A new orthosis reduces pain and mechanical forces in prone position in women with augmented or natural breast tissue: A pilot study

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KEYWORDS
Breast augmentation failure; Breast tissue mechanical stress; Symmastia; Pain

Summary Background: Breast augmentation, post-mastectomy patients as well as some women with natural breast tissue, and lactating, women often experience discomfort in prone activities. Our study, for the first time, examines pain levels, mechanical force and peak pressure in natural, reconstructed and augmented breast tissues with and without a new orthosis designed for reduction of displacement, compression and loading forces through the breast tissue during prone activities.

Methods: Twelve females with natural, lactating or augmented breast tissue, and cup-sizes C – F volunteered for the study. Pain perception was measured using an 11-point visual-analogue-scale without and with different sizes/textures of the orthosis. Magnetic-Resonance-Imaging captured segmental transverse and para-sagittal mid-breast views, and provided linear measurements of breast tissue displacement and deformation. Capacitance-pliance sensorstrips were used to measure force and pressure between the breast tissue and the surface of a standard treatment table. Measurements were taken whilst the participants were load bearing in prone positions with and without the orthosis.

Results: The new orthosis significantly reduced pain and mechanical forces in participants with natural or augmented breast tissue with cup-sizes C – F. Larger orthotic sizes were correlated with greater reduction in pain and mechanical forces, with all participants reporting no pain with the largest size orthotic. A size-3 orthotic decreased load on the breast tissue by 82% and reduced peak pressure by 42%. The same orthotic decreased medio-lateral spread of breast tissue and implant whilst increasing height.

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Introduction

Recent media reports have heightened the level of public awareness of breast augmentation failure rates and complications. An estimated 5–10 million women worldwide have breast implants.1 Breast augmentation complications continue to occur despite advances in surgical techniques, implant structure and manufacturing from their early inception, with 20% of primary augmentation patients requiring removal/revision due to complications within a 10 years.1 The longer they have their implants the greater the likelihood that a problem will develop.2 Advances in both surgical approach and material composition have been unable to prevent many of the fundamental complications patients’ experience.

The introduction of foreign material, of any type, often complicated by reconstructive tissue procedures significantly alters anatomy and the structural biomechanics of the anterior chest wall. Comparable to space occupying lesions such as lymphomas, the implant material is vulnerable to trauma and damage. Tissues adjoining the implant are also highly susceptible to damage as the material attempts to move when it is displaced, compressed and deformed. This appears most evident during activities where the patient is in a prone load bearing position (i.e. face down).

The main reasons for reoperation in primary augmentation patients for implant removal or reconstruction among a three year MemoryGel® trial was for capsular contracture grade II, III and IV.3–5

Activities such as sleeping, sun-tanning, lounging and undergoing therapeutic procedures and examinations such as medical examinations, massage (including trainers), acupuncture, osteopathic, chiropractic and physiotherapy, place the soft tissues of the anterior chest under extensive compression and displacement. This may cause significant deformation and derangement of these vulnerable tissues and structures, specifically the implant material.6

Accumulated micro-trauma and macro-trauma events may contribute to many of the complications reported by implant patients. It is this area of patient management that needs to be enhanced to not only decrease pain and discomfort for patients, but to help improve surgical outcomes. By reducing exposure to breast compression and deformation in prone activities, it is hoped to reduce discomfort and the incidence of complications and failure rates for implant patients.

Until now efforts focused in this area of post-operative management have resulted in patients and practitioners haphazardly resorting to use of rolled towels and bolsters, pillows and modified tables with holes for the breasts to ‘be received’ into. Often patients avoid activities requiring prone load bearing.

In addition, patients with breast tenderness or lactating breast tissue experience pain or discomfort when lying prone, but could potentially benefit from therapies requiring prone positioning.

Our study, for the first time, examines pain levels, mechanical force and peak pressure in natural and augmented breast tissues with and without a new orthosis developed and designed for reduction of displacement, compression and loading forces through the breast tissue, primarily during prone activities.

Methods

Study design and participants

Participants

Twelve females, aged 22–48 years, with breast cup sizes ranging from C–F volunteered for the open-label study. One half had augmented breast tissues (n = 6), the other half had natural breast tissue (n = 6), including one lactating (Table 1). All women in the augmented group had bilateral, complete, silicone implants, with no capsular contracture by infra-mammary incision, with submuscular positioning (n = 5) and reconstructed (n = 1).

