Toward a Consensus Aproach for Assessing Capsular Contracture Severity and Progression: A Systematic Review

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Background: Breast implants are the most commonly used medical devices in plastic surgery, and capsular contracture (CC) is one of the most common complications. However, our assessment of CC is based largely on Baker grade, which is problematically subjective and affords only four possible values.
Methods: The authors performed a systematic review concluding in September of 2021 in compliance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. It identified 19 articles that propose approaches to measuring CC.
Results: In addition to Baker grade, the authors identified several modalities reported to measure CC. These included magnetic resonance imaging, ultrasonography, sonoelastography, mammacompliance measuring devices, applanation tonometry, histologic evaluation, and serology. Capsule thickness and other measures of CC inconsistently correlated with Baker grade, whereas the presence of synovial metaplasia was consistently associated with Baker grade I and II, but not III and IV capsules.
Conclusions: There remains no particular method to reliably and specifically measure the contracture of capsules that form around breast implants. As such, we would recommend that research investigators use more than one modality to measure CC. Other variables that can impact breast implant stiffness and associated discomfort beyond CC need to be considered when evaluating patient outcomes. Given the value placed on CC outcomes in assessing breast implant safety, and the prevalence of breast implants overall, the need for a more reliable approach to measuring this outcome persists. *(Plast. Reconstr. Surg.* 153: 7, 2024.)

Capsular contracture (CC) is the most common complication of breast augmentation and reconstruction with implants.[1–4] The original classification scheme, developed by Spear and Baker,[5] is the most broadly adopted and provides a straightforward metric for evaluating CC in countless studies that have shaped our understanding of outcomes in breast implant surgery. The Baker classification (Table 1) considers physician and patient perceptions of implant palpability, visibility, breast firmness, and pain to generate a score ranging from I to IV.[5] By strict definition, though, CC refers specifically to morphologic and physiomechanical changes to the fibrous capsule that forms around breast implants.[4] Although the palpability, visibility, firmness, and pain that develop around a breast implant can result exclusively from contracture of the periprosthetic capsule, there are myriad factors that may influence this. Despite a thoughtful modification of the Baker grade to evaluate CC following

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Table 1. Capsular Contracture Classification Systems for Breast Augmentation and Modification for Breast Reconstruction

Classification	Description
Breast augmentation[5]	
I	Absolutely natural; cannot tell breast was augmented
II	Minimal contracture; surgeon can tell surgery was performed, but patient has no complaint
III	Moderate contracture; patient feels some firmness
IV	Severe contracture; obvious just from observation
Breast reconstruction[5]	
IA	Absolutely natural; cannot tell breast was reconstructed
IB	Soft, but the implant is detectable by physical examination or inspection because of mastectomy
II	Mildly firm reconstructed breast with an implant that may be visible and detectable by physical examination
III	Moderately firm reconstructed breast; the implant is readily detectable, but the result may still be acceptable.
IV	Severe capsular contracture with an unacceptable aesthetic outcome and/or significant patient symptoms requiring surgical intervention

breast reconstruction,[5] this cohort of patients with breast implants have an even greater number of factors that may limit the utility of using Baker grade to measure CC (Table 1). Implant type, skin versus implant surface area and compliance, device positioning, fibrosis of the pectoralis major muscle, and replacement of the capsule with acellular dermal matrix (ADM) may all affect Baker grade or mammary compliance independent of any alteration of the periprosthetic capsule, limiting the value of the Baker grade.[6]

This review is not intended to diminish the role of Baker grade for measuring CC. We acknowledge that it is the most popular grading scale specifically used by plastic surgeons to assess CC. Rather, because of its popularity, it has had tremendous influence in shaping our perception of CC outcomes reported in numerous basic science,[7] translational,[8–11] clinical,[12] and industry-sponsored core studies.[13–16] There remains an unmet need for a tool to specifically measure changes to the periprosthetic capsule itself, particularly in research, independent of confounding variables, conserved, and reproducible between raters, if our field is to truly understand and research the impact of devices, interventions, and time on CC formation.

PATIENTS AND METHODS

Search Strategy

This systematic review sought to identify studies using objective strategies for determining severity of CC. Studies directly evaluating (Fig. 1) a proposed measure of CC severity were assessed. A systematic review of the PubMed, Web of Science, and Cochrane databases was conducted in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines[17] for articles (reviewed by A.S.M. and

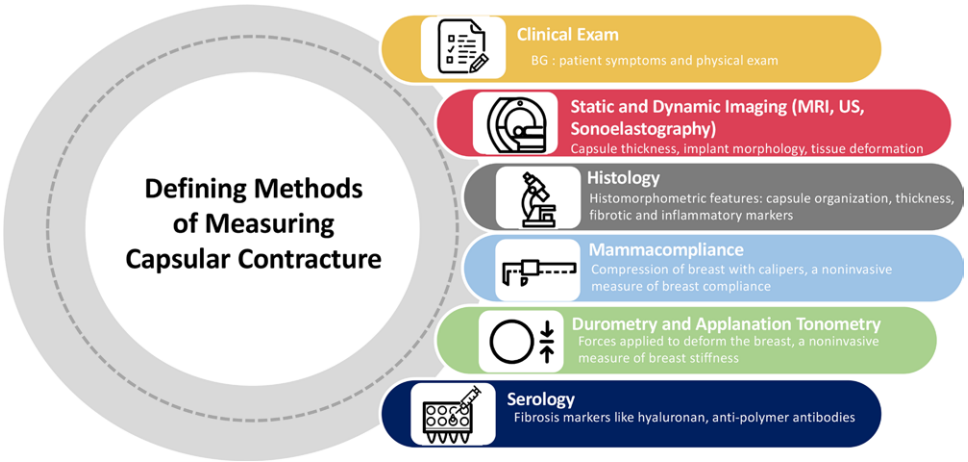

Fig. 1. Approaches used for measuring capsular contracture.

