Original Article: Clinical Science

American Academy of Cosmetic Surgery

The American Journal of Cosmetic Surgery
2020, Vol. 37(4) 189–194

DOI: 10.1177/0748806820925722
journals.sagepub.com/home/acs
SAGE

A Durometer (Mammometer) for Objective Measurement Capsular Contraction Following Breast Implant Surgery

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Abstract

The importance of measuring breast firmness reproducibly to monitor postsurgical progress has been appreciated for many years. This study ascertains whether a durometer can be used to quantify capsular contraction and to provide an objective, reproducible measure of fibrosis around an implant. Patients with clinically detected Baker 3 or 4 capsules following breast augmentation underwent firmness measurements using a durometer prior to corrective surgery. Durometry was undertaken on both breasts by an operator who was blinded to the clinical diagnosis. Firmness measurements were taken in each breast quadrant and directly over the nipple-areolar complex on each side. In the study, 16 patients were included. Capsules presented 16 to 714 weeks following surgery (mean 217, standard deviation (STD) 205.4 weeks). Differences in pressure were demonstrated in all quadrants of the breast and at the nipple-areolar complex except the lower inner quadrant. All significant differences demonstrated a higher pressure in the encapsulated breast. The mean pressure in an encapsulated breast was 0.66 kPa (STD 0.25) and 0.46 kPa (STD 0.16) in the normal breast. The durometer can reproducibly describe changes in pressure associated with capsular contraction compared with the contralateral breast. It provides a means of objectively describing capsular contraction following breast augmentation surgery for research and patient care.

Keywords

breast augmentation, capsular contraction, durometry

Background

Although palpation has been used for centuries as a means of firmness of human tissues in surgical practice, it is very subjective and extremely operator and experience dependant. Replication of what 1 surgeon may feel is almost impossible to describe to other practitioners in a reproducible manner.

The importance of measuring breast firmness to monitor postsurgical progress, whether it is a normal or pathological course, after breast implant surgery has been appreciated for many years.[1] An objective measurement of breast firmness is required to document postoperative issues such as resolution of swelling, development of capsular fibrosis, and potential changes associated with implant rupture. Several technologies have been adapted to address this dilemma, using applanation tonometry and caliper deformation or "mammary compliance." The concept of mammary compliance was introduced by Barker[2] who identified the need for an objective measure of postsurgical firmness. The device was a spring caliper which could manually deform the breast with a fixed force, measuring the deformation on a scale, which could be correlated by the operator to the clinical state.

Previously, we have demonstrated that a durometer[3] can be used to detect resolution of swelling following breast implant surgery in a reproducible manner

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Figure 1. The durometer.

(Figure 1). The durometer is designed to generate a stable and calibrated deformation of the breast from which it can calculate and store the force necessary to make this deformation in a reproducible manner (Agrosta, Serqueux, France). It uses a pressure transducer (range: 0-34 kg/m s^2 or Pa), and a signal conditioner is based on the HX711 processor which provides 24-bit data. The pressure range of 34 Pa is divided by 16 777 216 increments, producing a high accuracy.

Currently, capsular contraction is measured using the Baker[1] scale, which is a subjective clinical assessment of breast firmness. It is not standardized between observers and provides no gradation within the categories. Consequently, research on the topic is highly subjective, as the clinical grading system currently employed cannot distinguish in a noncategorical manner the degree of capsular contraction.

The aim of this study is to ascertain whether the durometer previously described for measuring postoperative swelling following breast implant surgery can be used to detect capsular contraction and to provide an objective, reproducible measure of fibrosis around an implant. The study tests the null hypothesis, that is, there is a difference between the firmness of the left and right breast measurable in an objective manner at the time of presentation with a clinically graded capsule using a durometer. As such, this outcome would provide a means of objectively describing capsular contraction following breast augmentation surgery and would permit further research to describe the natural history of the condition when used to follow a single patient over time following breast implant surgery.

Materials and Methods

Study Design

The study is a prospective, observational design of a cohort of patients undergoing breast implant surgery who represent with a capsular contraction following breast implant surgery.

Description of Technology

The durometer (Figure 1) was designed to generate a stable and calibrated deformation of the breast from which it can calculate and store the force necessary to make this deformation in a reproducible manner (Agrosta, Serqueux, France). It uses a pressure transducer (range 0-34 kg/m s^2 or Pa), and a signal conditioner is based on the HX711 processor which provides 24-bit data. The pressure range of 34 Pa is divided by 16 777 216 increments, producing a high accuracy. We have previously reported that the instrument produces acceptable interobserver and intraobserver error.[3] The approximate cost of the device at the time of writing was US $5200 inclusive of worldwide shipping.

Patients

All patients provided written consent to the study under the guiding principle outlines in the World Medical Association Declaration of Helsinki concerning ethical principles for medical research involving human participants.

