimientos quirúrgicos más frecuentes en cirugía plástica. Los implantes mamarios se encuentran entre los dispositivos médicos con mayor cantidad de informes por eventos adversos en el país. La extracción del implante es el estándar de oro ante la sospecha de la ruptura del mismo; sin embargo, hay poca claridad respecto a qué estrategias e imágenes son las adecuadas para la evaluación no invasiva de estos. La ecografía de alta resolución ha mostrado ser una alternativa para la evaluación inicial. Debido a la variabilidad de los implantes es necesario reconocer sus características imagenológicas. En este artículo se presentan los hallazgos ecográficos de los implantes, incluyendo aquellos que se pueden generar por marquillas o distintivos propios de la marca, y los propios de las complicaciones más comunes asociadas a ellos.

Augmentation mammoplasty is one of the most frequent surgical procedures in plastic surgery, both for reconstructive surgeries and for augmentation mammoplasty (1). Although there is no clear figure on how many patients have had the procedure, Collett, in JPRS2, estimates that 35 million women had breast implants by 2016 (2).

Several criteria have been used to classify breast implants used in mammoplasty: according to their composition –silicone or saline–; according to their envelope –smooth or textured–; according to their shape –anatomic or round–; by their volume –variable or fixed–; by the number of compartments –single lumen or bilumen–, and, additionally, each brand has some physical characteristics that differentiate the implants among them (3), including valves for filling or the closure seal on the back of the implant (4). The most

common breast implants are single lumen implants, which contain silicone as filler (5).

In Colombia, according to the database of the Programa Nacional de Tecnovigilancia 2005-2018 of the Instituto Nacional de Vigilancia de Medicamentos y Alimentos (Invima), breast implants rank sixth among the medical devices with the highest number of reports for adverse events and incidents (6). Implant removal is the gold standard for suspected implant rupture; however, there is little clarity regarding which strategies and images are adequate for noninvasive evaluation of implants (7).

Magnetic resonance imaging (MRI) has been considered the non-invasive gold standard for the evaluation of silicone gel breast implants, with a sensitivity greater than 90% (8). Its limitations are cost, claustrophobia and incompatible metallic elements (7,

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9). Mammography is not considered the ideal tool for the evaluation of implants, due to its low sensitivity in the detection of intracapsular rupture of the implant (23%) (7, 8, 10). High resolution ultrasound, in the hands of a trained radiologist, is a more available, fast, painless and less expensive alternative for the evaluation and follow-up of breast implants. This procedure does not expose the patient to ionizing radiation and is better accepted than MRI. Its sensitivity is between 59-70 % (9-11). This is limited by the high frequency transducers (12-18 MHz) which generate a better image quality, but with a resolution limited to more superficial planes, so it does not evaluate the whole thickness of the implant (7).

Therefore, authors such as Cilotti and collaborators are clear in saying that ultrasound is the first image that should be performed for the evaluation of the implant, by an experienced operator, and MRI should be used only when the diagnosis is uncertain and the clinical suspicion of intracapsular rupture is very high (10) or when the treating physician is in clinical disagreement with the ultrasound finding.

The ultrasound evaluation of breast implants includes the revision of their morphology, contours, peri-implant breast tissue and axilla (5, 10); the regularity of the implant margins, the capsule, its content and homogeneity of the lumen, the presence or not of periprosthetic liquid, free silicone or granulomas in the breast or axillary ganglions (5, 10).

This article aims to review and describe the ultrasound findings of breast implants, and includes those registered in the INVIMA, those that have left the market, but that were widely used in the decade 2010-2020, the brands that have changed their name and the products that do not have INVIMA registration. As of the writing of this article, in 2020, in Colombia there are five companies distributing breast implants with INVIMA registration, and a total of eight types of implants are marketed - in Colombia, the most widely used brands are Mentor (Johnson and Johnson), Natrelle, CUI, BRST (Allergan), Motiva (Establishment Labs S. A.) and the Refimax and Hansbiomed Corp. Marketers (6).

1. Results

They are presented grouped according to characteristic physical findings (not by brand or commercializing company), and include those that can be generated by marks or distinctive of the commercial brand, and those of the most common complications associated with breast implants, each one with its corresponding ultrasound image. The purpose of this presentation is to serve as a guide when the radiologist is faced with a difficult diagnostic image (figures 1-6).

