Ultrasound Criteria and Baker Scale for Breast Implant Capsular Contracture Diagnosis

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Background: Due to the subjectivity of the Baker scale in grading capsular contracture (CC), an objective and reproducible measurement tool is necessary to estimate the presence and grade of CC in patients with breast implants. This study aimed to assess the capacity of breast ultrasonography to identify CCs using the Baker grading system.
Methods: This study included patients who underwent breast augmentation with implants or implant-based breast reconstruction. Patient demographics, surgical type, and ultrasonographic variables were analyzed. The Kruskal–Wallis test was used to determine differences between means, and the Fisher exact test was used for binary variables.
Results: A total of 21 patients (28 breasts) with smooth surface implants were included. In total, 39.2% of breasts had a score of Baker I, 25% had Baker II, 17.9% had Baker III, and 17.9% had Baker IV. When comparing breasts graded Baker I to IV, a mean capsule thickness of 0.6 ± 0.2, 1.0 ± 0.53, 1.68 ± 0.99, and 1.52 ± 0.46 mm, respectively, was shown ($P = 0.0044$). The breast implant deformity variable was significantly different between Baker grades I to IV (0.0218). Finally, Baker III and IV categories were five times more likely to have abnormal wrinkles than Baker I and II (odds ratio, 5.25; 95% confidence interval, 0.82–33.45; $P = 0.0496$).
Conclusion: Ultrasound is a useful tool for evaluating the presence of augmented thickness, implant shape deformity, and abnormal wrinkles of the implant shell in correlation with the severity of CC. *(Plast Reconstr Surg Glob Open 2022;10:e4582; doi: 10.1097/GOX.0000000000004582; Published online 19 October 2022.)*

INTRODUCTION

Since the first reported use of silicone implants in 1962 by Cronin and Gerow,[1] breast cosmetic surgery has increased consistently over time. In 2018, 329,914 patients underwent implant-based surgery in the United States.[2] These implants are widely used by plastic surgeons for two major purposes: breast reconstruction after mastectomy for confirmed breast cancer and cosmetics. The main goals of these procedures are to restore the breast mound and achieve an acceptable and aesthetic appearance of the female breast, which consequently improves quality of life and social and psychological satisfaction.[3–5] As in other procedures, implant-based surgery has some related potential complications, such as infections, seroma, implant rippling, implant flipping, and implant rupture.[6] One important long-term complication is capsular contracture (CC), which continues to be frequent even years after the surgical procedure with a reported incidence of 1.5%–30%.[6] In addition, an important risk factor for developing CC is radiotherapy, increasing its risk up to 10%–13%.[6–8]

Owing to the increased rate of breast implant augmentation and implant-based reconstruction (IBR) surgery, a significant percentage of patients have developed CC.[9] Annually, approximately 45,000 patients are diagnosed with CC by surgeons.[10] This condition results in pain and distortion of the shape and volume of the breast, leading to patient and surgeon dissatisfaction.[8,11,12] Therefore, an objective and reliable tool should be used as a complement for the diagnosis of this pathology, as an accurate diagnosis is indispensable for surgical reintervention.

Traditionally, the diagnosis and severity of CC have been assessed in a clinical examination based on a

subjective classification system proposed by Baker in 1978. This integrates the appearance, texture, and tenderness of the breast.[13] Subsequently, Spear and Baker proposed some modifications, such as the addition of categories Baker IA and IB, which helped discriminate between palpable and nonpalpable implants in soft breasts and adapt them to IBR surgery. The pain was added as a new parameter, but it was not clear when it was added to the classification.[14,15] Currently, the Baker grading system (BGS) is the standard method used for CC diagnosis. It assesses physical appearance, palpable sensation, and the presence of pain.[13,16] However, due to its subjectivity, there is a lack of consensus between surgeons regarding CC diagnosis and severity.

