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Adherence to best practice consensus guidelines for implant-based breast reconstruction: Results from the iBRA national practice questionnaire survey

Senthurun Mylvaganam a, Elizabeth J. Conroy b, Paula R. Williamson b, Nicola L.P. Barnes c, Ramsey I. Cutress d, e, Matthew D. Gardiner f, g, Abhilash Jain f, g, Joanna M. Skillman h, Steven Thrush i, Lisa J. Whisker j, Jane M. Blazeby k, Shelley Potter k, l, *, Christopher Holcombe m, l, on behalf of the iBRA Steering Group 2, the Breast Reconstruction Research Collaborative 2

Abstract

Introduction: The 2008 National Mastectomy and Breast Reconstruction Audit demonstrated marked variation in the practice and outcomes of breast reconstruction in the UK. To standardise practice and improve outcomes for patients, the British professional associations developed best-practice guidelines with specific guidance for newer mesh-assisted implant-based techniques. We explored the degree of uptake of best-practice guidelines within units performing implant-based reconstruction (IBBR) as the first phase of the implant Breast Reconstruction Evaluation (iBRA) study.

Methods: A questionnaire developed by the iBRA Steering Group was completed by trainee and consultant leads at breast and plastic surgical units across the UK. Simple summary statistics were calculated for each survey item to assess compliance with current best-practice guidelines.

Results: 81 units from 79 NHS Trusts completed the questionnaire. Marked variation was observed in adherence to guidelines, especially those relating to clinical governance and infection prevention strategies. Less than half (n = 28, 47%) of units obtained local clinical governance board approval prior to offering new mesh-based techniques and prospective audit of the clinical, cosmetic and patient-reported outcomes of surgery was infrequent. Most units screened for meticillin-resistant staphylococcus aureus (recommended for IBBR) were not widely-available with less than 1 in 5 units having regular access. Peri-operative antibiotics were widely-used, but the type and duration were highly-variable.

Keywords:
Survey
Implant-based reconstruction
Acellular dermal matrix
Dermal sling
Mesh
Guidelines
Current practice

* Corresponding author. Bristol Centre for Surgical Research, Population Health Sciences, Bristol Medical School, University of Bristol, 39 Whately Road, Clifton, Bristol, BS8 2PS, UK.
E-mail address: shelley.potter@bristol.ac.uk (S. Potter).

1 SP and CH are joint senior authors for this study.

2 Members of the iBRA Steering Group and Breast Reconstruction Research Collaborative are PUBMED citable collaborators in this study and are listed at the end of the manuscript.

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Introduction

National Institute for Health and Care Excellence (NICE) guidelines recommending the routine offer of immediate breast reconstruction to women requiring mastectomy for breast cancer were introduced in 2002 [1], but in 2008, the National Mastectomy and Breast Reconstruction Audit (NMBRA) demonstrated marked variation in the availability and outcomes of breast reconstruction in the UK [2–5].

There was a need to standardise practice and to improve outcomes for patients. In response to the NMBRA findings, The British breast and plastic surgical professional associations (Association of Breast Surgery, ABS and British Association of Plastic Reconstructive and Aesthetic Surgeons, BAPRAS) subsequently developed ‘Oncoplastic Breast Reconstruction: Guidelines for Best Practice’ [6]. The guidelines were based on consensus opinion informed by best published evidence. They covered all types of breast reconstruction and included recommendations for each stage of the clinical pathway from diagnosis to post-operative follow-up. The guidelines included 25 quality criteria (QC) and were proposed as a standardized ‘framework that should be used to assess current practice and deliver high quality care’ [7].

Implant-based breast reconstruction (IBBR) is the most commonly performed reconstructive procedure in the UK [8] and a rapidly-evolving technique. Traditionally a two-stage procedure, the introduction of biological (e.g. acellular dermal matrix, ADM) and synthetic (e.g. titanium-coated polypropylene) meshes for lower pole coverage offered patients the possibility of single-stage, direct-to-implant reconstruction without the need for painful and time-consuming expansions and a second operation [9]. The more natural-looking ptotic breasts created using mesh also resulted in time-consuming expansions and a second operation [9]. The more natural-looking ptotic breasts created using mesh also resulted in time-consuming expansions and a second operation [9].

Despite the proposed benefits of mesh, concerns were raised that complication rates in mesh-assisted IBBR were unacceptably high [11–13]. The ABS and BAPRAS therefore published supplemental guidance on mesh-assisted implant reconstruction [14] to support surgeons offering the technique. The guidelines included recommendations for patient selection and unit and organization criteria for centres wishing to be commissioned to perform mesh-assisted reconstruction. Evidence to support the recommendations was acknowledged to be lacking and in the absence of evidence, the guidelines were based largely on expert opinion [14]. The need for outcome data was highlighted and one of the main aims of the guidance was to identify clinical standards and quality indicators against which centres offering the technique could audit their results [14]. Key recommendations for the practice of IBBR from both the Oncoplastic Breast Surgery Guidelines for Best Practice [6] and supplemental ADM guidelines [14] are summarized in Table 1.

