

# Breast Durometer (Mammometer): A Novel Device for Measuring Soft-Tissue Firmness and Its Application in Cosmetic Breast Surgery



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**Abstract** The measurement of soft-tissue firmness has many potential applications in medical practice. This study reports a user-friendly, novel device that is capable of measuring changes in soft-tissue firmness in a reproducible manner. The study reports the development of the equipment and how it has been applied to breast implant surgery. The device was tested for both intra- and inter-observer variability on an in vitro model, using a breast implant. Once reproducibility was confirmed, breast firmness was measured on a series of patients who underwent sub-fascial breast augmentation ( $n = 50$ ) to examine how it varied post-operatively. Firmness in the upper half of the breast increased to a maximum level two weeks post-surgery (0.44–0.61 Pa), reducing to pre-operative levels by 6 weeks (0.37–0.54 Pa). There was no further significant change at 12 weeks. Firmness in the nipple areolar complex (NAC) and at the lower outer quadrant (LOQ) followed a similar pattern, but remained firmer at 12 weeks. We interpret these patterns as implying that measurements taken at the upper half of the breast are indicative of post-operative oedema, whereas those at the NAC and LOQ represent changes in firmness produced by the breast implant composite. We consider the potential for this novel device in the measurement of soft-tissue firmness in aesthetic breast surgery and would encourage other researchers to explore novel applications.

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**Keywords** Breast · Firmness · Tissue turgor · Measurement

## Introduction

Palpation has been used for centuries as a means of ascertaining soft-tissue quality in many areas of medical and surgical practice. However, it is a very subjective test that is extremely operator and experience dependant. Replication of what a medical practitioner feels requires an objective means of dynamic palpation to measure and quantify that changes in viscoelastic properties soft-tissue can exhibit under certain conditions (whether pathological or rehabilitation) compared with the normal state. Clinically, detection of firmness for a single observer could claim to have a degree of reproducibility; however, that assessment cannot be transferred meaningfully to another clinician.

The idea of measuring breast firmness to monitor post-surgical progress following breast implant surgery is not a new one. It has been appreciated for many years that an objective measurement of breast firmness is required in order to document post-operative issues such as resolution of swelling, development of capsular fibrosis and potential changes associated with implant rupture. A number of different technologies have been adapted to try and resolve this dilemma, using applanation tonometry and calliper deformation or “mammary compliance”.

The concept of mammary compliance was introduced by Barker [1] who identified the need for an objective measure of post-surgical firmness. The device was a spring calliper which could manually deform the breast with a fixed force,

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measuring the deformation on a scale. There is no report of reproducibility of results, although as a single observer a comparison was made with the clinical assessment.

The concept was expanded by Burkhardt et al. [2], and the apparatus improved in 1993 by Hoflehner et al. [3, 4]. It consists essentially of a calliper device which has to be set at the highest diameter of the implant or breast and compressed to record the relationship between force and distance through a pair of 9-mm-diameter pads.

While good correlations were reported between use of this device and the Baker subjective rating system [3], only a single operator was involved. However, several operators were used in the work of Mazzocchi et al. [5] which also involved tests over eight different diameters. This was carried out using the Anton Parr system for which the apparatus appears to be essentially the same as those developed earlier. The apparatus was rather rudimentary and simply reproduced electronically the thumb and index finger approach used by experienced surgeons. No good inter- or intra-observer reproducibility measurements have been published for this method. There would appear to be many ways in which inconsistencies could arise, and the results are, at best therefore, empirical.

Applanation tonometry is based on the principle used in the Goldmann procedure for measuring eyeball internal pressure. The technique has been applied to breasts by Moore [6] and Alfano et al. [7]. It involves a 200-mm-diameter, 213-g Perspex disc placed on the breast and the contact area measured by seeing through the Perspex or, in the later work, by use of a dye to mark the contact area on the disc. The internal pressure is then calculated and expressed in cm of water. The authors accept that this approach is rather crude and was introduced as a screening test.

Hayes and McLeod [8] describe an indentation tonometer and a procedure which involves use of two probes. Each is fitted with a spring and a deformation measuring device (a linear variable differential transformer). One probe is pressed into the breast by a fixed amount and has stiff spring, while the other can be pushed into a variable depth and has a more sensitive spring. They assume that the fixed-depth probe is influenced by stiffness at depth while the other one is influenced by material nearer the surface. Tests were carried out using both probes at four locations on a 2-cm-diameter circle centred on the areola. No indication is given to the units in which the results are expressed.