Some studies have been conducted to find a more objective, reliable, and reproducible tool to assess CC.[17,18] Sonography and magnetic resonance imaging (MRI) have been described as potential tools.[19] In ultrasound, normal findings of a breast implant fibrous capsule form a three-layered appearance image (two echogenic lines and an anechoic line between them).[20,21] Hence, if a difference or disturbance in such a pattern is present, a probable association could be made with CC.[20] Other ultrasound findings, such as an increased number of radial folds, calcification areas, and deformation of the implant, have been described in association with CC.[17] Therefore, this study aimed to assess the correlation of ultrasound findings, such as capsular thickness, the presence of calcifications, implant shape deformity, and abnormal wrinkles using BGS.

METHODS

Study Design and Setting

This cross-sectional study included patients who underwent IBR and implant augmentation procedures in our institution, Hospital Universitario San Ignacio in Bogotá, Colombia, from February 2018 to February 2020, following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[22] The study was approved by the institutional review board of the local ethics committee. Informed consent was obtained for clinical evaluation and ultrasound analysis.

Participants

This study retrospectively analyzed 28 breasts of 21 consecutive patients who underwent smooth surface implants from 2018 to 2020. Patients 18 years of age and older who underwent breast silicone implant surgery (aesthetic and reconstructive) and were referred to our outpatient clinic with a CC diagnosis were included in the study. Patients with breast implant ruptures or associated infections were excluded from the study.

Patients were examined clinically by two plastic surgeons in our division, and the grade of CC was determined based on the Baker scale.[13] Interobserver agreement was measured using the Cohen kappa method, indicating substantial agreement. After the clinical examination, patients were referred to a qualified radiologist specializing in

Takeaways

Question: Is there any relationship between the ultrasound findings of CC and the severity of this disease?

Findings: A cross-sectional study design was performed to identify possible associations of ultrasound findings with severity of capsular contraction. The study showed statistically significant findings when evaluating ultrasound variables such as capsule thickness, abnormal shell wrinkling and implant shape deformity.

Meaning: The ultrasound represents a useful tool to evaluate the presence of augmented thickness, implant shape deformity, and abnormal wrinkles of the implant shell in correlation with the severity of capsular contraction.

breast imaging at our institution, who performed ultrasound measurements using a Canon Aplio 500 Ultrasound System with mode-B and a high-frequency linear transductor of 18 MHz. Patients were scanned in the same location in a supine position, and an evaluation of the periphery and center of the implant was performed once (Fig. 1).

Outcomes

Our main objective was to determine the relationship between ultrasound findings and each category of BGS. The primary outcome was the assessment of the mean difference in peri-implant capsular thickness (PCT) between the BGS. Secondary outcomes were the presence of calcifications, implant shape deformity, and abnormal wrinkles of the shell associated with BGS. Further explanation of these variables is presented below.

Variables and Data Measurement

Each plastic surgery staff member collected the information and uploaded it individually in an Excel format. A data analyst (S.T.) unified the databases used. Our variables of interest included age, type of breast surgery (reconstructive versus aesthetic), history of radiotherapy, and ultrasound variables, such as capsule thickness, presence of calcifications, implant shape deformity, and abnormal wrinkles of the shell.

To measure peri-implant capsular thickness, three echogenic lines representing the capsule-shell complex of most silicone implants were considered normal. The external echogenic line represents the outer aspect of the fibrous capsule, and the middle echogenic line is composed of the inner surface of the fibrous capsule and the outer surface of the elastomer shell. The internal echogenic line represents the inner surface of the elastomer shell.[20] The space between the external and middle echogenic lines (anechoic line) represents the thickness of the capsule. The abnormally thickened capsule is often isoechoic and bordered by echogenic lines on both surfaces (outer and middle thin lines)[21] (Figs. 2 and 3). Therefore, we considered a measurement that would represent the size of the fibrous capsule as an anechoic-isoechoic line.

