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*Cover Letter

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1 July 2019

Prof. Julie Nightingale
Editor-in-Chief

Dear Julie

Submission to Radiography

Please find attached a submission to the journal Radiography. I can confirm that this has received full ethics committee approval and is not under consideration by another journal. All authors have participated in the production of this manuscript and are aware of this submission.

With best wishes

Andrew England
Senior Lecturer in Radiography (E a.england@salford.ac.uk)

*Title Page (with author details)

A comparative~~, observational,~~ study of pain experienced during successive mammography examinations in patients with a family history of breast cancer and those who have had breast cancer surgery

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*Abstract

Abstract

INTRODUCTION: To measure mammography-related pain in two groups of women undergoing regular surveillance as a baseline for future care.

METHODS: Following ethical approval, two hundred women aged 32 to 84 years (mean 54), were invited by written invitation to participate in the study. 100 women had a family history (FH) of breast cancer, 100 had undergone conservative surgery (FU) for breast cancer and were currently asymptomatic. A validated pain scale was used to score the participants' perceived pain *before* compression based on memory, immediately *after* compression and *one week later*. A series of baseline parameters were also captured including compression force, breast size/density, menstrual history and any adverse events following mammography to allow the investigation of relationships.

RESULTS: There was a strong correlation ($r=0.79$, $p<0.001$) between previous pain scores and current pain scores, no significant correlations were found between breast size, breast density or total compression force and pain. Pain scores reduced between previous and current examinations and there was consistency in overall pain scores, despite variations in the compression forces applied.

CONCLUSION: Physical side effects from mammography can develop and extend beyond the ~~initial~~ examination period. Patients' prior experience of pain was the only significant predictor of current pain in this study.

IMPLICATIONS FOR PRACTICE: Data on past mammography experiences are essential to improve future pain outcomes. Post-mammography aftercare should be a routine feature of the examination.

Introduction

Breast cancer is the most common cancer in women, with 54,751 cases reported in the United Kingdom in 2015(1). Mammography is currently the most effective tool for the detection of early breast cancer for women over 40 years(2, 3).

Mammography requires compression of the breast and the resultant image quality is dependent on obtaining adequate compression whilst minimising movement unsharpness(4). Pain from compression is a well reported phenomenon and can deter women from attending screening(5). There is, however, limited data relating to mammography-related pain in patients outside of the screening service, such as those who have undergone breast-conserving surgery or patients with a high risk of developing breast cancer.

The aim of this study was 1) to measure mammography-related pain in two groups of women undergoing regular surveillance as a baseline for future care and 2) evaluate any prolonged physical effects from mammography after a week.

Materials and methods

Approval from the Health Research Authority (17/EE/0199) for this research was obtained. Patients who attended for annual surveillance mammography between May and October 2017 were considered for inclusion in the study. Recruited patients fell into two groups, patients attending with 1) a family history of breast cancer (FH) and 2) who have had surgery for cancer (FU).

All patients had standard two-view bilateral digital mammography. For consistency all patients had previous mammography at the same institution, using the same equipment and performed by the same mammographer.

Images were acquired using a GE Senographe Essential (GE Medical Ltd, Little Chalfont, UK) mammography machine which undergoes six monthly quality assurance testing. The equipment is serviced bi-annually by the manufacturer incorporating consistency checks for compression force. Compression forces applied were at the discretion of the mammographer and did not breach maximum levels; this is standard practice within the NHSBSP(3).

Data collection

Breast size measurements were undertaken prospectively using a standard technique (**Figure 1**; **Table 1**) (6). Age at the time of mammography, previous attendances, when and where the mammogram was taken and by whom was recorded. Previous compression forces were extracted from databases but were withheld from the mammographer. Menopausal status and the date of the last menstrual period were recorded. Breast density was classified using the BI-RADS 5th Edition (7) breast composition descriptors and scored by two observers.

Study sample

Uchiyama and colleagues in 2015(8) investigated pain perception prior to mammography and reported a mean visual analogue score (VAS) for pain of 5.1 in 24 otherwise healthy women. Within our study, it was expected that there would be a minimum VAS pain score change 1.0 (expectation versus reality), in either direction, as such this would require a minimum of 62 participants per group. A difference of 1.0 was selected since it is the minimum incremental difference between scores in the scale used(7). Also, owing to differences in the populations between the study cohort and work and Uchiyama et al., (9) it was decided to raise the sample to 100 participants per group.

