

Direct to implant breast reconstruction with biological acellular dermal matrices

Abstract

Breast cancer is the most commonly diagnosed female cancer in the UK, with one in eight women receiving a cancer diagnosis during their lifetime. Forty per cent of women diagnosed with breast cancer undergo mastectomy as their primary therapeutic procedure. While a full range of choices is offered, breast reconstruction using implants is the patient-preferred method of reconstruction following mastectomy. This review discusses the evolution of implant-based reconstruction, focusing on the recent trend towards prepectoral breast reconstruction. Key quality indicators in the current literature are considered, including oncological outcomes, aesthetics and patient-related outcome measures, as are the health-care economics of this emerging surgical technique.

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Introduction

Breast cancer is the second leading cause of cancer death among women, accounting for 30% of all new malignant diagnoses in 2018 (Siegel et al, 2018). Despite the improved understanding of tumour biology, advances in adjuvant therapies and the trend towards breast-conserving treatments, mastectomy rates continue to rise significantly. In the USA, mastectomy rates rose from 40% to 51% over the last decade (Walia et al, 2018), while the number of women undergoing bilateral mastectomies more than tripled, from 9 out of 100 000 women in 2005 to 30 out of 100 000 women in 2013 (Agency for Healthcare Research and Quality, 2016). A considerable proportion of this increase is the result of an increasing demand for contralateral prophylactic mastectomies (Neuberger et al, 2013; Wong et al, 2017) that is in part patient driven through the perception of risk and in part by surgeons in a quest for optimal symmetry. Genetic testing has become more widespread and the incidence of risk-reducing mastectomies has also increased as people who carry genes which predispose to a high risk of breast cancer are identified (Liede et al, 2018).

Breast reconstruction following mastectomy plays a vital role in restoring quality of life, body confidence and psychosexual wellness in women with breast cancer. In the UK, 21% of women opt for breast reconstruction during their treatment for cancer and this can range from autologous options such as free or pedicled flaps to implant-based reconstruction. Final decisions on reconstruction choices are based on patient choice, body habitus, comorbidities and access to surgical services (NHS Information Centre, 2011).

Implant-based breast reconstruction remains the preferred restorative technique by patients in the UK, with data from 2017 indicating that implant-based reconstruction makes up 70% of the reconstructive caseload (Mylvaganam et al, 2017). The technique of implant-based reconstruction has been the subject of much debate in the last half century, with refinements in implant technology, adjunctive procedures to augment the quality of soft tissue cover, and developments in fat grafting. The ideal anatomical plane for placement of the prostheses remains controversial. The driving force in implant-based reconstruction is the reproduction of a natural breast mound, with recreation of ptosis where necessary and maintenance of projection.

This review focuses on the evolution of implant-based reconstruction, drawing on the resurgence of prepectoral implant-based reconstruction. It discusses contemporary key quality indicators in the literature including oncological outcomes, breast aesthetics and patient-related outcome measures, and discusses the health-care economics of this emerging surgical technique.

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Early implant-based breast reconstruction and the evolution of anatomical plane placement

Cronin and Gerow (1963) fathered implant-based breast reconstruction with the introduction of the silicone gel breast implant in 1963. The early breast reconstruction pioneers often faced difficult post-mastectomy tissue conditions with the reconstruction performed in the delayed setting. It was not until 1971 that Snyderman and Guthrie conceptualised implant placement in the subcutaneous plane immediately following mastectomies (Snyderman and Guthrie, 1971). However, high complication rates ensued with subcutaneous implant breast reconstruction, particularly with mastectomy flap necrosis, implant extrusion, high capsular contraction rates (Gruber et al, 1981; Slade, 1984) and poor aesthetic outcomes with visible contours and palpable implants (Snyderman and Guthrie, 1971; Gruber et al, 1981).

These limitations drove implant placement into the submuscular plane, where implant coverage with well-vascularised muscle helped significantly to address these concerns (Woods et al, 1980). Partial or total submuscular coverage of the implant or expander can be achieved beneath the pectoralis major muscle, with or without incorporating the anterior fibres of serratus anterior laterally and the abdominal fascia anteriorly. With the development of inflatable permanent expander implants such as the Becker and McGhan 150 implants, one-stage immediate breast reconstructions were popularised in the 1990s.

Raising muscle for pocket creation can be associated with significant postoperative pain in the short term, and animation of the implant on contraction of the pectoralis major in the longer term. Controlling the implant pocket can be challenging with a tendency towards dislocation of the implant into the superior pole or lateral axilla. Poor inframammary fold definition can further contribute to poor aesthetic results. The subpectoral pocket is an unnatural tissue plane and can be limited in its accommodation of fixed volume implants in direct to implant reconstruction.