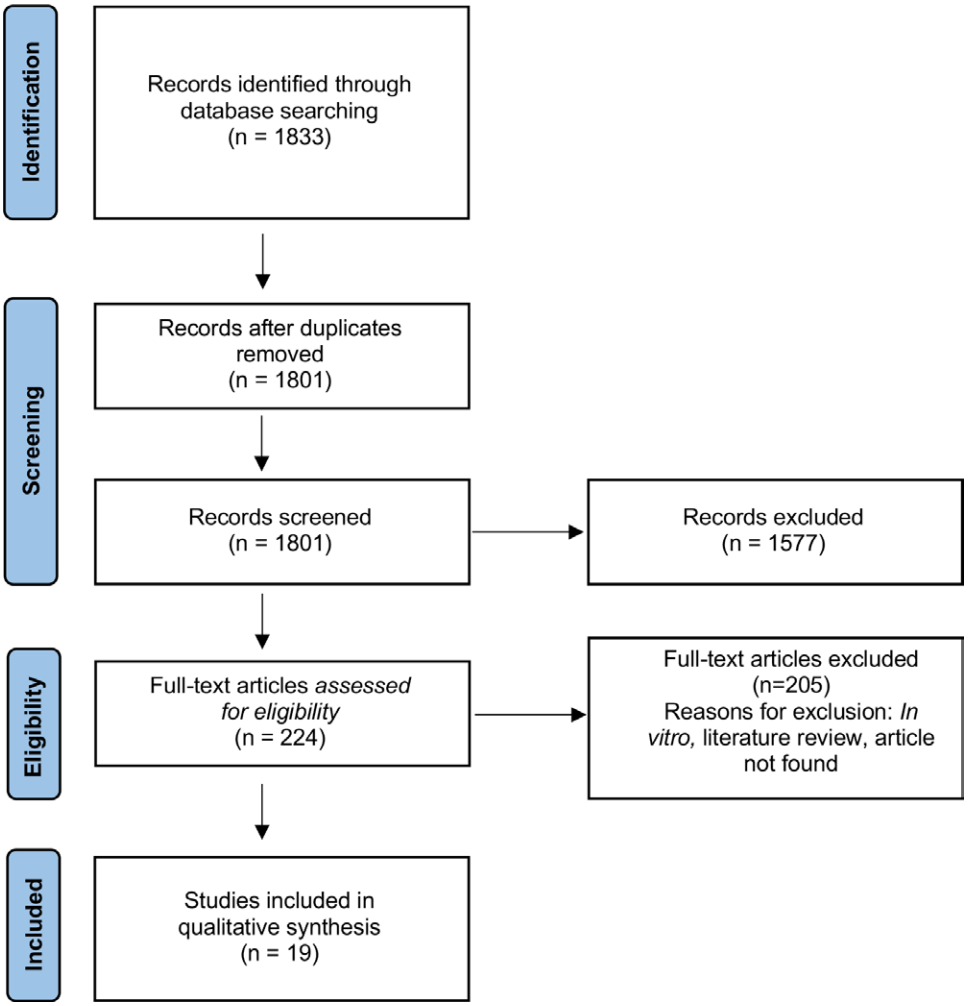

Fig. 2. Screening and study approach performed in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. (From Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71.)

T.M.M.) and published up to September of 2021 (Fig. 2). All articles directly assessing an objective strategy for staging CC against an established standard measure were included. Search terms including "capsular contracture," "Baker grade," "sonoelastography," "mammacompliance," and "breast applanation tonometry" were used. This yielded 19 articles.

Data Extraction

Data extracted from the articles included authors; date of publication; endpoint measures; results; statistical analyses; number of patients; number of samples with distribution by Baker grade; methodology of assigning Baker grade; duration, type, and anatomical location for implant placement; and indication for implant.

RESULTS

Magnetic Resonance Imaging

Investigators have used static imaging such as magnetic resonance imaging (MRI) to determine breast implant capsule thickness as a proxy for CC (Tables 2 and 3). Zahavi et al.[3] found that capsular thickness, as assessed by standard MRI protocols, including silicone and water suppression, was associated with Baker grade ($P = 0.017$) in a study of 20 augmentation and reconstruction patients. In the absence of a correlation statistic, the authors report a statistically significant association between capsule thickness and severity of CC. Capsular thickness in mild Baker grades (I and II) was 1.39 mm, whereas in severe Baker grades (III and IV), it was 2.62 mm ($P = 0.0017$).

Table 2. Imaging for Objective Evaluation of Capsular Contracture Severity

	Reference	No. of Patients or Implants	Indication for Implant	Implant Plane	Implant Surface and Fill	Duration of Implantation when Capsular Contracture Measured	Methodologic Details	Patients According to Baker Grade/ Important Findings
MRI								
MRI and ultrasound	Zahavi et al., 2006[3]	20 patients, 27 implants	Augmentation ($n = 12$) and reconstruction ($n = 15$)	UR	Standard silicone or saline	UR, 0.33–3.66 yr between MRI and clinical/ US evaluation	Measured by single senior plastic surgeon using Baker grade; MRI used to measure capsular anteroposterior and transverse diameters; US used to measure anteroposterior diameter, capsular thickness, and evidence of rupture	I: 13 II: 8 III/IV: 6
MRI	Tyagi et al., 2017[19]	50 patients	Reconstruction	UR	UR	Median time (mo) until MRI for I, II, III: 43.0, 43.5, 43.8; MRI within 6 mo of CC staging	Measured by team of 6 including plastic surgeon; quantified implant roundness, solidity, extent, eccentricity, and ratio length	I: 17 II: 14 III/IV: 19
Elastography								
Shear-wave sonoelastography and ARFI	Jung et al., 2020[23]	16 patients, 25 implants	Augmentation ($n = 7$) and reconstruction ($n = 9$)	UR	PU-coated implant	3 yr	Experienced physician	UR, assigned to breast regionally
Shear-wave and strain elastography	Sowa et al., 2017[24]	20 patients, 27 implants	Reconstruction	UR	Silicone, otherwise unspecified	UR	Two trained plastic surgeons	I: 6 II: 12 III: 5 IV: 4
Shear-wave sonoelastography	Prantl et al., 2014[22]	11 patients, 17 implants	Augmentation ($n = 7$) and reconstruction ($n = 3$)	Subpectoral, inframammary approach	Smooth silicone gel	1 wk–6 yr	Two examiners reached consensus	I: 6 II: 6 III: 3 IV: 2
Shear-wave elastography and tonometry	Paczkowska et al., 2016[20]	13 patients, 26 implants	Augmentation	Dual-plane	Textured, silicone (Allergan)	7 and 14 days, 8.5–21 mo; average, 14.4 mo	Surgeon	UR, III/IV: 0
Shear-wave sonoelastography	Rzymski et al., 2011[21]	2 patients	Augmentation	Subpectoral	UR	6–7 mo	UR	III: 2

UR, unreported; ARFI, acoustic radiation force imaging; PU, polyurethane.

