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ORIGINAL PAPER

Outcomes of prepectoral implant-based breast reconstruction with Braxon® acellular dermal matrix—a single-centre experience

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Abstract

Background Single-stage direct-to-implant reconstruction is the most common method of reconstruction in the UK after a mastectomy. Prepectoral implant placement with full implant coverage using acellular dermal matrix (ADM) is a relatively new technique. We report on long-term outcomes of prepectoral immediate breast reconstruction (IBR) using Braxon® ADM from a single institution.

Methods All patients operated for a mastectomy with IBR using Braxon® from January 2016 to March 2018 were included in the study. The demographic details, treatment details and short- and long-term outcomes were evaluated. Factors affecting complication rates were analysed. Patient-reported outcome measures were studied using BREAST-Q questionnaires.

Results One hundred and sixteen reconstructions performed in 98 patients were included in the study. The median age was 50 years with a mean body mass index of 27.33 kg/m^2. The median follow-up period was 440 days. The implant-related major complication rate was 17%, with an unplanned readmission rate of 22.4% and a return to theatre rate of 21.4%. Early complications were significantly higher in patients with node-positive disease. Delayed complications were seen in nine patients. The implant loss rate was 4.3%. The mean BREAST-Q scores were 78 for satisfaction with treatment and 64 for satisfaction with breast domains. The outcomes were comparable to reported national data.

Conclusions Prepectoral implant-based reconstruction with Braxon has comparable complication rates with good long-term aesthetic and patient-reported outcomes. Further studies with larger cohort and longer follow-up are needed.

Level of Evidence—Level III, therapeutic study.

Keywords Breast reconstruction · Acellular dermal matrix · Implant-based reconstruction

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Introduction

Immediate breast reconstruction (IBR) after mastectomy is a standard treatment approach in the United Kingdom (UK) in eligible patients. With the introduction of biological and synthetic meshes to aid implant-based reconstruction, there has been a gradual shift from the classical two-stage approach to a single-stage direct-to-implant reconstruction. Hence, the last decade has seen a steady rise in the rates of post-mastectomy immediate implant-based reconstructions, with about 54% of IBR being implant-based in 2013, almost doubling over a 7-year period [1]. Subpectoral placement of implant has been the conventional technique of implant-based reconstruction. Placement of implant in the subpectoral pocket and complete implant coverage with acellular dermal matrix (ADM) or a synthetic mesh provides a larger pocket and better control of the inframammary fold. However, animation deformity and post-operative pain, probably related to detachment of the pectoralis major muscle, remain a matter of concern [2–4].

Prepectoral implant-based IBR using ADM is a relatively new technique with limited evidence in literature reporting on short-term and long-term outcomes. Main advantages of the prepectoral method over the subpectoral approach include avoidance of pectoralis major muscle disruption, no animation deformity and probably less capsular contracture [2, 5]. Available data on this novel approach has been published from few centres [6–10] with emerging evidence demonstrating equivalent outcomes between prepectoral and subpectoral approach using synthetic or biological meshes [5, 11, 12]. Braxon® (MBP Biologics, Neustadt-Glewe, Germany, licence holder Decomed, Marcon, Venezia, Italy) is a novel biological mesh used for prepectoral implant-based IBR. It is a porcine dermis-derived ADM up to 0.6 mm in thickness, available as a pre-shaped mesh to be wrapped around the implant ex vivo. Thus, it allows complete coverage of the implant to be placed in the prepectoral pocket created after a skin or nipple-sparing mastectomy. Two recent multi-centre studies from Europe using Braxon have shown acceptable peri-operative outcomes comparable to subpectoral reconstructions [9, 10]. Our centre has adopted the technique of prepectoral implant-based reconstruction using Braxon® since 2016 for patients deemed suitable for implant-based reconstruction. We report on short-term and long-term post-operative and patient-reported outcomes of 116 prepectoral implant-based reconstructions using Braxon®.