The new method of measuring breast firmness, which is described in this present paper, overcomes the problems associated with previously described techniques and has been shown to produce reproducible results in vitro and in vivo when used by a single or multiple operators, using recognised units of pressure (Pa). As such, the equipment is potentially employable by diverse research groups interested in biological tissue turgor.

## Materials and Methods

### Description of Technology

The mammometer 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 ms<sup>-2</sup> or Pa), and a signal conditioner is based on the HX 711 processor which provides 24-bit data. The pressure range of 34 Pa is divided by 16,777 216 increments, producing a high accuracy.

The first prototype (Fig. 1a) had a static probe with a fixed abutment of 10 mm. The device recorded the maximal pressure exerted by an operator during the test for the abutment to make contact with the breast. Once the exerted pressure exceeds 3 Pa, the instrument starts to take measurements each millisecond, until the pressure fell below 3 Pa. On conclusion of the test, the instrument records, stores and displays the maximum pressure measured.

The second prototype (Fig. 1b) was altered by including an electrical touch sensor which caused cessation of the measurement once the plate had abutted onto the breast. A third device (Fig. 1c) incorporated a more ergonomic hand grip on the probe for ease of use.

### Study Design

#### *Reproducibility of Measuring Device*

The following protocol was undertaken for each of the three prototypes to assess the effect on modification of the device on inter- and intra-observer reproducibility.

Ten observers measured breast implant firmness at nine different regions of a single silicone breast implant (Nagor Ltd. GFX-425, Cumbernauld, UK), placed on a hard, flat surface. Each observer measured the same point (marked on the implant, Fig. 2), ten times consecutively. Inter-observer reproducibility was the consistency of pressure readings between different observers on the same point on the implant. Intra-observer reliability was the consistency of pressure readings each observer made on the same point on the implant. Alpha coefficients were calculated across the nine points comparing both within and between observers.

#### *Assessment of Swelling Following Breast Implant Surgery*

Patients undergoing cosmetic breast augmentation were assessed using the mammometer (second prototype, Fig. 3) prior to surgery. Surgery was undertaken by the same

**a** Prototype 1**b** Prototype 2**c** Prototype 3

**Fig. 1** Breast durometer (mammometer) showing three prototypes. **a** Prototype 1, **b** Prototype 2 and **c** Prototype 3

surgeon using a sub-fascial technique previously described [9]. All patients provided written consent to the study under the guiding principles outlined in the WMA Declaration of Helsinki concerning ethical principles for medical research involving human subjects. Implants of the same firmness were used in all patients (Nagor Ltd. GFX range, Cumberland, UK).

All measurements were taken with the patient lying at forty-five degree 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.

Measurements were repeated 1, 6 and 12 weeks post-operatively, all by the same operator.

## Results

### Inter- and Intra-observer Variability of Equipment

Analysis was conducted to investigate the reproducibility of measurements by single observers and between observers by comparison of variability of measurements taken by the same observer to the total variation across all measurements and all observers. Separate analyses were conducted for each of the nine points on the breast implant in order to identify any weakness points in the machine. An  $\alpha$  result of 0.50–0.80 is considered good, and anything above 0.80 is considered excellent.

Results derived from the second prototype comparing how well each of the observers compared to one another indicating that point 1 (0.882), point 3 (0.97) and point 8 (0.89) were excellent. Points 4 (0.77), 5 (0.77), 6 (0.73), 7 (0.80) and 9 (0.75) were considered good. Finally point 2 only had a result of 0.56; however, this was still significant at  $p < 0.05$ .