Women were assigned to either the FH or FU groups. Several patients were not suitable for inclusion in the study and were eliminated, these included patients with previous mammography examinations performed at another institution, having mammography for the first time, those with breast implants and any patients with an inability to provide consent.

Patients were asked to self-evaluate their previous mammography pain (experience) from memory using the Wong-Baker faces scale(9) (**Figure 2**). Patients scored their pain a second time, immediately following their current mammogram. This pain score was then followed-up one week later by a post-mammography telephone interview. This was used to assess whether there was any prolonged pain. Within the telephone conversation a history was also taken regarding any adverse events, for example bruising or skin tears.

Statistical analysis

Data that were normally distributed were summarised as mean values plus their standard deviations. If the data were non-parametric, then median values together with inter-quartile ranges were reported. Inferential statistics were used to establish if there were any statistical differences between prior experience and the current examination. Subgroup analyses, including correlations assessed relationships between pain and breast size, density and compression force. P values of less than 0.05 were considered significant.

Results

During the six-months of data collection, 530 patients were considered eligible for inclusion. Forty-two (17%) patients declined to participate (10, [4%] FH) and (32, [13%] FU) (**Table 2**). The majority of those who declined 13 (31%) provided no reason. Seven (17%) patients had attended screening previously, a further seven (17%) had issues relating to consent. Several patients (n=89) were not eligible for inclusion in the study (**Table 3**).

All included patients were female, and the age range was 32 to 84 years (median 50.0; IQR 46.0 to 59.0). Within the FU group the minimum age was 32 years and the maximum 84 years (median 57.5; IQR 52.0 to 67.5). For the FH group the minimum age was 36 years and the maximum age was 60 years (median 47; IQR 44.75 to 49.0).

Pain evaluation

Patients were asked to score their pain at three different time points using the validated pain scale. The time points were as follows,

1. From memory, the pain during their last mammogram (*previous* pain score*)*
2. Immediately after the current mammogram (*current* pain score*)*.
3. After 5-7 days, (*prolonged* pain score*),* from the telephone interview.

Pain scale scores were categorised as low, moderate and severe according to the work by Dworking et al.,(10) and Meretoja et al.,(11). As can be seen from **Table 4**, 199 patients recorded a *previous* pain score (one patient could not recall). Approximately half of these patients (94, [46%]) recalled pain as moderate, 57 (30%) low, 32 (16%) severe and 16 (8%) no pain from their previous mammogram. For

current pain, 88 (43%) reported moderate pain, 68 (36%) low, 27 (14%) severe, 16 (8%) no pain. In the prolonged pain group, 156 (80%) of patients scored no pain, 15 (10%) moderate, 20 (8%) low and 3 (2%) severe pain. Comparison of previous (recalled) and current pain scores indicated that patient expectations were close to the actual experience with most patients had no *prolonged* pain (> 1 day). Comparison between previous and current pain scores following mammography are presented in **Figures 3** & **4** demonstrating a strong positive correlation between pain at the two time points (**r=0.79, P<0.001**).

Factors affecting post-mammography pain scores

The mean±SD compression forces, between the FH (previous 8.5±2.5 vs current 8.3±2.5 DaN) and FU groups (previous 7.2±2.2 vs current 6.9±2.1 DaN) demonstrated no significant differences between the time points, within the groups (P>0.05). When comparing between groups (FH & FU) there were statistically significant differences between all the time points and projections (P<0.05). A mean compression force for all four projections was adopted and used to analyse the whole study group to show any trends between *previous pain* and *current pain*. For previous pain, there was a weak negative correlation (r=-0.26; P<0.001) between the compression force applied and patient reported pain levels. For current visits, there was also a weak negative correlation (r=-0.21; P=0.004).

An evaluation of the performance of each mammographer against pain scores per projection are illustrated in **Table 5**. There were some variations in compression forces applied between the mammographers in the study.

The most common breast cup size within the study was size E (52, [26%]). A Pearson's correlation coefficient was generated for *breast size* against *current pain scores* and resulted in a very weak, non-significant, negative correlation (r=-0.011, P=0.88)**.** In terms of breast density, most patients were BI-RADS-B, the second highest category was BI-RADS-C. Correlation coefficients between *current* breast pain and breast density score for reader 1 was r = 0.18 and for reader 2, r = 0.14 indicating weak correlations between density and pain.

