 



**A National Audit**

**of the Practice and Outcomes of**

***T*h*e*r*a*peutic *Mammaplasty***

**The TeaM Study Group on behalf of the Mammary Fold Academic and Research Collaborative**

**Study Protocol Version 6**

**22nd May, 2016**

**The TeaM Study**

**A national audit of the practice and outcomes of therapeutic mammaplasty**

**TeaM Study Steering and Protocol Management Group**

|  |  |
| --- | --- |
| Miss Shweta Aggarwal  Locum Consultant Oncoplastic Breast Surgeon  Barts Health NHS Trust  Whipps Cross University Hospital  [drshweta@gmail.com](mailto:drshweta@gmail.com) | Mr Naren Basu  Consultant Oncoplastic Breast Surgeon  QE Hospital Birmingham  [Naren\_basu@hotmail.com](mailto:Naren_basu@hotmail.com) |
| Miss Elizabeth Baker  ST8 Breast Surgery  Yorkshire and the Humber Deanery  Project Originator  ([elbaker@doctors.org.uk](mailto:elbaker@doctors.org.uk)) | Mr Olivier Branford  Consultant Plastic Surgeon  Royal Marsden NHS Foundation Trust  RSTN Representative  [Olivier.branford@totalise.co.uk](mailto:Olivier.branford@totalise.co.uk) |
| Miss Lisa Brock  Research Co-ordinator  Nottingham Breast Institute  [Lisa.brock@nuh.nhs.uk](mailto:Lisa.brock@nuh.nhs.uk) | Ms Patricia Fairbrother  Independent Cancer Patients’ Voice  Patient Representative  [Pat@icpv.org.uk](mailto:Pat@icpv.org.uk) |
| Mr Matthew Gardiner  Clinical Lecturer, University of Oxford  Specialist Registrar in Plastic Surgery  Mid Essex Hospitals  RSTN Representative  [matthew.gardiner@kennedy.ox.ac.uk](mailto:matthew.gardiner@kennedy.ox.ac.uk) | Miss Charlotte Ives  ST8, Breast Surgery  Penninsula Deanery  Mammary Fold Academic and Research Collaborative Representative  [Charlotte.ives@nhs.net](mailto:Charlotte.ives@nhs.net) |
| Professor Chris Holcombe  Professor of Breast Surgery  Royal Liverpool Hospital  ABS Academic and Research Committee Representative  [Chris.Holcombe@rlbuht.nhs.uk](mailto:Chris.Holcombe@rlbuht.nhs.uk) | Mr Abhilash Jain  HEFCE Clinical Senior Lecturer in Plastic and Hand Surgery, University of Oxford, Honorary Consultant Plastic Surgeon, Imperial College Healthcare NHS Trust  RCS SSL in Plastic and Hand Surgery  [abhilash.jain@kennedy.ox.ac.uk](mailto:abhilash.jain@kennedy.ox.ac.uk) |
| Mr Baek Kim  ST6 Breast trainee  Yorkshire and the Humber Deanery  Project Originator  Mammary Fold Academic and Research Collaborative Representative  ([kimbaek@doctors.net.uk](mailto:kimbaek@doctors.net.uk)) | Mr R Douglas Macmillan  Consultant Oncoplastic Breast Surgeon  Nottingham Breast Institute  City Hospital  Senior Protocol Advisor  [douglas.macmillan@nottingham.ac.uk](mailto:douglas.macmillan@nottingham.ac.uk) |
| Mr John Murphy  Consultant Oncoplastic Breast Surgeon  University Hospital South Manchester  Senior Protocol Advisor  [John.Murphy@uhsm.nhs.uk](mailto:John.Murphy@uhsm.nhs.uk) | Miss Shelley Potter  Academic Clinical Lecturer  Centre for Surgical Research  University of Bristol  [Shelley.potter@bristol.ac.uk](mailto:Shelley.potter@bristol.ac.uk) |
| Mr Tim Rattay  NIHR Doctoral Fellow  Department of Cancer StudiesUniversity of Leicester  [tr104@leicester.ac.uk](mailto:tr104@leicester.ac.uk) | Mr Dennis Remoundos  Consultant Oncoplastic Breast Surgeon  Oxford  [dremoundos@gmail.com](mailto:dremoundos@gmail.com) |
| Mr Richard Sutton  Consultant Oncoplastic Breast Surgeon  Royal United Hospital Bath  [richardsutton@nhs.net](mailto:richardsutton@nhs.net) | Mr Adam Trickey  Research Associate  School of Social and Community Medicine, University of Bristol  Statistician and methodology  [Adam.trickey@bristol.ac.uk](mailto:Adam.trickey@bristol.ac.uk) |
| Miss Kate Williams  National Oncoplastic Fellow  President, Mammary Fold  University Hospitals South Manchester  [kwilliams@doctors.org.uk](mailto:kwilliams@doctors.org.uk) | Methodological Support  Bristol Surgical Trials Centre  School of Social and Community Medicine  University of Bristol  [csr-bristol@bristol.ac.uk](https://mail.google.com/mail/?view=cm&fs=1&tf=1&to=csr-bristol@bristol.ac.uk) |
|  | |

**On behalf of the Mammary Fold Academic Committee (mfac.research@gmail.com)**

**Website: www.themammaryfold/research-collaboratives-3/**

**Contents**

|  |  |
| --- | --- |
| 1. **Background**...................................................................................................................   1.1 Therapeutic mammaplasty........................................................................................  1.2 Trainee research collaboratives................................................................................ | 5  5  6 |
| 1. **Aims and objectives.**................................................................................................... | 6 |
| 1. **Definitions.**.....................................................................................................................   3.1 Therapeutic mammaplasty........................................................................................  3.2 Clinical outcomes.....................................................................................................  3.3 Oncological outcomes............................................................................................... | 7  7  7  8 |
| 1. **Audit standards**............................................................................................................. | 9 |
| 1. **Methods**.........................................................................................................................   5.1 Hospital episode statistics analysis……………………………………………………...  5.2 Prospective audit…………………………………………………………………………  5.2.1 Logistical and clinical governance issues........................................................  5.2.2 Patient inclusion and exclusion criteria...........................................................  5.2.3 Participant identification and recruitment........................................................  5.3 Design of a multicentre cohort study…………………………………………………… | 10  10  10  11  12  14  14 |
| 1. **Data collection**............................................................................................................... | 15 |
| 1. **Data validation and quality assurance**……………………………………..……………. 2. **Data management and storage**.................................................................................... | 24  25 |
| 1. **Sample size and data analysis**....................................................................................   8.1 HES Analysis………………………………………………………………………………  8.2 Prospective audit…………………………………………………………………………..  8.2.1 Sample size......................................................................................................  8.2.2 Data analysis.................................................................................................... | 26  26  26  26  26 |
| 1. **Publication and authorship policy**..............................................................................   9.1 Citable collaborators.................................................................................................  9.2 Acknowledged collaborators..................................................................................... | 27  28  28 |
| 1. **Research governance**................................................................................................... | 28 |
| 1. **Study management**....................................................................................................... | 28 |
| 1. **Study time lines**............................................................................................................   12.1 Study Gantt chart..................................................................................................   1. **References**..................................................................................................................... | 29  30  31 |
|  |  |