The implant shape deformity usually described in mammographic imaging is measured using ultrasound analysis. To assess this variable, the transverse and anteroposterior
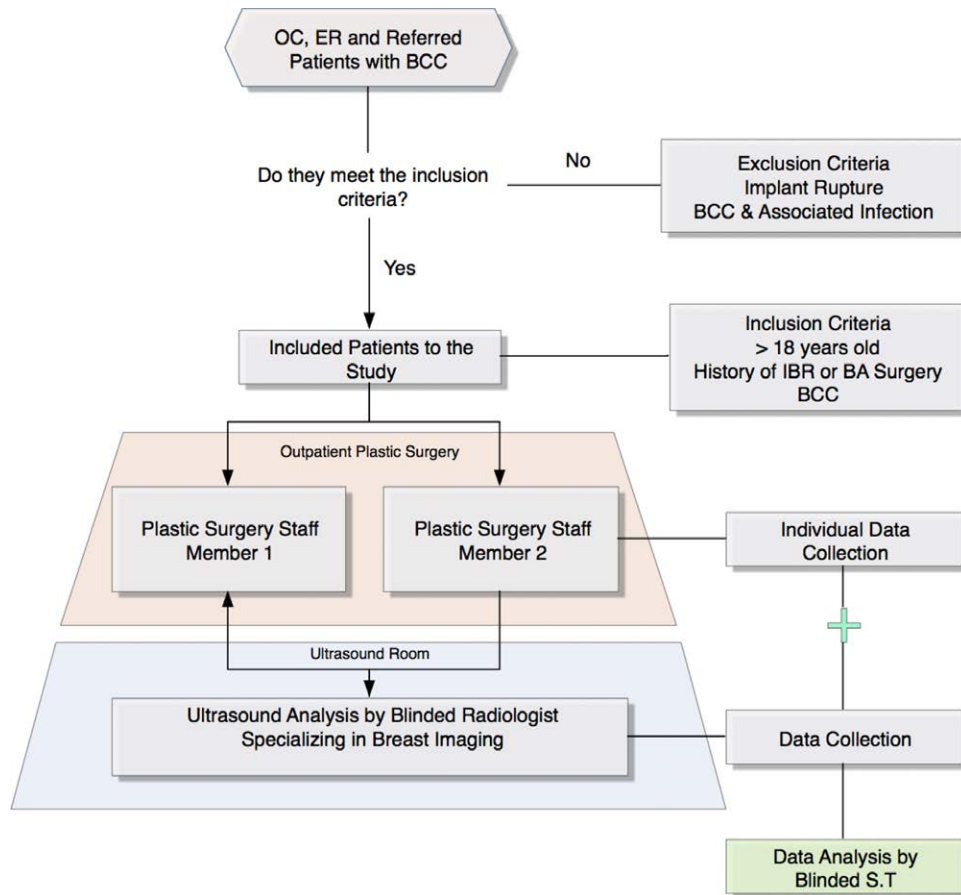
Fig. 1. Flow chart for diagnostic follow-up and data collection. BA, breast augmentation; BCC, breast capsular contracture; ER, emergency room; OC, outpatient clinic.
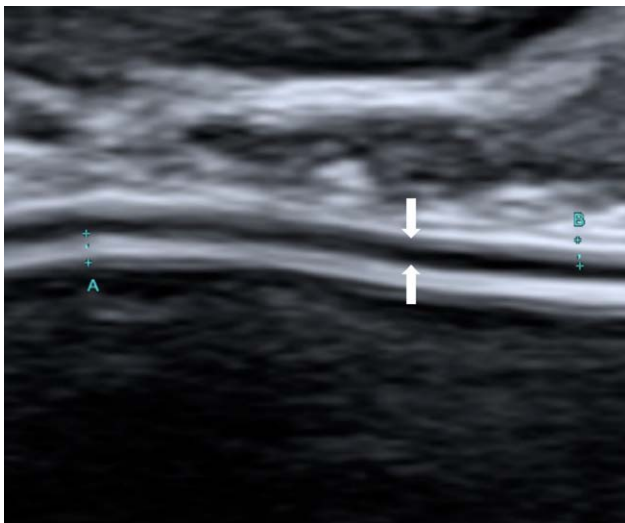