Comparison of pain scores between pre- and post-menopausal women

Mean±SD *previous* pain score in the premenopausal group was 6.3±3.6 and for the *current* pain score it was lower 3.2±2.3 (P<0.001). The mean±SD *previous* pain score in the postmenopausal group was 7.7±3.7 and this was again was lower for the *current* pain scores 4.6±2.7 (P<0.001). Data from this study demonstrated no statistically significant difference for pre- and postmenopausal patients (P>0.05).

Post-mammography events

There were a considerable proportion of patients (79, [39%]) who had visible redness to the skin following compression. There were four individuals (2%) who experienced skin tearing, three of these were in the FH pre-menopausal group. The other patient was in the FU group who unfortunately was admitted on Day 5 with marked cellulitis. This patient had a previous wide local excision and radiotherapy and it was difficult to determine whether the cellulitis had been triggered by the mammogram or was post-radiotherapy cellulitis. Five patients (3%) reported bruising to the breast. One patient (1%) had bruising immediately post-mammography but reported taking anticoagulants. Two patients (1%) reported by telephone interview that they had bruising under the breast and two (1%) had some bruising on the top of the breast. Five patients (3%) recorded pain in other areas such as sternum, elbow, armpit and shoulder which could relate to positioning.

Discussion

This was the first study to evaluate mammography-related pain in those attending for FH and FU mammography in the UK. Whilst similarities were found between the two groups in terms of pain experienced, there were differences in age distribution and menopausal status, which affected both study recruitment and comparisons.

Multiple factors contribute to pain during mammography. Some of these relate to equipment design, practitioner technique and some are unique to the individual patient. Pain can result in a failure to attend subsequent mammography examinations and patient experience is, therefore, paramount for patients with a FH who can have up to ten mammograms before entering the NHSBSP(2). FU patients can also undergo annual imaging for five years post-treatment(12), and have the added problems associated with post-surgical breast changes(13). Data from this study suggests that patients FU patients may be more susceptible to mammography-related pain resulting from post-surgical changes. By improving mammographic

experiences for patients, it is hoped that uptake will increase translating into earlier diagnosis and increased survival(14, 15). Additionally, it is an important healthcare priority to reduce non-attendance rates in terms of cost savings and time(16).

This study compared *previous* and *current* mammography examinations and data showed that there was strong correlation of pain between the two time points ($r = 0.79$, $P < 0.001$, **Figure 4**). This replicates the findings of Rutter et al.(17), Kornguth et al.,(18) and Aro et al.,(19). A more recent study by De Groot et al.(20), also found strong correlation but indicated that the process of measurement itself may heighten pain sensitivity. De Groot's study(21) recognised that there are personal characteristics relating to pain that are patient specific, such as psychological state and individual pain thresholds. The implications of this in clinical practice are that the patients may improve their perception of pain over time with experience.

Having a baseline pain score, which can be available for discussion between the mammographer and patient prior to mammography at their next attendance, is likely to be advantageous. This can help the mammographer give an appropriate level of support. Findings from this study have demonstrated an improvement in pain between *previous* and *current* mammograms implying experience improves with time and that more support should be available for first attenders.

A secondary aim of this research was to identify other predictive factors. During mammography the breast is compressed to reduce breast thickness and optimise image quality(22). Compression is operator dependent and is multifactorial in nature(23). Applied compression force was compared against pain scores. Results showed that there was a weak negative correlation between previous pain and compression force for both groups and a very weak negative correlation with current pain. Study findings indicated that compression was not found to be linked to pain in this study and was similar to the findings of De Groot et al.(24). In a more recent study(21), pain was found to be strongly correlated with compression during the phase where the breast is fully clamped and indicated that the timing of the pain assessment is important.

Variations in the applied compression force has been extensively evaluated by Mercer et al.,(23, 25, 26). Average compression scores across the FU/FH groups, for both projections, was 7.4 daN and within the recommended range(27).