1.1. Generated by brand names or distinctive trademarks



Figure 1. Mentor anatomical prosthesis. In the image on the right, the marking is seen on the inferior pole of the anterior face, vertical and linear. In the image on the left, the posterior seal in the center and two round badges on the upper pole and another vertical one on the lower pole. Ultrasonographically they are observed as a small curve with a double reflective line. It serves as an intraoperative guide to avoid rotation.



Figure 2. Anatomic prosthesis, McGhan brand. In the image on the right, there are two round distinctive features in the inferior pole and anterior face that are represented ultrasonographically in the upper image as two small curves of about 5 mm with a double reflective line. In the left image, the posterior seal as a thickening of the capsule or a single horizontal echogenic subcapsular line that is sonographically represented in the lower image.



Figure 3. Round prosthesis, PIP brand, does not present distinctive features in its anterior face, but the posterior seal or tag is present. Ultrasonographically it appears as an echogenic line parallel to the implant capsule, incomplete or a “posterior thickening” of the implant shell.

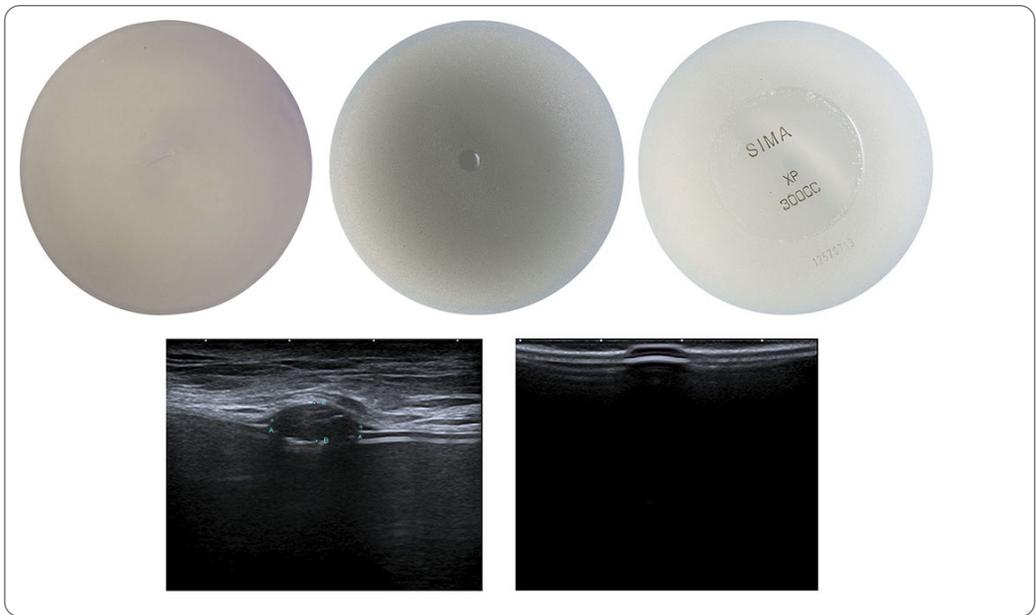


Figure 4. Round prosthesis, SIMA brand, presents two different forms of anterior markers, round and small. Ultrasonographically it is observed in the left image as a widening of the double reflective line with a pseudocystic anechoic center and in the right image as a small curve of about 5 mm with a double reflective line.