**1. Background**

**1.1 Therapeutic mammaplasty**

Breast conserving surgery (BCS) and adjuvant radiotherapy is an established treatment for early breast cancer[1](#_ENREF_1), [2](#_ENREF_2). While many women may prefer breast conservation to mastectomy, in many cases, standard BCS may result in unacceptable cosmetic outcomes[3](#_ENREF_3) which may adversely impact on patient satisfaction and quality of life[4](#_ENREF_4). Therapeutic mammaplasty (TM) describes ‘the oncoplastic application of breast reduction and mastopexy techniques to treat selected breast cancers by breast conserving surgery (BCS)’[5](#_ENREF_5), [6](#_ENREF_6). These techniques effectively extend the boundaries of traditional BCS by allowing adequate resection of larger tumours in women with medium to large breasts without compromising cosmetic outcome[7-10](#_ENREF_7); provide an alternative to mastectomy +/- reconstruction in those with ptotic breasts[5](#_ENREF_5) and may improve outcomes for women with large breasts in whom standard BCS followed by radiotherapy may be associated with lymphoedema, fibrosis and chronic pain[11](#_ENREF_11).

Despite the widespread adoption of these techniques into routine practice, there is limited high-quality evidence to support benefits of this approach. TM procedures are more complex than standard BCS with significant associated resource implications and concerns have been raised regarding both complication rates and oncological safety when TM is performed. Although these concerns are not supported by the literature[12](#_ENREF_12), [13](#_ENREF_13), the majority of published studies are small, retrospective single centre, often single surgeon case series with limited follow-up that are poorly designed and reported with inconsistent end-points[14](#_ENREF_14) that limit cross-study comparison such that the findings cannot be relied upon. Two recent systematic reviews[11](#_ENREF_11), [15](#_ENREF_15) have highlighted the paucity of high-quality clinical, oncological and cosmetic outcome data and emphasised the urgent need for well-designed prospective studies to establish the indications and outcomes of therapeutic mammaplasty to determine best practice. Uncertainties relating to the current indications for TM including the practice and outcomes of TM in large tumours (>4cm) not traditional managed by BCS; rates and management of margin positivity; predictors of adverse outcomes; the impact of TM on delivery of adjuvant therapy and appropriate assessment of key patient reported outcomes including, but not limited to, aesthetic end-points, as well as long term data on recurrence rates in particular need to be addressed if the procedure is to be offered and bench-marked appropriately.

Although RCTs provide the best evidence for the effectiveness of an intervention, trials are largely inappropriate in this context. A high-quality prospective multicentre cohort study exploring the practice and outcomes of these techniques is therefore essential to support the safe practice of TM, generate guidelines, guide decision-making and inform health policy.

**1.2 Trainee research collaboratives**

There are a number of established barriers to the conduct of large prospective multicentre studies, but the trainee research collaborative model has emerged as a time and cost-effective means of conducting large-scale prospective research and audit in surgery[16](#_ENREF_16), [17](#_ENREF_17). Trainee collaboratives have an excellent track record in the design and delivery of well-designed prospective cohort studies[18-20](#_ENREF_18) and randomised clinical trials[21](#_ENREF_21), [22](#_ENREF_22) in general surgery including the national appendicectomy audit which recruited 3326 patients from 95 centres over 2 months and the ROSSINI trial which randomised 760 patients from 21 centres to a wound protection device versus standard care. The trial recruited ahead of schedule and had minimal loss to follow-up[22](#_ENREF_22). Recent successes with iBRA (implant Breast Reconstruction evAluation Study)[23](#_ENREF_23), [24](#_ENREF_24) and MasDA (Mastectomy Decisions Audit) have demonstrated that the methodology is both feasible and effective within the context of breast surgery.

The TeaM (***T***h***e***r***a***peutic ***M***ammaplasty) Study therefore aims to work with the Mammary Fold Academic and Research Collaborative (MFAC) trainee network to deliver a high-quality prospective audit of the practice and outcomes of TM in the UK.

1. **Aims and objectives**
2. To identify the number of units performing TM across the UK and the volumes of procedures performed
3. To describe the current practice of therapeutic mammaplasty (TM) including the indications and techniques used
4. To evaluate the clinical outcomes of TM using different techniques and explore predictors of adverse outcome.
5. To determine the impact of TM on the delivery of adjuvant therapy
6. To determine best practice with regards to TM with a view to generating national guidelines
7. To establish a network of units performing TM willing and able to participate in future research studies
8. To inform the feasibility, design and conduct of a prospective multicentre cohort study exploring the clinical, patient-reported and oncological outcomes of TM
9. **Definitions**

**3.1 Therapeutic mammaplasty**

For the purpose of this study, ‘therapeutic mammaplasty’will be defined as ‘*the application of breast reduction or mastopexy techniques to treat selected breast cancers by breast conserving surgery*.’[6](#_ENREF_6) A therapeutic mammaplasty will *always* involve *some degree of skin excision and reduction of the skin envelope*. Level one oncoplastic procedures involving glandular remodelling with or without nipple re-positioning following wide local excision will be excluded.

**3.2 Clinical outcomes**

The following definitions of complications also will be used for this audit.

**Seroma** - A symptomatic collection of fluid requiring aspiration.

**Haematoma** - A collection of blood following the TM procedure

* **Minor –** managed conservatively by aspiration in clinic or
* **Major –** requiring surgical evacuation.