Mammographers involved in this study all work in the same unit and used the same equipment. They have had similar training but differing lengths of experience. The study by Mercer et al. (25) showed that compression varied amongst individuals and between screening visits and acknowledged that this variation may negatively impact on patient experience. Whilst there were slight variations between the four practitioners, there was little variation between previous and current examinations and all four mammographers applied compression forces which resulted in low to moderate average pain scores. Pain reduced between the previous and current mammograms for all mammographers. A limitation of this study is that the number of previous mammograms was not specifically considered.

Patient type was seen to influence pain score relating to anxiety level concerning the results(28). Patients attending who have had previous cancer and or attended symptomatic clinics may be expected to have higher scores than screening patients which may explain variations. Korngruth et al.(18) also found variations in the recorded pain based on demographic and medical factors in up to 20% of patients. In this study, both groups would have anxiety relating to cancer diagnosis but the psychological differences between the two groups was not evaluated.

Breast size/density and menopausal status were also evaluated against current pain scores. There was a very weak correlation (r=-0.0069) between breast size and pain and findings were similar to Rutter et al.,(17), Sapir et al.,(29) and Sharp et al.,(30). Recent studies have evaluated breast contact area rather than size in recognition that it is the pressure or force per unit area that is the key to compression tolerance(31).

In our study the majority of the 56 FH pre-menopausal patients were in week 1 of their cycle (n=20). The average current pain score was low and aligns with previous research(32, 33). Patients in the premenopausal group experienced less pain than the postmenopausal group and this was most marked in the *previous pain* scores. In the premenopausal group, the average *previous pain* score was 3.6 and the *current pain* score 3.1. In the postmenopausal group, the average *previous pain* score was 4.9 and the *current pain* score 4.6. Overall, both groups had a slight reduction in pain between the two time points.

There was a very weak correlation between breast density and pain. This shows agreement with Hovhannisyan et al.,(34) and Kashikar-Zuck et al.,(35). Breast density was found to be a factor for current pain in the study by Korngruth et al.,(18) however the results were flawed with a high percentage (72%) of patients having moderate/dense breasts. In addition, 28% of patients had taken oral painkillers prior to the examination.

In conclusion this study found a strong correlation between a patient's previous experience of pain and their current pain scores with a slight reduction in pain overall seen between visits. A small percentage of patients experienced skin tearing and/or bruising and should be informed in advance about these risks. A small minority of patients (2%) reported prolonged pain and could benefit from additional support.

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Figure 1

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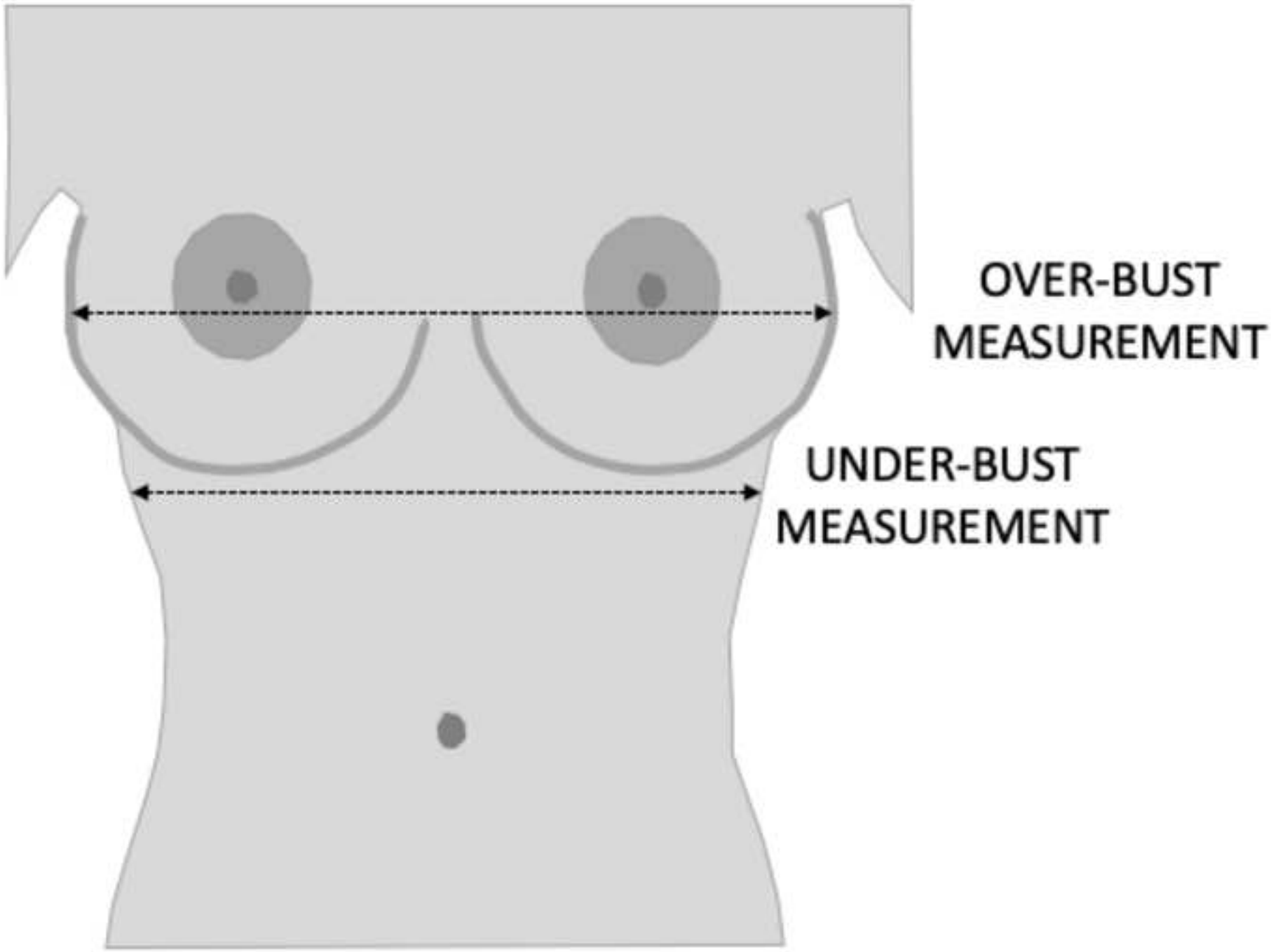