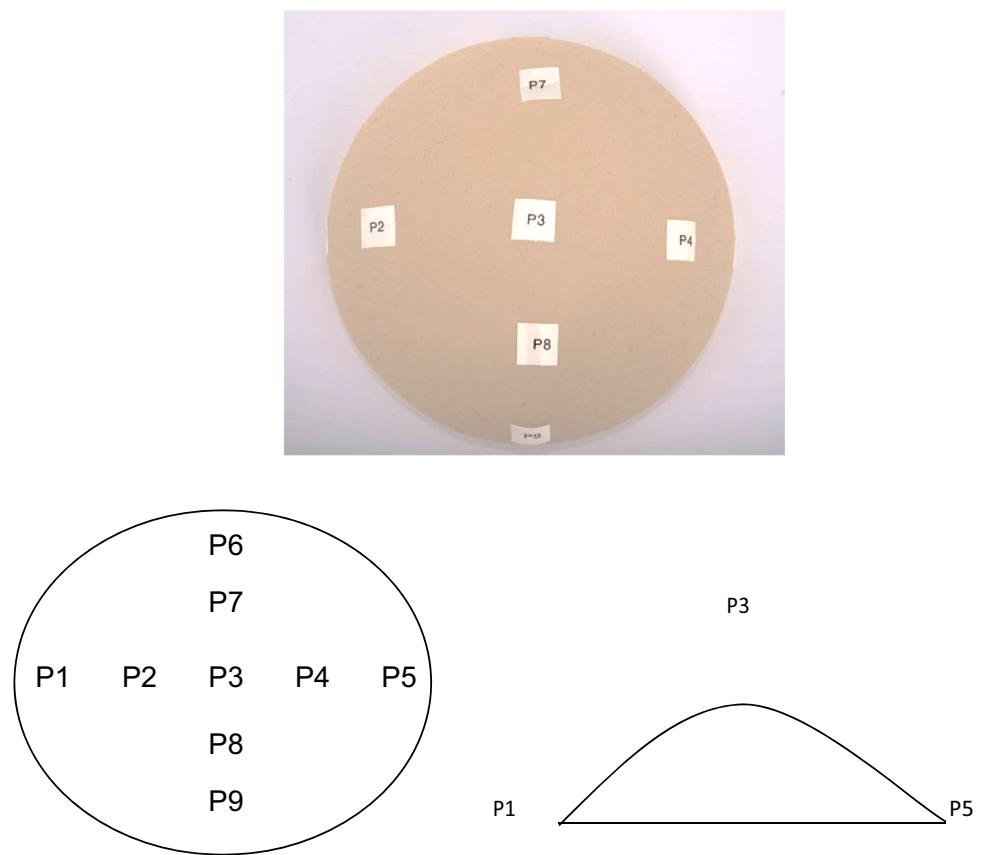
Results assessing the consistency of an individual observer's measurements at each point (intra-observer variability, Table 1) were all significant ( $p < 0.05$ ) but were lower than those comparing observers to one another (inter-observer variability, Table 2). Only point 3 (0.75) was good, with point 1 (0.43) and point 8 (0.45) less than 0.50 and points 2 (0.11), 4 (0.25), 5 (0.25), 6 (0.21), 7 (0.28) and 9 (0.23) lower than 0.30. This indicated that measurements between observers were more consistent than measurements by one observer.

The implication is that the second prototype was more difficult to use due to the head size. A third prototype (Fig. 1c) was modified to replicate the ergonomic aspects of the first model.

### Analysis of Breast Firmness After Breast Augmentation

Prior to analysis, data were screened for missing and incorrectly coded data. There were missing data on various measures in five cases and no incorrectly coded data. An inspection of all ten breast measurement points at each of the four time points indicated acceptable normality for all variables, with skewness and kurtosis figures within the  $\pm 3.29$  range, nor did any significant outliers influence the data substantially.

**Fig. 2** Position of measurement undertaken on breast implant to assess inter- and intra-observer variability



**Fig. 3** Breast durometer in use

Means and standard deviations for the measurements were calculated at each breast location (UOQ, UIQ, LOQ, LIQ, NAC) at each of the four time points (pre-surgery, 2,

6, 12 weeks post-surgery). Separate repeated measures ANOVAs were conducted to test for significant changes in measure across each breast location, over the four time points (pre-operatively, week 1, week 6 and week 12 post-operatively). Table 3 outlines the results of each of the ANOVAs with a significant main effect of time experienced for each breast location.

Follow-up post hoc tests with a Bonferroni adjusted  $\alpha = 0.008$  indicated that firmness reduced to pre-operative levels in the RUOQ, LUOQ, RUIQ, LUIQ and RLIQ; however, they were significantly higher than pre-operative measures at week 12 for RLOQ, LLOQ, LLIQ, RNAC and LNAC. Figure 4 illustrates the change in firmness measurement in each breast location over time, with standard error bars included.