**Infection** - A hot, red swollen breast associated with one of the following; a temperature, pus at the wound site, a raised white cell count; a positive wound culture within the first 30 days following surgery. This will be further classified as:

* **Minor** – requiring oral antibiotics only;
* **Major 1** – requiring admission for IV antibiotics and/or debridement;
* **Major 2** – requiring surgical drainage/debridement

**Skin necrosis** - any area of skin loss on the operated breast including T junction

* **Minor** – managed conservatively with dressings
* **Major** – requiring surgical debridement under general anaesthesia (GA)

**Wound dehiscence –** separation of skin edges at any of the wound sites

* **Minor** – treated conservatively;
* **Major** – requiring return to theatre

**Nipple necrosis –** Any area of necrosis of the nipple areolar complex (NAC)

* **Minor** – managed conservatively with dressings;
* **Major 1** – requiring surgical debridement under GA;
* **Major 2** – complete nipple loss

**In hospital complication –** any complication that occurs during the patient’s initial hospital stay at the time of their TM. This includes systematic complications such as DVT/PE and procedure specific complications such as haematoma.

**Readmission to hospital –** any re-admission to hospital in 30 days following surgery directly related to the procedure (e.g with infection requiring antibiotics or systemic complications including pulmonary embolus)

**Return to theatre –** Return to the operating theatre at any time during the first 30 days following surgery to deal with any complication of the TM.

**Major complication -** Any complication requiring readmission to hospital or return to theatre

**Minor complication** - Any other complication

**3.3 Oncological outcomes**

The following definitions of outcomes related to oncological safety will be used:

**Positive margins** – invasive tumour or DCIS at or close to resection margin requiring further surgery (re-excision of margins or completion mastectomy) as defined by local MDT policy (e.g. tumour at ink/<1mm/<2mm)

**Re-excision of margins** – the removal of additional tissue in a second operation due to one or more involved margins as recommended by the MDT

**Completion mastectomy** – removal of all of remaining breast tissue in a second procedure due to involved margin(s) as recommended by MDT or elected by patient choice

**Time to adjuvant therapy** – time from last surgery to delivery of 1st adjuvant therapy (radiotherapy or chemotherapy).

**Delay to adjuvant therapy** - time to adjuvant therapy exceeds 31 days from last procedure[25](#_ENREF_25).

1. **Audit standards**

There are currently no guidelines specific for the practice of therapeutic mammaplasty in the UK. Therapeutic mammaplasty, however, can be considered within the spectrum of ‘oncoplastic breast surgery’. The joint Association of Breast Surgery (ABS) and British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS) Oncoplastic Breast Reconstruction: Guidelines for Best Practice[26](#_ENREF_26) have been developed to ‘*establish key elements of best practice in the management of patients considering reconstructive oncoplastic breast surgery (OPBS), using established techniques to reconstruct the breast after total mastectomy* ***or after partial mastectomy to prevent deformity following breast conservation***[***26***](#_ENREF_26).’ It is therefore appropriate to apply relevant quality criteria from this guidance to the current audit. Additional standards relating to the maximum numbers of procedures that should be performed in women undergoing BCS[27](#_ENREF_27) and timing of the delivery of adjuvant therapy[25](#_ENREF_25) following breast surgery produced by the professional associations[27](#_ENREF_27) and National Institute of Health and Care Excellence (NICE)[25](#_ENREF_25) respectively will also be applied.

1. **Unplanned return to theatre for local complications**

<5% of patients return to theatre for local complication (wound infection, wound problems requiring debridement or haematoma requiring evacuation)(QC16)[26](#_ENREF_26)

Assessed prospectively and by review of notes at 30 days.

1. **Unplanned readmission**

5% of patients require re-admission to hospital within 3 months (QC17)[26](#_ENREF_26)

As any complications from TM requiring re-admission are unlikely to occur after 30 days, this time frame will be used for the purpose of this audit. Unplanned readmission will be assessed prospectively and by review of notes at 30 days.

1. **Re-excision of margins**

To minimise the number of therapeutic operations, 100% of patients should have 3 or fewer procedures[27](#_ENREF_27). Number of procedures to be assessed and recorded prospectively.

1. **Delivery of adjuvant therapy**

‘Start adjuvant chemotherapy or radiotherapy as soon as clinically possible within 31 days of completion of surgery.’ Delivery of adjuvant therapy more than 31 days following the completion of surgery (TM or excision of margins, if required) will be considered ‘a delay’[25](#_ENREF_25). To be assessed prospectively.

1. **Methods**

This is a trainee collaborative project which will be co-ordinated by the Mammary Fold Academic and Research Collaborative (MFAC) Committee.

The study will have 3 phases

1. Exploration of trends in the national practice of TM using Hospital Episode Statistics (HES) data
2. A multicentre prospective audit of the clinical outcomes of TM
3. Design of a multicentre cohort study
   1. **Hospital episode statistics analysis**

The provision of TM across the UK will be explored using Hospital Episode Statistics (HES) data. Data will be extracted regarding the numbers of TM procedures performed between 2005 and 2015 on a national and individual unit basis. Data will also be extracted regarding the numbers of mastectomies with and without immediate breast reconstruction that are performed over the same period. Variation in OPCS Classification of Interventions and Procedures coding for TM will be explored.

The aims of this phase of the study will be to:

1. Investigate variations in the provision of TM across the UK
2. Explore how the provision of TM and the numbers performed have varied over time, nationally and by Trust
3. Explore whether the introduction of TM procedures have led to a reduction in local mastectomy rates (+/- immediate breast reconstruction) compared with units in which the procedures are not offered
4. Investigate how TM procedures are coded by individual units
5. Identify units performing TM to target for inclusion in the prospective audit phase of the study.

**5.2 Prospective audit**

Any breast or plastic surgical unit performing TM as defined by the application of breast reduction or mastopexy techniques to treat breast cancer using BCS will be eligible to participate in the audit. Units will be invited to participate through the Association of Breast Surgery, the Mammary Fold, the Association of Surgeons in Training (ASiT), the Reconstructive Surgery Trials Network (RSTN), the British Association of Plastic Reconstructive and Aesthetic Surgeons and the national research collaborative network. Units identified through phase 1 as performing high volumes of TM (>20/year) will also be specifically targeted for inclusion in the study by the steering group.

A local study lead, ideally a senior trainee with an interest in breast surgery will be identified at each centre. In units without trainees, the unit lead can be any regular member of the surgical team (e.g a clinical nurse specialist; Speciality or Associate Specialist (SAS) doctor, research team, breast or plastic surgical consultant). If the lead is a trainee, they will be required to identify a supervising consultant to act as principal investigator (PI) for the study. Unit leads will responsible for obtaining the support of other members of the team.