Figure 2

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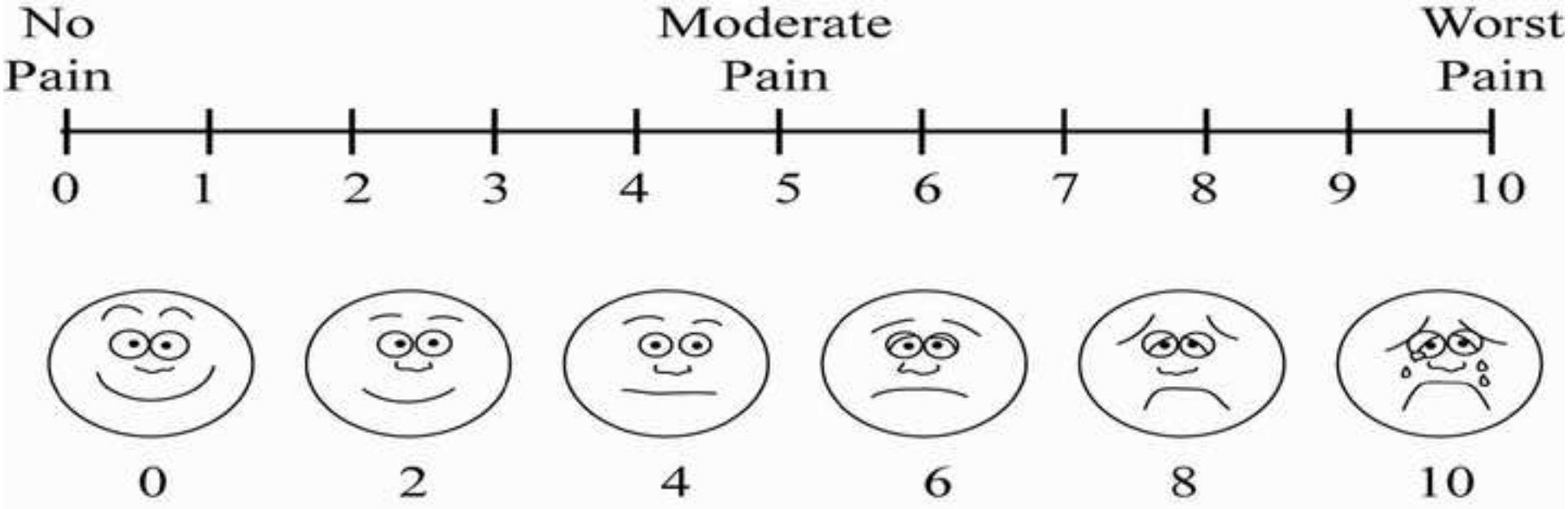