Separate paired samples *t* tests were conducted to compare the left and right breast across each breast measurement point to determine whether they could be combined or should be treated separately. Results indicated a significant difference in RUOQ,  $t(53) = 7.00$ ,  $p < 0.001$  with the right breast scoring significantly higher than the left; however, all other measurement points (UIQ, LOQ, LIQ, NAC) did not differ significantly, ( $p > 0.05$ ) for all comparisons (Table 4).

**Table 1** Inter- and intra-observer reproducibility of firmness measurements across nine points on a breast implant using second prototype durometer

| Region | Inter-observer $\alpha$ coefficient | Comment    | Intra-observer $\alpha$ coefficient | Comment    |
|--------|-------------------------------------|------------|-------------------------------------|------------|
| P1     | 0.882                               | Excellent  | 0.3                                 | Acceptable |
| P2     | 0.56                                | Acceptable | 0.11                                | Acceptable |
| P3     | 0.97                                | Excellent  | 0.75                                | Good       |
| P4     | 0.77                                | Good       | 0.25                                | Acceptable |
| P5     | 0.77                                | Good       | 0.25                                | Acceptable |
| P6     | 0.73                                | Good       | 0.21                                | Acceptable |
| P7     | 0.8                                 | Good       | 0.28                                | Acceptable |
| P8     | 0.89                                | Excellent  | 0.45                                | Acceptable |
| P9     | 0.75                                | Good       | 0.23                                | Acceptable |

A result of 0.50–0.80 is considered good, and >0.80 is considered excellent

**Table 2** Average firmness measurements/Pa, ( $n = 10$ ) for ten observers across nine points on a single breast implant using mammometer

| Observer | P1    | P2    | P3    | P4    | P5    | P6    | P7    | P8    | P9    |
|----------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 1        | 0.197 | 0.293 | 0.431 | 0.338 | 0.235 | 0.245 | 0.297 | 0.295 | 0.214 |
| 2        | 0.483 | 0.39  | 0.355 | 0.254 | 0.644 | 0.618 | 0.337 | 0.292 | 0.426 |
| 3        | 0.285 | 0.337 | 0.354 | 0.354 | 0.256 | 0.282 | 0.377 | 0.365 | 0.25  |
| 4        | 0.298 | 0.755 | 0.761 | 0.755 | 0.572 | 0.463 | 0.43  | 0.426 | 0.335 |
| 5        | 0.291 | 0.613 | 0.695 | 0.673 | 0.546 | 0.562 | 0.719 | 0.632 | 0.704 |
| 6        | 0.191 | 0.338 | 0.355 | 0.369 | 0.278 | 0.259 | 0.393 | 0.444 | 0.278 |
| 7        | 0.488 | 0.628 | 0.671 | 0.663 | 0.928 | 0.581 | 0.762 | 0.782 | 1.326 |
| 8        | 0.304 | 0.361 | 0.596 | 0.455 | 0.534 | 0.451 | 0.643 | 0.607 | 0.7   |
| 9        | 0.87  | 0.707 | 0.759 | 0.656 | 0.879 | 1.06  | 0.701 | 0.659 | 0.973 |
| 10       | 1.117 | 0.756 | 1.023 | 1.255 | 1.786 | 1.846 | 1.044 | 1.437 | 1.44  |

**Table 3** Mean (standard deviation) and ANOVA analysis of firmness at each location on the breast at different times before and after sub-fascial breast augmentation

