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ORIGINAL PAPER

De novo experience of resorbable woven mesh in immediate breast reconstruction post-mastectomy

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Abstract
Background Implant based reconstruction (IBR) is the most common form of breastreconstruction. IBR has advantages; uncomplicated surgery, no donor site and goodaesthetic outcome. However, disadvantages include infection with implant loss andphysical limitation to the size of breast which can be used. The use of surgical matricesto increase the size of implants used has gained in popularity, however concernsregarding increased complication rates exists. Here we describe our initial experienceusing a resorbable mesh in post mastectomy patients.
Methods Post mastectomy patients after cancer surgery or for risk reducing surgerywere examined. We examined our initial experience over an 18 month period ofpatients undergoing reconstruction with the use of resorbable mesh and implant basedreconstruction. Patients were followed for major or minor complications including flap necrosis, implant loss, haematoma, seroma and infection rates.
Results Few major complications were encountered. There were no instances of flap necrosis or haematoma formation. However, 5 reconstructed breasts (n=74, 6.7%)resulted in loss of the implant due to infection. These losses were associated withpatients who were either current or ex-smokers, or in patients who had or wereundergoing either radiation or chemotherapy. Minor complications such as superficialwound infections were seen in 8 of 74 (10.8%) reconstructed breasts. The overallcomplication rate was 17.5%, or 13 of 74 reconstructed breasts.
Conclusions The use of resorbable mesh provides excellent cosmetic outcomes withminimal complications. To avoid major complications discretion should be used inpatients with risk factors such as smoking and radiation therapy.
Level of Evidence: Level IV, therapeutic study.

Keywords Breast · Reconstruction · Mesh · Post-mastectomy · Implant · Expander · Radiation · Brca · Oncology · Acelullar dermal matrix

Introduction

Oncoplastic breast surgery aims to improve aesthetic and psychological outcomes following breast cancer surgery [1, 2]. Breast reconstruction rates have increased in recent years as several reconstructive options have become more widely available [3]. Broadly, these include implant-based reconstruction and autologous tissue reconstruction. Suitability for each type of reconstruction is determined primarily on the patients preference, previous surgery, previous irradiation to the chest, overall size and ptosis of the breast and skin quality [4]. Complications related to tissue expander and implant reconstruction are focused around implant loss, flap necrosis and aesthetic outcome. Patients who have undergone or are due to commence adjuvant radiation therapy after surgery are at an increased risk of complications when compared to the non-irradiated group [5, 6].

Implants and tissue expanders are used in the majority of women undergoing breast reconstruction post-mastectomy [7]. Tissue expanders allow for a two-stage reconstruction either at the time of mastectomy or as a delayed procedure. The tissue expander is inserted under the pectoralis major muscle superiorly, with the serratus anterior or rectus abdominis muscle

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creating a pocket inferiorly. The expander is inflated with saline over several weeks depending on patient's tolerance and the size of the expander. Two-stage reconstruction has the drawback of necessitating a second surgical procedure.

Concerns related to implant-based reconstructions include delay to further oncological treatment; however, these concerns have somewhat diminished with evidence supporting no determent to oncological safety with regards to detection or recurrence rates [8, 9]. Implant-based reconstruction requires complete coverage to avoid contact with the skin incision and subcutaneous pocket [10]. This can restrict the expander or implant which may cause the implant to settle in a superior manner, resulting in a "high riding" implant [10].

We describe our initial experience using a resorbable mesh in breast reconstruction. This mesh is a synthetic polymer which provides variable absorption and tissue integration. This is accomplished by a combination of fast absorbing co-polymer of glycolide, lactide and trimethylene carbonate and slow absorbing lactide and trimethylene carbonate which retains 50 % of its strength at 6 months and is fully integrated and absorbed at 3 years [11]. To determine the safety and effectiveness of resorbable surgical mesh, we examine the outcomes and complications encountered in patients who underwent immediate or delayed breast reconstruction as either a one-stage or two-stage procedure through the use of retrospective analysis of a prospective maintained database of patients.

Materials and methods

All surgeries were carried out in a single hospital institution by two surgeons between October 2014 and February 2016. Patients were fully counselled after diagnosis of breast cancer or as part of risk reducing surgery and the recommendation of mastectomy following multidisciplinary team discussion. Immediate reconstructive options were offered and explained in detail to each patient. Standard consultation includes the risk of surgery and complications associated with implant-based reconstruction. Patients deemed candidates for the use of the resorbable surgical mesh were those undergoing either unilateral or bilateral mastectomies. Patients not deemed candidates for reconstruction using the surgical mesh were those who declined reconstruction or who opted for alternative reconstructive options such as autologous tissue transfer in the form of either latissimus dorsi flap or deep inferior epigastric perforator (DIEP) flap reconstruction. Some women opted for delayed reconstruction after completion of their chemotherapy and radiation therapy. All women were at least 18 years of age and able to give informed written consent. There were no absolute contraindications to the use of the surgical mesh. Included in this cohort were patients with prior breast surgery (either oncologic or aesthetic), whole breast irradiation and other co-morbidities such as diabetes or smoking. Patients in this higher risk category were counselled on the potential increase risk of their surgery and were included in this analysis.