Methods

A prospectively maintained database of post-mastectomy IBR was analysed. All consecutive patients operated for a skin or nipple-sparing mastectomy with IBR using a prepectoral direct-to-implant and Braxon® from January 2016 to March 2018 were included in the analysis. As Braxon® was the only ADM available as a pre-shaped envelope to be wrapped around the implant, it was used as the ADM of choice for the reconstruction. About 98% of the implant-based reconstructions in the unit are performed as direct-to-implant with ADM with use of expanders limited to unsuitable or high-risk patients. The patients had a minimum follow-up period of 3 months and were operated in a single unit by oncoplastic breast surgeons. A uniform operative and post-operative management protocol was followed for all patients. The ABS and BAPRAS guidelines for implant-based reconstructions using ADMs were used for patient selection [13]. All patients were discussed in oncoplastic multidisciplinary meetings (MDMs). Patients with reconstructions using tissue expanders or any form of autologous reconstructions, with or without implant, were not included in the study. Demographic factors, tumour characteristics and peri-operative outcomes were evaluated.

Outcomes studied included early and delayed complications, unplanned readmissions, rate of reoperation for complications and implant loss. Early complications were defined as those up to 90 days after surgery. Delayed complications were recorded from day 91 to 1 year after surgery. All complications with Clavien-Dindo grade III or higher were classified as major complications [14]. Surgical intervention with implant removal was recorded as loss of implant. Re-exploration requiring implant exchange or placement of an expander was recorded as a major complication. Age, body mass index (BMI), indication of surgery (invasive cancer versus DCIS or risk reduction), surgical learning curve, implant size, nodal status, chemotherapy and adjuvant radiation therapy were the factors evaluated for their impact on complication rates. Specific complications recorded were minor complications like seroma and redness and major complications like infection, skin necrosis, wound dehiscence and post-operative haematoma. Delayed complications analysed included capsular contracture (recorded as per Baker's classification [15]), wound complications, implant rippling or rotation. Surgical learning curve was analysed by comparing outcomes in the first 50% of patients as compared to the next 50%. The factors mentioned above were evaluated for their effect on all early complications including minor and major complications for up to 90 days after surgery. Their impact on major complications was analysed separately. All outcomes were audited and recorded in the prospective database, and all post-operative complications were discussed in oncoplastic MDMs. Patients were followed-up for clinical examination at 1 week and 3 weeks post-operatively and then every 6 months. Patients were referred for clinical photography before and

after surgery. Patient-reported outcome measures were evaluated for post-operative outcomes using the validated BREAST-Q questionnaire for reconstruction. All patients with a minimum of 6 months follow-up period were contacted, and the post-operative module of the reconstruction BREAST-Q questionnaire was sent to them by post.

Surgical technique and peri-operative care

Mastectomy was performed using a skin sparing, nipple sparing or a skin reducing technique. The approach was decided on a case-to-case basis depending on tumour location, proximity of cancer to the nipple, patient's wishes and extent of breast ptosis. A skin-reducing approach was adopted for ptotic breasts using a Wise pattern incision or an elliptical incision if the nipple needed to be excised. An implant sizer was used to determine the implant size. All standard aseptic measures were followed to minimise surgical site infections. All prepectoral reconstructions were performed using Braxon®. The Braxon® was wrapped around the implant ex vivo using 3–0 PDS sutures and was tacked on the pectoralis major muscle with a three-point fixation at 3, 9 and 12 o'clock positions. A parachuting technique was used when needed. A drain was routinely placed in the resection cavity and was managed as per unit protocol. The peri-operative antibiotic prophylaxis included a single dose on intravenous Co-amoxiclav and gentamicin with oral Co-amoxiclav continued till drain removal.

Statistical analysis

Data was presented as mean, median or frequency (percentage) as was appropriate. Group comparisons were made using independent *t* test or Mann-Whitney *U* test for continuous variables and using chi-square test or Fischer's exact test for categorical variables. Multivariate analysis was performed using logistic regression. A p value of less than 0.05 was considered to be significant. Statistical analysis was carried out using SPSS version 21 for Windows SPSS 21.0 software (SPSS Inc., Chicago, IL USA).