| Region            | Pre-operatively | Week 1      | Week 6      | Week 12     | <i>F</i> |
|-------------------|-----------------|-------------|-------------|-------------|----------|
| RUOQ <sup>b</sup> | 0.41 (0.10)     | 0.47 (0.11) | 0.42 (0.11) | 0.38 (0.08) | 7.024*   |
| LUOQ <sup>b</sup> | 0.32 (0.07)     | 0.46 (0.15) | 0.37 (0.09) | 0.33 (0.10) | 21.22**  |
| RUIQ <sup>b</sup> | 0.42 (0.08)     | 0.59 (0.13) | 0.51 (0.14) | 0.45 (0.14) | 24.89**  |
| LUIQ <sup>b</sup> | 0.42 (0.09)     | 0.61 (0.17) | 0.54 (0.15) | 0.46 (0.14) | 19.17**  |
| RLOQ <sup>a</sup> | 0.26 (0.08)     | 0.46 (0.10) | 0.38 (0.11) | 0.32 (0.08) | 61.86**  |
| LLOQ <sup>a</sup> | 0.25 (0.08)     | 0.46 (0.12) | 0.37 (0.09) | 0.33 (0.07) | 62.90**  |
| RLIQ <sup>b</sup> | 0.26 (0.10)     | 0.46 (0.11) | 0.38 (0.09) | 0.33 (0.08) | 44.84**  |
| LLIQ <sup>a</sup> | 0.27 (0.09)     | 0.47 (0.13) | 0.38 (0.12) | 0.35 (0.10) | 36.72**  |
| RNAC <sup>a</sup> | 0.24 (0.06)     | 0.39 (0.11) | 0.32 (0.10) | 0.30 (0.08) | 36.624** |
| LNAC <sup>a</sup> | 0.23 (0.07)     | 0.39 (0.11) | 0.33 (0.24) | 0.30 (0.09) | 32.53**  |