Support will also be sought from the professional associations – the Association of Breast Surgery (ABS) and the British Association of Plastic and Reconstructive Surgery (BAPRAS). We will ask that they encourage all Consultant members who are carrying out TM to support their trainees in this audit and to enter all patients undergoing TM in to the study as per ‘Guidelines for Best Practice’ quality criteria 22[26](#_ENREF_26).

**5.2.1 Logistical and clinical governance issues**

Phase 2 is a clinical audit.

The unit lead will be responsible for registering their unit with the TeaM study team (via www.mfacteamstudy@gmail.com); obtaining local audit approvals for study participation and forwarding a copy of the approvals to the TeaM study team prior to the study start date (5th September 2016).

If the unit lead is a trainee, the named supervising consultant will act as the principal investigator for the unit for registration purposes.

Patient recruitment and data collection will be completed by the unit lead. It is anticipated that each unit lead will identify a small team of 2-3 people to help conduct the audit and will liaise with the wider team including oncologists and breast care and reconstructive nurses.

The study will be piloted in two to three centres (Bath/Nottingham/Manchester) prior to national roll-out of the audit to evaluate the acceptability and completeness of data collection pro-formas and methods of data management.

**5.2.2 Patient inclusion and exclusion criteria**

***Inclusion criteria***

All female patients over the age of 16 under the care of either a breast or plastic surgeon undergoing a therapeutic mammaplasty defined as the application of breast reduction or mastopexy techniques including removal of skin to reduce the skin envelope to treat invasive or pre-invasive (DCIS) breast cancer using BCS will be eligible for inclusion in the study.

This will include any of the following techniques, performed using appropriate glandular or dermoglandular pedicles at the time of tumour removal *including the removal of skin to simultaneously reduce the skin envelope* (figure 1):

* Wise pattern, ‘inverted T’ or inverted anchor reduction patterns
* Single vertical scar or LeJour reduction mammaplasty techniques
* Benelli mastopexy
* Round block or donut techniques with excision of skin (see figure)
* Grisotti flaps for central cancers removing the nipple
* Melon-slice or horizontal wedge excision with or without nipple preservation

***Exclusion criteria***

The following patients will be excluded:

i. Women undergoing standard BCS not using reduction or mastopexy techniques with removal of skin to reduce the skin envelope

ii. Women undergoing BCS involving glandular remodelling only with or without nipple recentralisation (Level 1 techniques)

iii. Women undergoing BCS combined with volume replacement procedures such as LD mini-flaps, TDAP or LICAP flaps

iv. Women undergoing breast reduction or mastopexy to improve the appearance of the breast in a separate procedure from the initial resection of the tumour.

v. Women undergoing mastectomy with or without immediate reconstruction

v. Women undergoing surgery for indications other than invasive or pre-invasive disease

**Figure 1 – Types of therapeutic mammaplasty**

|  |  |
| --- | --- |
| **Wise pattern, inverted T or anchor reduction pattern techniques**[**5**](#_ENREF_5) | **Single vertical scar or LeJour reduction mammaplasty techniques**[**5**](#_ENREF_5) |
|  |  |
| **Benelli mastopexy technique** | **Round block or donut technique**[**5**](#_ENREF_5) |
| Adapted from[5](#_ENREF_5) |  |
| **Grisotti flap**[**28**](#_ENREF_28) **for central tumours excising the nipple** | **Melon slice or horizontal wedge excision (may or may not include nipple)** |
|  | Adapted from[5](#_ENREF_5) |

**5.2.3. Participant identification and recruitment**

It is expected that participating centres will recruit consecutive patients into the audit. The completeness of case ascertainment will be determined by comparing numbers of patients recruited with HES data from the same period and by independent validation of procedure numbers in selected sites. Any disparity will be explored with the unit concerned and any unit determined to have recruited patients selectively will be excluded from the analysis (see QA section).

Potential participants will be identified prospectively by the local audit team via clinics, local MDTs, consultant surgeons and clinical nurse specialists. Simple demographic, procedure and process data collected will be contemporaneously for each participant. Data will be recorded in an anonymised format using a unique alphanumeric study identification number on a secure web-based database (REDCap) designed by Vanderbilt University[29](#_ENREF_29), [30](#_ENREF_30) (<http://www.projectredcap.org/>). Data regarding in hospital complications will be collected prospectively and patients will be reviewed in clinic at 30 days to collect complication and oncology data. Note review will be performed in patients who do not attend for 30 day follow-up.

* 1. **Design of multicentre cohort study**

Data from phases 1 and 2 will be used to inform the design and conduct of a definitive multicentre cohort study.

Specifically, the TeaM study will establish the number and locations of units performing TM (to inform recruitment); the volumes of TMs performed (to inform sample size and feasibility of recruitment); the indications for surgery (to inform inclusion criteria); the techniques used (to inform study design and sample size); the short-term clinical outcomes (to inform choice of primary and secondary outcomes and sample size) and the timing of contralateral surgery (to inform the timing of PROMs assessments). Candidate study designs and outcomes will be explored with patient focus group to ensure the final study is acceptable and valuable to patients.

1. **Data collection**

The following data set will be collected prospectively based on relevant criteria outlined by Schaverien et al[14](#_ENREF_14).

1. **Patient demographics**
   1. Centre name and study ID
   2. Age (years)
   3. Height (m)
   4. Weight (kg)
   5. BMI
   6. Bra size
   7. Sternal notch to nipple distance (cm)
   8. Smoking status (non-smoker, ex-smoker >6/12, ex-smoker <4/52, current smoker, nicotine replacement)
   9. Diabetes (no/yes)
   10. Ischaemic heart disease (angina/previous MI) yes/no
   11. Connective tissue disease (e.g. SLE) yes/no
   12. Current steroid therapy (yes/no)
   13. Other comorbidities (free text box)
2. **Prior and neoadjuvant treatments**
   1. Previous radiotherapy to breast/chest wall (yes/no) with side if yes
   2. Neoadjuvant chemotherapy (yes/no)
   3. Neoadjuvant endocrine therapy (yes/no)
   4. Previous surgery to breast - (none/wide local excision/augmentation/reduction/other – please state) (date month/year
3. **Pre-operative planning data**
   1. Initial presentation