In the USA, two-stage reconstruction to allow the pectoralis major muscle to be stretched over time with expanders became the standard of care. Tissue expansion enabled the creation of a stable implant pocket and when the final volume had been achieved, the expander was exchanged for a final fixed volume implant. These techniques often resulted in a breast mound that lacked ptosis, and projection to match the contralateral could be difficult to achieve.

The era of biological meshes: the return to subcutaneous implant placement

The role of acellular dermal matrices in implant-based reconstruction first came to the fore in 2005 (Breuing and Warren, 2005), where a biological mesh was used as a hammock to support the inferolateral pole of the implant. The release of the inferior attachments of pectoralis major to the rib cage and the interposition of a sheet of acellular dermal matrix allowed for submuscular placement of an implant (Figure 1a), in effect by lengthening the subpectoral pocket, to improve lower pole projection and definition of the inframammary crease as well as the lateral breast fold (Salzberg et al, 2011; Scheffan and Colwell, 2014). Data from the USA from 2017 indicate that 59 774 of 106 295 breast reconstructive procedures incorporated the use of acellular dermal matrices (American Society of Plastic Surgeons, 2018).

Prepectoral reconstruction (Figure 1b) was recently coined as a return to the previous concept of subcutaneous implant-based reconstruction. Improved understanding of mastectomy planes has also encouraged the raising of safer vascularised mastectomy flaps, with consistent reliable viability. Technological advances allow intraoperative assessment of the mastectomy flap blood flow by means of laser or perfusion analysis using indocyanine green. While prepectoral and therefore subcutaneous implant placement had previously been abandoned for its high complication rate as a result of poor soft tissue cover, advances in biological mesh technology have been pivotal to the return of implant placement to the prepectoral plane. Avoidance of dissection to raise the pectoralis major potentially reduces postoperative pain, facilitating early recovery and hospital discharge, with lower risks of animation as the implant was no longer placed below the

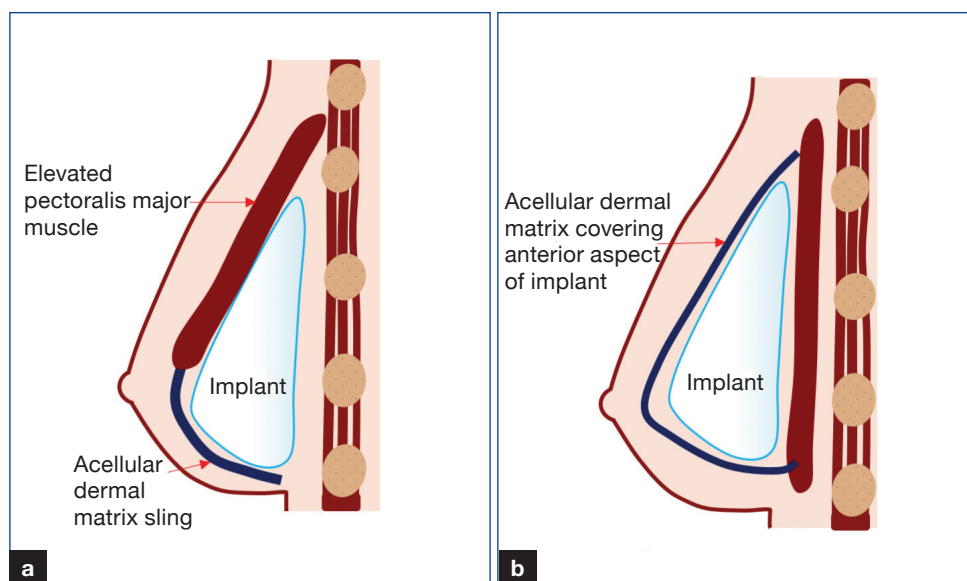


Figure 1. a. Subpectoral and (b) prepectoral implant-based breast reconstruction.

muscle. This early enthusiasm has seen prepectoral immediate breast reconstruction now accounting for 12–18% of all prosthetic breast reconstruction (Glasberg, 2017). Promoted as an adjunct to the skin envelope, acellular dermal matrices can shape and control the mastectomy pocket, and improve the definition of the reconstructed breast. Intersurgeon preferences vary in deciding between total implant coverage using acellular dermal matrix in the prepectoral plane (wrapping), or limiting the acellular dermal matrix to cover only the anterior aspect of the implant (tenting), thus suspending the implant on the anterior chest wall.