The practice of IBBR has continued to develop and over 85% of immediate breast reconstructions in the UK are now implant-based [8]. Despite the widespread adoption of mesh-assisted reconstruction into routine clinical practice, robust evidence for the safety and effectiveness of the techniques remains elusive [15,16]. Various biological and synthetic meshes have been introduced with significant variations in cost and in the absence of evidence of effectiveness, product selection is dependent on surgeon preference.

High-quality research is therefore required to establish best practice in IBBR [15,16] and the iBRA (implant Breast Reconstruction evAluation) study is a national trainee-led multicentre cohort study which aims to inform the feasibility, design and conduct of a randomized clinical trial in IBBR [17]. The first phase of iBRA was a national practice questionnaire (NPQ) where we aimed to explore current practice [10] and the degree to which units performing IBBR in the UK adhered to existing best practice guidelines to inform the design of a future trial.

Methods

The national practice questionnaire (NPQ, Appendix 1) was developed in February 2014 by members of the iBRA steering group based on a comprehensive review of the literature [15], current professional guidelines [6,14] and clinical expertise. It included unit demographic data and items assessing adherence to quality criteria and practice recommendations made in the joint ABS/BAPRAS oncoplastic breast reconstruction [6] and ADM reconstruction guidelines [14] with particular focus on clinical governance issues such as audit and infection reduction strategies to inform future trial design. The questionnaire was piloted with surgeons at two hospitals to ensure face and content validity prior to distributing the questionnaire nationally.

All breast and plastic surgical units performing mastectomy with or without immediate breast reconstruction in the UK were eligible for inclusion. Trainees were invited to participate via the Mammary Fold breast trainees’ group and the Reconstructive Surgery Trials Network (RSTN). ABS and BAPRAS endorsed the study and encouraged units to participate. Each participating trainee was required to identify a consultant lead in their unit. The trainee completed the questionnaire with this consultant ensuring that responses reflected the practice of the unit as a whole, rather than those of an individual surgeon.

Data were collected and managed using REDCap electronic data capture tools hosted at University of Edinburgh [18].

Analysis

Descriptive summary statistics were calculated for each survey item to evaluate adherence to each guideline or recommendation. Categorical data was summarized by counts and percentages. Continuous data was summarized by median, interquartile range (IQR) and range. No data imputation methods were used for items with no response and when a unit did not complete a specific section of the questionnaire, it was assumed that the unit did not offer that approach. Statistical Analysis Software (SAS® 9.1.3; SAS Institute Inc., Cary, NC, USA) was used for all analyses. Free text responses were collated and analysed using content analysis.

Results

Participation

81 responses were received from 79 NHS Trusts. Two trusts had independent responses from the breast and plastic surgical units.
**Table 1**

Summary of current best practice guidelines for implant-based breast reconstruction.

