Indications and Pitfalls of Prepectoral Breast Reconstruction with Braxon® Acellular Dermal Matrix (ADM): A preliminary plastic surgical experience

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Prepectoral breast reconstruction by total implant coverage using Braxon® (Decomed SrL, Venezia, Italy) porcine Acellular Dermal Matrix (ADM) is a novel technique designed to minimize the drawbacks of subpectoral implant-breast reconstruction notably pain and animation deformity (**Figure 1**).[1] Although increasingly adopted by UK oncoplastic breast surgeons (Association of Breast Surgery - personal communication) the role of prepectoral breast reconstruction per se has yet to be defined especially in practices offering the full spectrum of breast reconstructions. A review of the indications and patient outcomes for Braxon® total implant coverage in a plastic surgeon's reconstructive breast surgery practice (2016-2019, minimum of 12 months follow-up) was undertaken. Our technique for Braxon® preparation and implant wrapping prior to insertion into the prepectoral pocket is illustrated in an accompanying video **(Supplementary material 1)**. Patients were identified from the departmental prospective breast reconstruction register and data extracted from the hospital's totally-electronic patient record system (Epic 2014, Wisconsin, USA).

Braxon®-wrapped epipectoral reconstructions (22 breasts in 16 patients, 6 bilateral) comprised 12% of the surgeon's immediate breast reconstruction workload. Other reconstructions were three non-Braxon prepectoral and 39 subpectoral reconstructions, 63 DIEPs, 15 SIEAs, 11 bipedicled DIEPs (i.e., 22 hemi-DIEPs), 10 LD flaps, three PAP flaps, one TUG, one free TRAM, 14 therapeutic mammaplasties and 0 local perforator flaps. **Figure 2** includes patient demographics and indications for Braxon® reconstruction, demonstrating the wide range of applications for this technique. Most patients underwent nipple-sparing mastectomies (69%). The commonest implants used were anatomical fixed-volume prostheses. However, one third were permanent expanders (i.e., expandable implants) namely McGhan Style 150s (prior to the 2018 EU-wide ban) and subsequently Mentor Becker-35s. In general, expandable implants were used for breasts in which the nipples were sacrificed and constitute a type of *direct-to-implant* technique as there is no planned expander-to-implant exchange.

Acceptable cosmetic outcomes were achieved (**Supplementary material 2-4**). The mean follow-up from surgery to the last visit was 19 months (minimum 12 months).

Our early surgical outcomes showed a high reoperation rate of 37% and a 33% incidence of large seromas. As with other prepectoral reconstructions there were no documented breast animation deformities or reductions in arm movements in our series. No implant malrotations were observed (one patient had a transient left implant malposition which self-corrected). Whilst our complications rates are high, they are in keeping with other early experiences of prepectoral reconstruction with Braxon® ADM,[2] and may represent a learning curve. Adaptations in our technique, namely substituting the aqueous betadine pocket-irrigation solution with a gentamicin-saline mixture after ADM hydration and prior to implantation appears to have reduced seroma formation, although our patient numbers are insufficient for a meaningful comparison. Similar to other porcine ADM studies, two patients (three breasts) with "Red Breast" symptoms were admitted for IV antibiotics and nonsteroidal anti-inflammatories as per current literature recommendations.[3] With hindsight, readmitting these patients was probably unnecessary in the absence of raised inflammatory markers and this would have reduced the high readmission rate to about one third (6/16). Furthermore, the complications were not all technique-related. Haematomas (1) can occur regardless of implant pocket or ADM type and the Braxon® was not responsible for a patient developing a urinary tract infection which led to bilateral implant infection and explantation. Although excluding these ADM-unrelated events improves the complication profile, large seromas occurred in several patients (33%) and this might be related to this ADM's porcine constitution (Braxon is a preshaped freeze-dried porcine ADM) similar to what is seen with another popular porcine product, Strattice® (Allergan Plc, Dublin, Ireland).[4]