All measurements were taken during a one day session for each participant. Capacitance pliance® sensors strips were used at the Victoria University biomechanics lab. Magnetic Resonance Imaging (MRI) were performed at Medical Imaging Australia (MIA Victoria) in East Melbourne. Women’s pain perception, tissue displacement and loading through the anterior chest/breast tissue during prone activities without and with different sizes/textures of the new orthosis were assessed. The study was approved by the Human Research Ethics Committee at the National Institute of Integrative Medicine, Melbourne, Australia.

The orthosis

The orthosis is currently being developed in multiple sizes to allow for variations in breast tissue size. Additionally density variants are available for individual comfort according to personal preference. These firm and soft variants can be chosen depending on the hardness of the surface on which the patient is lying on, the activity undertaken, and
Table 1  Baseline characteristics, n = 12.

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<td>3 implants, 1 mth, 2–3 yrs (x2), post-mastectomy</td>
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<td>2 implants for aesthetic purposes, 4–5 yrs</td>
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| Reconstructedb     | 1       |
| 1 implant for aesthetic purposes, 18 mth post-surgery | |

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Abbreviations: mth, month; n, number; SD, standard deviation; yr, year.

a All silicone implants, bilateral, complete, no capsular contracture by infra-mammary incision (n = 6), with sub-muscular positioning (n = 5) or reconstruction (n = 1).

b Reconstruction because of previous implant failure due to capsular contracture grade 3.

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the weight of the patient. Figure 1 illustrates the orthosis and patient positioning.

Pain

Measuring comfort/pain levels with each orthosis being tested was used to establish a preferred orthosis for participants. Women were required to relate pain perception to the type of orthosis used. Pain was assessed on a visual analogue scale using a validated 11-point numerical pain rating scale, ranging from 0 = 'no pain' to 10 = 'worst possible pain'.

Mechanical force and peak pressure

Capacitance pliance sensor strips were used as a means of measuring force (Newton, N) and pressure (kilo pascal kPa) from the breast tissue. Two 3 × 15 cm sensor strips with a measurement area of 1 cm² each and sensitive to 4 kPa at a sample rate of 50 Hz were placed onto a standard treatment table in the area under where the participant’s right breast was positioned. Sensors were aligned to a standardised scale assuring comparable positioning of all participants.

Measurements with body weight alone to simulate sleeping/lounging conditions were taken as a baseline. In some participants a 15 kg passive load applied directly opposing the breast tissue on the anterior surface of the thoracic cage was applied to simulate therapeutic massage, and the force and pressure on the anterior surface of the breast tissue recorded. In some participants a measurement was taken at the moment of a two hand prone dorsal thrust to simulate a thoracic spinal and rib manipulation commonly performed by manipulative therapists.

Measurements were taken whilst the participants were load bearing in a prone position. Comparisons between lying with and without the orthosis were made for all conditions. Measurements using different sized orthoses were taken to determine the variance in breast tissue displacement.

MRIs performed showing segmental transverse and parasagittal mid-breast views, providing linear measurements in millimetres (mm) of breast tissue displacement and compression (Siemens 1.5 T Magnetom Espree).9

Analysis

A comparison of the perceived level of pain with a range of different orthosis to no orthosis by paired sample t-test was carried out. The ratio between any pain and no pain was tested by Chi-square. An analysis of all participants and two subgroups of women with natural or augmented breast tissue were undertaken. Correlations between cup-size or body mass index (BMI) and pain level were calculated by Spearman Rho test. Statistical significance was set at p < 0.05.

Mechanical forces were measured threefold, with no weight bearing, 15 kg weight, or manipulation, without or with different types of the orthosis. A comparison of maximum force and peak pressure between the different sizes of the orthosis and no orthosis by paired sample t-test was evaluated. Not all women tried all sizes or firmness level of the orthosis. Correlation between mechanical forces and different orthosis sizes was assessed using the Spearman Rho test.