Results

Ninety-eight patients were operated in the given study period and of these, 18 patients had a bilateral reconstruction. Thus, the analysis included 116 prepectoral implant-based reconstructions. Median age of the cohort was 50 years and the mean BMI was 27.33 kg/m^2. Demographic factors, tumour-related factors and treatment details are shown in Table 1. Sixty-four of the 98 patients were treated for invasive cancer and received further adjuvant treatment as indicated (Table 1). The median follow-up period was 440 days. Twenty-five patients (25.5%) had a major complication. Of these, 17 patients (17%) had an implant-related major complication and another 17 patients (17%) had a minor complication. The details of major complications are given in Table 2. Of the minor complications, more than 75% patients had a post-operative seroma and were managed conservatively. Twenty-two patients (22.4%) required an unplanned readmission for early complications and 21 patients (21.4%) had a surgical intervention. Of the factors evaluated for their impact on all early complications, including major

Table 1 Patient and treatment characteristics

Factor	Number (percentage/range)
Total patients	98
Total procedures	116
Laterality	
Unilateral	80 (81.63)
Bilateral	18 (18.37)
Median age (years)	50 (20–74)
Mean BMI[a] (kg/m^2)	27.33 (18–40)
Indication of Surgery	
Invasive cancer	64 (65.31)
DCIS[b]	21 (21.42)
Risk reduction surgery	13 (13.27)
Type of mastectomy	
Skin sparing	65 (66.33)
Nipple sparing	33 (33.67)
Mean implant size (ml)	359 (105–520)
Mean specimen weight (grams)	438.5 (65–1125)
Mean hospital day (days)	1.5 (1–10)
Management of axilla	
Axillary nodal clearance	23 (23.4)
Sentinel node biopsy	62 (63.2)
None	13 (13.3)
Chemotherapy	
Neoadjuvant	15
Adjuvant	30
Total	45/64[c] (70.31)
Adjuvant radiation therapy	25/64[c] (39.06)

[a] Body mass index

[b] Ductal carcinoma in-situ

[c] Sixty-four patients were operated for invasive cancers and thus eligible for adjuvant treatment

Table 2 Major complication details—early and delayed

Early complications	
Complication	Number
Haematoma	8
Surgical site infection	7
Redness/seroma[a]	4
Skin necrosis	3
Wound dehiscence	2
Nipple congestion	1
Total	25/98 (25.52%)
Delayed complications	
Complication	Number
Skin necrosis	3
Wound dehiscence	2
Skin redness	1
Total	6 (6.12%)

[a] Redness/seroma were classified as minor complications but as this subset of patients needed an unplanned readmission or an operative intervention, hence were categorised as major complications

and minor complications taken together, node-positive disease had a significant impact on early complications ($p = 0.029$). None of the other factors reached statistical significance. When the factors were analysed for their impact specifically on major complications, none of the factors had a significant effect. In this series, four patients had an implant removal within 90 days of the primary surgery. One patient had a bilateral implant loss; thus, 5 implants out of 116 implants were removed with an implant loss rate of 4.3% at a median follow-up of 17.5 months, as there were no implant losses after 3 months.

Nine patients (9%) had a delayed complication. Of these, six patients required a surgical intervention (Table 2), one patient had persistent surgical site pain and two patients had capsular contracture. None of the patients with delayed complications lost their implants. Thirteen patients (13.26%) underwent an additional cosmetic procedure during the follow-up period, which included contralateral symmetrisation, lipomodelling or nipple reconstruction.

The post-operative module of BREAST-Q questionnaire was sent to patients with a minimum follow-up of 6 months to measure patient-related outcomes. Thirty-five of the 74 (47.3%) patients responded with completed questionnaires. The mean BREAST-Q scores for satisfaction with breasts and satisfaction with treatment outcome was 64 and 78 respectively. Patient-reported outcome measures and mean BREAST-Q scores for each domain are shown in Fig. 1. Short- and long-term treatment outcomes are shown in Figs. 2 and 3.