Fig. 2. B-mode ultrasound of the capsule of a breast implant. Arrows indicate the anechoic line. The letter A indicates the measurement of the midline echogenic line. The letter B indicates the measurement of the external echogenic line.

distances of the implants were calculated. Abnormal findings were considered when the anteroposterior dimension was greater than the transverse one (Fig. 3).[17,20,23]

Wrinkles on the surface of the shell were considered abnormal when they were less lobulated or flat. These findings can be observed in the ultrasound enlargement view of the breast (Fig. 3A). Radial folds differ from wrinkles because when folds are present, the shell invaginates and separates from the capsule, creating a space between them.

Statistical Methods

Descriptive analyses are presented as frequencies and percentages for categorical variables. For continuous variables, means and SDs were used if a normal distribution was achieved; otherwise, median and interquartile ranges were used. The Shapiro–Wilk test was used to assess normal distribution. If the P value was less than 0.05, we considered that the data were not normally distributed.

For inference analysis, the Kruskal–Wallis test was conducted to determine the differences between group means for PCT in the categories of the BGS. The Dunn test was performed to determine which specific means were significant. Following the hierarchy system of the severity of the Baker scale, and considering that the following variables to be analyzed are binary, Baker I/II and III/IV were grouped separately for analysis. Finally, the difference under pain condition between Baker IV and the others was considered. Baker categories I, II, and III
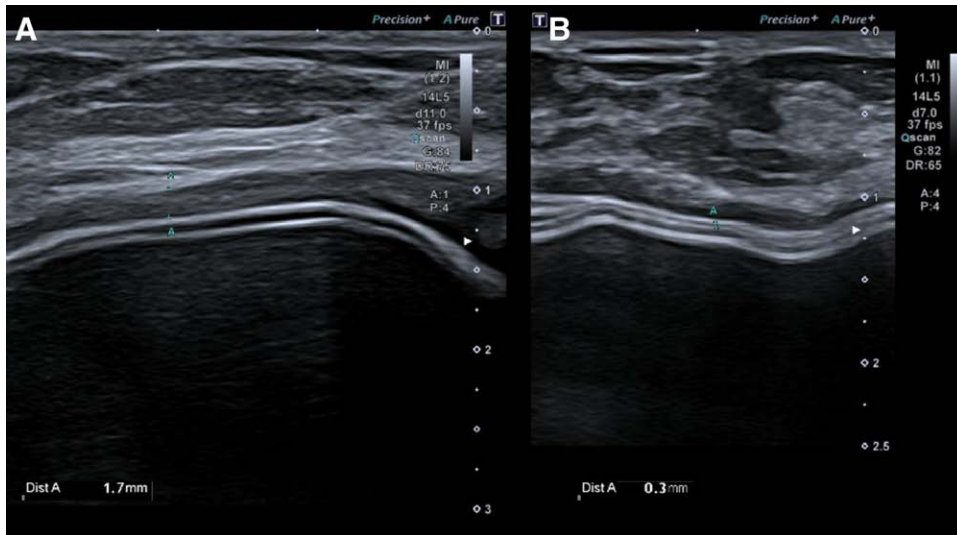
Fig. 3. Comparative B-mode ultrasound images. A, The image on the left depicts the enlargement of a breast implant showing thickening of the fibrous capsule (1.7 mm) (left letter A), associated with decreased lobulations and wrinkles, findings that suggest capsular contracture. In comparison, the image on the right shows a normal breast implant with a thin fibrous capsule of 0.3 mm (right letter A). B, Comparative ultrasound panoramic view of a capsular contracture and a normal breast implant. The image on the left corresponds to the patient's right breast with an implant where an increase of the AP diameter in relation to the transverse diameter is evident. The right image shows the left breast of the same patient with an implant with a larger transverse diameter than the AP diameter.

were grouped and compared with Baker IV for the analysis of the last variable (implant shape deformity). The Fisher exact test was used for categorical data (abnormal shell wrinkles, implant shape deformity, and the presence of calcifications). Analyses were performed using Stata Basic Edition version 17 for Mac.

