The Baker Classification for Capsular Contracture in Breast Implant Surgery Is Unreliable as a Diagnostic Tool

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Background: Breast implants are frequently used in cosmetic and reconstructive breast surgery. Capsular contracture, the most common long-term complication, is usually graded using the Baker classification. Despite its widespread use, the reliability of the Baker classification has never been established. The aim of this study was to determine the interobserver reliability and agreement of the Baker classification.

Methods: Sixty women who had undergone cosmetic breast augmentation were included. They were examined independently by two plastic surgeons from an observer pool. The Baker score was determined, along with firmness, dislocation, symmetry, and pain using four-point scales. Patients were asked to complete the BREAST-Q postaugmentation module. The interobserver reliability and agreement were calculated for all variables with a quadratic weighted kappa.

Results: The interobserver reliability of the Baker classification was poor (kappa, 0.55; 95 percent CI, 0.37 to 0.72). Interobserver reliability of the clinical parameters firmness (0.64; 95 percent CI, 0.49 to 0.79), dislocation (0.49; 95 percent CI, 0.26 to 0.73), and symmetry (0.61; 95 percent CI, 0.34 to 0.88) was also poor. Pain scores seemed more reliable (0.72; 95 percent CI, 0.56 to 0.89); however, most patients had no pain. The interobserver agreement for the Baker score was 48 percent; in 43 percent, the observers differed one category; and in 12 percent, the difference was more than one category.

Conclusions: Interobserver reliability and observer agreement of the Baker classification for capsular contracture were poor. Consensus about how to adequately rate the symptoms of capsular complaints is lacking. A more reliable method of measurement or description is needed, especially for scientific research purposes, to assess the long-term problems associated with breast implants. (*Plast. Reconstr. Surg.* 146: 956, 2020.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Diagnostic, IV.

Breast augmentation using implants is one of the most frequently performed cosmetic operations. Furthermore, the method of breast reconstruction used most is implant-based.

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In The Netherlands, approximately 3.3 percent of women have breast implants. Between 2015 and 2017, approximately 11 of the 60,000 inserted breast implants, or 25 percent of the procedures, were for reconstructive purposes in The Netherlands. Capsular contracture is reported as a common long-term complication associated with breast implants and is usually the primary reason for reoperation.[1] Reported incidences range from 0.6 to 17.4 percent for primary augmentation and 21.1 to 47.7 percent for breast reconstruction.[2] In addition, revision surgery in both groups is

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Table 1. Baker Classification of Capsular Contracture after Augmentation Mammaplasty*

Class	Description
I	Breast absolutely natural; no one could tell breast was augmented
II	Minimal contracture; I can tell surgery was performed, but patient has no complaint
III	Moderate contracture; patient feels some firmness
IV	Severe contracture; obvious just from observation

*From Baker JL Jr. Augmentation mammaplasty. In: Owsley JQ Jr, Peterson RA, eds. *Symposium on Aesthetic Surgery of the Breast.* St. Louis: Mosby; 1978:256–263.

Table 2. Baker Classification of Capsular Contracture*

Grade	Description
1	Grade 1 capsular contracture is asymptomatic (producing or showing no symptoms). The formation of scar tissue around the implant does not interfere with the size, shape, or texture of the breasts. The breasts appear natural and remain soft to the touch.
2	Grade 2 capsular contracture usually presents itself with only minor cosmetic symptoms. The breasts will usually appear normal in shape but feel somewhat firm to the touch.
3	Grade 3 capsular contracture presents itself with obvious cosmetic symptoms. The breasts will be firm to the touch and appear abnormal (e.g., they will be overly round and hard-looking, and the nipples may be misshapen. However, this grade of capsular contraction often does not cause much (if any) pain.
4	Like grade 3 capsular contracture, grade 4 capsular contracture causes the breasts to become hard and misshapen. Patients with grade 4 capsular contracture also experience breast soreness; their breasts will often be tender and painful to the touch.

*From Tehrani K. What is capsular contracture and how can it be treated? Available at: https://www.plasticsurgery.org/news/blog/what-is-capsular-contracture-and-how-can-it-be-treated. Accessed July 23, 2019.

reported to result in a higher incidence of capsular contracture.[2]

After implantation of any implant, a host response is evoked, resulting in the formation of a fibrotic capsule around the prosthesis. This is part of a normal foreign body response. Normally, the fibrous tissue remains thin and supple, and most patients do not experience any complaints. However, in an adverse course, the capsule may thicken, tighten, or even contract. The type of implant, surgical technique, low-grade infection, and postoperative radiotherapy are factors described to be associated with capsular problems.[2] Clinically, these capsular changes can cause hardening of the breast or even deformation and may result in implant dislocation and asymmetry of the breasts. Some patients may experience tenderness or pain. The symptoms can occur in isolation or in any combination. In addition, they can present at various time points after surgery and can progress at different rates. In other words, the presentation of capsular-related complaints is very heterogeneous.