Discussion

The introduction of ADM in implant-based reconstruction has made prepectoral implant placement with complete implant coverage possible with encouraging early results. Our centre has been routinely performing direct-to-implant subpectoral

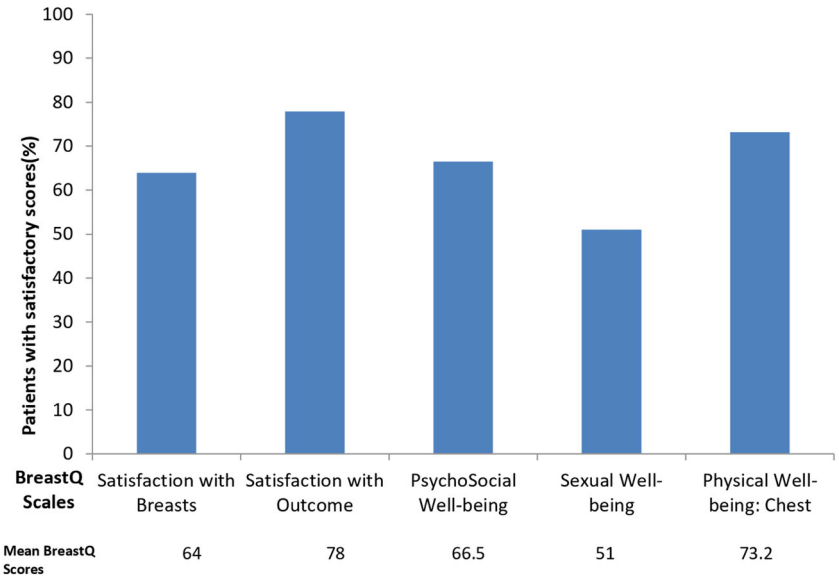

Fig. 1 Post-operative mean breast-Q scores and patient-reported outcomes. (Single column fitting image, colour figure)

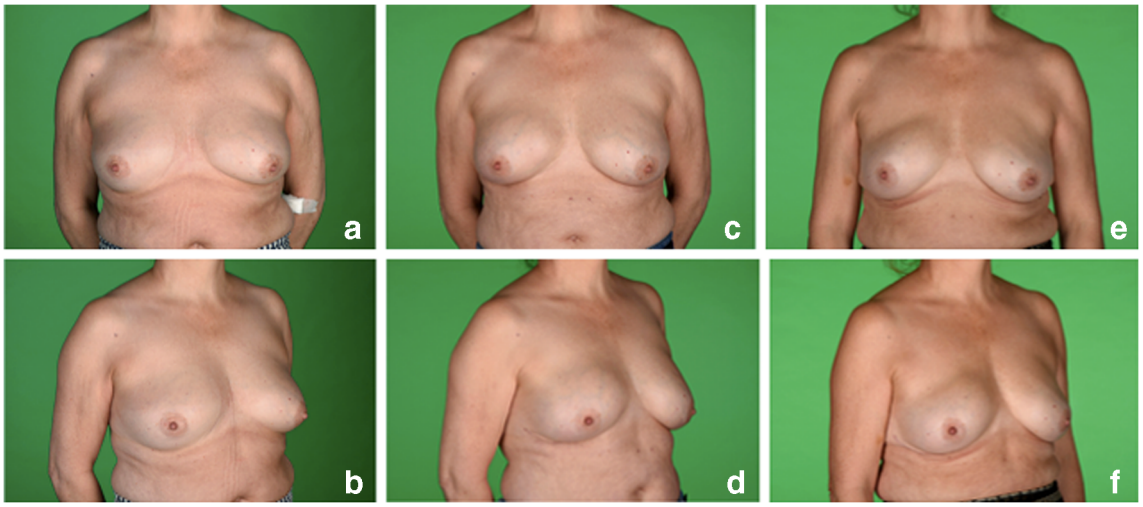

Fig. 2 Bilateral nipple-sparing mastectomy with prepectoral reconstruction. **a**, **b** Pre-operative. **c**, **d** Four weeks post-operative. **e**, **f** Twelve months post-operative outcomes (2 column fitting image, colour figure)

and prepectoral reconstructions in the last 6 years, and we have recently published comparable post-operative surgical outcomes between these two techniques [12]. Our current series on prepectoral direct-to-implant procedure using Braxon® has demonstrated satisfactory short- and long-term outcomes, including patient-reported outcome measures and an acceptable implant loss rate of 4%.