Various preparations of biological matrices and synthetic meshes have been used in implant-based reconstruction, with products of varying cost. They may differ in composition of the material, from human cadaveric (Alloderm, DermaMatrix), to porcine (Strattice, Cellis, Braxon, Artia, Permacol, Protexa) or bovine (Veritas, SurgiMend) in biological matrices or synthetic polymers (TiLoop, TIGR, GalaFlex). Matrices vary in preparation and design, and are available as sheets that may be fenestrated with slits of differing lengths and orientations, round or shaped perforations, true expandable meshed products with wide open spaces, or pre-formed sheets designed for use as wraps or ‘internal bras’. The method of storage of the acellular dermal matrix, ie pre-wetted ‘ready-to-use’ or freeze-dried, does not affect complication rates (Lee and Mun, 2016). **Table 1** summarises the properties of some of the more widely used biological acellular dermal matrices. A meta-analysis demonstrated no significant difference in complication rates between the various types of acellular dermal matrices currently used in implant-based reconstruction (Lee and Mun, 2017).

In the UK, 75% of implant-based reconstructions are performed with acellular dermal matrices (Mylvaganam et al, 2017). Initial complication rates in mesh-assisted, implant-based reconstructions were high, with reported infection and implant loss rates of up to 11.5% and 12.5% respectively (Lardi et al, 2014), but studies such as these are likely to include the learning curves of surgeons while case selection criteria were refined. More recent studies show considerably lower infection and implant loss rates, such as 4% and 2% respectively in a prospective multicentre study (Vidya et al, 2017).

Prepectoral acellular dermal matrix-covered, implant-based reconstruction has an equivalent complication profile to that of partial-cover or subpectoral, acellular dermal matrix-assisted implant-based reconstruction (Sinnott et al, 2018). Patient selection is key, with independent studies demonstrating that mastectomy weight is a significant correlate of complication rates. Other factors including post-mastectomy radiation therapy, adjuvant chemotherapy, patient comorbidities (body mass index, diabetes, immunosuppression) and age, while important, may not necessarily have such an impact if careful consideration is given to surgical approaches and patient selection (Negenborn et al, 2018).

Table 1. Properties of commonly used biological acellular dermal matrices in immediate breast reconstruction

Trade name	Tissue of origin	Initial treatment, transportation and epidermis removal	Post treatments	Comments
AlloDerm regenerative tissue matrix	Human	Buffer solution, antioxidants, antibiotics, protease inhibitors, smooth muscle relaxant	Prefreezing solution (dextran, sucrose, raffinose, EDTA and buffer)	Requires long rehydration times (up to 40 minutes) Requires two separate soaks Surface orientation required
Braxon	Porcine	Data unavailable	Freeze dried and ethanol sterilized	Hydrates in 5 minutes
FlexHD acellular hydrated dermis	Human	Warm sodium chloride	Peracetic acid	Supplied in ethanol solution. Rinse required
Strattice Tissue Matrix; recent addition Artia	Porcine	Warm sodium chloride Buffers, detergents 0.5% sodium dodecyl sulphate	Prefreezing solution (dextran, sucrose, raffinose, EDTA and buffer), irradiation	Rinse required
SurgiMend PRS collagen matrix; recent addition SurgiMend PRS meshed to fenestrated sheets	Bovine (fetal calf)	Mechanical defleshing	Freeze-dried from purified water, low temperature ethylene oxide sterilization	Hydrates in 1 minute
Veritas	Bovine (pericardium)	Sodium hydroxide	Electron beam radiation	Ready for use

EDTA = ethylenediaminetetraacetic acid solution

Capsular contracture and the impact of postmastectomy radiotherapy

Several studies have reported reduced capsular contracture rates from the use of acellular dermal matrix in implant-based breast reconstruction (Stump et al, 2009; Basu et al, 2010; Cheng et al, 2013; Lardi et al, 2014; Lee and Mun, 2016; Glasberg, 2017), with a suggestion that total implant coverage may minimise overall capsular contracture (Highton et al, 2017). These data should be interpreted with caution because of short follow-up duration.

There are limited data on the outcomes of prepectoral implant-based reconstruction following postmastectomy radiotherapy which can be associated with increased incidence of capsular contracture, reconstruction distortion leading to poor aesthetic outcome and increased likelihood of revision surgery (Magill et al, 2017; Ricci et al, 2017). A prospective multicentre cohort study recently demonstrated that 18.7% of patients with implant-based breast reconstruction who received radiotherapy lost their implants within 2 years (Jagsi et al, 2018). Sinnott et al (2018) compared patients with subpectoral and prepectoral reconstructions undergoing postmastectomy radiotherapy and demonstrated that the subpectoral group had a three times greater rate of capsular contracture than the prepectoral group (55.2% vs 16.1%) at a mean follow-up time of 19 months. Furthermore, the subpectoral group had a higher incidence of Baker III/IV capsular contracture (Sinnott et al, 2018).