With the increasing popularity of breast implants over recent decades, the number of patients with complaints attributed to pathologic changes in the fibrous capsule has increased progressively. In the medical literature, the concept of "capsular contracture" is used as a generic term for the collation of capsule-related complaints. With the recognition of these capsular problems related to breast implants, attempts were made to classify capsular contracture with regard to the severity of the symptoms. In 1978, Baker introduced a clinical classification of capsular contracture for the first time. His original classification is still the most widely used and generally accepted.[3] It uses a four-point scale ranging from grade I (natural) to grade IV (severe contracture) (Table 1). Notably, the scale does not specify how this contracture presents. The classification was later modified by Spear and Baker to accommodate for the reconstructed breast by adding sublevels IA and IB.[4] The Baker score is used in research settings to report incidence rates of capsular contracture in studies on the performance of implants or surgical techniques,[5–7] and it is used in more fundamental research in which clinical data (e.g., Baker scores) are correlated with biomedical data (e.g., histology, immunologic data).[8] The classification is frequently used for clinical diagnoses in individual patients. In The Netherlands, reimbursement even depends on this classification; the capsular contracture should be classified as severe with a Baker grade IV score to obtain (partial) reimbursement by the health insurers for surgical treatment. Pain is one of the factors deemed necessary for this reimbursement. Although pain was not originally included in the Baker classification, pain has found its way into various versions of the Baker classification published in journals and online (Tables 2 through 4). T2-T4 It is unclear when pain exactly appeared in the classification. Because pain can be found in multiple versions of the Baker classification, it seems that many authors consider pain to be essential to grade capsular contracture. Nevertheless, it is remarkable that so many different versions of one classification exist.

Despite of its wide use, the reliability of the Baker classification has not yet been established. The aim of this study, therefore, was to determine

Table 3. Baker Classification*

Grade	Description
I	Soft
II	Minimal, implant palpable, not visible
III	Moderate, palpable, and visible
IV	Severe, hard, painful with distortion

*From Hodges A. *A-Z of Plastic Surgery*. Oxford: Oxford University Press; 2008. 10.1093/acref/9780199546572.001.0001.

Table 4. Baker Classified Capsular Contracture*

Grade	Description
I	The augmented breast feels as soft as an unoperated one
II	Minimal—implant palpable, but not visible
III	Moderate—implant easily palpable, and it (or distortion from it) is visible
IV	Severe—the breast is hard, tender, painful, and cold; distortion is often marked

*From Richards A, Dafydd H. *Key Notes on Plastic Surgery*. Chichester, UK: Wiley; 2014. 10.1002/9781118757017

the reliability of the Baker classification by determining the interobserver reliability and observer agreement of the Baker classification. In addition, the interobserver reliability of rating the separate clinical symptoms associated with capsular contracture was determined.

PATIENTS AND METHODS

Study Population

This was a cross-sectional, observational, multicenter study. Women who had undergone breast augmentation surgery more than 5 years before inclusion and without a history of breast malignancy were eligible to participate in this study. The protocol was approved by the institutional review board at each study center. All patients provided written informed consent. The study was performed in accordance with the Declaration of Helsinki and guidelines for Good Clinical Practice.

Study Procedure

Eligible patients were recruited by means of two routes: (1) patients who underwent breast augmentation more than 5 years previously were identified from the hospital records and invited by phone to partake, and (2) eligible patients who visited the outpatient clinic visit for complaints related to the breast implant were asked to participate. After providing informed consent, patients were invited to the outpatient clinic.

Seven plastic surgeons with ample experience in breast surgery and who use the Baker classification in daily practice were asked to participate in the observer pool. Plastic surgeons were handed out the official Baker classification on paper and were instructed to classify capsular contracture as they would do in clinical practice. At the clinic, the patient's breasts were examined independently by two surgeons from the pool of observers. Breasts were scored according to the Baker classification and separately scored for the symptoms associated with capsular contracture. Patients were also asked to complete a questionnaire pertaining to the postaugmentation quality of life, the Dutch version of the BREAST-Q postaugmentation module. The BREAST-Q is a comprehensive patient-reported outcome measure, which evaluates satisfaction with breasts and impact on quality of life. It includes questions about symptoms, appearance, and satisfaction. It specifically asks for visible and sensible complaints about softness of the implants and pain.