In our single-plastic surgeon's series, several factors may have contributed to the adverse outcomes observed. The complications encountered allowed us to develop an initial list of indications both for and against offering Braxon®-ADM reconstruction (**Supplementary**

material 5). We have identified some pitfalls and relative contra-indications for this procedure **Figure 2 (Table)**, and as with all types of reconstructions, careful patient selection is mandatory to achieving low complication rates. Inherent disadvantages of prepectoral breast reconstructions include implant visibility, rippling and empty superior take-off due to the more superficial implant placement. However, this can be mitigated with the subsequent use of fat grafting. Currently surgeons who exclusively adopt this strategy always factor in a second stage fat grafting operation for all patients, committing patients to yet another operation, (perhaps unnecessarily) which in our opinion could be avoided in many such patients by performing subpectoral reconstruction in patients likely to need fat grafting.

In conclusion we feel that this technique should be applied with careful patient selection such as those with favourable soft tissue cover, no planned post-mastectomy radiotherapy, non-smokers and a clear/specific indication (as shown in **Supplementary material 5**). It is, therefore, not a panacea for all patients undergoing prosthetic reconstructions. Large-scale longitudinal studies are needed to determine the place of this surgical technique in current breast reconstructive practice.

References

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Disclosures

The authors have no financial or other interest in Braxon® and are not in any way linked to Raise Healthcare UK or Decomed Italy. The senior author (CMM) had his travel expenses reimbursed for lecturing at two Braxon® symposia organized by Raise Healthcare UK for no remuneration. He also received one-off honoraria for serving on the Medical Advisory Panels of Allergan (the then manufacturers of McGhan Style 150 expanders) and Johnson & Johnson (the owners of Mentor Medical Systems who produce the Becker-35 expanders).

FIGURES & LEGENDS

Figure 1: Total implant coverage using Braxon® Acellular Dermal Matrix as utilized in our practice. The photograph shows an expandable implant with a remote injection port totally covered in Braxon sutured with 3-0 PDS and the excess ADM trimmed off with scissors. The implant-ADM complex is shown here prior to insertion.