Table 3. Capsular Thickness and Association with Capsular Contracture Severity

	Reference	No. by Baker Grade	Average Capsular Thickness by Baker Grade	Association with CC Severity
MRI				
	Mori et al., 2018[18]	I: 17 II: 52 III: 11 IV: 1	I: 1.1 mm II: 1.2 mm III: 1.4 mm IV: 1.9 mm	No
	Tyagi et al., 2017[19]	I: 17 II: 14 III/IV: 19	I ≈ 0.14 cm II ≈ 0.13 cm III/IV ≈ 0.15 cm	No: Wilcoxon rank sum, I vs. ≥II, 0.020 and ≤II vs. ≥III, 0.414
	Zahavi et al., 2006[3]	I: 13 II: 8 III/IV: 6	I/II: 1.39 mm III/IV: 2.62 mm	Yes
Ultrasound				
	Zahavi et al., 2006[3]	I: 13 II: 8 III/IV: 6	I/II: 1.14 mm III/IV: 2.39 mm	Yes
Histology				
	Prantl et al., 2007[32]	I: 2 II: 10 III: 9 IV: 3	1–10 mm thickness, 3 mm average	UR; $P < 0.05$ noted in abstract, data not provided
	Prantl et al., 2005[34]	UR	Capsules significantly thicker with Baker grade III and IV than Baker grade II	UR; significance verbalized, data not provided
	Tan et al., 2011[52]	I/II: 3 III/IV: 4	0.5–1.4 mm, 0.84 mm average	No, data not provided

An association between MRI and Baker grade has also been studied in patients undergoing only implant-based postmastectomy breast reconstruction.[18,19] Following multiple regression analyses, Mori et al.[18] failed to identify a statistically significant association between capsular thickness and Baker grade severity. Tyagi et al.[19] corroborated these findings, also failing to identify differences in capsular thickness across Baker grades I to IV. Qualitatively, though, implants imaged with MRI assumed a more spherical shape accompanied by increasing severity of CC.[19] They defined and quantified a series of implant characteristics such that higher Baker grades (III and IV) were associated with significantly increased roundness, solidity, and extent and lower eccentricity and ratio length (Table 4). Roundness also distinguished between Baker grades I and II ($P = 0.009$). Ratio length was able to distinguish between both Baker grade I versus II ($P = 0.01$) and Baker grade II versus III or IV ($P = 0.06$), making this the most robust shape feature for distinguishing CC by Baker grade. For subpectoral implants, increasing pectoralis muscle thickness measured in the sagittal plane trended with progressively increasing Baker grade and was able to distinguish between Baker grade I versus III ($P = 0.02$).

Considered together, although a correlation between clinical CC and static MRI measures of capsular thickness remains elusive, a relationship between altered implant morphology and clinical CC holds more promise.

Table 4. Summary of Shape Features Quantified from MRI Images of CC[a]

Parameter	*P* Values for Distinguishing Baker Grade I vs. Baker Grade III and IV	Definition
Roundness	0.001	Similarity to a circle
Eccentricity	0.006	Deviation of elliptical path from circle
Solidity	0.04	Convexity
Extent	0.04	Ratio of area of object to a bounding rectangle, similar to solidity
Ratio length	0.001	Ratio of major and minor axis length

[a]From Tyagi N, Sutton E, Hunt M, et al. Morphologic features of magnetic resonance imaging as a surrogate of capsular contracture in breast cancer patients with implant-based reconstructions. *Int J Radiat Oncol Biol Phys.* 2017;97:411–419.

Ultrasound and Sonoelastography

Zahavi et al.[3] measured capsular thickness with ultrasound (Tables 2 and 3). Patients with Baker grades III and IV had significantly thicker (2.39 mm) capsules than those without clinically significant CC (1.14 mm). These authors subsequently proposed a classification system based

on capsule thickness measured by ultrasound to include (a) no visible capsule, (b) capsules smaller than 2 mm, and (c) capsules larger than 2 mm.

Sonoelastography is an advanced ultrasound technique that quantifies CC by noninvasively measuring the stiffness of tissue (Table 2). Strain elastography uses mechanical compression to deform tissues. Shear-wave sonoelastography uses ultrasonic beams to generate vibrations in tissue. The deformation caused by these transient shear forces, differentially quantified as the Young (elastic) modulus for fatty, glandular, muscular, and pericapsular tissues, provides more granular information on tissue compliance characteristics that may contribute to a firm breast.[20,21] The depth of penetration of the shear waves spans from skin to implant surface, but can also be increased to accommodate very thick breast tissue or submuscular implant placement.[21]

Rzymski et al. first reported use of sonoelastography in two patients who presented with Baker grades III and IV CC following submuscular breast augmentation.[21] Prantl et al. then looked for correlations between Baker grade and shear-wave sonoelastography in 11 patients.[22] A four-point score generated with shear-wave sonoelastography that measured capsule thickness as a proxy for stiffness was strongly correlated (r = 0.89) with Baker grade. To verify the utility of shear-wave sonoelastography, capsular elasticity in 13 healthy patients was followed prospectively after dual-plane breast augmentation for an average period of 1 year.[20] Real-time shear-wave sonoelastography, Baker grade, ultrasonography, and applanation tonometry outcomes were compared with no correlation found. Sample size, length of follow-up, and CC sampling (all patients were Baker grade I or II) significantly limited this study. More recent work found that tissue stiffness measured by either strain or shear-wave elastography positively correlated with increasing Baker grade.[23,24] Sowa et al. evaluated CC in 20 patients with strain and shear-wave elastography and Baker grade following breast reconstruction,[24] and Jung et al. examined 16 patients who had undergone revision following either aesthetic or postmastectomy breast reconstruction surgery.[23] Although both shear-wave and strain elastography analysis of tissue stiffness correlated with Baker grade, Sowa et al. found shear-wave elastography to have the stronger correlation. Interestingly the correlation between shear-wave and strain elastography was found to be weak. This was attributed to user dependence of the mechanical compression-based