Figure 3

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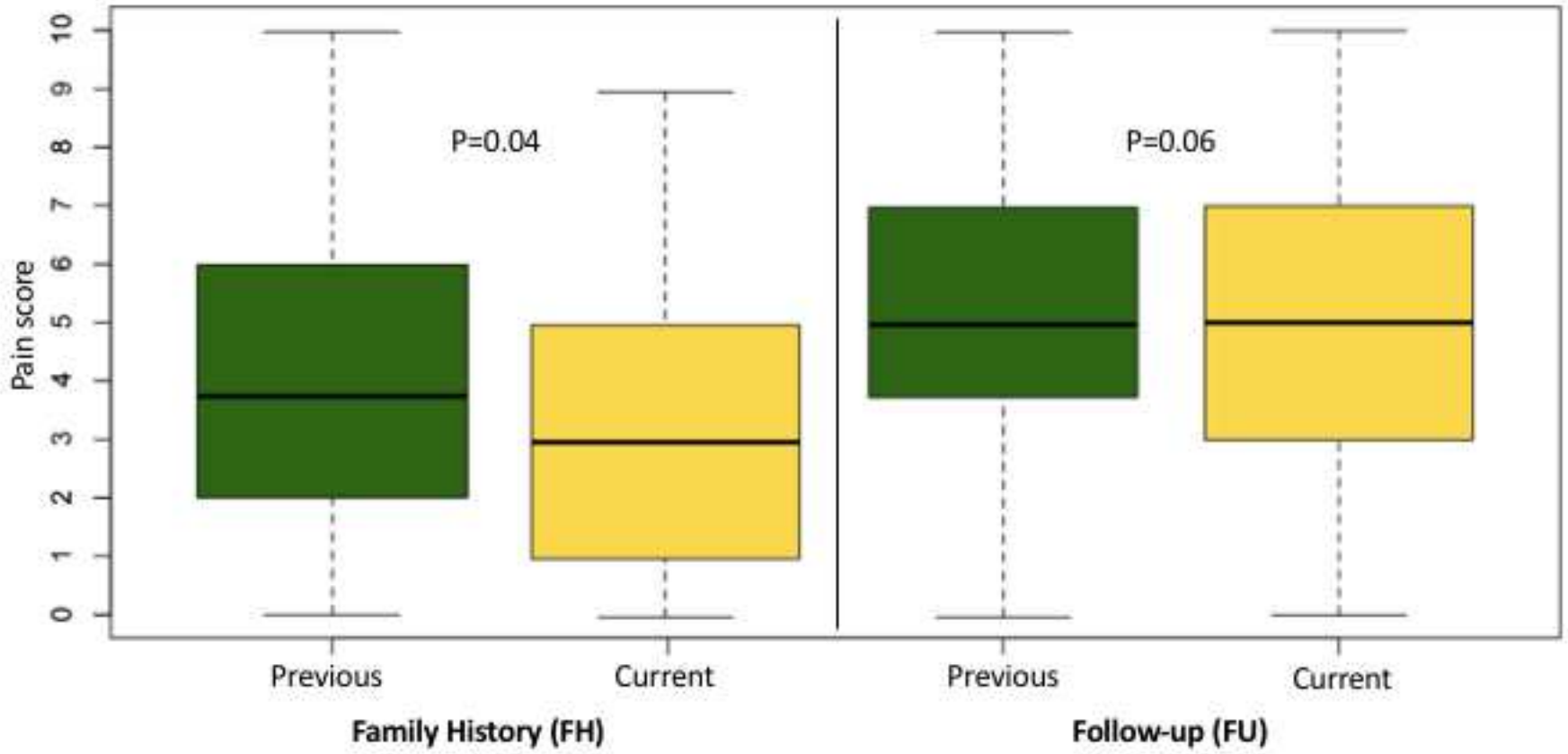