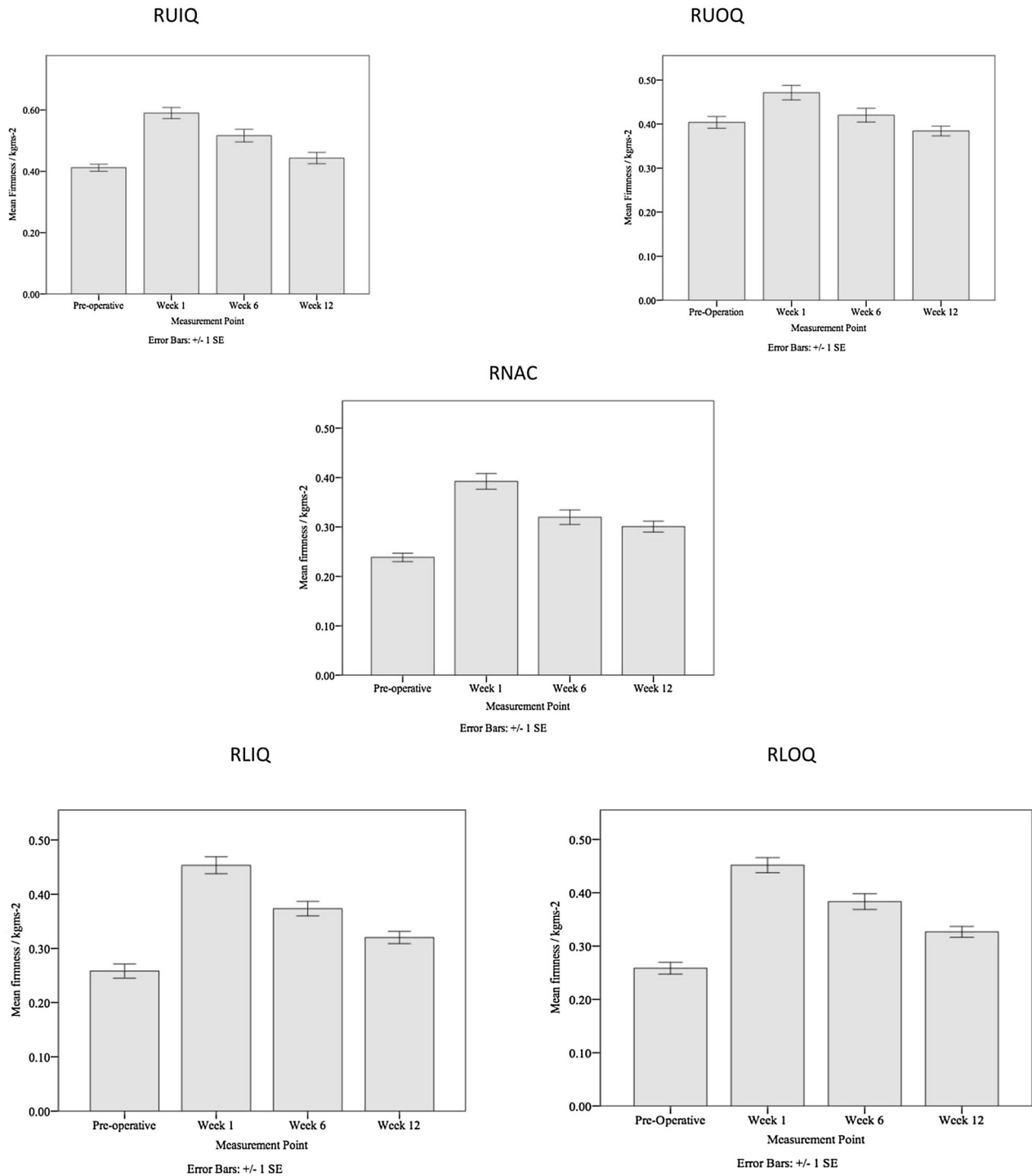
\*  $p < 0.01$ ; \*\*  $p < 0.001$

<sup>a</sup> Baseline significantly higher than Week 12

<sup>b</sup> No difference between baseline and Week 12

RUOQ Right upper outer quadrant  
 RUIQ Right upper inner quadrant  
 RLOQ Right lower outer quadrant  
 RLIQ Right lower inner quadrant  
 RNAC Right nipple areolar complex

LUOQ Left upper outer quadrant  
 LUIQ Left upper inner quadrant  
 LLOQ Left lower outer quadrant  
 LLIQ Left lower inner quadrant  
 LNAC Left nipple areolar complex



