The PartBreCon-Pro Study

PartBreCon-Pro Study: - A multi-centre PROspective study, including PROMS of PARTial BREast ReCONstruction with chest wall perforator flap

A BreCon project

A prospective multicentre cohort study to evaluate the clinical and patient-reported outcomes following breast-conserving surgery and partial breast reconstruction with chest wall perforator flap

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A study by the **Bre**ast **Con**sortium **(BreCon)**

Study Protocol
Version 4.1

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1 Background

1.1 Chest Wall perforator flap

Surgery remains the primary treatment for early breast cancer, with 7-8 out of 10 women with breast cancer undergoing breast conservative surgery (BCS) [1]. Although effective for smaller tumours, poor aesthetic outcomes after BCS can lead to adverse patient-reported outcomes for some patients, such as distorted body image, negative self-esteem, and loss of confidence in psychosocial and sexual settings [2]. Further, complications can worsen aesthetic outcomes [3,4] and patient experience following necessary radiotherapy [5,6].

Oncoplastic breast conservative surgery aims to ensure complete oncological resection whilst maintaining or improving current breast aesthetics. Oncoplastic techniques have evolved and expanded over the last 15-20 years, including volume replacement techniques of chest wall perforator flaps (CWPF) in partial breast reconstruction. Hamdi et al. described using these flaps in partial breast reconstruction in 2004 [7]. These versatile flaps are useful to replace breast volume loss of up to 30%, especially in small to medium-sized breasts (up to size C or D European Bra cup size), to avoid mastectomy for similar size tumours due to the relative lack of remaining breast volume following tumour excision.

CWPF surgery is an improvement over BCS and partial breast reconstruction techniques that used a strip of back muscle (Latissimus Dorsi, LD) [8,9] and resulted in more post-operative pain, longer hospital stays, longer recovery time and some compromise of shoulder function [10].

Although described a decade ago, the use of perforator flaps in volume replacement has increased only over the last few years. Evidence in the literature is based on small case series with relatively low volume experience and limited outcomes [11-15]. A systematic review [16] showed low complication rates. However, it included studies that had non-concordant datasets with variable follow-up. A large multi-centre series (15 UK centres, n = 507) by this BreCon collaborative[17] showed low complication rates (30-day haematoma, 4.3%; infection, 4.3%; delayed wound healing, 2.8% and 0.6% flap loss leading to readmissions in 2.6% and re-operations in 2.6%. However, the series is retrospective, with no PROM data and inadequate data on radiotherapy, which can influence aesthetic outcomes and, consequently, PROMs.

1.2 The impact of radiotherapy on surgical and patient-reported outcomes

There needs to be more trial data on the effect of radiotherapy on outcomes following OBS, including in the CWPF [3]. Before OBS, unrepaired defects following BCS filled with seroma (wound fluid). When the seroma resolved, the operated area used to deform with significant scarring that worsened with radiotherapy, leading to poorer outcomes evident in many radiotherapy studies [3]. Most radiotherapy trials will not have included these newer OBS procedures [3,18].

Any robust prospective surgical database needs to include radiotherapy data since this influences the post-operative condition of the breasts and, in turn, impacts both surgical and patient-reported

outcomes. For example, some patients need an extra dose (boost dose) to the original tumour bed in addition to standard whole-breast radiotherapy. An initial retrospective report attempted to understand the nuances of radiotherapy planning in CWPF and highlighted the complexities [19].

A recent literature review on boost radiotherapy reveals a lack of boost data in partial breast reconstruction, i.e., replacement type of oncoplastic breast surgery [20].

Therefore, it is necessary to audit radiotherapy data

- To better understand planning consistency, which is essential for oncological safety
- To ascertain the impact of radiotherapy on cosmetic outcomes following OBS

Additionally, analysis of robust outcome data may provide insights that can lead to future radiotherapy trials within OBS in a truly multi-disciplinary approach [21].