Outcomes

The main outcome was the Baker classification for capsular contraction (Table 1). Additional outcomes were (a) firmness of the breast, (b) dislocation of the implant, (c) pain, and (d) symmetry. Each of these outcomes was scored using a four-point Likert scale for the left and right breasts separately, except for (d) symmetry, which was scored comparing both breasts. For each of these measures, the interobserver reliability and the observer agreements were determined. A summed score of the items a + b + c was used to test the intraobserver validity by correlating the Baker score with this summed score. Additional outcomes were demographic data (i.e., age; date of augmentation; and, if applicable, revision surgery and implant type and size) and patient-reported outcomes (BREAST-Q post–augmentation module).

Statistical Analysis

A minimal sample size of 50 patients was estimated. This was based on a repeated measurement with two independent observers and a desired 95 percent confidence interval of 0.1 for an intraclass correlation coefficient of 0.8.[9] To establish a safe margin, a target sample size of 60 participants was decided on. Descriptive statistics were used for all variables. Interobserver reliability was determined by calculating the weighted kappa scores for the Baker classification and the individual clinical parameters using a quadratic weighting with VassarStats (Richard Lowry, Poughkeepsie, N.Y.)

Table 5. Patient Characteristics

Characteristic	Value (%)
No. of patients	60
Mean age ± SD, yr	49 ± 11
Type of prosthesis	
Silicone	55 (92)
Other (monobloc)	5 (8)
Mean size ± SD, cc*	307 ± 88
One-side augmentation	3 (1.6)
Revision surgery	21 (35)
More than once	8 (13)

*n = 44 (73%).

online statistical software.[10] For the cumulative clinical parameter scores, the intraclass correlation coefficient based on one-way analysis of variance was calculated.[11] Observer agreement was calculated for all parameters, which were rated using a four-point scale. To correlate observer and patient opinion, Pearson correlation coefficients were calculated between observer scores (Baker score and the summed item score) and patient-reported outcome measures (BREAST-Q postaugmentation module domains and question 1H which specifically asks for symmetry). All statistics were calculated using IBM SPSS Version 22.0 (IBM Corp., Armonk, N.Y.).

RESULTS

Patient Characteristics

Between 2017 and 2018, 60 patients were included in this cross-sectional study. Relevant patient characteristics are listed in Table 5. Nearly all [n = 55 (92 percent)] patients had received some type of silicone implant; the others had received monobloc implants, with a silicone shell and hydrogel filling. Sixteen patients (27 percent) did not know what their implant size was. Three women had undergone one-side augmentation; symmetry was not evaluated in those cases. Of all patients, 35 percent had already undergone revision surgery, 13 percent more than once (Table 5).

Baker Score and Separate Symptom Scores

An overview of the distribution of all scored parameters on the four-point Likert scales used is given in Figure 1. Baker score, firmness, dislocation, and pain were scored per breast, whereas symmetry was scored based on both. For all parameters, data are skewed, with a higher prevalence for lower symptomatic values. This was especially true for pain, which was scored 166 times as I (no pain) and only six times as IV (much pain).

Interobserver Agreement and Reliability and Intraobserver Validity

Interobserver reliability and observer agreement are presented in Table 6 for all parameters. For the Baker score, the interobserver reliability is rather low (kappa = 0.55). The observer agreement is also low, with the same score given in only 48 percent of breasts. In 41 percent of cases,