**Fig. 4** Changes in firmness following sub-fascial augmentation surgery at different locations on the breast over time

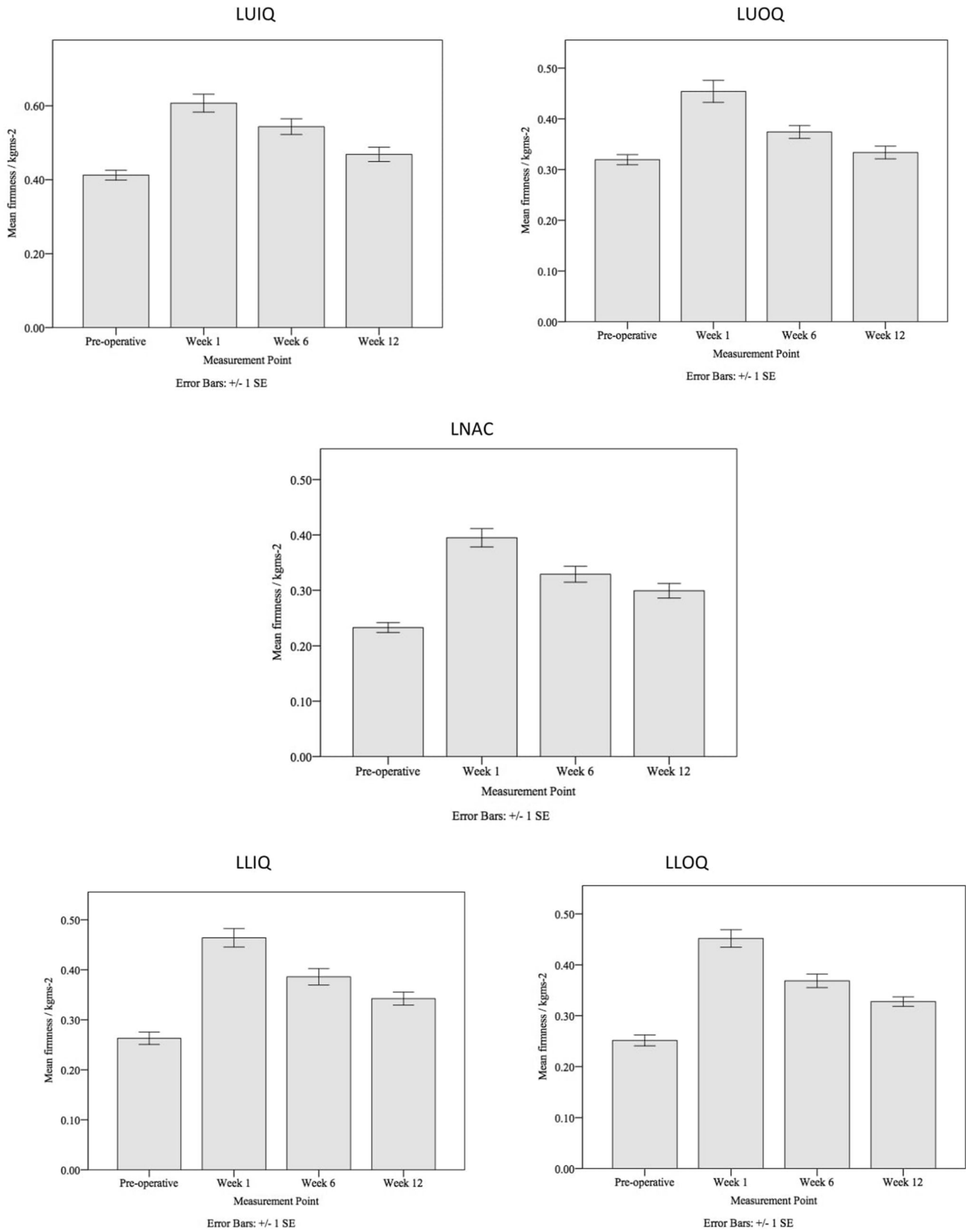


Fig. 4 continued

**Table 4** ANOVA analysis of combined left and right breast firmness pre-operatively, 1, 6 and 12 weeks post-operatively

| Region | <i>F</i> | $\eta_p^2$ |
|--------|----------|------------|
| UOQ    | 16.22    | 0.27**     |
| UIQ    | 25.94    | 0.37**     |
| LOQ    | 86.21    | 0.66**     |
| LIQ    | 49.70    | 0.53**     |
| NAC    | 43.89    | 0.50**     |

\*\*  $p < 0.001$

## Discussion

### Comparison with Previous Firmness Measuring Devices

The technology on which the mammometer has been based has been validated in other biological systems such as the dairy, meat and fruit industry [10]. These in vivo systems have recognised the issues of variable data between operators in particular, and much of the subsequent development has focused on ensuring that aspect of the technology was optimised before applying it to breast surgery.

The mammometer 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 papers have either used a single operator to undertake measurements [1] or have acknowledged the differences between operators [3, 7]. Some make no comment on the issue of inter- or intra-observer error [2, 4, 8, 11, 12]. One study [7] makes the comment that measurements are easily reproducible at follow-up appointments, but provides no supporting data.

We would argue that without inter- and intra-observer validation, the results utilising previous technologies are, at best, approximations and cannot be used as reliable research tools between institutions. The equipment described in this study can be reliably used by researchers worldwide to produce comparable data in different studies.

### Equipment Development

Measurements of firmness of the implant confirmed that inter-observer error was unacceptable with the first prototype. The limitations lay in the operator-dependent speed at which the probe was applied to the implant and visual assessment of when abutment of the base plate on the breast had occurred. Despite this, measurements made by the same operator using the first prototype (Fig. 1a) had good reproducibility and were therefore used in this study.

A second prototype (Fig. 1b) addressed the problem of inter-observer error by including a touch sensor on the abutment, so the contact was detected by the instrument ensuring consistent deformation of the implant or breast. The problem of inter-operator speed was resolved by including a timer that commences once the pressure reaches 3 Pa and stops as soon as the touch sensors are in contact with the breast. The intra-observer error is increased compared to the initial prototypes reflecting that the handle design was more difficult to use. These data account for an increase in intra-observer error with the second prototype, although inter-observer error remains the same, implying that all observers found the new prototype consistently difficult to employ. This issue has been resolved by changing the grip of the design to conform to that of the initial prototype (Fig. 1c).

### Method of Usage on the Breast

Only those studies that utilise tonometry [8, 12] measure breast firmness at multiple sites, whereas those utilising mammary compliance technology undertake a single assessment of firmness based on a two-point compression. The distribution of breast tissue is not even throughout the breast, and a mass measurement produced by a calliper would seem to be an oversimplification. Our data show that most variability is at the lower inner quadrant which we regard as an unreliable site for testing by 12 weeks, the upper half of the breast had firmness measurements that returned to normal, whereas the NAC and LLQ have a higher measurement than pre-surgery. These data suggest that measurements in the upper half of the breast reflect changes in surgical oedema, whereas those at the NAC and LLQ describe the behaviour of the breast implant composite. In addition, there are differences between the firmness of breast tissues on the left and right, which does not relate to handedness, but reflects observations from previous morphometric studies that in the majority of women, the right breast is larger than the left [13]. Based on these observations, we recommend that in monitoring a breast following implant surgery, three quadrant and NAC measurements are undertaken pre-surgery in addition to 12 weeks after the procedure. Morphometric measurements are also useful to assess any increase or decrease in the overlying breast tissue which may influence firmness measurements.