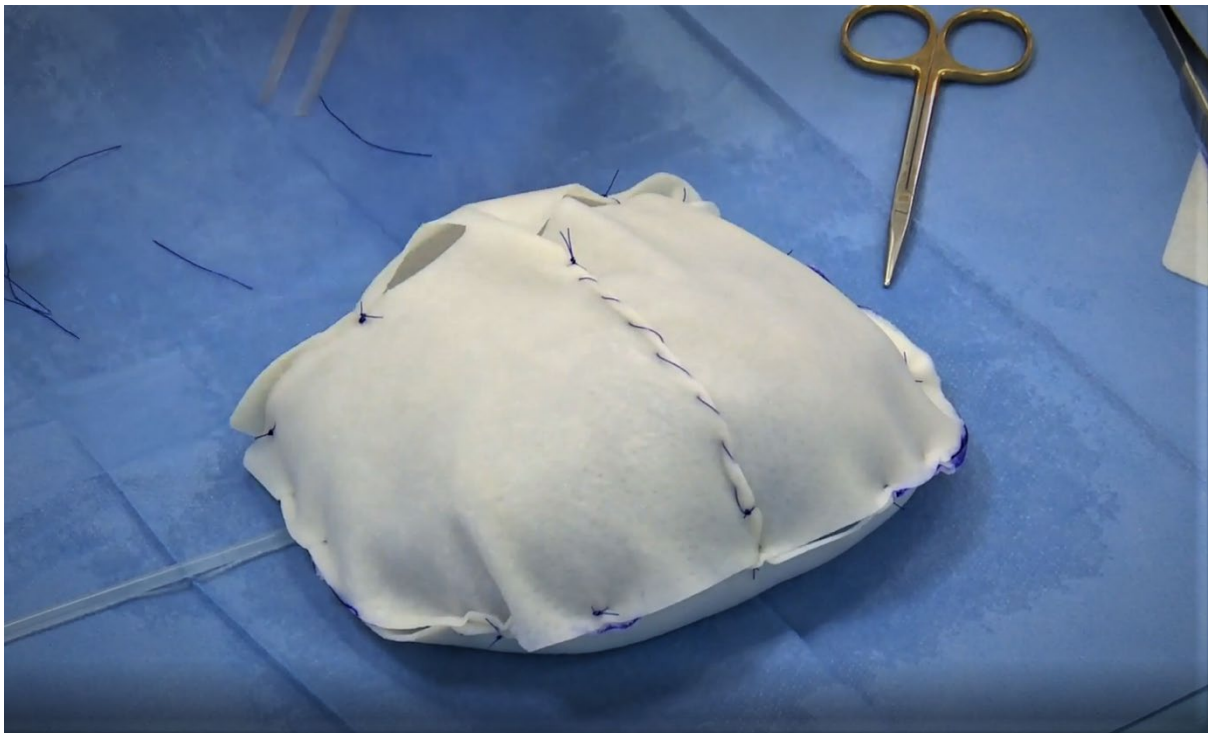


Figure 2: Patient demographics, indications for prepectoral over subpectoral reconstruction and complication profile.

PARAMETER	PATIENT
Total patient number	16
Number of breasts	22 (6 bilateral)
Age at operation (years)	43.5 (range 35-55)
BMI at operation (kg/m^2)	25.9 (range 21.7-50)
Indication (by number of breasts)	**Number of breasts**
Cancer	10

Risk-reducing mastectomy	10
Tertiary (salvage) reconstruction	2
Indications for Prepectoral rather than Subpectoral Reconstruction	**Number of patients**
Active mother wishing to lift children early post-operatively	3
Athlete who needed reduced recovery time	2
Co-morbidities which excluded them from major surgery	2
Desire to minimise operation time and recovery	2
Insufficient fat coverage and bilateral reconstruction	2
Temporising measure before future DIEP surgery	2
Hyperactive pectoralis major muscles	1
Previous complex reconstruction	1
Young patient (allowing for further treatment options if required in the future)	1
Mastectomy type (by breast number)	**Number of breasts**
Skin-sparing, nipple-sparing	14
Skin-sparing, nipple sacrifice	4
Skin-reducing, nipple-sparing	2
Skin-reducing, nipple sacrifice	2
Mastectomy incision type (by breast number)	**Number of breasts**
Peri-areolar incision	15
Inframammary incision	5
Hemi-Y incision	4
Wise pattern	3