| Guideline                                                                 | Source                                      |
|--------------------------------------------------------------------------|---------------------------------------------|
| **Organizational criteria for units wishing to be commissioned for ADM assisted reconstruction** | Joint ABS/BAPRAS ADM guidelines              |
| • Approval from New Procedure Policy/Clinical Governance Board specific to each hospital Trust |                                             |
| • Patient awareness that they are being offered a relatively new procedure |                                             |
| • Clear pathway and service arrangement to manage drains up to 3 weeks post-operatively |                                             |
| • Ongoing audit of all complications arising from all breast reconstruction operations |                                             |
| • Agreement to participate in future national clinical ADM audit and submit all cases |                                             |
| **Unit criteria for units wishing to be commissioned for ADM assisted reconstruction** |                                             |
| • Experience breast reconstruction team                                   | Joint ABS/BAPRAS ADM guidelines              |
| • Prospective record and photographic collection                           |                                             |
| • Guidelines to staff on post-operative management with agreed protocols of care (drains, follow-up, antibiotics) |                                             |
| • All cases should be audited prospectively                                |                                             |
| **Participation in research and audit**                                    |                                             |
| • Eligible patients are invited to take part in local and national clinical trials and audits of OPBS | OPBR-guidelines for best practice            |
| • Target: Screening for eligibility for clinical trials and national audits occurs in 100% of OPBS patients (QC22) |                                             |
| **Target standards from the National Mastectomy and Breast Reconstruction Audit (NMBRA)** |                                             |
| |                                             |
| **Pre-operative guidelines and proposed quality standards** |                                             |
| **Medical photography**                                                    | OPBR - guidelines for best practice          |
| • Medical photography (pre-and post-operative) is part of the clinical record |                                             |
| • Target: Medical photography is offered in 100% of BR patients (QC4)      |                                             |
| **Information provision**                                                  | OPBR-guidelines for best practice            |
| • Patients receive information in a format and level of detail that meets their individual needs. The letter to the GP summarises the information provided and is copied to the patient |                                             |
| • Target: Written information about the risks and benefits of breast reconstruction is provided to 90% of mastectomy patients |                                             |
| **Peri-operative guidelines and recommendations to reduce the risk of infection** |                                             |
| **Preoperative MRSA and MSSA screening**                                   | OPBR-guidelines for best practice            |
| • Patients are MRSA (= MSSA in implant cases) screened prior to admission and have topical suppression where positive in accordance with national/local policy |                                             |
| • Target: MRSA screening occurs in 100% of patients prior to admission (QC7) |                                             |
| **Peri-operative antibiotic use**                                          |                                             |
| • Patients undergoing implant-based reconstruction are given a single intravenous dose of appropriate antibiotic(s) on induction |                                             |
| • The antibiotic spectrum of prophylaxis should cover both Gram positive and Gram negative bacteria, particularly the most common cause of post-operative infection, Staphylococcus aureus |                                             |
| • Regimens may differ between hospitals and local prescribing policies but flucloxacillin and gentamicin or cefuroxime are appropriate options. In truly penicillin allergic patients, clindamycin and gentamicin or vancomycin/teicoplanin and gentamicin may be considered. The latter regimen should be used for patients known to be colonised with MRSA |                                             |
| • Target: All patients undergoing implant-based reconstruction receive intravenous antibiotics on induction (QC11) | Use of laminar flow theatres                 |
| • Ultra Clean Ventilation (UCV, ‘laminar flow’) is recommended in OPBS where such facilities are available: |                                             |
| • If unavailable, the number of personnel in theatre and ‘theatre traffic’ should be actively reduced to a minimum to reduce turbulent air flow and minimize the bacterial load in the theatre air. |                                             |
| • A policy of minimal movement of personnel within the operating theatre is a recommended principle whatever the theatre ventilation system |                                             |
| **Skin preparation**                                                       |                                             |
| • 2% chlorhexidine with 70% isopropyl alcohol with tint provides the best skin decontamination for the most prolonged period. It should be applied to the whole area to be decontaminated, but sparingly to avoid pooling. |                                             |
| • Povidone iodine or isopropyl alcohol are less effective alternatives. |                                             |
| **Implant cavity irrigation**                                              |                                             |
| • The implant cavity may be washed out to remove any necrotic material |                                             |
| **Minimal implant handling and glove change**                             |                                             |
| • The implant should be opened just before use to reduce contamination from airborne bacteria. |                                             |
| • The surgeon should use a ‘minimal or no touch’ technique where possible to reduce the risks of contamination of the implant. Care should be taken when changing gloves. A safe option is to leave existing gloves on and double glove just before handling the implant or to wear two pairs of gloves from the start of the procedure, removing the outer gloves before handling the implant. |                                             |
| **Post-operative guidelines and proposed quality standards** |                                             |
| **Antibiotic use for suspected post-operative infection** | Joint ABS/BAPRAS ADM guidelines              |
| • Infection <10% of patients require antibiotics within 3 months of their surgery for suspected infection |                                             |
| **Assessment of clinical outcomes**                                        | OPBR-guidelines for best practice            |
| • Implant loss, unplanned return to theatre, unplanned readmission (QC15, QC16, QC17) at 3 months are assessed and audited |                                             |
| • Post-operative complications, return to theatre and length of stay are documented in departmental BR database |                                             |
| • Target: There is a regular audit and discussion of all patients with post-operative complications (QC18) |                                             |
| **Assessment of patient reported outcomes**                               | OPBR-guidelines for best practice            |
| Patients’ satisfaction with BR outcome is measured using standardized assessment tools: |                                             |
| • Satisfaction with information at 3 months (QC19); Target: Satisfaction with information provision is reported by 80% of patients at 3 months |                                             |
| • Satisfaction with appearance clothed at 18 months (QC20); Target: At 18 months, over 90% of BR patients report satisfaction with their appearance clothed (QC20) |                                             |
Each of these was considered an independent unit with different practices despite stemming from the same trust. 67 of 144 (47%) breast units and 14 of 53 (26%) plastic units in the UK participated. Responses were received from both high and low volume centres with participating units performing a median of 35 IBBR per year (range 0–230). Of the participating breast units, 23/67 (34%) had on-site plastic surgical services with access to free-flap reconstruction. Demographics of participating units are summarized in Table 2.

Compliance with clinical governance guidelines for mesh-assisted procedures

79/81 (98%) units provided details of the types of IBBR performed. Of these 60/79 (76%) performed biological mesh (BM) assisted reconstruction and 24/79 (30%) offered patients IBBR with synthetic mesh (SM).

Compliance with recommendations for the introduction of mesh-assisted IBBR was low. Only 28/60 (47%) units offering BM and 4/24 (17%) units offering SM had sought approval from a ‘New Techniques and Devices’ or other appropriate clinical governance committee prior to introducing the technique. Formal written unit protocols regarding the management of patients undergoing mesh-assisted reconstruction were uncommon with only a third (n = 21, 35%) of units using BM and less than 20% (4/24, 17%) of those using SM reporting having agreed policies for the management of drains and antibiotics in this group. Specific written information for patients undergoing mesh-assisted reconstruction was similarly lacking with only a third (23/60, 38%) of units offering BM and a quarter (4/24) of units offering SM reporting that this was available locally.