### Limitations

While in our hands we have described the limits of inter- and intra-observer variability, the device does require some familiarity before good results can be obtained. When first



using the equipment, it is important that the probe is held perpendicular to the breast to obtain a reading. As such we recommend that the potential user undertakes a limited reproducibility study for themselves prior to embarking on any study, particularly if multiple users are responsible for collecting the data.

We also accept that changes in body composition such as fat loss or gain can influence the results and suggest that morphometric data are collected each time breast firmness is assessed. It is our practice to measure weight, under girth and fat thickness at the lateral sternal margin on each occasion that firmness is measured to track any changes.

### Potential Applications

All sites of measurement were able to show demonstrable changes in breast firmness in the post-operative period consistent with the development and resolution of surgical oedema, but the upper half of the breast is most reliable. Changes in firmness correlate well with observed recovery of nerve sensation at 12 weeks following surgery [14] and patient assessment of breast size [15]. Firmness reached a maximum level a week after surgery and returned to pre-surgical levels by six weeks post-operatively.

The addition of an implant influences the firmness measurement of the breast at the NAC and LOQ, indicating that the equipment is truly measuring breast implant composite rather than simply parenchymal changes in these areas. This differs from the findings of Mulder et al. [12], who found that placing an implant in a retro-pectoral position did not influence measurements taken with a tonometry-based system from retro-mammary implants, provided that the pectoral muscle was relaxed. As with our results, they demonstrate little change in breast firmness after 6 weeks post-surgery. Unfortunately, there are no pre-operative measurements of breast firmness in any previous studies with which we can make comparisons as to whether other devices are able to detect the differences in surgical oedema rather than breast implant composite.

### Capsular Contraction

Encapsulation of breast implants remains a subjective clinical diagnosis, graded by a system described by Baker [16]. Patients may only present once a Baker IV capsule occurs, and this may be many years after its initial development. Several studies have utilised both tonometry [8, 12] and mammary compliance [3–5, 7, 11] to measure the development of capsular fibrosis in an objective manner following breast augmentation surgery. Burkhardt et al. [2] have made the point that a calliper system compresses the implant in an indistensible capsule until excessive force

would be required to rupture the capsule and argue that it can therefore be used without the need for standardisation or measurement of the compressive force itself. It makes the point that there is good correlation between their calliper system and Baker's grading. We would argue that the objective measurement cannot equate to a subjective measurement, which are 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. As such, early capsular contraction may be detectable and provide information as to possible aetiology. We have a small number of patients with a Baker 3–4 capsule on one breast that have a measurable difference with the contralateral, normal breast. At present our numbers do not allow a rigorous statistical comparison but are indicative that the equipment will have a use in providing a non-subjective measure of capsular contraction. However, given the low rate of capsular contracture with sub-fascial implants (<1% at 3 years), our ongoing measurement of breast firmness as a routine part of a breast augmentation consult and follow-up will yield further data in the future.

### Implant Selection

Vegas and Martin del Yaro [17] have highlighted the importance of mechanical properties of breast tissue and how application of stress may influence changes in its response to an implant. Tebbetts also acknowledges the relevance of breast firmness in the "high 5" system [18] which includes a subjective assessment of soft-tissue elasticity as part of selecting the appropriate match of implant characteristics to those of a breast. The mammometer would permit further research to build and develop this subjective assessment and could form part of advanced sizing systems when taken with subsequent outcome measures.

### Conclusions

We have reported a novel user-friendly device for measuring soft-tissue firmness and obtained results from a single observer and between observers both in vitro and in vivo which allow us to draw the following conclusions:

1. The device is able to reliably track the resolution surgical oedema in breast augmentation patients.
2. We have proposed a number of potential applications in the field of aesthetic breast surgery.
3. Further research is required to demonstrate the full potential of our device, and we would encourage researchers to examine other uses for it.

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#### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflicts of interest to disclose.

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