Screening or symptomatic

* 1. Breast affected

Right/left/bilateral

***For each affected breast***

3.3 Predominant location of tumour, by quadrant

1. Upper outer
2. Upper inner
3. Lower inner
4. Lower outer
5. Central (immediately behind or involving the nipple)

3.4 Type of lesion

1. Ductal carcinoma in situ only,
2. Invasive ductal cancer,
3. Invasive lobular cancer,
4. Other

3.5 Grade of cancer (1/2/3) or DCIS (low/intermediate/high)

3.6 Maximum size of lesion on pre-operative imaging in 2 dimensions (mm) x (mm) at DIAGNOSIS

3.7 Maximum size of lesion on pre-operative imaging AFTER neoadjuvant therapy (if used) and pre-surgery (mm) x (mm)

3.8 Focality

1. Unifocal – one lesion
2. Multifocal – two distinct separate lesions with apparently normal breast tissue between them

3.9 Contralateral symmetrisation

1. Planned at same time as TM

2. Planned for a later date

3. Patient does not want symmetrisation

3.10 What other treatment options were offered to the patient? (please tick all that apply)

1. Standard wide local excision

2. Mastectomy alone

3. Mastectomy with immediate implant-based breast reconstruction

4. Mastectomy with immediate autologous breast reconstruction

3.11 Indications for therapeutic mammaplasty (please tick all that apply)

1. To avoid mastectomy

2. To avoid poor cosmetic outcome associated with standard wide local excision

3. To avoid problems associated with radiotherapy in patients with large breasts

4. Large tumour

5. Quality of life benefits

6. Other (free text)

1. **Operative data**
   1. Date of procedure
   2. ASA grade (I-IV)
   3. Name of consultant surgeon
   4. Duration of procedure (knife to skin to dressings on) in minutes
   5. Procedure performed on right
2. None
3. Therapeutic mammaplasty
4. Reduction/mastopexy for symmetrisation
5. Mastectomy alone
6. Mastectomy and implant-based breast reconstruction
7. Mastectomy and autologous breast reconstruction
8. Other (free text)
   1. Procedure performed on left
      * 1. None
        2. Therapeutic mammaplasty
        3. Reduction/mastopexy for symmetrisation
        4. Mastectomy alone
        5. Mastectomy and implant-based breast reconstruction
        6. Mastectomy and autologous breast reconstruction
        7. Other (free text)

The following data will be collected for each TM procedure performed. The fields will self-populate or collapse as appropriate.

**Right breast – TM dataset**

* 1. Grade of operating surgeon (consultant/associate specialist/senior trainee/junior trainee/other)
  2. Number of therapeutic mammoplasties performed using this method in total (supervised and unsupervised)
  3. Number of therapeutic mammoplasties performed using this method unsupervised (<5, 5-10, 10-25, >25)
  4. Pre-operative localisation yes/no
  5. If yes – bracketed yes/no
  6. Nipple preserved (yes/no/free nipple graft)
  7. Skin incision used
     + 1. Peri or circumareolar with skin excision (round block/Benelli/Racquet)
       2. Wise-pattern/Inverted T
       3. Single vertical scar/LeJour
       4. Grisotti – for central cancers removing nipple
       5. Melon slice or horizontal wedge excision (+/- nipple)
       6. Other
  8. Pedicle(s) used to preserve the nipple (if nipple preserved)
     + 1. Superior
       2. Superiomedial
       3. Medial
       4. Inferior
       5. Central mound
       6. Dual pedicle
       7. Other
  9. How was tumour excised?
     + - 1. Wide local excision performed first, specimen removed followed by the reduction/mastopexy
         2. Wide local specimen incorporated in reduction specimen – both procedures performed simultaneously
  10. Intraoperative confirmation of excision

1. None
2. Specimen X-ray
3. Intra-operative frozen section
4. Margin probe/iKnife/intraoperative technology
5. Other
   1. Volume of wide local excision (grams)
   2. Total volume of breast tissue excised (wide local excision + all excised breast tissue) (grams)
   3. Method of marking tumour bed

(None/Single clip/Clips to all margins)

* 1. Axillary surgery performed

(None/sentinel node/clearance)

* 1. Drains used (yes/no)

**Right breast (reduction dataset)**

* 1. Grade of operating surgeon (consultant/associate specialist/senior trainee/junior trainee/other)
  2. Number of reductions performed using this method in total (supervised and unsupervised)
  3. Number of reductions performed using this method unsupervised (<5, 5-10, 10-25, >25)
  4. Skin incision used

1. Peri or circumareolar with skin excision (round block/Benelli/Racquet)
2. Wise-pattern/Inverted T
3. Single vertical scar/LeJour
4. Melon slice or horizontal wedge excision (+/- nipple)
5. Other
   1. Pedicle(s) used to preserve the nipple (if nipple preserved)
6. Superior
7. Superiomedial
8. Medial
9. Inferior
10. Central mound
11. Dual pedicle
12. Other
    1. Total volume of breast tissue excised (wide local excision + all excised breast tissue) (grams)
    2. Drains used (yes/no)

**Left breast – TM dataset**

* 1. Grade of operating surgeon (consultant/associate specialist/senior trainee/junior trainee/other)
  2. Number of therapeutic mammoplasties performed using this method in total (supervised and unsupervised)
  3. Number of therapeutic mammoplasties performed using this method unsupervised (<5, 5-10, 10-25, >25)
  4. Pre-operative localisation yes/no
  5. If yes – bracketed yes/no
  6. Nipple preserved (yes/no/free nipple graft)
  7. Skin incision used
     + 1. Peri or circumareolar with skin excision (round block/Benelli/Racquet)
       2. Wise-pattern/Inverted T
       3. Single vertical scar/LeJour
       4. Grisotti – for central cancers removing nipple
       5. Melon slice or horizontal wedge excision (+/- nipple)
       6. Other
  8. Pedicle(s) used to preserve the nipple (if nipple preserved)
     + 1. Superior
       2. Superiomedial
       3. Medial
       4. Inferior
       5. Central mound
       6. Dual pedicle
       7. Other
  9. How was tumour excised?
     + - 1. Wide local excision performed first, specimen removed followed by the reduction/mastopexy
         2. Wide local specimen incorporated in reduction specimen – both procedures performed simultaneously
  10. Intraoperative confirmation of excision

1. None
2. Specimen X-ray
3. Intra-operative frozen section
4. Margin probe/iKnife/intraoperative technology
5. Other
   1. Volume of wide local excision (grams)
   2. Total volume of breast tissue excised (wide local excision + all excised breast tissue) (grams)
   3. Method of marking tumour bed