All patients underwent subfascial breast augmentation via an inframammary crease incision as previously reported under the care of a single surgeon.[4] Exclusion criteria were patients who have undergone previous revisional breast implant surgery or had undergone surgery at another clinic for which there were no presurgical data. Inclusion criteria were patients for whom breast augmentation represented the first procedure on their breasts at our clinic who subsequently presented with a clinical capsular contraction.

Patients presenting with a Baker grade 3 or 4 capsule clinical capsular contraction underwent firmness measurements prior to corrective surgery, at the time of presentation with a clinically detected capsule. Durometry was undertaken on the left and right breast by an operator who was blinded to the clinical diagnosis (Figure 2). All measurements were taken with the patient lying at 45° by the same observer on each occasion. Firmness measurements were taken in each breast quadrant and directly over the nipple-areolar complex on each side.

Statistical Analysis

Data for clinically encapsulated breasts were pooled for each area, as was those data for what was deemed a normal breast. Paired parametric *t* tests were employed to examine firmness at each quadrant and nipple-areolar complex, for the clinically encapsulated breast compared with the contralateral, unaffected breast. Significance was taken at a *P* value less than .05.

Results

In the study, 16 patients were included, 12 with right-sided capsule. Details of participants and the implants are shown in Table 1. Capsules presented 16 to 714 weeks following surgery (mean 217, STD 205.4 weeks).

Pressure measurements at each quadrant of the breast and nipple-areolar complex are shown in Table 2. Significant difference between the encapsulated and non-encapsulated breast was taken as a P value less than .05.

Differences in pressure were demonstrated in all quadrants of the breast and at the nipple-areolar complex (Figure 3) except the lower inner quadrant (LIQ). All significant differences demonstrated a higher pressure in the encapsulated breast. The mean pressure in an encapsulated breast was 0.66 kPa (STD 0.25) and 0.46 kPa (STD 0.16) in the normal breast.

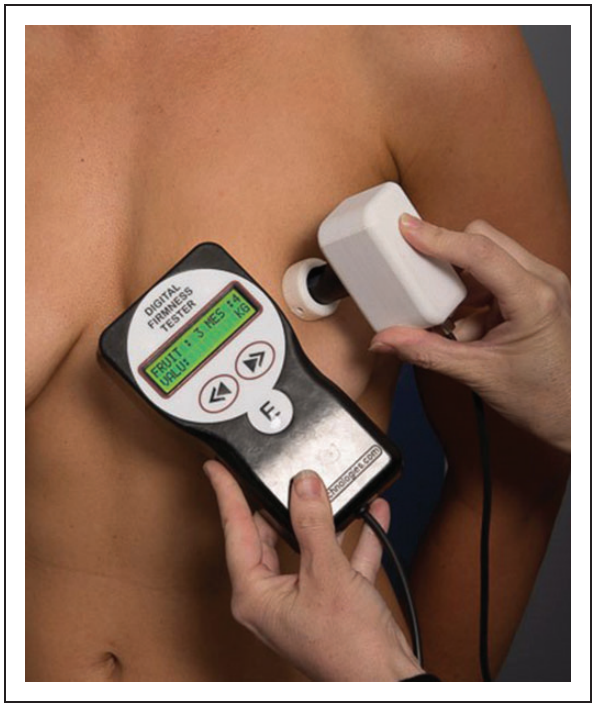

Figure 2. The durometer in use.

Discussion

Comparison With Previous Firmness-Measuring Devices

The technology on which the durometer is based has been validated in other biological systems such as the dairy, meat, and fruit industry.[5] The problem of inter-observer and intraobserver error has been a particular issue, which has been resolved with this technology prior to applying it to breast surgery.

Consequently, the durometer described in this work has advantages over previous technologies in that it generates reproducible data when used by a single operator and also multiple operators. Previous attempts to measure breast firmness have either used a single operator to undertake measurements[2] or acknowledged the differences between operators,[6,7] while others have failed to address the issue of interobserver or intraobserver error.[8–12] Without interobserver and intraobserver validation, results derived from previous technologies are, at best, approximations and cannot be used as reliable research tools between researchers.

Method of Usage on the Breast

Only tonometry-based devices[10,12] measure breast firmness at multiple sites, whereas those utilizing mammary compliance undertake a single assessment of firmness based on a 2-point compression. The breast tissue is unevenly distributed, and a mass measurement produced by a caliper is therefore inaccurate. Previously, we have reported[3] that most variability for pressure measurements is at the LIQ, which we regard as an unreliable site for testing, and this present study confirms that result.

Limitations

Although we have previously reported good interobserver and intraobserver reproducibility with the durometer, accurate use of the device does require some familiarity with its application. In particular, attention

Table 1. Details of Patients and Implants.