1.3 PROMS in Breast Conserving Surgery and CWPF

It is estimated that at least two-thirds of women following treatment for breast cancer will live beyond 15 years. Whilst interrelated with clinical outcomes, a patient's perception and satisfaction with their cancer treatment include elements beyond objective clinical measures of survival or function. The desired aesthetic outcome is vital for these women's QoL considerations (body confidence, psychosocial and psychosexual health) to allow them to lead a 'new normal' life. Therefore, patient-reported outcomes (PROs) are vital to demonstrating cancer treatment success.

The UK NCRI Living With and Beyond Cancer Group have identified short- and long-term effects and psychological impact among research priorities [22].

There has been a growing use of PROMs in health care over the last 20 years [23]. Routine use provides an opportunity to help drive changes in how health care is organised and delivered [24]. PROMs are routinely used to monitor elective surgery. A systematic review [25] identified two validated PROMs specifically for breast cancer surgery (BIBCQ and Breast-Q). BIBCQ does not address any aesthetic issues after breast reconstruction. Although Breast-Q has individual modules for BCS and LD surgery, it does not address outcomes specific to CWPF.

Breast-Q (©2017, Memorial Sloan Kettering Cancer Centre and the University of British Columbia) is a commonly used validated psychometrically developed and validated multiscale, multimodule tool for Patient Reported Outcomes Measures (PROMs) for oncoplastic and reconstructive breast surgery [26,27]. Breast-Q provides scores ranging from 0-100, with 100 being the highest in both patient satisfaction and Quality of Life (QOL) domains.

Due to a lack of specific PROMS in CWPF, after due licence-holder permission, a combination Breast-Q (combined Breast Conserving Therapy, BCT and Latissimus Dorsi flap, LD modules) has been used following CWPF [28,29]. Two University hospitals explored the combination of Breast-Q's BCT and LD flap modules [30]. The baseline data from 36 patients, 6-12 months after radiotherapy, revealed a minimum of 80% patient satisfaction in all domains with two lower-scoring domains: sexual 60% and physical well-being 76%. The LD module showed 90% satisfaction with the back appearance and 77% with shoulder and back function.

The lack of pre-operative baseline data, small numbers, and the absence of patient demographics, disease, and treatment data limits the interpretation. However, without specific CWPF PROMs, they show the feasibility of combining Breast-Q's Breast Conserving Therapy module and the back sub-scale of the LD flap module for CWPF. Also, the current Breast-Q LD flap module studies complete back muscle (LD) use for full breast reconstruction following total mastectomy (and not BCT). However, CWPF does not use muscle.

Therefore, the evidence gap needs addressing to establish outcomes standards commensurate with current and increasing 'replacement' procedure options that improve women's choices.

2 Methods

2.1 Study Design

A non-interventional observational multicentre prospective cohort study

2.2 Aims

This multicentre prospective cohort study aims to evaluate the surgical outcomes of CWPF partial breast reconstructions following breast-conserving surgery for early breast cancer. This project aims to create a performance standard for CWPF procedure based on robust, reliable, and valid data.

Therefore, a prospective, representative dataset is needed from which to extract reliable and valid statistical distributions that show:

1. The impact of surgery on the clinical outcome.
2. The impact of radiotherapy on the clinical outcome
3. Patient Reported Outcome Measures (PROMs)

2.3 Objectives

Aims will be achieved in three parts of the audit:

Part A: Surgical treatment dataset
Part B: Oncological treatment dataset
Part C: PROMS (Optional)

Part A: Surgical treatment dataset

It will include surgical variables that can be prospectively fed into the RedCap™ database and maintained prospectively, including surgical outcomes at 30 days (in line with NHS Health Episode Statistics) with determination and analysis of

- Patient demographics, tumour, and surgical characteristics
- Complications rate and types
- Re-excision rates

Part B: Oncological treatment dataset

It would be the audit dataset that all centres are encouraged to work with their Oncology colleagues in a multi-disciplinary fashion to collate oncological treatment records, specifically radiotherapy data, to inform the consistency of oncological therapies and outcomes.