(None/Single clip/Clips to all margins)

* 1. Axillary surgery performed

(None/sentinel node/clearance)

* 1. Drains used (yes/no)

**Left breast (reduction dataset)**

* 1. Grade of operating surgeon (consultant/associate specialist/senior trainee/junior trainee/other)
  2. Number of reductions performed using this method in total (supervised and unsupervised)
  3. Number of reductions performed using this method unsupervised (<5, 5-10, 10-25, >25)
  4. Skin incision used

1. Peri or circumareolar with skin excision (round block/Benelli/Racquet)
2. Wise-pattern/Inverted T
3. Single vertical scar/LeJour
4. Melon slice or horizontal wedge excision (+/- nipple)
5. Other
   1. Pedicle(s) used to preserve the nipple (if nipple preserved)
6. Superior
7. Superiomedial
8. Medial
9. Inferior
10. Central mound
11. Dual pedicle
12. Other
    1. Total volume of breast tissue excised (wide local excision + all excised breast tissue) (grams)
    2. Drains used (yes/no)
13. **Pathology and post-operative MDT outcomes**

To be collected for each side from which TM was performed

**Right breast**

5.1 Invasive/DCIS

5.2 Grade

5.3 One tumour (unifocal)/ 2 or more separate lesions

5.4 Size of invasive tumour (mm) (largest if >1)

5.5 Total size of lesion including DCIS (mm)

5.6 Fully excised by local criteria? (yes/no)

5.7 Number of lymph nodes involved (macromets only)

5.8 ER status (positive/negative/not known)

5.9 HER-2 status (positive/negative/not known)

***If not fully excised:***

5.10 MDT decision

1. Re-excision of margins

2. Mastectomy

3. Chemotherapy followed by re-excision of margins

4. Chemotherapy followed by mastectomy +/- reconstruction

**Re-excision 1**

5.11 Date of surgery

5.12 Surgery performed (re-excision of margins/completion mastectomy+/- reconstruction)

5.13 Specimen weight (g)

5.14 Margins clear (yes/no)

**Re-excision 2**

5.15 Date of surgery

5.16 Surgery performed (re-excision of margins/completion mastectomy =/- reconstruction)

5.17 Specimen weight (g)

5.18 Margins clear (yes/no)

**Re-excision 3**

5.19 Date of surgery

5.20 Surgery performed (re-excision of margins/completion mastectomy +/- reconstruction)

5.21 Specimen weight (g)

5.22 Margins clear (yes/no)

5.23 Chemotherapy recommended by MDT

Yes/No/ Neoadjuvant chemo already given

If yes

5.24 Date of recommendation

5.25 Patient accepts chemotherapy yes/no

5.26 Date of commencement of treatment

5.27 Radiotherapy recommended by MDT

Yes/No

If yes

5.28 Date of recommendation

5.29 Boost to tumour bed (yes/no)

5.30 Date of commencement of treatment

1. **30 day complication data (from date of initial TM surgery) – data for right and left breasts to be collected separately**

6.1 Seroma requiring aspiration (right/left/no)

6.2 Haematoma

6.2.1 Major (surgical drainage) (right/left/no)

6.2.2 Minor (conservative management) (right/left/no)

6.3 Wound infection

6.3.1 Minor (oral Abx) (right/left/no)

6.3.2 Major 1 (IV Abx) (right/left/no)

6.3.3 Major 2 (surgical drainage +/- debridement) (right/left/no)

6.4 Skin necrosis – including T junction necrosis

6.4.1 Minor (conservative management) (right/left/no)

6.4.2 Major (requiring surgical debridement) (right/left/no)

6.5 Nipple necrosis

6.5.1 Minor (conservative management) (right/left/no)

6.5.2 Major I (requiring debridement) (right/left/no)

6.5.3 Major II (complete NAC loss) (right/left/no)

6.6 Wound dehiscence

6.6.1 Minor – managed conservatively

6.6.2 Major – requiring return to theatre

6.7 In-hospital complication including systemic complications e.g. DVT/PE at time of initial surgery (yes/no with details)

6.8 Readmission to hospital within 30 days (yes/no with reason)

6.9 Re-operation for complication within 30 days (yes/no with reason)

6.10 Initial length of stay (day-case/23 hour stay/inpatient)

**7. Data validation and quality assurance**

Following data collection, only data sets with >95% data completeness will be included in the analysis[31](#_ENREF_31). For quality assurance purposes, the Consultant principal investigator at selected sites will be asked to identify an independent person to validate a proportion of the submitted data. Overall, approximately 5% of the datasets will be independently validated. The independent assessors will also be asked to examine theatre logbooks, operating diaries and Trust computer systems to check case ascertainment. HES data will also be used for this purpose. If concordance between the number of cases submitted on REDcap and those identified independently is <90%, the Unit’s data will be excluded from the analysis. This is consistent with the quality assurance procedure used in other large collaborative audit projects[31](#_ENREF_31).

1. **Data management and storage**

Data collection will occur in accordance with Caldicott II principles. Data for each patient will be anonymised using a unique alphanumeric study identification number. No patient identifiable data will be recorded for the purpose of the audit.

Study data will be collected and managed using REDCap electronic data capture tools hosted at University of Oxford[30](#_ENREF_30). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

**9. Sample size and data analysis**

All data analysis will occur centrally and will be led by TeaM Study Steering Group with support from statisticians and methodologists at the Bristol Surgical Trials Centre.

**9.1 HES Analysis**

HES data will be analysed using simple summary statistics. Data will be tested for distribution and variation in the number of procedures performed over time and mastectomy rates compared using unpaired t-tests, Mann-Whitney U tests and Chi squared tests as appropriate.

**9.2 Prospective audit**

**9.2.1 Sample size**

Data regarding the numbers of TM procedures performed nationally is lacking. Publications of single centre case-series, however, suggest that 10 and 20 procedures per year may represent a reasonable estimate of volume per centre. It is anticipated that the majority of the 144 breast units in the UK will offer the procedure to their patients. Based on experience from the iBRA study, it may be anticipated that 40% of units will chose to participate in the audit. Complication rates in the literature range from 10-91% with a median of 23%. Using these figures, taking 15 procedures per year as an estimate of volume per centre, we estimate that we will have a sample size around 432 (15 procedures, multiplied by 144 centres, multiplied by 0.4 to take account of unit participation, divided by 2 due to the use of half a year's recruitment) with recruitment for half a year. Using the median complication rate from the literature we would estimate around 99 adverse outcomes.