Routine prospective audit of the clinical, cosmetic and patient-reported outcomes of reconstructive surgery is a key recommendation, but compliance was also low. Only half of units (31/60 BM units and 12/24 SM units) prospectively audited the short and long-term clinical outcomes of mesh-assisted IBBR with a further 25–30% (15/60 (24%) BM units and 7/24 (29%) SM units) reporting that audit was undertaken retrospectively. Cosmetic outcomes were audited by approximately half of units (33/60, 55% BM and 10/24, 42% SM units) but less than a third assessed patient-reported outcomes (Table 3).

Procedure coding for reimbursement is important for the integrity of national data sets and units were asked how mesh-assisted IBBR was coded locally. Two-thirds of respondents provided either an OPCS (Office of Population Censuses and Surveys) or a HRG (Healthcare Resource Group) code and the responses varied. Commonly-reported OPCS codes were of ‘skin-sparing mastectomy’ (B27.6) with ‘insertion of prosthesis for breast’ (B30.1) and ‘reconstruction of the breast, Other specified’ (B30.8). The generic HRG code JA162 ‘Mastectomy and breast reconstruction’ was often used but between 20% (12/60 BM units) and 30% (7/24 SM units) units offering mesh-assisted IBBR reported being unsure how the procedure was coded (Table 3).

Compliance with strategies to reduce infection

80/81 (99%) units responded to items relating to compliance with best-practice for infection prevention. Most units (66/80, 83%)

| Table 2 | Demographics of participating units. |
| --- | --- |
| **Unit characteristic** | **N = 79** |
| **Types of breast reconstruction offered** | |
| Implant-based reconstruction | 79 (100) |
| Pedicled flaps | 76 (96) |
| Latissimus dorsi | 31 (39) |
| Pedicled TRAM | 34 (43) |
| Free flaps | 24 (30) |
| DIEP | 75 (95) |
| Other autologous (e.g SGAP, IGAP, TUG, SIEA) | 77 (97) |
| Revisional surgery | 70.0 (50.0–80.0) |
| Number of staff performing breast and reconstructive surgery | 70.0 (50.0–80.0) |
| Breast surgery | 70.0 (50.0–80.0) |
| Number of consultant surgeons with an interest in breast surgery (FTE, median, IQR, range) | |
| 3.0 (2.0–3.8) |
| 2.5 (2.0–3.0) |
| Plastic surgery | 70.0 (50.0–80.0) |
| Number of consultant plastic surgeons with an interest in breast surgery (FTE, median, IQR, range) | 70.0 (50.0–80.0) |
| 1.0 (0–3.0) |
| 2.0 (1.0–3.0) |
| Number of immediate implant-based breast reconstructions performed per year (median, IQR, range) | 70.0 (50.0–80.0) |
| 35 (20–50) |
| Percentage of immediate breast reconstructions that are implant-based (median, IQR, range) | 70.0 (50.0–80.0) |
| 79 (100) |
| Approaches to implant-based reconstruction offered | 79 (100) |
| Standard 2 stage submuscular placement | 60 (75.9) |
| Reduction pattern with dermal sling | 66 (83.5) |
| Acellular dermal matrix assisted reconstruction | 59 (74.7) |
| Other non-dermal biological-assisted reconstruction | 19 (24.1) |
| TLOOP assisted reconstruction | 19 (24.1) |
| Other synthetic assisted reconstruction | 8 (10.1) |

DIEP — deep inferior epigastric perforator; FTE — full time equivalent; IQR — interquartile range; TRAM — transverse rectus abdominis myocutaenous flap.
screened patients for methicillin-resistant Staphylococcus aureus (MRSA) prior to implant surgery but less than a third (25/80, 31%) screened for the methicillin-sensitive strain, MSSA. Use of ultra clean ventilation is recommended for implant cases but just 1 in 5 centres (15/80, 19%) routinely had access to laminar flow theatres.

Skin preparation with 2% chlorhexidine with 70% isopropyl alcohol is the recommended but almost 20% of units (14/80, 18%) reported using iodine preparations for skin decontamination and a further third (27/80, 34%) reported the selection of skin preparation to be surgeon dependent. Surgeon glove change prior to implant handling was routinely performed (59/80, 74%) but mastectomy pocket wash to remove debris was standard practice in just 60% of units (47/80) (Table 4). In line with best practice guidelines, all units reported the use of prophylactic antibiotics in IBBR but significant variability was seen in both the type and duration of antibiotics used. Broad-spectrum antibiotic prophylaxis with coverage of both Gram-positive and Gram-negative organisms is recommended and while most units reported using appropriate regimens either alone (e.g co-amoxiclav) or in combination (e.g teicoplanin and gentamicin), one in 10 units used narrower spectrum drugs such as flucloxacillin only (6/60, 10%). Few units (8/60, 8% BM units and 2/24, 8% SM units) adhered to the recommended single intravenous dose at induction. Duration of antibiotic courses following both BM and SM-assisted reconstruction were highly-variable ranging for

Table 3
Adherence to clinical governance guidelines for implant-based breast reconstruction.