Part C: PROMS

PROMS (Breast-Q's BCT and LD flap back modules will be given pre-operatively and 6 months after radiotherapy. In addition, the DASH (Disability of Arm, Shoulder and Hands) questionnaire for shoulder function. Those centres using PROMS are requested to complete this component, too. However, centres not using PROMS in their routine practice cannot audit this component (Part C). Once patients return the PROMs Scores, they must be inputted into the database.

2.4 Main Outcomes and Measures

A) Patient Demographics and Tumour characteristics

1. Patient demographics: age, body mass index (BMI), comorbidities
2. Preoperative tumour characteristics and location influencing surgical planning

B) Treatment characteristics

1. Surgical: operative data, including flap types and distribution
2. Oncological: systemic therapies (adjuvant and neoadjuvant), radiotherapy

C) Primary outcome: Surgical

1. Complications
2. Oncological clearance: Re-excision rates, conversion to mastectomy

D) Secondary outcomes

1. Revisional surgery
2. Surveillance
3. Oncological: Recurrence and Mortality

E) Patient-reported outcomes

1. Pre-operative
2. Post-operative (pre-radiotherapy)
3. Post-radiotherapy (6 months)

2.5 Outcome Conclusions

- It will be the first prospective audit of CWPF practice; it will provide a baseline for re-audits
- Shared learning experience leading to an improvement in practice
- Patient feedback will lead to improvement

2.6 Setting, Participants and Exposure

Each surgeon in each centre should have performed 10 CWPF cases to demonstrate experience beyond the early learning phase that could influence surgical outcomes. Each centre anticipates that approximately 10 CWPF Patients will be performed each year.

Patients would have been offered all options (simple wide local excision, therapeutic mammaplasty, mastectomy with or without immediate whole breast reconstruction) in keeping with UK oncoplastic guidelines [31]. We will collect data on consecutive patients in each centre according to the prospectively maintained local database on CWPF surgery, and this will reduce selection bias.

PROMs: They will be given pre-operatively and 6 months following radiotherapy (please see enclosed pre-operative and post-operative versions). Therefore, the earliest post-operative PROMs is expected from March 2024, and the latest will be January 2026 to allow for the completion of the following:

- Adjuvant radiotherapy only: standard commencement within 3 months and up to 4 weeks duration
- Adjuvant chemo-radiotherapy: Standard commencement is within 3 months and usually extends over 9 months.

2.7 Inclusion and Exclusion criteria

Inclusion criteria:

- Patients undergoing partial breast reconstruction using CWPF for primary breast cancer
- Delayed correction of breast deformity following previous BCS
- Each surgeon is to have performed a minimum of 10 CWPFs
- Each centre anticipates completing a minimum of 10/year

Exclusion criteria:

- Patients undergoing volume displacement BCS
- Patients undergoing mastectomy +/- immediate breast reconstruction

2.8 Study Duration

Audit duration: 36 months (01 June 2023 – 31 May 2026)

Audit entry period: 24 months (01 June 2023 – 31 May 2025) – all patients who undergo CWPF during this period.

Data lock and cleaning: 2 months (01 March 2026 – 30 April 2026)

Data analysis: 1 month (01 May 2026 – 31 May 2026)

2.9 Surgical Technique

According to the published anatomical landmarks and operative steps, CWPF surgery will be performed either by an oncoplastic breast surgeon alone or jointly with a plastic surgeon [7,11,32,33]. In a single-stage procedure, once the cancer resection is completed, the CWPF can be raised as a turnover flap (folded 180°), a pendulum type flap based on longer pedicles (TDAP/LTAP) or a propeller flap (with skin replacement), to reconstruct the tumour excision defect.

A drain could be used based on individual intra-operative circumstances (e.g., simultaneous axillary node clearance). If used, this will usually be placed across the donor site and the breast cavity. Alternatively, patients may undergo a 'two-stage' approach if there is a pre-operative concern regarding achieving clear margin status (e.g., pure DCIS or invasive lobular cancer). This latter approach usually involves initial cancer resection, filling the resection cavity with water/saline. Patients return within 4-6 weeks for second-stage partial breast reconstruction [15].