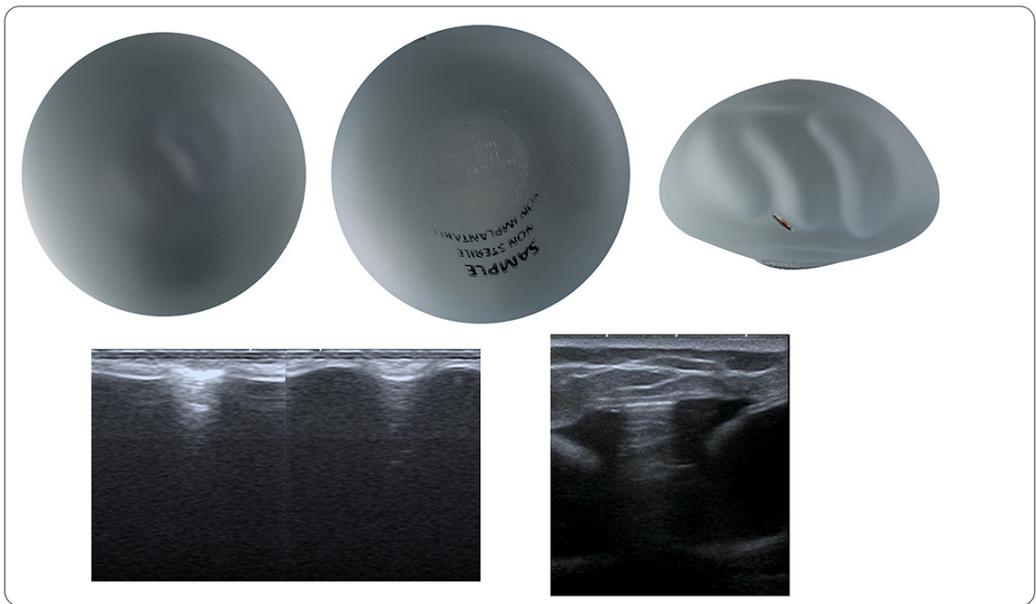


Figure 5. Round prosthesis, Motiva brand, has a chip in lateral face. Ultrasonographically it is identified as a hyperechogenic image that generates reverberation compatible with the chip (the lower right image corresponds to a patient with this implant).



Figure 6. Saline solution prosthesis. Ultrasonographically it shows an anechoic line anterior to the implant capsule of 5 mm length and a small inverted curve of about 6 mm with a double reflective line that represents the implant valve (black arrow).

1.2. Ultrasound findings typical of breast implants

1.2.1. Folds, lobulations or invaginations. The image is variable and is produced when the surface of the implant wrinkles during positioning in a pocket created by the surgeon, either subglandular (prepectoral) or subpectoral (under the pectoralis major muscle). They are echogenic wavy lines that are known as radiated folds, without associated capsular thickening, stiffness, periprosthetic fluid, or pain referred by the patient (5) (figure 7).

1.2.2. Reverberation. They are echogenic images that occupy in a linear and horizontal way all the superficial field of the echographic image, by reverberation of the sound through the capsule. They depend on the thickness and calcification of the implant capsule (of the silicone elastomer), the density of the silicone and the resolution of the ultrasound. They do not indicate rupture of the implant and are a normal finding (5, 9) (figure 8).

1.2.3. Periprosthetic liquid. It can be in variable quantity, it is physiological. It should be an anechoic liquid like water, without internal echoes or septa. It is believed to be the result of an inflammatory response and is not indicative of rupture (12) (figure 1).

1.2.4. Silicone seal in the posterior part of the implant or surface marker. The implants have a capsule made of a silicone elastomer that can vary from 1-2 mm. Most of them, when manufactured, have a hole of several centimeters in their posterior part that closes late once the implant lumen is filled. This patch, specific to each brand, is made of a thicker silicone elastomer that is adhered with a special silicone glue. Other implants are filled with a needle through the patch and the small hole is also closed with silicone glue. Normally this finding is not seen by ultrasound because it is small and very posterior, which is distorted with the ultrasound beam passing through the implant (4, 9) (figure 9).