| Approval from the New Techniques and Devices Committee/Clinical Governance Board prior to introducing technique |
|---------------------------------------------------------------|
| ADM (n = 60, %) | TiLOOP (n = 24, %) |
| Yes | 28 (47) | 4 (17) |
| No | 14 (23) | 13 (54) |
| Unsure | 18 (30) | 5 (21) |
| Missing | 0 (0) | 2 (8) |

| Formal written unit protocol or agreed guidelines for the management of patients undergoing mesh assisted (e.g regarding antibiotic prophylaxis and drain management)? |
|---------------------------------------------------------------|
| ADM (n = 60, %) | TiLOOP (n = 24, %) |
| Yes | 21 (35) | 4 (17) |
| No | 34 (57) | 15 (63) |
| Unsure | 5 (8) | 2 (8) |
| Missing | 0 (0) | 3 (13) |

| Availability of specific written information available to women considering mesh assisted reconstruction |
|---------------------------------------------------------------|
| ADM (n = 60, %) | TiLOOP (n = 24, %) |
| Yes | 23 (38) | 6 (25) |
| No | 30 (50) | 15 (63) |
| Unsure | 6 (10) | 1 (4) |
| Missing | 1 (2) | 2 (8) |

| Audit of outcomes |
|---------------------------------------------------------------|
| Short term complications (<3 months) |
| Prospectively | 31 (52) | 12 (50) |
| Retrospectively | 15 (25) | 7 (29) |
| Not audited | 11 (18) | 3 (13) |
| No response/missing | 3 (5) | 2 (8) |
| Long term complications (>3 months) |
| Prospectively | 24 (40) | 9 (38) |
| Retrospectively | 15 (25) | 8 (33) |
| Not audited | 17 (28) | 4 (17) |
| No response/missing | 4 (7) | 3 (13) |

| Cosmetic outcomes using pre and post-operative photographs |
|---------------------------------------------------------------|
| Prospectively | 24 (40) | 6 (25) |
| Retrospectively | 9 (15) | 4 (17) |
| Not audited | 17 (28) | 10 (42) |
| No response/missing | 4 (7) | 3 (13) |

| Procedure coding |
|---------------------------------------------------------------|
| OPCs Codes |
| R27.4 Total mastectomy NEC | 1 | 0 |
| B27.6 Skin-sparing mastectomy | 9 | 2 |
| B29 Reconstruction of breast | 2 | 2 |
| B29.8 Reconstruction of breast, Other specified | 13 | 6 |
| B30 Prosthesis for breast | 1 | 2 |
| B30.1 Insertion of prosthesis for breast | 10 | 5 |
| B30.8 Prosthesis for breast, Other specified | 1 | 0 |
| S37.4 Xenograft of skin NEC | 1 | 0 |
| Y27.3 Xenograft to organ NOC | 2 | 0 |
| Y27.6 Prosthetic graft NOC | 0 | 1 |
| Y36.2 Introduction of therapeutic implant into organ | 1 | 0 |
| B3014/B3013 Mastectomy and immediate | 1 | 0 |
| reconstruction using a fixed prosthesis (B3013) | 0 | expandable prosthesis (B3014) |

| HRG codes |
|---------------------------------------------------------------|
| JA16Z Mastectomy and breast reconstruction | 7 | 1 |
| Unsure/no specific code | 12 | 7 |
| Missing | 20 | 8 |

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Table 4
Use of strategies to reduce risk of infection.