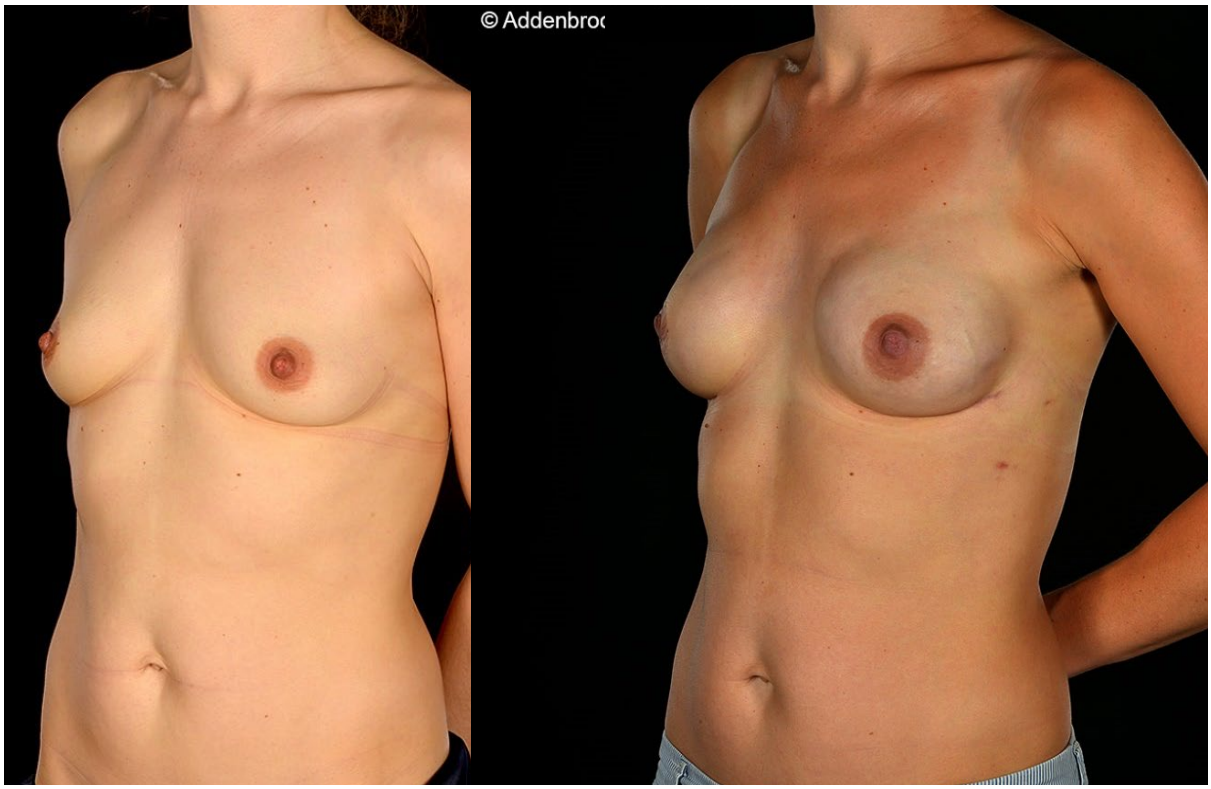
Mastectomy weight (mean)	359g (range 104-2045)
Implant type	**Number of breasts**
Fixed volume	15
Permanent expander	9
• McGhan Style 150s	6
• Mentor Becker-35s	3
Mean hospital stay (in days)	4.6 (range 2-7)
Mean time to drain removal (in days)	7.9 (range 3-25)
COMPLICATION	
Uneventful healing (patients, breast number)	7 (11 breasts)
Unplanned re-admission	8 patients (6 returned to theatre)
Return to theatre (1 hematoma, 3 seromas, 3 infections, 1 nipple problems)	6 patients (2 required 2 operations)
Major Adverse Outcomes (by number of breasts) *	**Number of breasts**
Explantation (implant loss)	6 (27%)
Seromas requiring aspiration	8 (36%)
Infection (including implant loss)	6 (27%)
Partial nipple necrosis- reconstruction salvaged Supplementary material 4	1 (4.5%)
"Red Breast"	3 (14%)
Haematoma	1 (4.5%)
Minor Adverse Outcomes (by number of breasts)	**Number of breasts**
Transient localised tenderness at superior fixation points	3 (13%)

Exercise-induced "partial dislodging”	1 (4.5%)
Transient implant malposition	1 (4.5%)
Visible rippling (not requiring fat grafting thus far)	4 (18%)
Individual patient co-morbidities (by patient number) Urinary tract infection during admission (1) Smoker (1) Former smoker (2) Ventricular septal defect & Factor VII deficiency (1) ACA embolic stroke (1) Depression, rheumatoid arthritis, Hepatitis C (1) Cerebrovascular accident, patent foramen ovale (1) Embolic stroke (1)	**Complication developed by patient** Bilateral seromas with implant loss No complications 1 infection & bilateral implant loss Infection leading to implant loss Seroma needing aspiration No complications No complications Cellulitis & Red Breast