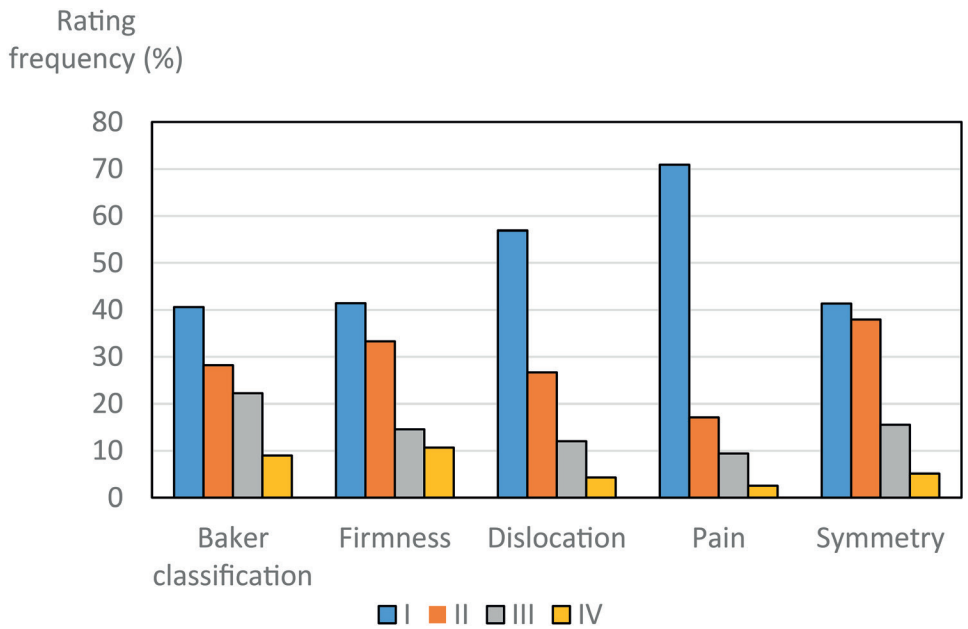

Fig. 1. Distribution of scored characteristics by all observers. Each breast was scored for all parameters except symmetry, which was based on both breasts. It shows a skewed distribution toward fewer symptoms for most women.

Table 6. Interobserver Reliability and Observer Agreement*

	Interobserver Reliability		Observer Agreement (%)	Observer Agreement ± 1 (%)
	Kappa†	95% CI		
Baker	0.55	0.37–0.72	48	89
a) Firmness	0.64	0.4–0.79	55	92
b) Dislocation	0.49	0.2–0.73	61	91
c) Pain	0.72	0.5–0.89	75	97
Symmetry	0.61	0.3–0.88	52	97
Summed item score (a + b + c)	0.72‡	0.62–0.80‡		

*Observer agreement indicates the percentage of cases in which observers rate equally, observer agreement ± 1 indicates the percentage of cases in which there is maximally one-level difference between observers.
†All kappa values were calculated using quadratic weighting.
‡Intraclass correlation coefficient.

observers differ by one category, whereas in 11 percent of cases they differ by two or more categories. Similar outcomes are found for the individual symptoms. The highest agreement is met when rating pain. However, it should be noted that, in 64 percent of cases, this agreement was reached on having no pain (scoring I by both observers). From the BREAST-Q, domains 1 (Satisfaction with Breasts) and 5 (Physical Well-being) correlated weakly to moderately with the given Baker scores and the cumulative clinical parameter score (Pearson r between 0.295 and 0.393) (Table 7). The symmetry parameter correlated weakly (Pearson $r = -0.223$) with question 1H of the BREAST-Q, which specifically asks the patient to evaluate the symmetry of her breasts. There was a good correlation between the cumulative scores and the Baker score given by the same observer (Pearson $r = 0.84$), indicating that the intraobserver rating of capsular contracture is consistent.

DISCUSSION

This study aimed to assess the interobserver reliability of the Baker classification for capsular contracture, a well-established tool for grading capsular contracture in clinical practice and in research. We found that the interobserver reliability was quite poor, as was the interobserver agreement. In the majority of cases, the given Baker classification differed between the two observers and, in 11 percent, by more than one level.

Table 7. Correlation of Baker Score with the BREAST-Q*

	BREAST-Q Domain		
	1 (p)	5 (p)	1H (p)
Baker score (average all observers)	–0.295 (0.001)	–0.368 (0.000)	
Cumulative score (average all observers)	–0.393 (0.000)	–0.324 (0.000)	
Symmetry (average all observers)			–0.223 (0.017)

*Pearson correlation coefficients with p value between Baker and cumulative clinical parameter scores given and BREAST-Q domains 1 (Satisfaction with Breasts) and 5 (Physical Well-being), and between the observed symmetry and question 1H of the BREAST-Q, which specifically asks for symmetry.