Reviews demonstrate the oncological safety and patient satisfaction following prepectoral breast reconstruction (Sigalove et al, 2017; Vidya et al, 2017; Woo et al, 2017). While these initial findings are promising, the resurgence of the prepectoral technique is relatively new, and interpretation of outcomes must stand the test of time. If long-term data prove favourable, prepectoral immediate breast reconstruction is likely to gain further popularity for its improved patient recovery from reduced postoperative pain and functional disability.

Aesthetic and patient-reported outcomes in prepectoral implant breast reconstruction

Initial studies assessing the aesthetic outcomes in prepectoral breast reconstruction have reported good cosmetic outcomes (Casella et al, 2014; Bernini et al, 2015; Woo et al, 2017), with reliable reproduction of a natural breast shape and preservation of ptosis. This can be used in conjunction with a reduction in skin envelope for the overtly ptotic breast. Subcutaneous implant placement could lead to compromise in implant cover causing palpability, implant visibility, rippling and prominent implant edges. Fat grafting is now established in the breast reconstruction algorithm, with general acceptance of the oncological safety. Fat grafting also helps to address minor contour deformities and improves mastectomy flap thickness. While fat grafting has been reported at the time of primary surgery following the mastectomy, this is not widely practiced (Ter Louw and Nahabedian, 2017). The prepectoral placement of the implant is likely to result in less long-term animation and distortion from muscle contracture.

Careful patient selection, evaluation of the viability of the mastectomy flaps and consideration of the need for a simultaneous skin reduction procedure are important in achieving a successful outcome. Prepectoral implant-based reconstruction is best suited to small and moderate size breasts. As the implant size increases, so do the supportive demands on the mastectomy flaps leading to a rise in complication rates and poor aesthetic outcomes, perhaps more acutely so than with subpectoral implant placement. Accurate sizing of the implant to the mastectomy pocket and selection of high cohesion implants will help minimise rippling and contour step-offs.

Health economics of prepectoral breast reconstruction

The cost implications of total implant coverage with acellular dermal matrix are appreciably higher when compared to the smaller surface area of acellular dermal matrices required in subpectoral reconstruction. Cattalani et al (2018) published an economic analysis comparing subpectoral and prepectoral reconstruction. Initial direct hospital costs were higher in the prepectoral compared to the subpectoral direct to implant groups (€6080 and €3964 respectively). The study further suggests that prepectoral breast reconstruction is economically advantageous because of the reduced need for symmetrisation surgery in this patient group. There is indirect evidence suggesting that there is no difference in operation time or length of hospital stay in comparing submuscular and prepectoral breast reconstruction. Difficulties in interpreting cost analyses include compatibility of inclusion criteria between groups, and comparison of contemporaneous and historical patient series.

Recovery of upper limb function and return to work was quicker in the prepectoral group, a factor most likely associated with reduced postoperative pain (Glasberg, 2017). Quality of life, psychosocial wellbeing and patient satisfaction with cosmesis, as assessed by the validated questionnaire BREAST-Q, were in favour of the prepectoral group. The study did not consider the frequency of outpatient attendance, particularly in the case of two-stage reconstruction, where repeated patient attendance is required for serial expansions in preparation for the definitive implant exchange.

With breast reconstruction secondary procedures may be necessary to optimise breast form and symmetry. Implant breast reconstruction is also associated with the need for maintenance surgery over time. Other factors that need to be taken into account include preparation time of the various acellular dermal matrices and the implications of ex-vivo handling (extended wrap suturing procedures) on complication rates. Longer-term data on differences between prepectoral and subpectoral approaches on secondary revision procedures are awaited.

Conclusions

Early indications support the recent shift of acellular dermal matrix implant reconstruction into the prepectoral plane. The enthusiastic adoption of prepectoral implant-based breast reconstruction is borne of the marriage between the ease in surgical technique, and the promising preliminary results on improved patient outcomes. As with any new surgical technique, more evidence-based data are required to determine its longevity. Further studies on fiscal sustainability, clinical outcomes and patient satisfaction will drive future directions in acellular dermal matrix-assisted implant breast reconstruction.

Key points

- Prepectoral reconstruction is the natural evolution to subpectoral, implant-based breast reconstruction.
- Acellular dermal matrices are a widely used adjunct in one stage, direct-to-implant breast reconstruction.
- Prepectoral implant breast reconstruction is associated with high patient satisfaction and acceptable complication rates.

Conflicts of interest

The authors declare no conflicts of interest.

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