Results

Comfort/pain

All women reported less or no pain when lying in prone position with the orthosis as compared to lying in prone position without the orthosis (p < 0.05). The ratio of no pain vs any pain increased significantly with larger sizes of the orthosis. All women in both the natural and augmented breast tissue groups reported no pain with the largest size (size-3). Women with larger cup-size experienced less pain with larger size of orthosis (Table 2). There was no correlation between BMI, size of orthosis and pain reduction.

Mechanical forces

Maximum force and peak pressure were significantly reduced with the orthosis compared to no orthosis, alone, with weight or with manipulation. Larger pad sizes were associated with less mechanical force (Table 3). Increased cup-size was correlated to lower mechanical force possible (maximum force with manipulation (r = –0.91; p = 0.005), and peak pressure with 15 kg weight (r = –0.674,
Increased BMI was highly correlated with maximum force using manipulation ($r = -1.0$, $p < 0.0001$).

Figure 2 illustrates a DD Cup size augmented patient. Transverse views with no orthosis demonstrate an antero-posterior displacement (AP) value of 2.63 cm and medio-lateral displacement (ML) of 15.94 cm. Size-3 orthosis AP values were 5.21 cm, with an ML displacement 11.51 cm. AP values demonstrate a 49.5% increase in total breast and implant tissue measurement when using the orthosis and a 35% reduction in ML displacement.

In the para-sagittal view, the breast AP with no orthosis was 4.69 cm and ML was 21.30 cm, with implant values of 2.63 cm and 13.94 cm respectively (Figure 2C). With the size-3 orthotic, values were 8.33 cm AP and 19.01 cm ML for breast tissue and 5.21 cm AP and 11.51 cm ML for the implant.

AP values demonstrated a 49% increase in natural and implant tissue measurement, and a 10% reduction in ML displacement for the entire breast tissue and of 17% of the implant using the orthosis. Significant alterations in the
visual appearance and derangement of both natural breast tissue and the implant are seen in Figure 2 — left panel (without orthosis), which are not present in Figure 2 — right panel (with orthosis), the latter being the ‘ideal’ appearance sought after. 

Upon a 15 kg loading through the thoracic cage size-1 had a reduction to 13.3 N and 6.5 kPa, size-2 registered a drop to 8.5 N and 6.5 kPa and size-3 again a further reduction to 3.7 N and 4.5 kPa.

Force (N) reduced by 82% and pressure (kPa) reduced by 42% when comparing a size-1 to a size-3 orthosis under loading conditions. Prone dorsal thrust values with a size-1 orthosis were 45.4 N and 13.3 kPa, whilst size-3 had decreased values of 27.7 N and 8.5 kPa. This represents a 39% reduction in force and 36% reduction in pressure results between the size-1 and size-3 orthoses.

Figure 3 illustrates an F cup sized augmented participant, with implant insertion only 1 month post-operatively.

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<th>Table 2 Effect of orthosis on pain scores.</th>
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<td>Paired t-test; p-value</td>
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<td>Chi-square; p-value</td>
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All participants (n = 12)

No orthosis 4.9 (2.4) 2–10 0.664; p = 0.019
Size-1 1.5 (1.0) 0–3 0.6; p = 0.029 0.752; p = 0.005 <0.0001 0.47
Size-2 0.5 (0.7) 0–2 0.7; p = 0.01 0.707; p = 0.010 <0.0001 0.005
Size-3 0 0 1.0; p < 0.0001 0.515; p = 0.087 <0.0001 0.0001

Primary augmentation (n = 5)

No orthosis 6.2 (2.2) 5–10
Size-1 2.8 (0.8) 1–3 ns
Size-2 0.6 (0.5) 0–1 ns
Size-3 0 0 ns

Reconstruction (n = 1)

No orthosis/size-1/2 6/2/1

Natural (n = 5)

No orthosis 2.8 (0.8) 2–4 ns
Size-1 0.8 (0.9) 0–2 ns
Size-2/size-3 0 0 ns

Lactating (n = 1)

No orthosis/size-1/2/3 8/3/2/1

All participants experienced significantly less pain with the orthosis compared to no orthosis.
Ns, not significant; vs, versus.

Man, manipulation; Max, maximum; vs, versus.
The participant was too uncomfortable to lay prone without the orthosis hence no measurements were taken in this position.