RESULTS

Participants and Descriptive Data

A total of 28 breasts of 21 patients with smooth surface silicone implants with a mean age of 44.75 ± 12.2 years were clinically evaluated and classified according to BGS. All patients were women, and no male patients were recorded during the study period. The median time from breast surgery to CC diagnosis was 3 years (interquartile range, 6.75 years). Overall, 53.57% of the breasts underwent IBR, of which 60% underwent radiation therapy, and 46.43% underwent breast augmentation with implants (Fig. 4).

BGS and Ultrasound Findings

The main results of our study showed that 39.2% of the breasts had Baker I, 25% had Baker II, 17.9% had Baker III, and 17.9% had Baker IV. Table 1 shows the radiological variables that were assessed. From all the imaging variables analyzed, PCT, abnormal wrinkles of the implant shell surface, and implant shape deformity showed statistically significant differences in proportion between Baker groups. Mean capsule thickness for Baker I, II, III, and IV groups were 0.6 ± 0.24, 1.0 ± 0.53, 1.68 ± 0.99, and 1.52 ± 0.46 mm, respectively ($P = 0.0044$) (Fig. 5). Comparisons between groups using the Dunn test
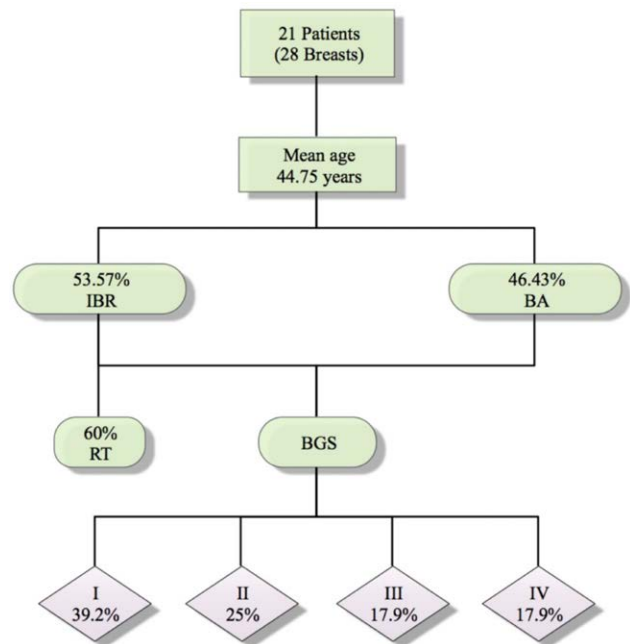
Fig. 4. Flowchart for participants' distribution.

Table 1. Ecographic Variables Assessed

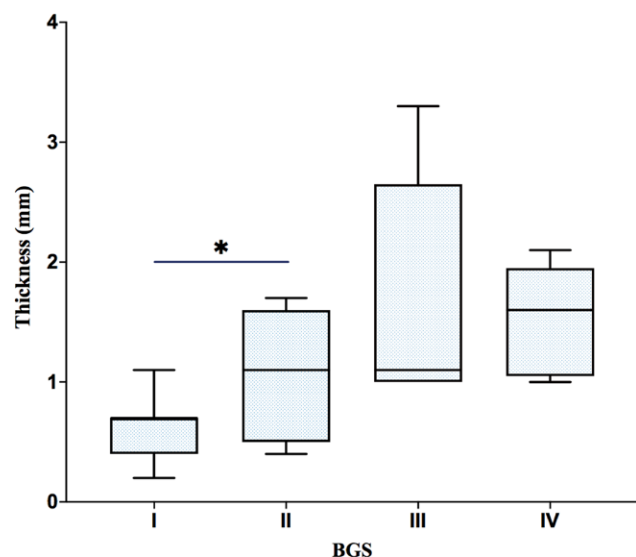|	Present (%)	Absent (%)
Abnormal wrinkles of the shell	35.7	64.3
Implant shape deformity	10.7	89.3
Capsular calcifications	7.1	92.9