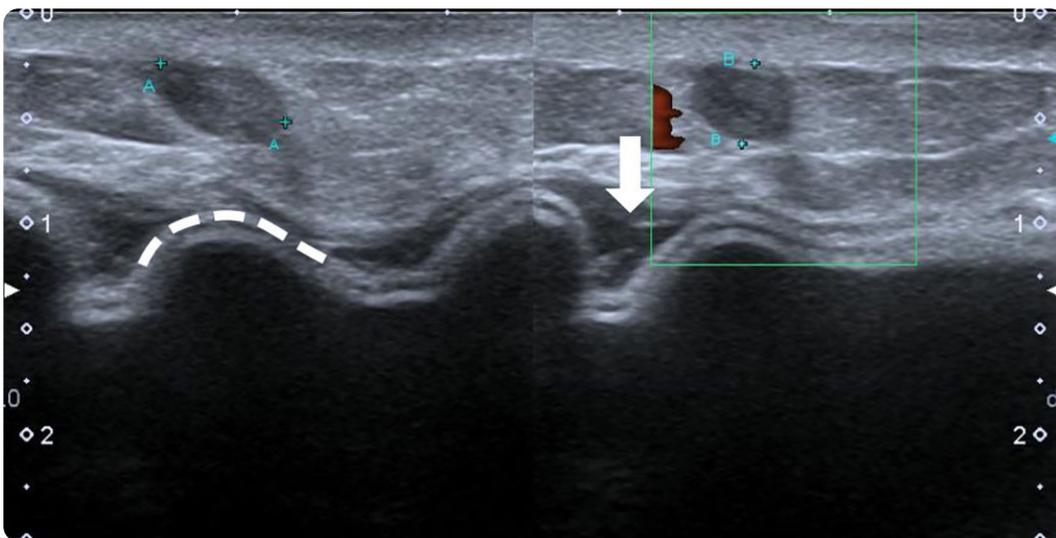


Figure 7. An implant with prominent radial folds (in white dashed line) is observed ultrasonographically. In this image it is possible to see the fibrous capsule that is separated from the implant capsule by anechoic periprosthetic liquid (white arrow).

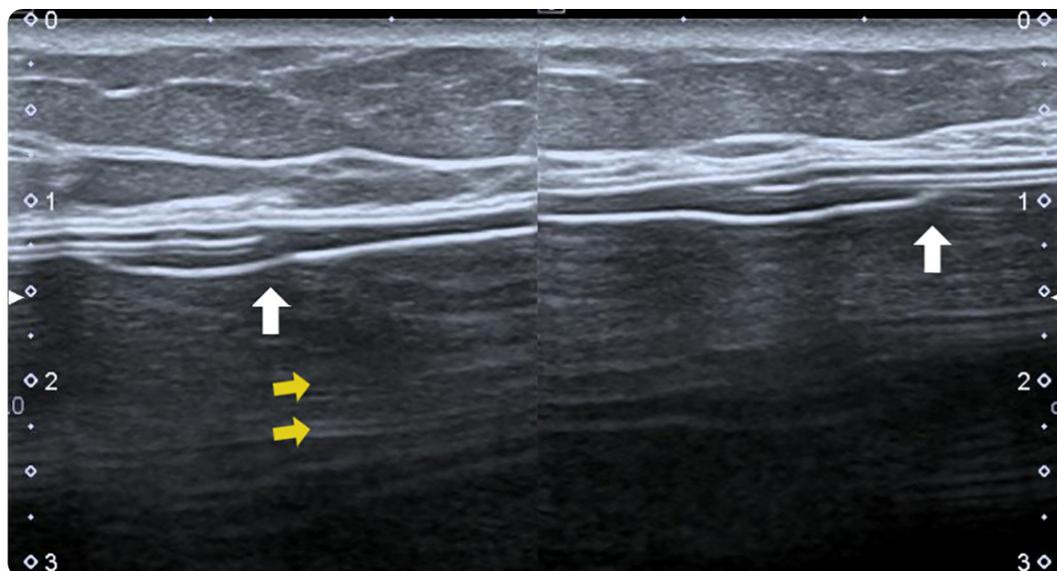


Figure 8. Echogenic images that occupy in a linear and horizontal way all the proximal and superficial field of the image, by normal reverberation (yellow horizontal arrows). In addition, in the anterior region of the implant the posterior marking is observed (white arrows) consistent with implant rotation.



Figure 9. Allergan implant. Ultrasonographically there is rotation of the implant in a 180° axis. The posterior notch is identified as a horizontal echogenic line parallel to the implant capsule, which is apparently discontinuous. It looks like a focal and posterior thickening of the implant capsule.