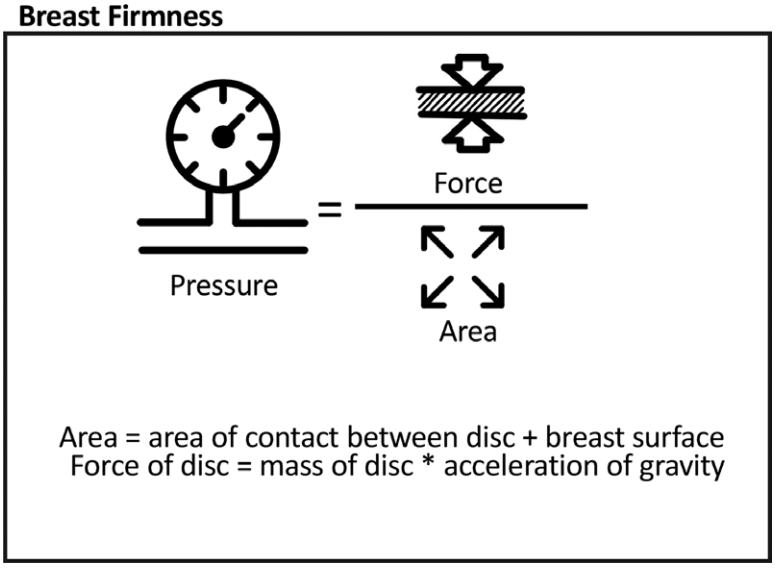

Fig. 3. Applanation tonometry treats the breast as a fluid-filled membrane. It can be performed by placing a flat disk of known weight on the breast. The area of contact created by deformation of the breast against the weighted disk is then measured. Breast firmness is quantified from the equation $P = F/A$, where P is the intramammary pressure, F is a constant determined by the weight of the disk (force of disk = mass of disk × acceleration of gravity), and A is the area of contact between the disk and the breast surface (Moore JR. Applanation tonometry of breasts. *Plast Reconstr Surg*. 1979;63:9–12).

strain elastography method.[24] Thus, ultrasound techniques, both basic and advanced, demonstrate promise for quantification of CC by means of capsule thickness or tissue stiffness.

Tonometry

Applanation tonometry, classically used to measure intraocular pressure, has been adapted to objectively measure breast firmness (Fig. 3) or intramammary pressure.[25] Alone, applanation tonometry is not specific enough to measure CC, particularly when comparing one study to the next, as different implants themselves can be more or less firm independent of their capsule. However, when repeated measures are obtained with the same type of implant and supplemented with other measures such as Baker grade or imaging, it is an objective and inexpensive tool for assessing CC over time.[9,26]

Durometry

Durometry determines the force required to deform the breast, thus providing a measure of breast stiffness (Table 5).[18,27] Baker grade I, II, and III have been associated with durometry values of 0, 0.2, and 2.0, respectively.[18] Whereas durometry correlated with Baker grade in this study, MRI findings did not,[18] perhaps because these modalities were not determined at the same time. Still, the ability of durometry to distinguish contracted from uncontracted breasts, coupled with its ease of use, makes it a potentially attractive approach to supplement Baker grade to longitudinally follow breast implants for CC.

Mammacompliance

In 1982, Burkhardt et al. developed a caliper-based technique to determine breast implant compliance. The breast was compressed between two handles of the caliper and total compression from resting breast diameter was recorded.[28] The Burkhardt calipers have since been iterated (Table 5) to standardize the technique and reduce variability.[29–31] Hoflehner et al. fitted the Burkhardt calipers with a force transducer to standardize compression of the breast and measure distance of implant compressibility versus force.[29] Addition of tissue sensors standardized the degree of skin contact. Mammacompliance quantified tissue compression by setting the calipers to apply a known force to the breast at the widest diameter (Table 5).

Mammacompliance values trended with Baker grade and could easily distinguish between patients with Baker grades I versus IV. With 20 N of set force, proposed cutoffs for grading CC suggested that mammacompliance values of up to 3.6 cm were associated with no CC, from 3.6 to 6 cm mild contracture, whereas values above 6 cm suggested severe contracture. Although the descriptive trend of mammacompliance and Baker grades showed promise in this study, no statistical analyses were conducted to determine the correlation of these findings.

Similarly, Gylbert modified the Burkhardt calipers to apply a preset constant compression force.[30] Breast compressibility was inversely proportional to the distance between caliper tips. At 10 N of standard applied caliper force, a modified version of Baker grade known as the breast augmentation classification scheme showed that breast compliance increased significantly over 1 year. Although this study was not designed to differentiate clinical stages of CC, it supports implementing mammacompliance techniques as an objective standardized metric for CC.

The most recent modification of the Burkhardt caliper for measuring CC (Fig. 4) was reported by Alfano et al.[31] using the Anton Paar Mammacompliance system (Table 5). The modification uses eight caliper positions and automates calculation of an average mammary compliance value. Although this study reports only the average values of mammary compliance and applanation tonometry determined for breasts in each Baker grade, the automation of the Anton Paar Mammacompliance system suggests that compliance can alternatively be quantified as a curve plotted against applied forces. At both 4 and 12 months postoperatively, worse mammary compliance scores correlated with Baker grade and force measures by applanation tonometry. Unfortunately, neither statistical significance nor a correlation coefficient was reported, thus diminishing the utility of these findings.

Thus, although these current works suggest mammacompliance as a promising strategy for quantification of CC, additional statistically rigorous studies are needed to establish the veracity of this approach.