UK Association of Breast Surgery consensus in 2015 adopted and accepted 1mm tumour resection margin for both invasive and in-situ disease [34]. Individual centres' policies should be reasonably consistent with or without local MDT amendments. Each centre will record the margin distance and whether that is deemed clear or positive following the MDT discussion.

2.10 Data Management

Each centre lead will acquire local clinical governance authority approval to collect anonymised data relevant to the study objectives prospectively. Agreed Protocol-based data variables will then be entered securely and accurately into the secure IG-approved central RedCap™ database. Centres, while awaiting database access, can enter data prospectively into a locally stored Microsoft™ Excel sheet (and move data later to the central database). RedCap will automatically allocate a study identification number. In the local spreadsheet, centres will enter patient data with a study identification number. The i**dentification number will be the first letters of the name of the hospital (e.g., Royal Breast Hosp = RBH) with the patient number in order of study entry (001 and so forth. Each participant will then be RBH001, RBH002, and so on.** This will allow for cross-checking data, which may be necessary, per Caldicott's principles (2013). No identifiable patient data will be centrally submitted or stored.

Part A: Surgical treatment dataset

This primary dataset will include surgery-related variables that will be prospectively fed into the database and maintained prospectively, including surgical outcomes at 30 days (in line with NHS Health Episode Statistics).

Part B: Oncological treatment dataset

This would be the dataset that all centres are encouraged to work with their Oncology colleagues in a multi-disciplinary fashion to collate oncological treatment records, specifically radiotherapy data (variables in Table 1). The routine practice variables include RT fractions and volume data:

1. **G**ross Tumour Volume (GTV) is the gross demonstrable tumour volume.
2. **C**linical Tumour Volume (CTV) contains the GTV plus a margin for sub-clinical disease.
3. **P**lanning Target Volume (PTV) is the geometrical planning to ensure that radiotherapy includes CTV.

A surgical trainee participating in this audit may sit with an Oncological trainee during RT planning for learning. In that case, it will foster mutual understanding and data sharing and, in the future, improve MDT interaction for better patient care.

Part C: PROMS

Those centres using PROMS are requested to complete this component, too. However, centres must already use PROMS in their routine practice to audit this component (Part C).

PROMS are to be given pre-operatively and 6 months after radiotherapy. We will use the following well-validated PROMs instruments, Breast-Q and QuickDASH (enclosed):

1. Breast-Q's Breast Conserving Therapy module
2. Back sub-scale of the LD flap module
3. QuickDASH (Disabilities of the Arm, Shoulder, and Hands) questionnaire

All PROMs will be given to the patient in paper format, and Response copies will be stored securely at each centre. Response variables must be inputted anonymously (linked with patient study ID) into the RedCap database for central analysis. For use outside this audit, if not already in the centre's routine use, each centre must apply for licencing. Both questionnaires are on public domains and are available for routine patient care. We encourage all centres to use PROMs in their everyday practice, too.
The application process for a licence is straightforward at the links below and is free to non-profit users for use in clinical practice. Please note that support is not free for non-academic use.

- Breast-Q (©2017, Memorial Sloan Kettering Cancer Centre and the University of British Columbia; https://qportfolio.org/breast-q/breast-cancer/) and
- QuickDASH (©Institute for Work & Health 2006-2020, Toronto, Canada; https://dash.iwh.on.ca/about-quickdash)

2.11 Clinical Governance

Data will be analysed after the evaluation to determine uptake, response rates and surgical outcomes. Data for individual centres will be evaluated, compared with the average measures (from this study itself) and fed back to individual participating units. Local collaboratives and hospitals will own their data at the end of the evaluation and after analysis and can present it locally if they wish.