Berna et al. first reported their outcomes on prepectoral reconstructions using Braxon® in a multi-centre series of 19 patients with 25 reconstructions. The implant loss rate was 12 and 8% patients had a seroma. Short-term outcomes had satisfactory clinical and aesthetic results [6]. They further reported long-term data on ten patients with a median follow-up of 49.2 months with none of the patients having capsular contracture or implant rippling [16]. Although encouraging, the results were limited to small numbers of selected patients treated in high-volume centres.

Two multi-centre reports have reported on short-term outcomes using Braxon®. The first multi-centre study included 100 reconstructions from nine centres across Europe; with two centres from the UK with a reported implant loss rate of 2% and a peri-operative complication rate of 11% [9]. Another multi-centre study from the UK

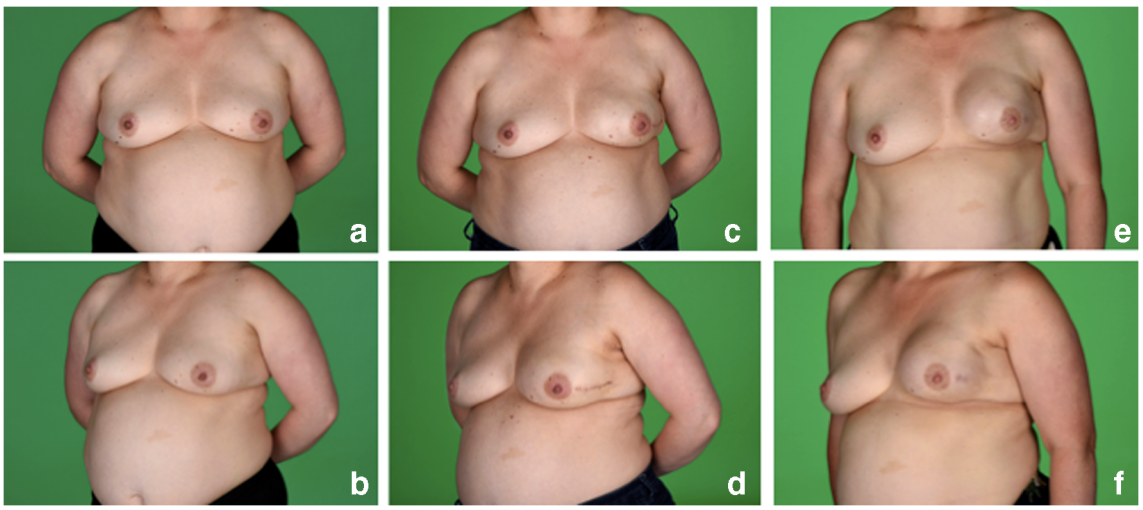

Fig. 3 Left nipple-sparing mastectomy with prepectoral reconstruction. **a**, **b** Pre-operative, **c**, **d** Four weeks post-operative. **e**, **f** Twelve months post-operative outcomes (2 column fitting image, colour figure)

Table 3 Comparison to ABS and BAPRAS recommended quality criteria, NMBRA and iBRA data

Quality criteria	ABS[a]/BAPRAS[b] recommendation	NMBRA[c] (%)	iBRA[d] (%)	Our study (%)
Unplanned readmission	< 5	16	17.8	22.4
Return to theatre for local complications	< 5	7.5	17.8	21.4
Post-operative infections at 3 months	< 10	25	25	7.1
Implant loss at 3 months	< 5	9	8.9	4.3

[a] Association of Breast Surgeons

[b] British Association of Plastic, Reconstructive and Aesthetic Surgeons

[c] National Mastectomy and Breast Reconstruction Audit

[d] Implant-based Breast Reconstruction evaluation

included 78 reconstructions, reported an implant loss rate of 10.2% with complication rates of about 20%. The complication rates although higher were comparable to the national data reported from UK [10, 17, 18]. The results from our study are comparable to that reported in the above series.