1.3. Hallazgos ecográficos asociados a complicaciones de los implantes mamarios

1.3.1. Rotation. It is one of the least reported complications and the rotation rate in the literature is 0-14% (9). Saline implants tend to rotate more frequently (up to 14%) than cohesive silicone gel implants (2.6%). When dehydrated, saline implants lobulate more, shrink and bend, which facilitates their rotation. Cohesive gel implants, because they are more rigid, maintain their shape and rotate less (13). Surgical techniques have been described, such as placing the upper pole or upper half of the implant under the superficial fascia of the pectoralis major muscle instead of subpectoral or retroglandular, to minimize this complication (14).

Markers on the anterior surface of the implant at the inferior pole are made for intraoperative monitoring by palpation to ensure proper positioning (14). When an implant is round and rotated, because of its more symmetrical shape, its clinical appearance does not change much,

but an anatomical implant does vary clinically when rotated and appears deformed (11, 13). Rotation may be symptomatic or asymptomatic, with deformity and asymmetry, and may require surgical correction (14). One theory about the cause of implant rotation is the lack of development of a connective tissue adhesion layer between the implant and the capsule, thus allowing the implant to move freely in the pocket. The texture of the implants is variable and so is the formation of the adhesion layer. Textured implants with larger pores decrease the possibility of rotation (13, 14). Large surgical pockets, seromas or periprosthetic hematomas, massages and exercise can favor rotation (12).

The sonographic finding is an incomplete subcapsular echogenic line of variable length from 1 to 4 cm, and should not be confused with a capsular detachment due to a rupture (Figure 8). It can also be observed as a disruption of the capsule associated with an oval or small semicircles that protrude anteriorly (14) (figure 4).

1.3.2. Capsular contracture. The fibrous capsule is a biological soft tissue that is produced after the insertion of the implant, as a phy-

biological response to a foreign body. The capsule can thicken or calcify with time and is more easily recognized when there is periprosthetic liquid (10,13) (figure 7).

The diagnosis of capsular contracture is clinical and Baker’s classification is used (10); however, ultrasound can confirm the clinical suspicion and provide additional information of the implant. Ultrasonographically the contracture is observed as an asymmetry in the shape of the implant with deformity of its contours, lobulations or increase in the depth of the folds and, in addition, of a capsular thickening that can vary, as a thick echogenic layer that surrounds the normal cover of the implant (5, 7).

1.3.3. Deterioration of the internal substance of the implant. Cilotti and collaborators have observed heterogeneity of the silicone content as discontinuous intrasubstantial echogenic punctiform foci. They do not indicate intracapsular rupture (Figure 10). Patients with this finding are clinically asymptomatic.

1.3.4. Gel bleed. It corresponds to a transudation of small and microscopic silicone molecules that go through the intact silicone capsule and the fibrous capsule, and migrate to the axillary ganglions by lymphatic way, in absence of rupture of the implant (5). They give the appearance of snowstorm (8, 15) (figure 11).

This finding must be differentiated from a rupture of an old implant with migration of silicone to axillary nodes. Patients with this finding are generally asymptomatic.

1.3.5. Rupture. Implant rupture can be intracapsular (77-89%) when the silicone shell ruptures, but remains confined within the fibrous capsule of the implant, or extracapsular (21%) when the contents pass through the fibrous capsule (5,8,10). Implant rupture rates increase with the time elapsed since their insertion, but may vary according to models and materials (7, 8, 16). The cohesive gel implants have less possibility of rupture, because they have a thicker external cover and a barrier layer in addition to a more viscous (cohesive) silicone gel that make them stable in their shape and, in case of rupture, the gel is confined inside the implant capsule (12). The rupture rate in anatomical implants is between 1-2.2% (12). The rupture is generally asymptomatic.

In an intracapsular rupture, an irregular morphology with loss of continuity of the implant is observed in the ultrasound, with undulating echogenic lines that represent parts of the capsule floating inside the silicone and mobile echogenic silicone between the two layers of the implant (10). Heterogeneity of the internal substance with the “ladder” sign, which are linear, multiple and discontinuous echoes in the lumen, without filtration to axillary nodes (10) (figure 12).

Ultrasonographically in an extracapsular rupture, signs of intracapsular rupture and the association of echogenic intramammary or axillary masses with loss of posterior detail of the silicone or echogenic posterior noise are observed, known as “snowstorm” image, in addition to hypoechogenic masses associated with echogenic noise around them (10,17). The “snowstorm” sign has a sensitivity of 85.7% and a specificity of 100% (14) and it is possible that the appearance of this sign is related to the amount of silicone in the mass or in the lymph node (15) (figure 11).