Histology

The Wilflingseder score represents an early attempt to grade CC severity based on histologic characteristics (Table 6). A moderate correlation between the Wilflingseder histologic score and Baker grade ($r = 0.587$; $P < 0.05$) is reported.[32] More recent studies to associate histology with the severity of CC focus on specific histomorphometric features such as capsule organization, thickness, and select fibrotic and inflammatory markers (Table 3). Some characterize the

Table 5. Evaluation of Capsular Contracture with Durometry and Mammacompliance

	Reference	No. of Patients or Implants	Indication	Implant Plane	Implant Surface and Fill	Duration of Implantation When Capsular Contracture Measured	Methodologic Details	Patients According to Baker Grade/ Important Findings
Durometer								
MRI and durometer (this article also assesses static imaging)	Mori et al., 2018[18]	81 patients	Reconstruction	Subpectoral	Various commercial anatomical cohesive gel implants	3 yr for MRI, average of 110.7 mo for Baker grade and durometer	Single senior plastic surgeon measured the force in nanometers required to deform the breast 3 cm above the nipple to a preset depth, normalized on a scale of 1–100; annual durometry and Baker grade alone with MRI every 3 yr used to detect CC following mastectomy implant breast reconstruction	I: 17 II: 52 III: 11 IV: 1 The patient with Baker grade IV CC received a durometer score of 8; receiver operating characteristic curves showed optimal cutoff between no CC (Baker I and II) and CC (Baker III) to be durometer measure of 0.5 (sensitivity 0.92, 1 – specificity, 0.17, area under the curve, 0.92)
Mammacompliance/ caliper								
	Gylbert, 1989[30]	38 patients, 76 breasts	Primary augmentation	Retroglandular, inframammary approach	Heyer-Schulte double lumen with silicone gel and saline	3, 6, 12 mo, POD 10 used as reference	UR	Breast caliper position significantly impacts compliance measures; fixed compression force enough to detect deep capsular firmness without patient discomfort; 10 N of force required as lower measures at 5.2 N did not correlate with CC; force values may need modification for deeper subpectoral implants; normal breast reference values recommended to account for the heterogeneity of breast tissue

(*Continued*)

Table 5. *Continued*

	Reference	No. of Patients or Implants	Indication	Implant Plane	Implant Surface and Fill	Duration of Implantation When Capsular Contracture Measured	Methodologic Details	Patients According to Baker Grade/ Important Findings
	Hoflehner et al., 1993[29]	Compared 59 untreated breasts to 68 implant-augmented or -reconstructed breasts with Baker grade I–III and tested an additional cohort with Baker grade IV to develop a reference range of mammacompliance	Augmentation and reconstruction	Subpectoral	UR	UR	One senior surgeon and one unbiased surgeon, took worse grade; the equation DXn = DX*10 cm/breast diameter was used to calculate mammacompliance (DXn) normalized to a breast size of 10 cm, where DX is the breast diameter at a set force value of X breast diameter is the resting diameter of the breast	I: 45 II: 15 III: 4 IV: 4
Anton Paar Mammacompliance system and applanation tonometry	Alfano et al., 2004[31]	60 patients, 120 implants	Primary augmentation and asymmetry procedures	Retroglandular, inframammary approach	Textured, patient-matched anatomical cohesive silicone gel and round double-lumen with silicone gel and saline	1, 4, and 12 mo	3 evaluators, discrepancies recorded	At 12 mo I: 40 II: 52 III: 19 IV: 9

POD, postoperative day; UR, unreported.

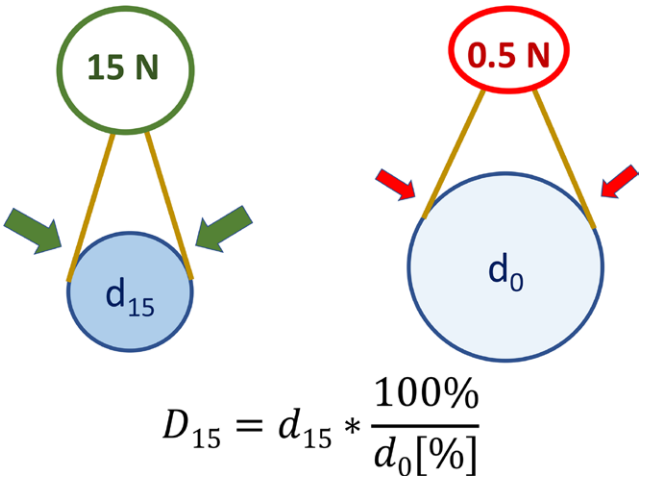

Fig. 4. The Anton Paar Mammacompliance system measures the distance between two caliper-mounted sensors in response to application of a known force. Breast diameters (d_0 to d_{15}) are measured with application of forces ranging from 0.5 to 15 N (Alfano C, Mazzocchi M, Scuderi N. Mammary compliance: an objective measurement of capsular contracture. *Aesthetic Plast Surg*. 2004;28:75–79).

Table 6. Wilflingseder Histologic Grading Scale for Capsular Contracture[a]

Type	Histologic Characteristics
I	Ideal, thin capsule
II	Evidence of constrictive fibrosis
III	Constrictive fibrosis with giant cells
IV	Constrictive fibrosis; giant cells; and additional vascularization, granulomas, and inflammatory cells

[a]Prantl L, Schreml S, Fichtner-Feigl S, et al. Clinical and morphological conditions in capsular contracture formed around silicone breast implants. *Plast Reconstr Surg.* 2007;120:275–284.

periprosthetic capsule as a consistently trilaminar structure (Table 6) that includes a luminal first layer composed of fibroblasts, macrophages, or a pseudosynovial lining. A second layer consists of loose connective tissue, whereas a third is composed of dense connective tissue.[4,32] By contrast, others have noted substantial variability,[33] with capsule architecture ranging from a single layer of collagen fibers to multiple layers of fibers with different densities and organization. Despite this architectural heterogeneity, progression from thin, loosely packed fibers in softer capsules to thick dense fibers in contracted capsules is noted.[33] Multiple studies also report synovial metaplasia at the capsule-implant interface.[4,32–35] Synovial metaplasia, hypothesized to be a response to mechanical stress to lubricate the interphase between the capsule and implant,[33] is more commonly reported in lower than higher Baker grade implant capsules (Table 7).[33,35]