**9.2.2 Data analysis**

Simple summary statistics will be calculated for each outcome and regression analysis used to control for predictive variables. Data will be tested for distribution and differences between groups using unpaired t-tests, Mann-Whitney U tests and Chi squared tests as appropriate. Exploratory analyses will be performed to explore predictors for adverse outcomes and generate hypotheses for future studies.

Summary statistics will be calculated for each participating Trust and fed back to individual units to allow comparison with national averages and ranges.

Full details of the analysis can be found in the Statistical Analysis Plan (SAP).

**10. Publication and authorship policy**

The TeaM Study Steering Group which will be responsible for drafting manuscripts and preparing them for publication.

All publications from this project will be ‘on behalf of the Therapeutic Mammaplasty (TeaM) Study Group and the Mammary Fold Academic and Research Collaborative’.

The International Committee of Medical Journal Editors (ICMJE) criteria (www.icmje.org) for authorship is based on the following four criteria:

1. Substantial contribution to the conception or design of the work; or the acquisition, analysis or interpretation of the data for the work and
2. Drafting the work or revising it critically for important intellectual content and
3. Final approval of the version to be published and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The ICMJE states ‘*when submitting a manuscript authored by a group, the corresponding author should specify the group name if one exists and clearly identify the group members who can take credit and responsibility for the work as authors. The byline of the article identifies who is directly responsible for the manuscript and MEDLINE lists authors whichever names appear on the byline. If the byline includes a group name, MEDLINE will list the names of individual group members who are authors or who are collaborators, sometimes called non-author contributors, if there is a note associated with the byline clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators*.’

All citable collaborators will therefore be listed at the end of the paper and their roles identified.

**10.1 Criteria for citable collaborators status**

Citable collaborators will have been required to make considerable contribution to the study. These will include leads at each centre and other team members (including consultant surgeons, SAS doctors, clinical nurse specialists or research nurses) who have recruited at least 5 patients to the study. Recruitment in this context includes the submission of ***at least five completed data sets***. Judgement may be used to determine participation according to local centre practice. Unit leads will be asked to provide details of their local team and whether individuals fulfil the criteria for citable or acknowledged collaborator status.

**10.2 Acknowledged collaborators**

Acknowledged collaborators will include consultant surgeons who contributed patients to the audit, but did not personally collect data and trainees who have made a lesser contribution to patient recruitment and data collection than that required for citable collaborator status. Trainees who are acknowledged contributors will also receive a certificate of participation for inclusion in their portfolios.

Local collaboratives and hospital Trusts will have ownership of their own data and will be able to present it locally if they wish.

**11. Research Governance**

The main aim of the audit is to determine the safety of therapeutic mammaplasty.

Data will be analysed at the end of the study period to determine mean complication and re-excision rates. These figures will be used for benchmarking and to determine acceptable complication parameters for the audit (mean +/- 3 standard deviations as per original NMBRA). Outcome data for each individual centre and/or surgeon (depending on number of patients recruited) will be calculated, compared with the national average and fed back to participating units.

**12. Study Management**

Oversight of the audit will be by the TeaM Audit Steering Group which will have wide representation from reconstructing surgeons, trainees, the professional societies, patient representative and those with experience of study management and statistics. This group is expected to meet twice per year, but may also meet more frequently if necessary.

There will in addition be a smaller executive group for day to day audit management. It is expected that most of this work will be done as a ‘virtual group’ by e mail.

**13. Study timeline**

The following study time line is proposed

* HES analysis
  + Feb – May 2016
* 3 centre pilot study
  + April 2016 onwards
* Registration of interest from breast units
  + Feb –September 2016
* Local audit approvals in participating units
  + February-September 2016

**\*\*\*\* All units must have registered, obtained local audit approvals for study participation and sent a copy of the form/email confirming audit approvals to the MFAC by the study start date 5th September 2016\*\*\*\***

* Patient recruitment
  + Patients with TM operation dates between 5th September 2016 – 10th February 2017 inclusive
* Data collection period
  + 5th September 2016- 12th March 2017 (allowing for 30 day FU)
* Closing date for data submission
  + 31St March 2017
* Data analysis
  + April-May 2017
* Write up and dissemination
  + June/July 2017
* Design of prospective cohort study and grant submission
  + Sept-Dec 2017

**Gantt Chart for TeaM Study**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **2016** | | | | | | | | | | | **2017** | | | | | | | | | | | |
| **F** | **M** | **A** | **M** | **J** | **J** | **A** | **S** | **O** | **N** | **D** | **J** | **F** | **M** | **A** | **M** | **J** | **J** | **A** | **S** | **O** | **N** | **D** |
| **Phase 1 HES Data Analysis Study** | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Registrations of interest and local audit approvals obtained** | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | **3 centre prospective audit pilot study** | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  | **National patient recruitment and data collection**  **5th September 2016 – 10th February 2017** | | | | | |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | **Data cleaning and**  **analysis** | | |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **Write up & dissemination** | | |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **Design of Prospective cohort study and funding submission** | | | |

**13. References**

1. Fisher B, Anderson S, Bryant J, Margolese RG, Deutsch M, Fisher ER, Jeong JH, Wolmark N. Twenty-Year Follow-up of a Randomized Trial Comparing Total Mastectomy, Lumpectomy, and Lumpectomy plus Irradiation for the Treatment of Invasive Breast Cancer. *New England Journal of Medicine* 2002;**347**(16): 1233-1241.

2. Veronesi U, Cascinelli N, Mariani L, Greco M, Saccozzi R, Luini A, Aguilar M, Marubini E. Twenty-Year Follow-up of a Randomized Study Comparing Breast-Conserving Surgery with Radical Mastectomy for Early Breast Cancer. *N Engl J Med* 2002;**347**(16): 1227-1232.

3. Haloua M, Krekel N, Jacobs G, Zonderhuis B, Bouman M, Buncamper M, Niessen F, HAH W, Terwee C, Meijer S, van den Tol M. Cosmetic assessment following breast conserving therapy: A comparison between BCCT.core software and panel evaluation. *International Journal of Breast Cancer* 2014;**Article ID 716860**.

4. Cochrane RA, Valasiadou P, Wilson ARM, Al-Ghazal SK, Macmillan RD. Cosmesis and satisfaction after breast-conserving surgery correlates with the percentage of breast volume excised. *British Journal of Surgery* 2003;**90**(12): 1505-1509.