Figure 10. Macroscopically, bubbles are observed on the surface of the implants. Ultrasonographically they are observed as heterogeneity of the internal content of silicone and discontinuous intrasubstantial echogenic punctate foci.

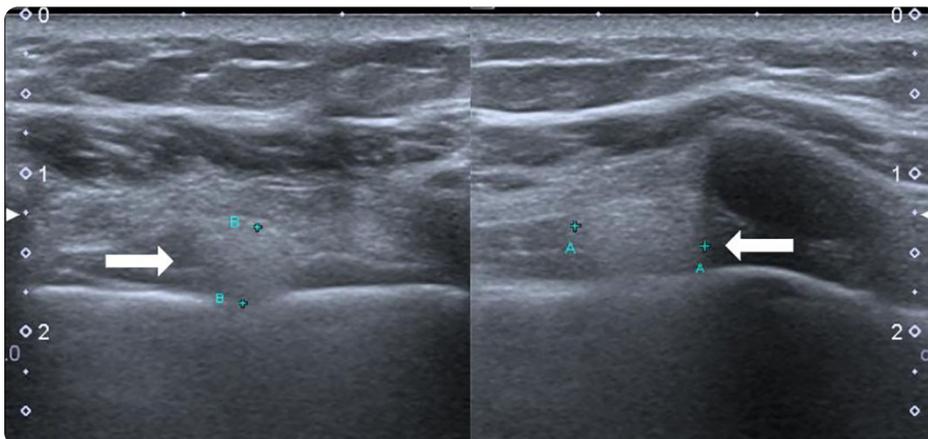


Figure 11. Extracapsular rupture. Ultrasound image of siliconoma in the internal mammary chain after implant rupture. Echogenic image with snowstorm appearance and poor definition of the posterior border. It is the same image for an intratissular siliconoma or in axillary nodes.

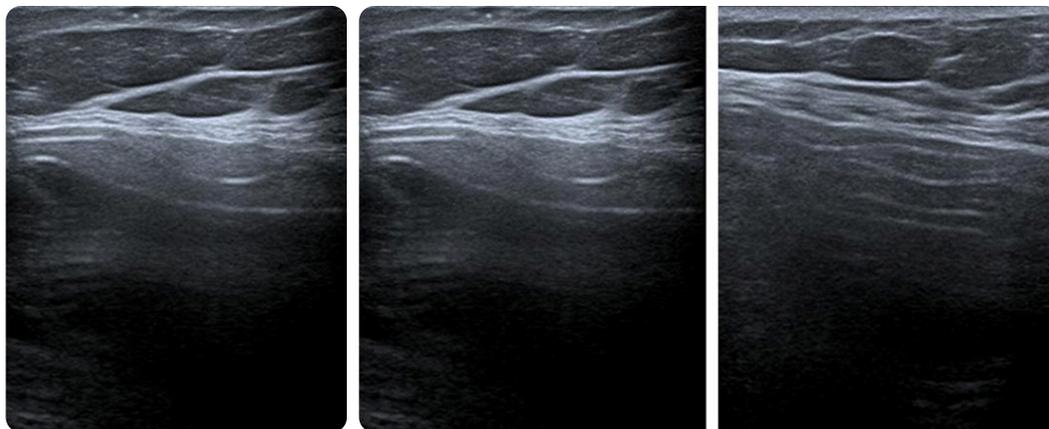


Figure 12. Intracapsular rupture. In the image on the left, loss of implant integrity with parallel wavy echogenic lines within the implant lumen due to capsular rupture and echogenic silicone contained within the external layer of the implant (white arrow). The image on the right shows the “ladder” sign.

Conclusion

High resolution ultrasound is a reliable technique and should be the first diagnostic method to assess normal findings in prostheses and their early and late complications. It should be performed by an experienced operator.

Knowing the brand of the implant in each patient and its variations and physical and morphologic characteristics help to obtain a better ultrasound diagnosis.

MRI should be considered in symptomatic patients, with abnormal sonographic findings and if there are diagnostic doubts.

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