Capsule thickness is the most frequently studied CC metric quantified by both imaging and histology (Table 3). Still, consistent correlation between histologic capsule thickness and severity of CC remains elusive. Most,[32,34,35] but not all,[36] studies report that capsular thickness positively correlates with Baker grade (Table 7). Bui et al. suggest a more nuanced association with a significant difference in capsule thickness based on increased duration of implantation and between Baker grade I and II versus III and IV, but not incrementally between Baker grades II, III, and IV.[33]

Potential relationships between the severity of CC and specific markers of fibrosis and the immune response remain inconsistent. Compared with Baker grade III and IV (Table 7), Baker grade I and II capsules manifest a T-cell infiltrate ($CD3^+$, $CD25^+$) in the pseudosynovium directly adjacent to the implant that skews toward a regulatory phenotype ($Foxp3^+$, $CD25^+$).[4,37] In primary cell culture, ex vivo regulatory T cells from Baker grades I and II capsules have a stronger capacity to suppress effector T cells than regulatory T cells cultured from Baker grade III and IV capsules, suggesting a role for effector T cells in worsening fibrosis.[37] Elevated silicone deposition and inflammation in capsules has been associated with thicker capsules and more severe clinical symptoms,[32] whereas a trend toward increased myofibroblasts is identified in Baker grade III and IV versus I and II capsules.[33] HA and TSG-6 are associated with lower Baker grades,[36] whereas there appears to be no relationship between Baker grade and the expression of toll-like receptors (TLRs) (Table 6).[38]

Serology

A link between expression of systemic markers of fibrosis and severity of CC makes intuitive sense.[34] Prantl et al. examined the relationship (Table 8) between Baker grade and serum fibrosis markers.[34] Serum levels of hyaluronan were significantly higher in patients with CC versus breast reductions without implants. A positive correlation between Baker grade and hyaluronan ($r^2 = 0.73$; $P < 0.05$) was found, whereas no correlation was found with aminoterminal propeptide of procollagen type III.

Wolfram et al.[39] found that the serologic markers antipolymer antibodies, procollagen type III, and circulating immune complexes were significantly higher in patients with Baker grades III and IV compared with Baker grades I and II and women with no breast implants (Table 8). Only circulating immune complexes, though, were shown to increase over controls from Baker

Table 7. Studies Assessing Association of Histologic Markers with Capsular Contracture

Reference	No. of Breast Capsules	Aim	Model	Approach	Findings
Prantl et. al., 2005[32]	24	Correlate Baker grade and Wilflingseder score	Breast augmentation	Correlations between the 4-point Wilflingseder score and Baker grade; capsule thickness measured; silicone deposition and inflammation measured	Moderate correlation between Wilflingseder score and Baker grade ($r = 0.587$; $P < 0.05$); 12 of 24 patients between the classification systems matched; three structural layers conserved for Baker grade I–IV; capsule thickness correlated positively with Baker grade; capsule thickness also positively associated with elevated silicone deposition, inflammation, and more severe clinical symptoms
Bui et al., 2015[33]	41	Correlate Baker grade and capsule histology	Submuscular and subglandular aesthetic and reconstructive implants	Presence of myofibroblasts, vector-based quantitative assessment of collagen fiber alignment and capsule thickness	Capsule architecture varied from single layers of collagen to multiple layers with heterogeneity in density and organization; synovial metaplasia of inner layer more common in Baker grade I and II than Baker grade III and IV; trend toward thick dense fibers in contracted capsules vs. thin, loosely packed fibers in the absence of CC; collagen fiber alignment increased with Baker grade but not duration of implantation; capsule significantly thicker in Baker grade III and IV vs. I and II but thickness differences not identified in Baker grade II, III, and IV; capsule thickness positively correlated with duration of implant ($r^2 = 0.151$; $P = 0.0076$); a trend, but no statistical significance, between higher α-SMA levels and Baker grade III and IV vs. Baker grade I and II; no relationship with CD68 (macrophage marker)
de Bakker et al., 2018[35]	20	Correlate histology of inner capsule layer with Baker grade	Unilateral CC after breast augmentation in 10 women with 20 explanted textured breast implants	Immunohistochemistry used to identify CD68 (macrophages), cytokeratin (epithelial cells), vimentin (fibroblasts) and H&E for morphology; cell density, presence of inner layer, and capsule thickness recorded	The presence of a pseudoepithelial or synovial-like inner layer was significantly more common in Baker grade I versus IV capsules ($P = 0.031$); all Baker grade I capsules showed an inner layer that was vimentin and $CD68^+$ and cytokeratin-negative ($P = 0.004$)
Prantl et al., 2005[34]	25	Correlate Baker grade, capsule histology, and serum fibrosis markers	Submuscular breast augmentation, smooth silicone implants	Examined relationship between Baker grade, histology, and serologic markers after blood draws and explanted capsule analyses	Capsule tissue consistently thicker with Baker grade III and IV than Baker grade II; synovial metaplasia and multinucleated giant cells identified in inner layer; activated $CD4^+$ cells, and multiple cell types, predominantly fibroblasts and macrophages but also polymorphonuclear leukocytes, lymphocytes, plasma, and mast cells identified in capsules
Tan et al., 2011[36]	7	Correlate Baker grade and expression of HU, TSG-6, and polypeptides in breast capsules	Textured ($n = 5$) and smooth ($n = 2$) implant capsules	Immunohistochemistry to identify HU, TSG-6, bikunin, heavy chain 1 and 2 was performed in samples of superior, inferior, anterior, and posterior capsules from Baker grade I–IV; TSG-6 gene expression levels through RT-PCR	Increased Baker grade correlated with less free HU ($r = -0.645$; $P < 0.001$) and TSG-6 ($r = -0.642$; $P = 0.002$) staining; escalating Baker grade negatively correlated with TSG-6 gene expression ($r = -0.0750$; $P = 0.001$) by RT-PCR

(*Continued*)