	Age (years)	BMI (kg/m^2)	Width (cm)	LSM (mm)	Implant volume (cc)
N	16	16	16	16	16
Minimum	23.0	17.8	12.40	10	300.00
Maximum	63.0	28.4	16.00	30	520.00
Median	41.5	22.2	14.00	20	440.00
Mean	41.6	22.6	14.15	21	414.38
Variance (n − 1)	153.3	9.7	0.81	35	4789.58
Standard deviation (n − 1)	12.4	3.1	0.90	5.94	69.21

Note. LSM = lateral sternal margin; BMI = body mass index.

Table 2. Pressure Values in Each Area of the Breast Comparing Encapsulated to Normal Side.

	n	Minimum (kPa)	Maximum (kPa)	M (kPa)	SD	*P* value
CLIQ	16	0.290	0.840	0.524	0.169	.007*
Non-LIQ	16	0.200	0.600	0.382	0.098	
CLOQ	16	0.310	0.780	0.541	0.159	.003*
Non-LOQ	16	0.270	0.530	0.401	0.069	
CNAC	16	0.190	1.050	0.646	0.236	.006*
Non-NAC	16	0.150	0.620	0.431	0.163	
CUIQ	16	0.290	0.840	0.554	0.163	.977
Non-UOQ	16	0.160	0.890	0.556	0.198	
CUOQ	16	0.280	1.500	0.783	0.289	.015*
Non-UOQ	16	0.160	0.890	0.556	0.198	

Note. The prefix "c" denotes encapsulated breast, and "non," a normal breast. LIQ = lower inner quadrant; LOQ = lower outer quadrant; NAC = nipple-areolar complex; UIQ = upper inner quadrant; UOQ = upper outer quadrant.
*Significant difference between encapsulated and normal breast.

should be made in application of the probe perpendicular to the test area.

One problem when employing durometry to measure changes in a breast over time is that changes in body composition such as fat loss or gain can influence the data. Breast firmness depends on many variables, including skin elasticity, ratio of glandular to adipose tissue, hormonal influences, firmness of the implant, and the surgical plane in which the implant is placed. As such, differences between breasts represent a useful control when dealing with individuals. However, once research investigations are undertaken, provided that measurements are taken for both breasts, nonparametric tests can be used to look for differences between sides. When comparing 2 treatment groups, given that there is normality in the distribution of firmness,[3] a similar statistical approach remains valid when using equipment which has acceptable interobserver error.

Consequently, it is our practice to measure weight, under girth, and fat thickness at the lateral sternal margin, along with a series of previous described morphometric measurements on each occasion that firmness is measured to quantify changes.[13] These considerations do not apply to the present study which examines a fixed endpoint of presentation with a capsular contraction.

Assessment of Capsular Contraction

Since the classic description of capsular contraction by Baker, it has been universally accepted that grading remains a deeply subjective clinical assessment.[14] It is often only at an endpoint, when patients present with a painful grade 4 capsule that a surgeon is aware of the condition, having not been afforded an opportunity to see encapsulation developing in its earlier stages.

A number of attempts have utilized both tonometry[10,12,15] and mammary compliance[6,7,9,11,16] to quantify capsular fibrosis objectively following breast augmentation surgery. Burkhardt et al[8] highlighted that a caliper system compresses the implant but makes the point that in distensible capsule, excessive force would be required to rupture the capsule for an accurate measurement and that, therefore, it cannot be used as a standardized measurement of compressive force itself. It makes the point that there is good correlation between their caliper system and Baker's grading. We would argue that the objective measurement cannot equate to a subjective measurement, which is the antithesis of each other, and the argument is fundamentally flawed. The mammometer in this study is able to produce a continuous rather than categorical measure of contraction.

The primary reason for measuring breast firmness lies both in research and patient management. Currently, there is no objective measure by which breast firmness can be communicated in a reproducible fashion either between surgeons or even by 1 surgeon at different times. Capsular contraction remains the commonest complication following breast implant surgery, and considerable effort has been put into reducing its incidence. The effectiveness of such measures such as surface texture, irrigation with antibiotics or steroid, or various surgical maneuvers can only be assessed by epidemiological studies of a large number of patients in whom different treatments have been employed. Unfortunately, without a defined outcome measure, even these gross studies remain inaccurate and dependant on an individual's assessment of the endpoint.

Adoption of routine durometry as part of a primary breast examination before and after surgery will yield valuable data concerning these interventions. Similarly, the natural progression of capsule formation can be followed, which could lead to information about its pathogenesis. There are implications of this methodology for the implementation of the capsular contraction warranty provided by many implant manufacturers.