Figure 4

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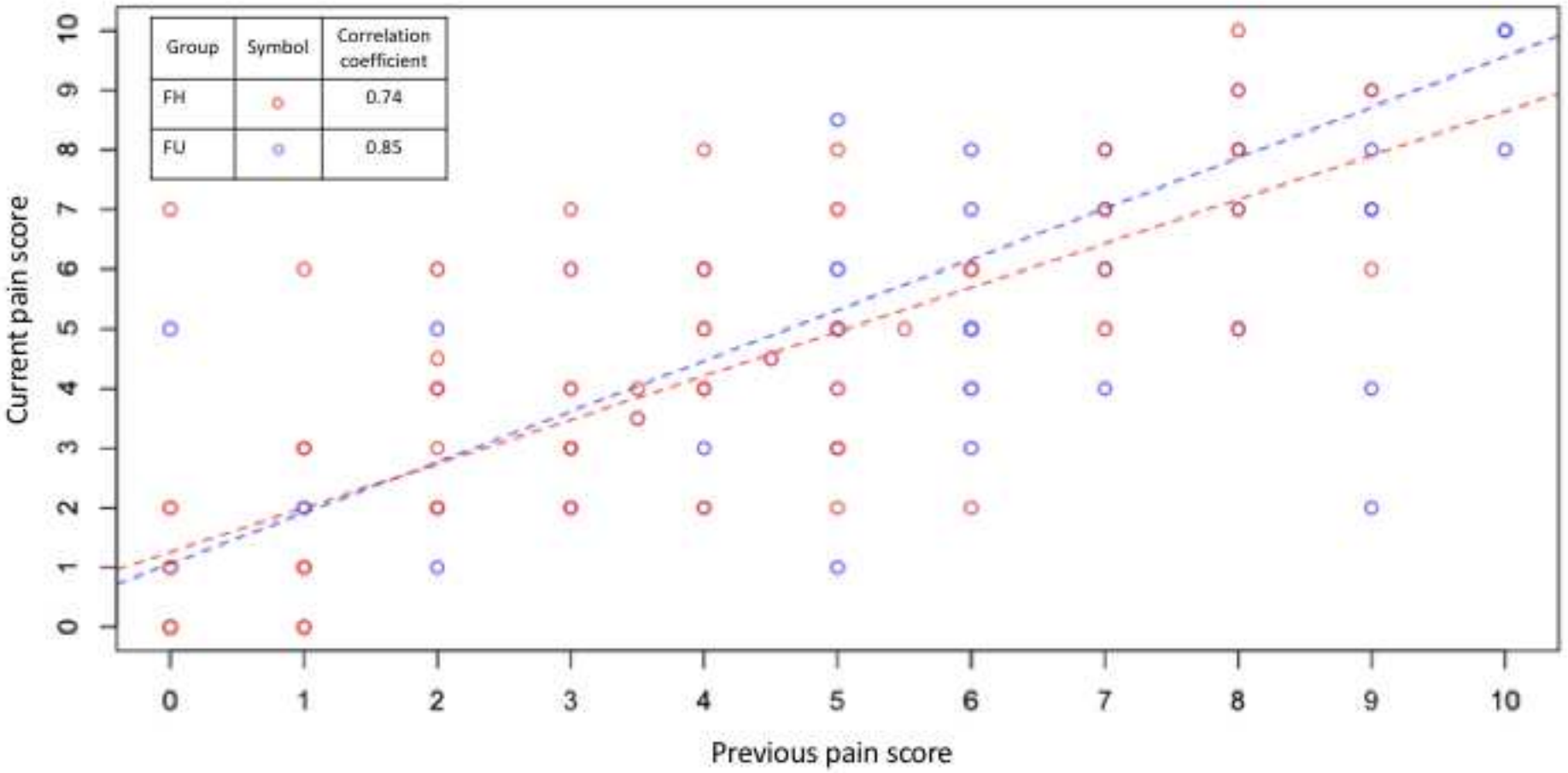

Legends for figures / tables

Figure 1. Schematic diagram of the bra cup measurement process

Figure 2. Pain scale used in the study(9)

Figure 3. Demonstrates a Box and Whisker Plot of the *previous* and *current* pain scores following mammography

Figure 4. Scatterplot of previous vs current mammography pain levels

Table(s)

Table 1. Method for converting chest circumferences to bra cup size(8)	
OVER-BUST CIRCUMFERENCE MINUS UNDER-BAND CIRCUMFERENCE (INCHES)	**UK BRA CUP SIZE**
less than 1"	**AA**
1"	**A**
2"	**B**
3"	**C**
4"	**D**
5"	**DD**
6"	**E**
7"	**F**
8"	**FF**
9"	**G**
10"	**GG**
11"	**H**