A recent report on prepectoral implant-based reconstructions by Highton et al. included 166 reconstructions in 106 patients. Complete implant coverage was obtained in 73.5% of patients using two sheets of Strattice® ADM or Strattice® and Artia® combination. The remaining patients had a prepectoral implant with ADM and dermal sling coverage. One hundred and thirteen reconstructions (68%) were IBRs, the rest being conversion of subpectoral to prepectoral reconstruction. A two-stage reconstruction using a tissue expander was performed in 9.2% of patients. Minor complication rate was 8.4% with major complications reported in three patients and the implant loss rate was 3%. Although our study did look at prepectoral IBRs, there were significant differences in the patient characteristics as compared to the above report. Our series included all patients with complete implant coverage operated in one stage using a single sheet of pre-shaped Braxon®. We did not include patients with two-stage reconstructions, subpectoral to prepectoral conversions or reconstructions with varying ADMs to avoid heterogeneity. Also, about 70% of the patients in the series by Highton et al. had a risk-reducing surgery as compared to only 13% in our series. This is an important finding as nodal positivity was a statistically significant predictor of early complication rates in our study (about 23% of our patients had an axillary nodal clearance). The difference in the complication rates thus probably reflects the difference in patient characteristics in the two studies. We have also included patient-reported outcome measure as a part of our study, with 35 out of 74 (47.3%) patients responding with completed BREAST-Q questionnaires.

Our study is the largest reported single-institution series of prepectoral breast reconstructions using Braxon®. Our selection criteria and surgical procedures were performed based on ABS and BAPRAS guidelines. Twenty-one patients had a BMI of more than 30 kg/m^2, but they were counselled of a higher rate of complications in this cohort [19]. Higher BMI did not have a significant impact on the overall complication rates in our analysis. All patients were provided with written information on breast reconstructions, which is one of the Quality Criteria recommendations of ABS and BAPRAS guidelines. The complication rates in our study were comparable to those reported in the National Mastectomy and Breast Reconstruction audit (NMBRA) and the recently reported iBRA study [17, 18]. These represent the largest available data across the country although the NMBRA reported on subpectoral implant reconstructions, and only about 2% of the reconstructions in the iBRA study had prepectoral placement of implant. We did have a much lower threshold for readmitting patients for persistent seroma or redness, and re-explorations for early complications with a view salvage the reconstructions. This could potentially explain the slightly higher readmission and return to theatre rates and comparatively less implant loss rates as compared to the NMBRA and iBRA reports (Table 3). We have included patient-reported outcomes as a part of our study. About 65 to 78% of patients were satisfied or highly satisfied with outcomes in each of the domains of the BREAST-Q questionnaire, except for sexual well-being. Multiple factors contribute towards sexual well-being in a cancer patient with surgery and reconstruction being one of them [20]. The patient-reported outcomes are comparable to the data available in literature reported from subpectoral reconstructions [21].

Our study does have some drawbacks. It is a retrospective analysis and will have its disadvantages accordingly [22]. The pre-operative module of the BREAST-Q questionnaire was not assessed. The immediate post-operative

pain scores were not evaluated. About 40% of the patients in our series have had adjuvant radiation therapy, and longer follow-up will be necessary to comment on long-term outcomes and capsular contracture rates in this set of patients. We acknowledge a relatively higher major complication of 25.5% rate in our series. However, the implant-related major complications were 17%, the rest being post-operative haematomas. Our current series had a relatively higher post-operative haematoma rate as compared to an average departmental rate of about 2%.

Conclusions

Prepectoral implant-based reconstruction with Braxon has comparable complication rates with good long-term aesthetic and patient-reported outcomes. Further studies with larger cohort and longer follow-up are needed.

Compliance with ethical standards

Conflict of interest statement Mihir Chandarana, Soni Soumian, Sadaf Jafferbhoy, Sekhar Marla and Sankaran Narayanan declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

Patient consent Patients provided written consent for the use of their images.

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