2.12 Statistical Methods

Data will be analysed within the RedCap and further examined using the statistical software R™ (version 4.1.1 or later) or another software if deemed necessary by the study statistician. Descriptive statistics for each variable will include counts and percentages of categorical data, whereas median and inter-quartile range (IQR) will be calculated for continuous data. Statistical significance will be determined using standard Wald tests and the default method in the R™. Shapiro-Wilk test will be used to test for the normality of the distribution of cases across all centres.

Multivariable logistic regression will be performed for possible predictors of postoperative events needing intervention (aspirable seroma and complications). A separate sensitivity analysis will be performed, including BMI [35] in the best-fit models. The analysis will commence using all variables and continue using backward elimination or forward selection as appropriate, removing or selecting variables aiming for the model with the best Akaike information criterion (AIC). The AIC is chosen as a criterion that deals with the risk of overfitting (by penalising the number of variables selected) and underfitting by performing a trade-off between the model's goodness of fit. Also, the model chosen by leave-one-out cross-validation is asymptotically equivalent to the model selected by AIC. AIC is primarily used in cases where the goal is prediction.

Breast-Q's scoring software, Q-score, provides enumerated scores from 1-100, with the lowest being the worst and 100 being the best. QuickDASH has a quick online calculation facility on the following link:
http://www.orthopaedicscore.com/scorepages/disabilities_of_arm_shoulder_hand_score_quickdash.html.

The study will be reported per the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [36].

3 Dissemination

3.1 Dissemination

Study outcomes will be disseminated via

- National and international scientific conferences
- Publication in peer-reviewed journals (3-4 scientific papers)
- Patient voices (including Independent Cancer Patients' Voice, NCRI consumer forum), social media.

3.2 Publication and Authorship Policy

The '**Bre**ast **Con**sortium (BreCon)' will make all references and outputs. The levels of authorship will be according to the International Committee of Medical Journal Editors (ICMJE) - https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Authorship

The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content AND
- Final approval of the version to be published AND
- 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.

Therefore, the anticipated Authorship will include the Principle and Co-Principle Investigator, the Steering Committee, and the Main Statistician.

Acknowledged Collaborators

All sites contributing at least ten patients will be recognised in any resulting publications as PubMed-citable co-authors. Flexible to service demands, no authorship limits will be imposed at a centre level, as many collaborating investigators are required, and work to support the project will be recognised in all future outputs. A corporate authorship model will be used.

4 Study Expertise

The PartBreCon-Pro study has had advanced interest with support letters from many centres, including from surgeons who have led in CWPF surgery, that will ensure experienced conduct and delivery of the project.

The Study's Chief Investigator is Mr Amit Agrawal, Cambridge. He will oversee the central database, including RedCap, hosted at Cambridge University Hospitals. The current Study Steering Committee (Mr Amit Agrawal, Chair; Mr Laszlo Romics, Glasgow; Ms PG Roy, Oxford; Mr John Murphy, Manchester) will lead, coordinate, and provide this study. The committee will meet regularly and strategically throughout the project to advise the team on emerging findings and decisions. International eminent advisors include Prof M Hamdi (Plastic Surgeon, Belgium) and Prof P Poortmann (Oncologist, Belgium).

5 Log of Protocol changes

1.1 - Original (April 2023)
1.2 2.1 - Revision (22 August 2023)
1.3 3.1 - Revision (28 September 2023)
1.4 4.1 – Revision (31 October 2023)

6 APPENDICES

6.1 **Table 1:** PartBreCon-Pro Study Dataset

6.2 **Enclosures**

1. Breast Q – BCT module
2. Breast Q – LD flap back module
3. QuickDASH

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Table 1: PartBreCon-Pro Study Dataset