5. McCulley SJ, Macmillan RD. Planning and use of therapeutic mammaplasty—Nottingham approach. *British Journal of Plastic Surgery* 2005;**58**(7): 889-901.

6. Macmillan D, James R, Gale K, McCulley SJ. Therapeutic mammaplasty. *Journal of Surgical Oncology* 2014;**110**: 90-95.

7. Mansfield L, Agrawal A, Cutress RI. Oncoplastic breast conserving surgery. *Gland Surgery* 2013;**2**(3): 158-162.

8. Piper M, Peled AW, Sbitany H. Oncoplastic breast surgery: current strategies. *Gland Surgery* 2015;**4**(2): 154-163.

9. Bamford R, Sutton R, McIntosh J. Therapeutic mammaplasty allows for clear surgical margins in large and multifocal tumours without delaying adjuvant therapy. *The Breast* 2015;**24**(2): 171-174.

10. Schaverien MV, Raine C, Majdak-Paredes E, Dixon JM. Therapeutic mammaplasty – Extending indications and achieving low incomplete excision rates. *European Journal of Surgical Oncology (EJSO)* 2013;**39**(4): 329-333.

11. McIntosh J, O'Donoghue JM. Therapeutic mammaplasty--a systematic review of the evidence. *Eur J Surg Oncol* 2012;**38**(3): 196-202.

12. Harvey J, Henderson J, Patel L, Murphy J, Johnson R. Therapeutic mammaplasty – Impact on the delivery of chemotherapy. *International Journal of Surgery* 2014;**12**(1): 51-55.

13. Kahn J, Barrett S, Forte C, Stallard S, Weiler-Mithoff E, Doughty JC, Romics Jr L. Oncoplastic breast conservation does not lead to a delay in the commencement of adjuvant chemotherapy in breast cancer patients. *European Journal of Surgical Oncology (EJSO)* 2013;**39**(8): 887-891.

14. Schaverien MV, Doughty JC, Stallard S. Quality of information reporting in studies of standard and oncoplastic breast-conserving surgery. *The Breast* 2014;**23**(2): 104-111.

15. Haloua MH, Krekel NM, Winters HA, Rietveld DH, Meijer S, Bloemers FW, van den Tol MP. A systematic review of oncoplastic breast-conserving surgery: current weaknesses and future prospects. *Ann Surg* 2013;**257**(4): 609-620.

16. Bhangu A, Kolias AG, Pinkney T, Hall NJ, Fitzgerald JE. Surgical research collaboratives in the UK. *The Lancet* 2013;**382**(9898): 1091-1092.

17. Dowswell G, Bartlett D, Futaba K, Whisker L, Pinkney T, on behalf of West Midlands Research Collaborative B, UK. How to set up and manage a trainee-led research collaborative. *BMC Medical Education* 2014;**14**(1): 94.

18. The UK National Surgical Research Collaborative. Safety of Short, In-Hospital Delays Before Surgery for Acute Appendicitis: Multicentre Cohort Study, Systematic Review, and Meta-Analysis. *Annals of Surgery* 2014;**Publish Ahead of Print**: 10.1097/SLA.0000000000000492.

19. Ferguson HJ, Hall NJ, Bhangu A, on behalf of the National Surgical Research Collaborative. A multicentre cohort study assessing day of week effect and outcome from emergency appendicectomy. *BMJ Quality & Safety* 2014.

20. National Surgical Research Collaborative. Multicentre observational study of performance variation in provision and outcome of emergency appendicectomy. *British Journal of Surgery* 2013;**100**(9): 1240-1252.

21. Bhangu A, Futaba K, Patel A, Pinkney T, Morton D. Reinforcement of closure of stoma site using a biological mesh. *Techniques in Coloproctology* 2013: 1-4.

22. Pinkney TD, Calvert M, Bartlett DC, Gheorghe A, Redman V, Dowswell G, Hawkins W, Mak T, Youssef H, Richardson C, Hornby S, Magill L, Haslop R, Wilson S, Morton D. Impact of wound edge protection devices on surgical site infection after laparotomy: multicentre randomised controlled trial (ROSSINI Trial). *BMJ* 2013;**347**.

23. Potter S, Holcombe C, Mylvaganam S, Thrush S, Whisker L, Skillman J. The iBRA study: A national multicentre audit of the outcomes of implant-based breast reconstruction with and without lower pole support. *Journal of Plastic, Reconstructive & Aesthetic Surgery* 2014;**67**(10): 1467-1468.

24. Potter S, Holcombe C, Mylvaganam S, Thrush S, Whisker L, Skillman J. 442. The iBRA Study: A national multicentre audit of the practice and outcomes of implant-based breast reconstruction. *European Journal of Surgical Oncology (EJSO)* 2014;**40**(11): S168-S169.

25. National Institute of Clinical Excellence. *Breast cancer (early & locally advanced): diagnosis and treatment*, 2009.

26. Rainsbury D, Willett A. Oncoplastic Breast Reconstruction: Guidelines for Best Practice: ABS and BAPRAS; 2012.

27. Association of Breast Surgery at BASO. Surgical guidelines for the management of breast cancer. *European Journal of Surgical Oncology (EJSO)* 2009;**35, Supplement 1**: S1-S22.

28. Grisotti A. Immediate reconstruction after partial mastectomy. *Operative Techniques in Plastic and Reconstructive Surgery* 1994;**1**(1): 1-12.

29. Obeid JS, McGraw CA, Minor BL, Conde JG, Pawluk R, Lin M, Wang J, Banks SR, Hemphill SA, Taylor R, Harris PA. Procurement of shared data instruments for Research Electronic Data Capture (REDCap). *Journal of Biomedical Informatics* 2013;**46**(2): 259-265.

30. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics* 2009;**42**(2): 377-381.

31. Vohra RS, Spreadborough P, Johnstone M, Marriott P, Bhangu A, Alderson D, Morton DG, Griffiths EA. Protocol for a multicentre, prospective, population-based cohort study of variation in practice of cholecystectomy and surgical outcomes (The CholeS study). *BMJ Open* 2015;**5**(1).

32. Duxbury PJ, Gandhi A, Kirwan CC, Jain Y, Harvey JR. Current attitudes to breast reconstruction surgery for women at risk of post-mastectomy radiotherapy: A survey of UK breast surgeons. *The Breast* 2015;**24**(4): 502-512.