Fig. 5. Capsular thickness in millimeters grouped according to the BGS. *P = 0.0385

indicated significant differences between Baker I and II, Baker I and III, and Baker I and IV (P 0.0385, 0.0026, and 0.0012, respectively). Breasts with Baker III/IV were five times more likely to have abnormal wrinkles of the shell on breast ultrasound compared to Baker I/II [odds ratio (OR), 5.25; 95% confidence interval (CI), 0.82–33.45; P = 0.0496]. The implant shape deformity showed a difference in the proportion of Baker IV patients compared to Baker grade I/II/III patients (P = 0.0218). In contrast, capsular calcifications, which tended to increase with the age of the implant, were not statistically significant variables in our analysis (P = 0.119). It was present in only one patient who underwent breast augmentation 20 years ago.

DISCUSSION

This study evaluated ultrasound findings related to CC in women who underwent breast reconstruction or augmentation mammoplasty. Statistically significant differences were found when evaluating the ultrasound thickness of the periprotective capsule in relation to the Baker scale (P = 0.0044). Our study also found statistically significant differences in the relationship of the Baker grade IV with implant deformity (10.7%; P = 0.0218) and the presence of abnormal wrinkles on ultrasound (35.7%; P = 0.0496). The other radiological variable under study (CCs) showed no statistically significant differences.

CC is one of the most important long-term reported complications in patients who underwent IBR and aesthetic augmentation, affecting patients' breast contour and their quality of life.[5,16,24] Therefore, it is critical for plastic surgeons to accurately identify this pathology in an objective complementary manner. BGS is a great tool for assessing CC in physical examinations as a first approximation to the diagnosis. However, this approach is very subjective, and discrepancies among plastic surgeons persist, affecting the patient's treatment orientation. Therefore, it is important to explore more objective tools to complement BGS.

In our study, CC was correlated with ultrasound findings. Ultrasound PCT, abnormal wrinkles of the implant surface, and implant shape deformity showed statistically significant differences between BGS categories, with P values of 0.0044, 0.0496, and 0.0218, respectively. These findings are consistent with those of previous studies.[19,25,26] In 1992, Ganott et al[25] found that CC was present in capsules with thickness greater than 1.5 mm. Moreover, in 2006, Zhavi et al demonstrated the correlation between capsular thickness and clinical BGS using an ultrasound scan and MRI (P = 0.002 and 0.017, respectively). With their findings, the authors propose a new classification of CC based on their results with a capsular thickness cutoff of 2 mm as a necessary tool for management in these patients.[19] Interestingly, the authors grouped categories I/II and III/IV, which could lose important information between the categories and could potentially be relevant from a clinical perspective. By unifying categories III and IV, we could miss differences related to pain. Conversely, in 2017, Tyagi et al[26] did not find a difference in capsular thickness between the BGS categories using MRI. To the best of our knowledge, despite all these advancements in evidence-based medicine, there is still no consensus in the literature regarding peri-implant capsule thickness in patients with CC.[26] In addition, in our study, the categories of Baker III and IV presented very close values of capsular thickness. This could be explained by the fact that the only difference between these two categories was the presence or absence of pain. The capsular thickness of these two categories was greater than those of the mild ones.