Table 7. *Continued*

Reference	No. of Breast Capsules	Aim	Model	Approach	Findings
Wolfram et al., 2004[4]	19	Analyzed the cellular and molecular composition of fibrous capsules	Baker grade III and IV ($n = 8$), concern for cancer recurrence ($n = 3$), aesthetic revision ($n = 4$)	Immunohistochemistry for lymphocytes, macrophages, dendritic cells, fibroblasts, smooth muscle, extracellular matrix proteins, HSP60 and adhesion molecules	Interface between capsule and implant included palisade-like single or multilayered cells containing $HSP60^+$ macrophages and fibroblasts; $CD4^+$ T cells expressing CD25 and CD45R0 and massive expression of ICAM-1 and macrophages underlie contact zone; inner capsule expressed fibronectin and tenascin
Wolfram et al., 2012[37]	37	Studied activation of the immune response in breast implant capsules by assessing T-lymphocyte phenotypic expression	Majority of capsules from silicone implants after various indications for reoperation.	Immunohistochemistry and functional suppression assays used to study T regulatory cells; the proportion of T-regulatory cells ($CD4^+$ CD25 $Foxp3^+$ CD127), T-cell receptor characteristics, and cytokine profiles in intracapsular lymphoid cells and peripheral blood mononuclear cells determined with flow cytometry	Relative to peripheral blood mononuclear cells, intracapsular lymphocytes demonstrated elevated $CD4^+$ cells; intracapsular T cells expressed IL-17, IL-8, TGFß1, and IF-γ; findings suggested a TH1/TH17 weighted local immune response, and a restricted T-cell receptor alpha/beta repertoire among intracapsular T cells; together, data suggest fibrosis around implant capsules results from dysfunction of local T-regulatory cells
Bachour et al., 2019[38]	50	Studied expression of pattern-recognition TLRs in increasing grades of CC	Capsule samples harvested at time of implant exchange for any reason; 94% aesthetic cases, and 5% reconstructive	qRT-PCR used to test for and quantify cDNA. Concentration of TLR1–10 related to clinical Baker grade	No relationship between Baker grade and TLR1–10 concentrations established

α-SMA, alpha-smooth muscle actin; H&E, hematoxylin and eosin; HU, hyaluron; TNF, tumor necrosis factor; TSG-6, TNF, stimulated gene-6; HSP60, heat shock protein 60; ICAM-1, intercellular adhesion molecule-1; IL, interleukin; TGF, transforming growth factor; IF, interferon; qRT-PCR, quantitative polymerase chain reaction; TLR, toll-like receptor.

Table 8. Studies Assessing Association of Serologic Markers with Capsular Contracture

Reference	No. of Breast Capsules	Aim	Model	Approach	Findings
Prantl et al., 2005[34]	25	Correlation of Baker grade, serum fibrosis markers, and capsule histology	Submuscular breast augmentation, smooth silicone implants	Examined relationship between Baker grade and serologic markers (HU, PIIINP) after blood draws and histologic analysis	Serum HU higher in patients with capsules than breast reduction controls; positive correlation between Baker grade and HU ($r^2 = 0.73$; $P < 0.05$); no correlation with PIIINP
Wolfram et al., 2008[39]	93	Correlation of silicone implants, systemic inflammatory disease, and Baker grade	Breast augmentation, silicone implants	Examined serologic markers APA, PI, PIII, CIC, cANCA, ANA, CL-Ab, RF, C3, C4, sICAM-1 in controls vs. Baker grade 1 and 2 vs. Baker grade III and IV	APA, PIII, and CIC significantly higher in Baker grade III and IV compared with I and II; but only CIC increased progressively from no implants through higher Baker grades; serologic markers did not increase over time from 1 to 5 yr; no associations were identified between Baker grade and PI, cANCA, ANA, CL-Ab, RF, C3, C4, or sICAM-1

HU, hyaluron; PIIINP, aminoterminal propeptide of procollagen type III; APA, antipolymer antibodies; PI, procollagen type I; PIII, procollagen type III; CIC, circulating immune complexes; cANCA, antineutrophil granulocyte cytoplasmic autoantibodies; ANA, antinuclear autoantibodies; CL-Ab, anticardiolipin antibodies; RF, rheumatoid factor; C3, complement component C3; C4, complement component C4; sICAM-1, human soluble intercellular adhesion molecule-1.

grades I and II, and progressively on to Baker grades III and IV. None of the evaluated markers showed progressive elevation over time from 1 to 5 years, suggesting that serologic markers are not impacted by duration of implantation.

DISCUSSION

Our review verifies that Baker grade is by far the most common approach used to quantify CC, given its simplicity, cost-effectiveness, and broad adoption. Baker grade serves as the accepted standard against which several clinical, serologic, and histologic measures have been compared. Since it was initially described, though, Baker grade has been used to describe CC in contexts where it is either highly unlikely, or even impossible for the periprosthetic pocket to have contracted. Hirsch et al.[40] recommended a nuanced change for irradiated patients to direct clinical management, adding an "R" to Baker grade to indicate involvement of deeper layers such as muscle or capsule, and "RS" to also indicate skin involvement. Moreover, in prepectoral reconstruction where an ADM is used and an actual capsule does not even form, any contracture that occurs following radiation therapy may be attributed to radiation-induced fibrosis of the skin, subcutaneous fat, ADM, or muscle rather than capsule.

Our review suggests that with limited strength of evidence and no single metric to discretely measure true CC, a multipronged approach for CC assessment may be best (Fig. 5). Static imaging with either ultrasound or MRI (Tables 2 and 3) to assess capsule thickness demonstrates limited utility, as some studies have found an association with Baker grade,[3] whereas others, especially in reconstruction-only cohorts, have not.[18,19] One explanation for this discrepancy may be the inherent imprecision of the Baker grade scale itself and the misclassification as Baker grades III or IV of patients undergoing breast reconstruction. Changes in breast implant morphology imaged with MRI (Table 4) may hold promise as a more sensitive measure of CC, but they have not gained traction as a reported outcome metric likely because of cost and access.[19] Ultrasonography is more accessible and increasingly performed by plastic surgeons,[41] but as capsule thickness remains a debatable proxy of CC, its value is limited (Tables 2 and 3). Sonoelastography, however, offers a more robust assessment by quantifying capsule stiffness. Shear-wave—more so than strain—sonoelastography offers a more sensitive analysis of stiffness of the implanted breast and distinguishes between the contributing tissue planes.[24] Moreover, simultaneous detection of seromas, masses, and device ruptures can be assessed. However, these advantages must be balanced against the limited availability and the specialized training required to apply sonoelastography.[22] Caliper-based techniques that measure