Table 2. Reasons why patients declined to participate.	
Reason	**n (%)**
No reason provided	13 (31)
Had recent screening mammogram in NHSBSP	7 (17)
Disabled or learning difficulties	4 (10)
Confused by paperwork	3 (7)
Felt anxious or unwell	2 (5)
Attended symptomatically	2 (5)
Implants not documented in clinical history	2 (5)
Unable to wait prior – time constraints	1 (2)
Physical reason - open sores on skin	1 (2)
Language barrier	1 (2)
Pregnancy	1 (2)

Table 3. Patients excluded from the study (n=89)	
Reason for exclusion	**n (%)**
Mastectomy patients	74 (83)
Implants	9 (10)
Previous mammogram elsewhere	4 (5)
Mammographer no longer employed at trust	2 (2)

Table 4. Frequencies (%) of pain scores during the different study time points.

Pain			**Time point**		
Score	**Category**	**Group**	**Previous (n=199)**	**Current (n=200)**	**Prolonged (n=193)**
0	No pain	FH	10 (10%)	12 (12%)	74 (76%)
		FU	6 (6%)	4 (4%)	82 (85%)
1-3	Low	FH	39 (39%)	44 (44%)	11 (11%)
		FU	18 (18%)	24 (24%)	9 (9%)
4 -7	Moderate	FH	43 (43%)	35 (35%)	12 (12%)
		FU	51 (52%)	53 (53%)	3 (3%)
8-10	Severe	FH	8 (8%)	9 (9%)	1 (1%)
		FU	24 (24%)	19 (19%)	2 (2%)

FH, family history; FU, follow-up.

Table 5. Previous and current compression force (DaN) values per mammographer per projection

	FU Group															
	Craniocaudal (CC)								**Mediolateral oblique (MLO)**							
	Previous				*Current*				*Previous*				*Current*			
Mammographer	**B**	**C**	**D**	**E**	**B**	**C**	**D**	**E**	**B**	**C**	**D**	**E**	**B**	**C**	**D**	**E**
Maximum	10.5	16.0	12.0	10.0	12.0	14.0	10.0	8.0	10.0	12.5	13.5	11.0	10.5	12.0	11.5	11.0
Upper Quartile	8.4	10.0	9.0	8.0	9.0	9.0	10.0	6.0	8.0	10.0	12.0	7.1	7.5	8.5	10.8	6.1
Median	7.6	9.0	8.1	6.6	7.6	8.5	8.8	5.6	6.7	8.5	9.6	6.4	6.9	7.8	9.6	5.6
Lower Quartile	6.0	7.8	6.4	5.5	6.0	7.4	8.0	4.9	5.5	6.8	7.2	5.5	5.5	6.8	8.4	4.5
Minimum	4.0	4.5	6.0	3.0	4.5	4.5	6.5	3.5	3.5	4.5	6.0	4.0	4.5	4.0	8.0	3.5
	FH Group															
	Craniocaudal (CC)								**Mediolateral oblique (MLO)**							
	Previous				*Current*				*Previous*				*Current*			
Mammographer	**B**	**C**	**D**	**E**	**B**	**C**	**D**	**E**	**B**	**C**	**D**	**E**	**B**	**C**	**D**	**E**
Maximum	16.0	14.5	12.0	12.5	15.0	12.5	11.5	12.0	16.5	14.0	6.5	12.5	14.5	13.0	8.0	11.0
Upper Quartile	9.5	13.0	12.0	8.5	10.0	10.5	11.5	7.4	8.8	12.0	6.5	8.4	10.0	10.0	8.0	6.9
Median	8.5	11.3	12.0	7.4	9.01	9.6	11.5	6.6	7.8	9.9	6.5	7.3	8.6	9.1	8.0	6.1
Lower Quartile	7.0	10.0	12.0	5.6	7.5	8.5	11.5	5.5	6.3	8.5	6.5	5.6	7.0	8.0	8.0	5.0
Minimum	5.0	8.5	12.0	4.0	5.5	7.0	11.5	3.5	3.0	5.5	6.5	3.0	3.5	6.0	8.0	3.5