Deformation of the breast silicone implant and wrinkles of the implant surface are also relevant considerations in CC. An increase in the AP dimensions, which gives the implant a more spherical configuration, is considered a deformity of the implant.[20,23] Our study found statistically significant differences in the outcome; however, this was found only in three patients. In our study, this variable was 14 times more likely to be present in Baker IV than in Baker I, II, and III (OR, 14.66; 95% CI, 0.69–309.38; P = 0.0218). These data were consistent with the findings of Tyagi et al. Using MRI, they observed a statistically significant difference in morphological features (roundness and eccentricity). This leads us to wonder whether the deformity of the implant is associated with symptoms in these patients. Therefore, there may be a strong association.

On the other hand, the wrinkling of the implant surface, which constantly varies between patients, is more evident in saline than silicone implants.[20] However, based on our experience, we hypothesized that nonthickened implants will have more lobulated wrinkles than thickened peri-implant capsules. Therefore, we assumed abnormal wrinkles of the implant surface if there was flattening of the wrinkles in the advanced grades of BGS. In this study, wrinkles on the implant surface were statistically different between the BGS categories and were more prevalent in the thickened peri-implant capsules. We found that Baker III/IV was five times more likely to have abnormal wrinkles (flattening effect) on the silicone implant shell surface than Baker I/II (OR, 5.25; 95% CI, 0.82–33.45; P = 0.0496). Although this is a secondary outcome and the borderline significance of the

Table 2. Breast Implant CC Ultrasound Grading System

Grade	Capsular Thickness, mm	Abnormal Wrinkles	Shape Deformity
I	≤0.5	-	-
II	> 0.5 < 1.5	-	-
III	≥1.5	+	-
IV	≥1.5	+	+

P value found, a tendency toward a positive association with our presumption is appreciated. Of note, a clear trend toward ultrasound capsule thickness, abnormal wrinkles, shape deformity, and BGS is evident. These findings led us to suggest an objective method to classify breast CC based on thickness, abnormal wrinkles, and shape deformity of the implant, which is the breast implant CC ultrasound grading system (Table 2). For its use, we suggest including all variables mentioned above.

Despite efforts to provide an objective and reproducible tool for measuring peri-implant CC, BGS remains the most accepted and widely used method in patients with breast implants.[13] Thus, different image techniques and punctual findings have been described in the literature for the evaluation of mammary implants, including mammography, ultrasound scan, MRI, and elastography.[11] The gold standard technique for mammary implant evaluation is MRI.[11] However, this imaging technique is time-consuming and represents high costs to the institutions. Low-/middle-income countries face limitations in accessing MRI[27]; therefore, we chose ultrasound as an accessible and reliable method for the evaluation of mammary implants in our study. Hence, we believe that our study provides important and relevant information to the medical and surgical literature for the improvement of the diagnosis and accurate identification of CC with an objective tool that complements the BGS and also provides support for decision-making.

This study has some limitations. First, our target population and convenience sampling were patients who assisted in our clinic, which limits the external validity and, consequently, the generalization of our study's results. However, strict eligibility criteria and blinding of surgeons were performed to avoid selection bias. In addition, ultrasonography was performed by one radiologist. We recognized that this type of imaging is operator-dependent in interpretation and might vary between radiologists, transducers, equipment, positions where measurements are taken, and expertise. Therefore, implant cohesiveness can be a confounding factor in the measurement of wrinkles. However, the radiologist in charge of ultrasound readings is a specialist in mammary breast imaging and has 6 years of experience.

CONCLUSIONS

A major strength of the current study is that it demonstrates that ultrasound could potentially represent a useful tool to evaluate the presence of augmented thickness, implant shape deformity, and abnormal wrinkles of the implant surface, due to its correlation with the BGS. Although the ultrasound analysis requires a breast imaging specializing radiologist, we consider this method as a useful tool to objectively evaluate the severity of CC and,

consequently optimize the diagnosis and decision-making. Therefore, we present the breast implant CC grading system based on ultrasound findings with statistical support that complements the BGS. However, we understand that in a research perception, studies with larger numbers applying these variables should be conducted to corroborate and give robustness to our findings and the applicability of the suggested grading system.

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