| Strategy                                      | N  | (%) |
|-----------------------------------------------|----|-----|
| **Routine pre-operative screening**           |    |     |
| MRSA                                          |    |     |
| Yes                                           | 66 | (83)
| No                                            | 4  | (5) |
| Missing                                       | 10 | (13)|
| MSSA                                          |    |     |
| Yes                                           | 25 | (31)
| No                                            | 45 | (86)
| Missing                                       | 10 | (13)|
| **Proportion of implant reconstruction cases performed in a laminar flow theatre** |    |     |
| None                                          | 38 | (48)
| Approximately 25%                             | 7  | (9) |
| Approximately 50%                             | 6  | (8) |
| Approximately 75%                             | 3  | (4) |
| All cases                                     | 15 | (19)|
| Missing                                       | 11 | (14)|
| **Type of skin preparation solution routinely used in patients having implant based reconstruction** |    |     |
| Aqueous iodine                                | 11 | (14)|
| Alcoholic iodine                              | 3  | (4) |
| Chlorhexidine                                 | 19 | (24)|
| 2% chloraprep                                 | 10 | (13)|
| Surgeon dependent                             | 27 | (34)|
| Missing                                       | 10 | (13)|
| **Use of cavity irrigation following mastectomy prior to implant insertion** |    |     |
| Yes                                           | 47 | (59)
| No                                            | 5  | (6) |
| Surgeon dependent                             | 18 | (23)|
| Missing                                       | 10 | (13)|
| **Surgeon glove change (or equivalent) prior to implant handling** |    |     |
| Yes                                           | 59 | (74)
| No                                            | 3  | (4) |
| Surgeon dependent                             | 8  | (10)|
| Missing                                       | 10 | (13)|
| **Antibiotic use for mesh based reconstruction** |    |     |
| **Biological mesh assisted implant reconstruction** | N  | 60 |
| **Antibiotic choice**                         |    |     |
| Co-amoxiclav only                             | 33 |
| Flucloxacillin only                           | 6  |
| Flucloxacillin and gentamicin                 | 5  |
| Co-amoxiclav in combination with another antibiotic (e.g. gentamicin) | 3  |
| Teicoplanin and gentamicin                    | 3  |
| Cefuroxime                                    | 2  |
| Flucloxacillin and ciprofloxacin              | 1  |
| Flucloxacillin and teicoplanin                | 1  |
| Teicoplanin only                              | 1  |
| Benzylpenecillin and flucloxacillin           | 1  |
| Benzylpenecillin and gentamicin               | 1  |
| Not specified                                 | 5  |
| **Antibiotic duration**                       |    |     |
| One dose only                                 | 5  |
| <24 h post-operative antibiotics              | 6  |
| 2 days                                        | 1  |
| 3 days                                        | 1  |
| 5 days                                        | 7  |
| 7 days                                        | 5  |
| 7–14 days                                     | 1  |
| 14 days                                       | 2  |
| Until drains are out                          | 25 |
| Variable/surgeon dependant                    | 4  |
| Not stated                                    | 5  |
| **Synthetic mesh assisted implant reconstruction** | N  | 24 |
| **Antibiotic choice**                         |    |     |
| Co-amoxiclav only                             | 13 |
| Flucloxacillin and gentamicin                 | 2  |
| Co-amoxiclav in combination with another antibiotic (e.g. gentamicin) | 2  |
| Teicoplanin and gentamicin                    | 2  |
| Teicoplanin only                              | 1  |
| Flucloxacillin/metronidazole/gentamicin       | 1  |
| Surgeon dependant                             | 1  |
| **Antibiotic duration**                       |    |     |
| One dose only                                 | 2  |
| Up to 24 h post-operative antibiotics (2–3 post operative doses) | 4  |
| 2 days                                        | 1  |
| 5 days                                        | 2  |
24 h to 14 days with oral antibiotics frequently continued until the surgical drains were removed (BM 25/60, 40%; SM 7/24, 29%) (Table 4).

Discussion

The iBRA national practice questionnaire suggests that adherence to current best practice guidelines for IBBR in the UK is poor. Few units reported obtaining clinical governance approval prior to offering the new technique; having unit-specific protocols for the management of patients undergoing mesh-assisted procedures or specific written information for patients considering surgery. Despite offering techniques with limited evidence for safety or effectiveness and guidelines recommending robust prospective evaluation of surgical outcomes, routine audit of cosmetic and patient reported outcomes was infrequent. Clinical outcomes were more commonly audited but this was often undertaken retrospectively. Procedure coding was highly variable making future study of the procedure through routinely available data sources such as Hospital Episode Statistics (HES) difficult. Despite the significant impact of infection and implant loss, adherence to current best-practice guidelines to minimize these complications is inconsistent [6]. Strategies such as MRSA screening; glove changes and peri-operative antibiotic usage were standard practice in many units, but few units screened for MSSA or had access to laminar flow for implant cases and antibiotic choice and duration was variable. There is therefore a need for units to consider implementing the best practice guidance and for high quality research to establish best practice.

Guidelines aim to reduce variability and standardize practice to improve outcomes for patients but despite these potential benefits [19], compliance with clinical guidelines in many settings [20] including breast [21] and plastic surgery [22] is known to be poor. Reasons why guidelines are not implemented in practice for this have been extensively investigated [20,23] and are likely to be multifactorial. One element key to successful implementation, was guideline validity and users’ confidence that the guidelines were evidence-based [23]. Evidence to support the practice of breast reconstruction in general and IBBR in particular is lacking. This is openly acknowledged in both the oncplastic [6] and ADM [14] guidelines and the lack of evidence to support proposed ‘best’ practice may partially explain why observed compliance with the guidelines is poor. A recent review [24] evaluated the evidence for infection prevention strategies in IBBR, many of which are currently considered best practice. The review found evidence to support the use of antibiotics; MRSA/MSSA screening; mastectomy pocket irrigation and surgeon glove change in reducing the risk of infection, but suggested the evidence to support the use of laminar flow and recommendation of specific skin preparation solutions in IBBR to be less strong [24]. Evidence regarding the optimal duration of antibiotics for infection prevention is also lacking. A recent single-centre RCT of two-stage IBBR with ADM compared infection rates in patients receiving 24 h of antibiotic treatment vs. continuing antibiotics until the surgical drains were removed [25]. This non-inferiority study which included 112 patients, demonstrated no significant difference in infection rates between the treatment groups (19.4% vs 22.0%). These results conflicted with earlier observational studies which suggest significant benefits with extended antibiotics in ADM-assisted reconstruction [26].

More research is needed and well-designed multicentre prospective studies and ideally RCTs are required to establish best practice.