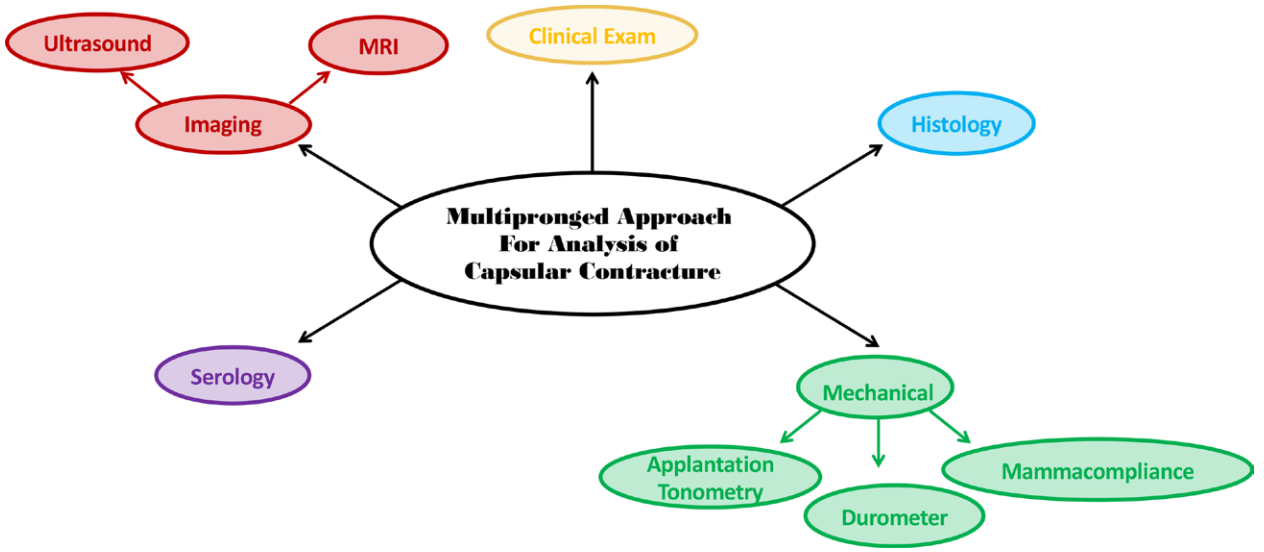

Fig. 5. Multipronged approach for the analysis of CC.

mammacompliance are promising options for measuring tissue stiffness with less technical requirements. In fact, Moore's approach can provide an inexpensive and accessible measure of intramammary pressure that complements Baker grade.[9,26,42] This assessment must account for differential contributions from the breast parenchyma versus the implant and capsule. Histologic and serologic analyses of CC have limited utility given their invasive nature and cost, but they provide a more granular characterization of the periprosthetic capsule with promising utility for continued evaluation of CC in the laboratory. The finding of synovial metaplasia, consistently identified along the luminal surface of the implant capsule in Baker grades I and II, but not III and IV, may be the most sensitive marker for CC.[4,32–35]

To address the current limitations of CC reporting, we would make several recommendations. First, Baker grade should remain the primary modality for confirming a CC diagnosis in today's clinical practice. A given patient can serve as their own control such that increasing Baker grade over time can reasonably be attributed to CC. A Baker grade III or IV should suffice for documenting pathologic CC in communications with breast implant vendors when managing warrantied cosmetic breast implants and obtaining preauthorization from insurance payers when performing corrective operations in reconstructive cases.

In the setting of research, though, investigators should report CC outcomes more precisely and use a multimodal approach (Fig. 5). CC is one of the most consequential adverse outcomes in plastic surgery and should be characterized with precise and reproducible metrics to enable comparisons of patients and studies to one another across devices and techniques. This would better enable compartmentalization of the impact of the capsule itself versus the multiple other unrelated factors that can impact Baker grade. As plastic surgery research uses more sophisticated methods to study the cause and mitigation of CC,[43–47] it behooves us to have more sensitive and specific measures so the conclusions of our studies are more impactful. Although a clinical Baker grade III or IV may be attributable to pathologic CC, it may also be affected by skin or pectoralis muscle fibrosis, an overfilled saline implant, or a more cohesive gel implant. In such cases, it would be more accurate to report these outcomes quantitatively using metrics such as intramammary pressure, mammacompliance, or mammometrics to report skin surface area because it is not necessarily clear that CC is the root cause of disease. Similarly, the lack of Baker grade III or IV CC in a prepectoral breast implant wrapped in an ADM should be intuitive because the absence of a true capsule precludes its ability to contract in the first place.[48–51] In this case, Baker grade can still provide a useful quantitative description of the palpability and firmness of the reconstruction, but not of the degree of CC because there is no capsule. By increasing the number of data points used to evaluate CC, investigators will be more likely to identify changes resulting from a particular implant, technique, or intervention.

In research studies that follow patients through capsulectomy and implant exchange or explantation, we recommend performance of quantitative histology (histomorphometry).

Researchers should evaluate capsule thickness using approaches that limit sampling bias, reporting the presence or absence of synovial metaplasia, and using immunohistochemistry to report the presence and relative density of relevant CC markers such as $CD3^+$, $CD25^+$, $Foxp3^+$, HA, TSG-6, and alpha-smooth muscle actin. Recognizing that CC is, by definition, a dynamic process, it should be reported longitudinally with repeated measures to show change over time. Finally, studies choosing to report CC as an outcome metric should acknowledge the factors that may confound their measures.

CONCLUSIONS

When clinically evaluating a particular patient over time, Baker grade remains a valuable tool for informing the decision to operate. In research studies, though, a more comprehensive analysis of CC is needed to precisely define outcomes that can be directly compared between different patient populations and studies. Many approaches to measure CC have been developed, but no single tool reliably and specifically measures the contracture of the breast implant capsule. This limitation can be mitigated to an extent through implementing a multipronged approach for measuring CC, limiting variables that can confound the measure of CC, and using repeated measures over time to define the dynamic nature of contracture.

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