In the para-sagittal view, breast with orthosis size-1 and cup-size F the dispersion was 10.55 cm (AP) and as 16.63 cm (ML). With size-3 orthotic values were 11.32 cm (AP), 6.8% less and 15.44 cm (ML), both 7.3% less displacement. The transverse MRI section demonstrated size-1 AP of 6.91 cm and ML of 12.95 cm, with size-3 changing AP to 7.95 cm and ML to 11.4 cm. No prone thrust data was recorded due to safety concerns with the recent insertion of implant material. AP recordings without the orthosis were 6.05 cm with an ML of 13.13 cm. Displacements with a size-2 orthosis were 7.7 cm and 12.6 cm respectively, resulting in a 21.4% reduction in AP and 4% ML values.

Force of 14.1 N and pressure of 11.3 kPa was transferred through the breast with a size-1 orthosis, with size-3 recording a reduction to 1.7 N and 4.3 kPa. This represents an 88% reduction in force and 62% reduction in pressure transferred through the breast.

**Figure 2** DD Cup size, augmented. Left: no orthosis, Right: size-3 orthosis, (A) MRI, transverse view, (B) force and pressure transferred through the breast (3D graphs), (C) MRI, para-sagittal view.

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**Figure 4** illustrates a D cup post-mastectomy, 18 months post-reconstruction surgery: AP without the orthosis was 4.45 cm, whilst it was 5.64 cm with a size-2 orthosis, leading to a 26.7% reduction in displacement. ML displacement was 16.93 cm without the orthosis and 15.02 cm using it, providing a 11.2% reduction.

Prone force and pressure data was 58.8 N and 11.9 kPa unloaded. Upon the introduction of load the values recorded increased to 70.9 N and 12.3 kPa. Using the orthotic reduced force values to 29.3 N and 7.3 kPa unloaded, and upon loading values recorded were 34.4 N and 8 kPa. This represents a 49% decrease when unloaded and 52% reduction in force measurements when loading was introduced, whilst pressure dropped 39% when unloaded and 35% when loaded with the size-2 orthosis. No testing with a size-3 was recorded with this participant with D cup breasts.
Figure 5 illustrates the transverse MRI views of breast tissue displacement of three participants with natural breast tissues with different cup sizes.

Figure 5A illustrates a lactating woman with EE-cup size: AP without the orthosis was 7.62 cm, whilst it was 8.32 cm with a size-3 orthosis, leading to a 9% reduction in displacement. ML displacement was 17.10 cm without the orthosis and 15.39 cm using it, providing a 10% reduction.

When exposed to the prone dorsal thrust, force through the breast tissue was 97.6 N, whilst with a size-3 orthosis a reading of 48.7 N was recorded, leading to a 50% reduction. Pressure reduced from 10.0 kPa without the orthosis to 5.3 kPa with the orthosis, a 47% reduction. When loaded without a thrust, values were 36 N and 7.5 kPa, whereas with the orthosis 6.9 N and 5.3 kPa were presented in 81% reduction in force and 30% in pressure when using the orthosis.

Figure 5B illustrates DD cup in transverse view with the anterior-posterior results showing 3.69 cm breast tissue (Figure 5B left) without the orthosis, whilst it was 5.06 cm with a size-3 orthosis (Figure 5B right), a 37.8% reduction in displacement. Medio-lateral displacement was 14.35 cm and 10.85 cm respectively, providing 24% less displacement. Once again significant visual differences in the tissue organisation can be seen between the views with and without the use of the orthosis loading through the breast was 43 N and 9 kPa without the

Figure 3  F cup size, augmented with implant insertion only 1 month previous. Left: no orthosis, Right: size-3 orthosis, (A) MRI, transverse view, (B) force and pressure transferred through the breast (3D graphs), (C) MRI, para-sagittal view.
orthosis and 11 N and 5.8 kPa with it. This represents 75% less force and 36% less pressure through the breast tissue.

Figure 5C illustrates a C cup with AP values of 1.63 cm without the orthosis (Figure 5C left) and 3.88 cm (Figure 5C right) with the orthosis provided 58% less compression. ML displacements of 16.94 cm and 11.5 cm respectively were seen, a 32% reduction in displacement.