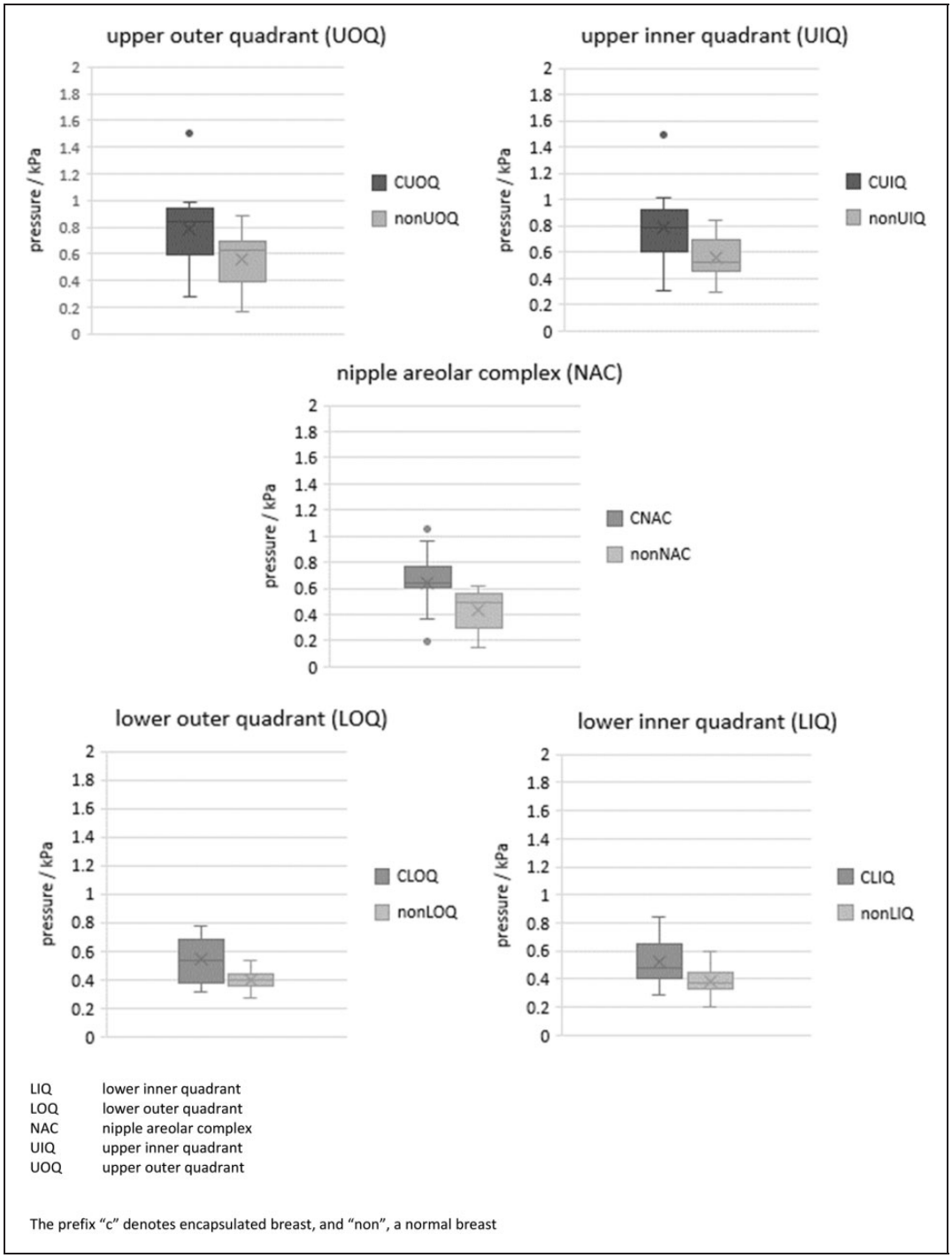

Figure 3. Pressures at different regions of the breast (kPa) comparing encapsulated with normal side.
Note. The prefix "c" denotes encapsulated breast, and "non," a normal breast. LIQ = lower inner quadrant; LOQ = lower outer quadrant; NAC = nipple-areolar complex; UIQ = upper inner quadrant; UOQ = upper outer quadrant.

We have successfully used the durometer to assess patients presenting with an acute swelling of the breast secondary to a presumed pericapsular tear, and to follow up the resolution of the increased firmness over a short period, without the need for more invasive imaging.

Further studies being considered include a longitudinal study observing a series of implants over a prolonged period such that early development of capsular contraction could be identified, and whether early nonsurgical treatment might alter long-term outcomes.

Conclusion

The durometer can reproducibly describe changes in pressure associated with capsular contraction compared with the contralateral breast. As such, this outcome would provide a means of objectively describing capsular contraction following breast augmentation surgery, and would permit further reproducible research to describe the natural history of the condition and treatments to ameliorate this common complication.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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Tim Brown is a plastic surgeon specializing in evidence based cosmetic surgery.