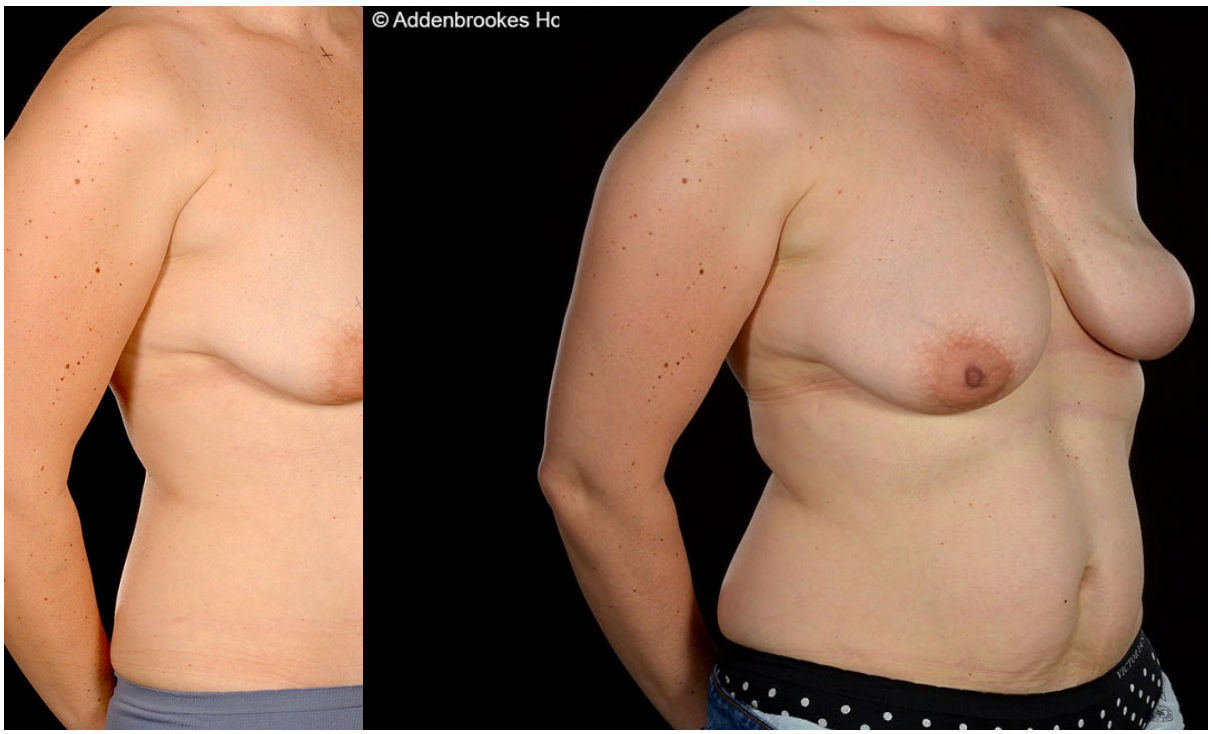
* There was an overlap in these complications for instance some patients developed major seromas which led to readmission, re-exploration and implant loss. Similarly the haematoma patient develop infection of both breasts and these were explanted. The readmissions included the 2 patients with Red Breasts (3) who were readmitted out of an abundance of caution.

Supplementary material 1: Video illustrating the Braxon® preparation and wrapping technique employed in the series.