Discussion

This study suggests the new orthosis as a tool to significantly reduce pain and mechanical forces in women with natural or augmented cup-sizes C and above. This reduction is of clinical significance, as reduced pain and mechanical force are associated with greater comfort and reduced pressure and displacement. There was a reduction in antero-posterior and medio-lateral displacement measurements across all participants when the orthosis was used, with greater reduction in force and pressure found in augmented breast patients, which indicates the lack of tissue mobility in their altered anterior chest wall structure.

This was the first study to test this orthosis and its effect on pain, pressure, and displacement on breast tissue in a prone position. We acknowledge that our sample size was relatively small and we did not have a control group per se, however participant numbers were sufficient to detect a statistically significant difference in pain and mechanical forces when comparing the effect of the orthosis within the group of women.

We demonstrated that prone loading can be reduced in both augmented and natural breast tissue by a properly fitted orthosis. Use of the orthosis led to greater comfort in all women, reduced risk of tissue damage, and potentially other complications in augmented patients, and enabled prone positioning in one lactating woman and one recently augmented woman in our study, who was not able to tolerate lying face down without an orthosis.

Derangement of the breast tissues without the use of the orthosis was highly visible in MRI views. Coupled with no nerve innervations of the implant tissue it is clear how implant recipients can report silent ruptures and how movement of the implant. The orthosis decreases the breast tissue and implant material exposure to the potentially damaging forces of compression and displacement.

Breast tissue was incrementally protected as each participant used a larger size orthosis, with comfort being the main parameter for 'preferred' size for each participant. There appears to be an ideal size, with some C and D cup participants preferring a size-2 orthosis over a larger size-3, even if their breast tissue was more 'protected'. It appears too much loading can place discomfort on the sternum and rib cage and this can become uncomfortable.
after a period of a few minutes. The surface the individual is laying on also appears relevant to sizing preference.

Whilst larger DD–F cup participants were unable to fit their entire breast tissue adjacent to the smaller orthosis they did not report this to be uncomfortable. It is important that the correct size be used for optimum results, using as large a size as tolerable by the load bearing tissues. It would appear relevant that individuals may require multiple sizes or densities of the orthosis, depending upon the firmness of the surface they are prone on and the activity they are participating in. When undergoing therapeutic manipulation on a firm examination/treatment table a different orthosis may be preferable to when lying (such as sleeping) on a softer mattress. Variations in firmness of the orthosis also allows for individual ‘feel’ to be accommodated.

When the introduction of implant material occurs in the body the pre-existing anatomy must adapt to accommodate the new tissue. In the instance of breast augmentation and reconstruction it appears that if individuals wish to continue undertaking prone activities they require significant protection to minimise potential trauma to the anterior chest wall soft tissue and implant material. Combined with the absence of neurological feedback of the implant it is understandable that silent ruptures occur with accumulated micro-trauma, and indeed macro-trauma.

Manual therapists should also be highly aware of the altered mechanical capacity of augmented breast tissue.

Figure 5 Different cup-sizes, natural. Left: MRI, no orthosis, transverse view, Right: MRI, transverse view size-3. (A) EE cup, natural (lactating), (B) DD cup, natural; (C) C cup, natural.
and should make every endeavour to reduce discomfort and potentially damaging forces to which patients are exposed during prone procedures. Patients should also be educated as to their augmented breasts’ altered function and vulnerable new structure.

Uses for the orthosis are not only for augmented breast tissue patients but any woman where breast tissue is painful, damaged or vulnerable to loading when prone. Applications include surgical theatres, manual therapy and beauty clinics, gymnasiums and yoga studios. Using a personally fitted orthosis in clinical settings is highly recommended for all therapists and clinicians when performing prone procedures. Understanding how to fit the orthosis is essential, and should be carried out by a qualified and certified healthcare professional.

It is the role of plastic surgeons to become the leaders in education and preventative management strategies in breast augmentation to ensure optimal outcomes for all implant recipients. We recommend this orthosis for immediate post-operative care and for ongoing use when patients are undertaking any prone activities, where loading occurs through the anterior chest wall.

Based on the promising results of this first pilot study a larger study is warranted to test changes in pain and pressure with and without an orthosis in comparable groups of women.

Furthermore, future long term studies should track women with augmented breast tissue to compare failure and reconstruction rates between those who used a properly fitted orthosis in prone positions and those who did not use an orthosis.

Funding

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Conflict of interest

PMcL is a consultant to novel.de, but no funding was received for this study.

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References