This study has identified poor compliance with best practice guidelines for IBBR in the UK but several factors require consideration. This is a national practice survey and it is possible that the reported practice differs from actual practice. As the survey suggests poor compliance with guidelines however, this is unlikely. It is also possible that the survey responses reflected the practice of a single surgeon rather than the unit as a whole. While this is possible, a significant proportion of units reported ‘surgeon dependent’ practice which suggested the views of the whole unit were included. Overall response rate was relatively low with only 50% of breast units and 25% of plastic surgical units in the UK completing the survey. This suggests that plastic surgical units were relatively underrepresented but the poor response rate may reflect the fact that the majority of IBBR in the UK is now performed by breast rather than plastic surgeons. Plastic surgical units therefore may not have perceived the study to be relevant to their practice. Despite relatively low response rates the study population represents a geographically diverse sample that includes data from both high and low volume centres and those with and without on-site specialist plastic surgical services. This suggests that the results reflect an accurate snap-shot of broad national practice.

While it may be justifiable that surgeons do not adhere to guidelines that they do not perceive to be evidence-based or cannot comply with recommendations due to lack of organizational infrastructure (e.g access to theatres with laminar flow systems), failure of units to comply with clinical governance recommendations such as obtaining appropriate local approvals prior to offering a new technique; providing specific written information for patients considering surgery and failure to routinely audit the results of the new technique is a previously unappreciated problem. Despite increasing awareness of the need for transparent and robust evaluation of novel interventions, particularly if meshes are used. The IDEAL [28] (Idea, Development, Exploration, Assessment and Long-term study) framework provides a methodology by which this may be achieved and the iBRA-NET initiative supported by the professional associations ABS and BAPRAS aims to promote the development and delivery of IDEAL phase 2a/2b studies in reconstructive breast surgery using a multicentre collaborative approach. Early phase protocol-driven prospective studies and registries of new techniques can provide early safety data, capture shared learning and determine if and when an intervention is sufficiently stable for formal evaluation, ideally in the context of a well-designed trial.

Table 4 (continued)

| Strategy                        | N  – 80 (%) |
|--------------------------------|-------------|
| 6 days                         | 1           |
| 7 days                         | 3           |
| 7–10 days                      | 1           |
| 7–14 days                      | 1           |
| Until drains are out           | 7           |
| Variable/surgeon dependant     | 1           |
| Not stated                     | 1           |

MRSA – methicillin resistant staphylococcus aureus; MSSA – methicillin sensitive staphylococcus aureus.

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The project is still in the development phase but breast and plastic surgeons will need to work together and commit to the concept of ‘no innovation without evaluation’ if this approach is to become standard practice.

There is a need for high quality evidence to inform best practice in all areas of breast reconstruction but implant-based surgery is an area where this is particularly lacking. The iBRA study [17], which aims to inform the feasibility, design and conduct of a future trial in IBBR may be the first important step in generating this evidence. The prospective cohort stage of iBRA has recruited over 2000 patients from 70 centres across the UK and suggests that surgeons are willing to evaluate when appropriate resources and infrastructure are available. iBRA is the largest prospective study of new approaches to IBBR worldwide and so in addition to informing key trial feasibility parameters such as outcome selection and sample size, it is also anticipated that the dataset will provide a significant resource for exploring best practice. This data will inform the ‘Getting it Right First Time’ (GIRFT) initiative in breast surgery (http://gettingitrightfirsttime.co.uk/surgical-specialty/breast-surgery/) which aims to improve the quality of care within the NHS by reducing variation and disseminating best practice.

Conclusions

Compliance with breast practice guidelines for IBBR in the UK is variable. Reasons for this are likely to be multifactorial but the lack of high-quality evidence to support practice together with a lack of infrastructure to meet recommendations may partially explain these findings. Units’ failure to comply with clinical governance recommendations, in particular registration of new procedures and prospective audit of outcomes was a previously unanticipated finding and potentially a cause for concern. A development of surgical culture with a commitment to a policy of ‘no innovation without evaluation’ and a focus on undertaking high-quality collaborative research is urgently needed to guide and support best practice in breast reconstruction.

Author contributions

SM analysed the data and wrote the first draft of the paper; EJC designed the study provided methodological and statistical expertise and analysed the data; PW designed the study provided methodological and statistical expertise for the study; MG inputted on the study design and provided plastic surgical and collaborative expertise and leadership; LW designed the study and provided surgical expertise; JS designed the study and provided surgical expertise; JB designed the study, was involved in gaining grant funding, read and appraised the manuscript; NB designed the study, refined the questionnaire based on pilot experience and provided surgical expertise; RC designed the study and provided surgical and methodological expertise and critically reviewed the manuscript; ST designed the study and questionnaire and provided surgical expertise; SP designed the study and questionnaire, wrote the initial proposal, provided trainee collaborative expertise and critically revised the manuscript; CH designed the study, developed the protocol and provided surgical expertise and leadership. SP and CH are joint senior authors on the paper. All authors read and approved the final manuscript.

Collaborators

The iBRA Steering Group (in alphabetical order) comprises: N L P Barnes, J M Blazey, O A Branford, E J Conroy, R I Cutress, M D Gardiner, C Holcombe, A Jain, K McEvoy, N Mills, S Mylvaganam, S Potter, J M Skillman, E M Teasdale, S Thrush, L J Whisker, P R Williamson.