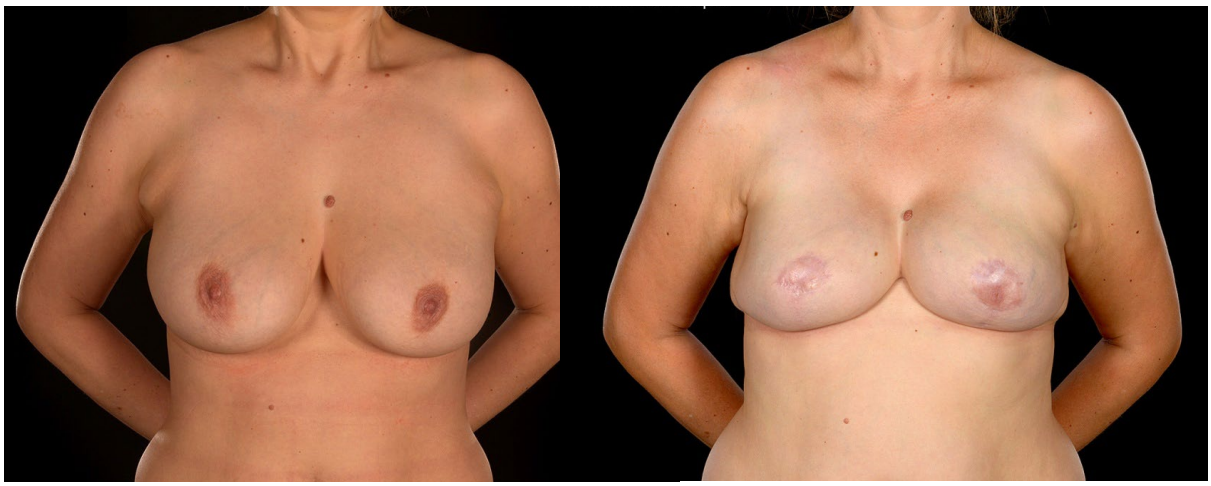
Supplementary material 2: 36-year-old with bilateral nipple sparing (risk reducing) mastectomies and immediate reconstruction with 250cc fixed volume implants and total Braxon ADM cover. The mastectomies (Right breast: 210g, Left breast: 195g) were performed through IMF incisions and the implants "parachuted" into the pockets and secured to the pectoral fascia with PDS sutures.



Supplementary material 3: 39-year-old who underwent a left-sided skin-reducing (Wise pattern) mastectomy and immediate epipectoral reconstruction with a dermal sling, fixed volume implant (Sebbin anatomical 375cc) and Braxon®-ADM. She requested immediate reconstruction without damage to her pectoralis muscle since she had young children. She noticed partial "dislodging" of the implant superiorly and onset of visible rippling after cartwheeling with her daughter. She declined both a balancing contralateral mastopexy and ipsilateral fat grafting.



Supplementary material 4: 38-year-old with bilateral skin-reducing (Wise pattern), nipple-sparing mastectomies (risk-reducing) and immediate reconstruction with fixed volume implants (Sebbin anatomical 290cc), Braxon® -ADM and dermal slings. Post-operatively she developed bilateral wound breakdown at the T-junctions and partial nipple necrosis. At debridement and washout the implants were found to be still covered by the dermal slings and Braxon®-ADM and were salvaged. 2 years post-operatively she underwent bilateral capsulotomies and implant exchange from Sebbin textured anatomical to Nagor Impleo 330cc round smooth implants (indication palpable implant knuckle, early capsular contraction, nipple tethering and implant malrotation).



Supplementary material 5: Proposed indications and contra-indications (CI) for prepectoral reconstruction with Braxon® ADM.

Indication for Patient Selection	Relative CIs	Absolute CIs
• Athletes wishing early return to exercise or no muscle damage • Parents of young children (wish to lift them early in recovery) • Unsuitable for major surgery - needing a quick operation e.g., - Comorbidity: after CVA* - High BMI: >40	• RT[#] planned or likely • Severe breast ptosis • Requirement for SRM with nipple sparing • High BMI ≥ 35 (if SRM[¥] planned) • Previous reduction scars can compromise mastectomy flaps	• Current smokers • Poor soft tissue cover • Recent/ongoing infection anywhere • Poorly perfused mastectomy flaps

[#] RT = radiotherapy; *CVA - cerebrovascular accident, [¥] SRM = skin-reducing mastectomy