The diverse presentation of (local) problems associated with breast implants is well known by all plastic surgeons dealing with these implants. Most of these problems are collectively referred to as capsular contracture and graded using the Baker classification. Although widely accepted, the Baker classification is inconsistently defined in both reference works and in scientific literature.[2,12–14] Several other methods and classifications have been proposed over the years. All, excluding applanation tonometry, are four-point Likert scales similar to the Baker classification, with similar generic descriptions.[15–18] The reliability of these classifications has not been assessed, nor have they gained broad support. Applanation tonometry is used in various studies to evaluate breast softness or hardness and could be used to measure that one aspect of capsular-related complaints more reliably. It has gained limited use in daily clinical practice and has been described as unreliable when comparing differently shaped implants, which would severely limit its use in daily clinical practice.[19,20]

It may be expected that grading the severity of problems with a very diverse presentation, on a single ordinal scale, poses a challenge. This was shown to be the case. To address this challenge, plastic surgeons in this study were also asked to separately grade the main symptoms associated with capsular contracture: firmness, dislocation pain, and asymmetry. Remarkably, rating these specific symptoms by plastic surgeons also proved unreliable. Although there is a notion among plastic surgeons of the concept of capsular contracture and its symptoms, these ideas do not seem to match. Within the individual surgeon, a consistent rating of symptoms and the Baker score exists, but between surgeons, it seems that no consensus

exists on what "firmness" or "dislocation" exactly are, or when either of those symptoms is mild, severe, or normal. To categorize these symptoms reliably, we need to reach consensus on the interpretation of symptoms. This may be achieved by describing these symptoms in more detail. We propose to describe the symptoms of (local) breast implant–related complaints separately, using a more qualitative approach. We suggest that using more qualitative descriptions will result in clearer communication and better comparability.

This qualitative approach should include and discriminate between physical findings such as firmness, dislocation, and symmetry and experienced symptoms such as pain or tenderness. We propose to refer to these complaints as "breast implant–related complaints." We purposefully use the term breast implant–related complaints because the presence of actual capsular abnormalities can be established only by operating on the breast.

To improve the assessment of implant-related complaints, it is important to bear in mind the purpose of the classification. The Baker classification is broadly used for two main purposes: clinical and scientific. First and foremost, it is used by health care professionals in clinical practice (i.e., to assess capsular complaints in individual patients, decide whether intervention surgery is necessary, and exchange this information between colleagues). A clearer definition of symptoms may be helpful, especially with regard to communication between health care professionals. Nevertheless, intervention remains a very personal preference for both patient and surgeon and depends on many factors. Therefore, we propose to refrain from labeling a certain grade as an indication for surgery.

Second, the Baker classification is used in scientific research. Many studies aim to compare different surgical methods or implant materials in breast implant procedures with regard to their long-term complication rate. When the measurement of capsular contracture is unreliable, this poses a major problem. For this purpose, a more reliable way of describing the presence and severity of the collation of problems associated with capsular contracture is warranted. Our expectation is that better definitions and more consensus on how these symptoms are described and classified will improve reliability. Future exploratory studies are necessary to prove this. For scientific research, in particular, it is necessary that each study describes the classification they used to conduct their research in detail and to use multiple observers.

The main reason why the Baker classification has become so popular is probably because it is simple. In creating a new method of classifying breast implant–related complaints, a choice will have to be made between a more simple, clinical oriented classification, or a more extensive, descriptive classification. In both cases, a clear consensus and instructions are needed to improve reliability. The more descriptive measure will probably be more complex, needing more training and consensus to achieve good reproducibility. The latter could, therefore, be less applicable in daily clinical practice.

This study has several strengths and limitations. In this study, no extensive instruction on grading using the Baker classification was given beforehand. All participating surgeons were familiar with the classification and use it in daily practice. In the study setup, it was decided to conduct the scoring as it is being performed in normal practice. Surgeons will have used the classification as they have been taught, possibly influenced by their personal experience since then. Providing extensive instructions might therefore improve the agreement. Not all grades of the Baker classification were equally represented in the population. In our population, women with no/few symptoms were overrepresented. Although this is a representation of the prevalence of capsular contracture, for the sake of assessing reliability, a less skewed distribution might have been preferable. Each patient was rated by two observers from a pool of seven observers. Therefore, we cannot assess whether systematic differences existed between the observers. In contrast, multiple observers mimic clinical practice, and the results are more representative of all plastic surgeons than if only two observers had rated all patients.

CONCLUSIONS

The interobserver reliability of the Baker classification for capsular contracture is poor. Although there is a general notion of what capsular complaints are (i.e., dislocation, firmness, asymmetry, and pain), individual plastic surgeons have different interpretations about what these symptoms entail and how to grade their severity. A more reliable method of measurement or description is needed, especially for scientific research purposes.

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