Item	Definition
Centre	Name of unit (in 3 letters abbreviation) e.g., Royal Breast Hosp-RBH
Study ID	ID from the given unit -starting 001
Date of birth	Age in years
Date of diagnosis	month / year
Date of surgery	month / year
Presentation	symptomatic / screener / family history / other
Breast size	Bra size (Band and Cup e.g., 28C)
BMI	
Significant co-morbidities	free text
Smoking within 3 months	y/n
Largest Tumour size on any imaging (mm) at diagnosis (cT)	largest tumour diameter on any imaging [mm]
Largest post-NACT tumour size (ycT)	largest diameter on any imaging [mm] after neo-adj chemo / hormonal Rx
Position of tumour(s) in breast	UOQ, LOQ, UIQ, LIQ, central
If Multifocal, Largest resected tumour plus distance between foci (EXTENT)	If multifocal, largest distance between foci on any imaging [mm]
Axillary USS lymph node status	abnormal / normal / not applicable
If abnormal USS nodes (n)	n = number of nodes abnormal
If Axillary core biopsy / FNA (cN+ or cN0)	metastasis (cN+) / normal (cN0)/ not applicable
If cN+, Post-NACT nodal status (ycN)	
Joint operation with plastic surgeon	y/n
Type of Flap	LICAP, LTAP, AICAP, MICAP, etc. Combined
Stage - single vs two-stages (delayed, if any)	
Placement (propeller or flip)	Propeller or flip
Specimen weight [gram]	
Contralateral symmetrisation	y/n
Axillary surgery, type	none / SNB / Sampling/ TAD/ ANC / ANC following SNB
Drain (days)	days (zero if none)
Length of hospital stay [days]	days (zero if day case; 1 if 23 hours stay; and so on)

Post operative complication (Clavien-Dindo)	y/n
Major / minor	major = required readmission or reoperation
Infection	y/n
Any positive microbiology	y/n; if yes, growth
Antibiotics	IV/Oral, which
Haematoma/Seroma	y/n
Fat necrosis	y/n
Delayed wound healing	y/n
Flap loss - full, partial or none	full, partial or none
Unplanned readmission to hospital within 30 days	y/n
Unplanned return to theatre within 30 days	y/n
Additional optimising procedures (in m/delayed)	free text

Tumour Type	DCIS, ductal, lobular, etc.
Whole tumour size [mm]	
Invasive Tumour size [mm]	
pT	
ypT	
Grade	1/2/3 if invasive, no need to indicate if DCIS
ER	pos / neg
PR	pos / neg
HER-2	pos / neg
Multifocal	y/n
Closest margin distance (mm)	
Margins, clear or not (MDT)	involved / clear
Number of re-excisions for involved margins	
pN	
ypN	
Neo-adjuvant chemo incl. anti-HER-2 treatment	anti-HER2 regime
Neo-adjuvant immunotherapy	y/n
Neo-adjuvant hormonal therapy ≥ 3 months	y/n
Neo-adjuvant radiotherapy if any	free text
Gene array testing score if performed	Oncotype DX, Prosigna, others
Adjuvant chemotherapy	y/n

Adjuvant anti-HER2	y/n
Adjuvant endocrine therapy	y/n
Adjuvant CDK4/6 inhibitors	y/n
Adjuvant bisphosphonates	
Adjuvant radiotherapy	y/n
Adjuvant radiotherapy dose	
Adjuvant radiotherapy fractions	
Adjuvant radiotherapy fields included	2 / 3 / 4 field
Boost RT	y/n
Boost dose	
Boost fractions	
Boost method	integrated / IMRT
Boost volume - GTV	As determined by Oncologist – GTV (Gross Tumour Volume)
Boost volume - CTV	As determined by Oncologist - CTV (Clinical Tumour Volume)
Boost volume - PTV	As determined by Oncologist – PTV (Planning Tumour Volume)
Boost volume - Surgical	Optional (as by Surgeon, include 5mm tissue around flap)

Date of last follow-up (clinical/mammogram)	month / year
Recall Biopsies	y/n
Local Recurrence	y/n
Regional recurrence	y/n
Distal recurrence	y/n
Date of recurrence	month / year
Death	y/n
Death breast cancer related	y/n
Death NOT breast cancer related	y/n

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