Local investigators (alphabetically by centre) of the Breast Reconstruction Research Collaborative were: L Tang, D Nguyen (Abertawe Bro Morgannwg University Health Board NHS Trust); R Johnson, V Muralkrishnan, S Chopra (ABM University Health Board); A Reid, S Benyon (Addenbrookes), C Murphy (Airedale NHS Foundation Trust); F Soliman, V Lefemine (Anuein Bevan Health Board); S Saha, K Ogedegbe (Barking Haverning and Redbridge NHS Trust); O S Olyinka, J R Dick (Barnsley District General Hospital); N Manoloudakis, F Conroy (Bedford Hospital/Bedfordshire NHS Trust); G Irwin, S Mcintosh (Belfast Health and Social Care Trust); I Michalakis (Blackpool Teaching Hospitals NHS Foundation Trust); S Higgett, R Linforth (Bradford Teaching Hospitals NHS Foundation Trust); R Rathinaezhil, H Osman (Brighton and Sussex University Hospitals NHS Trust); K Anesti, M Griffiths, R Jacklin (Broomfield Hospital Mid Essex NHS Trusts); A Waterworth (Calderdale and Huddersfield NHS Foundation Trust); R Foulkes, E Davies (Cardiff and Vale); K Bisarya, A Allan, J Leon-Villapalos (Chelsea and Westminster Hospital NHS Foundation Trust); F A K Maziari, I Azmy (Chesterfield Royal Hospital NHS Foundation Trust); S George, F S Fahmy, A Hargreaves, J Seward, S Higgett (Countess of Chester Hospital NHS Foundation Trust); J Huntion, T Collins (County Durham and Darlington NHS Foundation Trust); G Irwin, P Mallon (Craigavon Hospital – Southern Health and Social Care Trust); J Turner, W Sarakbi (Croydon University Hospital); I Athanasiou, C Rogers (Doncaster and Bassetlaw Hospitals); M Youssef, T Graja (Dorset County Hospital NHS Foundation Trust); S Huf, H Deol (East and North Herts NHS Trust); R Brindle, S Gawne (Great Eastern Lancashire Hospitals Trust); D Egbeare (Frimley Health NHS Foundation Trust (Frimley Park Hospital site)); I Dash, M Galea (Great Western Hospital – Swindon); S Laws (Hampshire Hospitals NHS Foundation Trust); S Tayeh, L Parvanta (Homerton University Hospital); S Down (James Paget University Hospital Trust); V Westbrook, JW Roberts (Kings College Hospital); J Massey, P Turton, R Achutan (Leeds Teaching Hospital NHS Trust); M Fawzy, M Dickson (Lister Hospital, East and North Herts); AR Carmichael (London Breast Institute); A Akingboye, R James, K Kirkpatrick (Luton and Dunstable University Hospital); E Nael, R Vidya (Mid Staffordshire NHS Foundation Trust); S Potter, A Thorne (Musgrove Park Taunton); M Rostom, I Depasquale (NH Grampian); S M Cawthorn (North Bristol NHS Trust); T Gangamihardja (North Middlesex University Hospital); S Joglekar, J Smith (Northern Lincolnshire and Goole Hospitals NHS Foundation Trust); A Halka, D MacMillan (Nottingham University Hospitals NHS Trust); S Clark (Poole Hospital NHS Foundation Trust); B Pearce, L Mansfield (Portsmouth Hospitals NHS Trust, Queen Alexandra Hospital); I King, A Hazari (Queen Victoria Hospitals NHS Foundation Trust, East Grinstead); B Smith (Royal Berkshire Hospital); A J Volleamere (Royal Bolton Foundation Trust); D Egbeare, D Ferguson (Royal Devon and Exeter NHS Foundation Trust); N Barnes C Holcombe (Royal Liverpool and Broadgreen); A Knight, F MacNeill (Royal Marsden NHS Foundation Trust); A Conway, T Irvine (Royal Surrey County Hospital NHS Foundation Trust); S Mylvaganam (Royal Wolverhampton Hospitals NHS Trust (New Cross Hospital); N Dunne, S Kohlhardt (Sheffield Teaching Hospitals); C Hoo, S Kirk (South Eastern Trust, Northern Ireland); J HU, S Ledwidge (St Bartholomew’s Hospital); S Tang, D Banerjee (St George’s Healthcare NHS Trust); S Waheed (Surrey and Sussex NHS Trust); V Vojnov, S Soumian (University Hospitals North Staffordshire NHS Trust); J Henderson, J Harvey (University Hospital South Manchester); S Robertson, R I Cutress (University Hospital Southampton); S Mylvaganam, R Waters (University Hospitals Birmingham); A Carbine, J Skillman (University Hospitals Coventry and Warwickshire); Ansar Farooq (Warrington & Halton Hospitals NHS Foundation Trust); H Tafazal, D Clarke (Warwick Hospital); D Cocker, L M Lai.
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Conflicts of interest statement

The authors have no conflicts of interest to declare.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.ejso.2018.01.098.

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[29] Table 1. Summary of the iBRA study. 

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