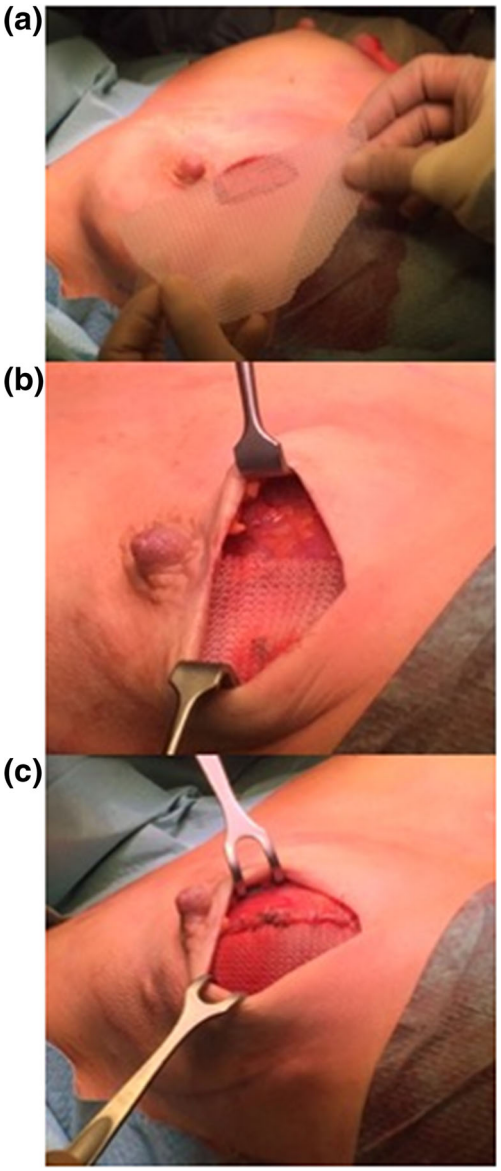

Fig. 1 Intraoperative representation of insertion and fixation of resorbable surgical mesh. **a** The mesh is first measured and cut to the specifications to create the pocket necessary for implant insertion. The inframammary fold and the lateral boarder of the are contoured based on the physical anatomy of the patient and for the implant to be used. **b** The mesh is then sutured to the pectoralis major muscle, the inframammary fold and to the serratus anterior. A defect is maintained medially to allow for delivery of the implant into the pocket. **c** This demonstrates the pocket containing the implant in its position prior to skin closure

The mesh used was a TIGR® Surgical Mesh (Novus Scientific Pte Ltd., Singapore) a combination of fast absorbing co-polymer of glycolide, lactide and trimethylene carbonate, and slow absorbing lactide and trimethylene carbonate. The

Table 1 The demographic of the patients including the reason for mastectomy, either as risk reducing surgery for BRCA mutation carrier, or for primary oncological surgery

Average age	51 +/− 9.26 (36–80 years)	
Average follow-up	259 days +/− 146.9	
Patients demographics (n = 56)		
BRCA carrier	11	19.6 %
Cancer	45	80.3 %
Radiation therapy	14	25.0 %
Chemotherapy	22	39.3 %
Smoker	4	7.1 %
Tissue expander	35	62.5 %
Direct to implant	21	37.5 %
Major complications (n = 74 reconstructed breasts)		
Flap necrosis	0	0 %
Implant loss	5	6.7 %
Haematoma	0	0 %
Minor complications (n = 74 reconstructed breasts)		
Seroma	0	0 %
Wound infection	8	10.8 %
Other	0	0 %
Overall complications	13	17.5 %

Risk factors for complications were included as well as the number of patients undergoing either tissue expander insertion or direct to implant surgery. Major and minor complication rates are also demonstrated

use of mesh was explained to each patient, as well as potential benefits such as the possibility of one-stage over two-stage surgery. Patients then made an informed decision as to which surgical option they wished to proceed.

In cases of immediate reconstruction removal of the breast tissue was performed as either a nipple-sparing mastectomy (NSM) or as a skin-sparing mastectomy (SSM) depending on suitability. All patients were given intravenous antibiotics at induction of surgery. Nagor™ (Nagor Ltd., Douglas, Isle of Man) breast implants and tissue expanders were used. At the time of the mastectomy, the sub-pectoral pocket was raised. To facilitate the implant or expander, the inferior margin of the pectoralis major muscle was released. Depending on the size of the breast, ptosis, and patient preference the suitability of one versus two-stage implant reconstruction was made. Where possible a permanent anatomic breast implant was used as a definitive reconstructive option, if additional volume was required then a suitable tissue expander was used. The resorbable mesh was used to create the inferior pole of the sub-pectoral pocket from the lateral pectoral edge, inframammary fold, lateral mammary fold out to lateral pectoral edge (Fig. 1). The mesh was sutured in place with 2/0 polyglactin 910 (Vicryl) sutures [12] (Ethicon US, LLC, USA). Depending on the procedure, one or two drains were left in position at the inferior margin of the reconstructed breast. Drains and a local anaesthetic infusion catheter were left in the mastectomy pocket. Drains remained until output was less than 30 ml in 24 h and infusion catheters were removed at 48 h. Patients were discharged on post-operative day two and remained on oral antibiotics until drains were removed.

Patients were followed up in the outpatients regularly at 2 weeks post-surgery to monitor for infection and removal of drains. In the cases where tissue expanders were used, inflation of the expanders with sterile normal saline was conducted in the outpatients setting at intervals dictated by the size of the expander and by patient tolerance of the procedure.

Patients were monitored for complications categorised as either major or minor. Major complications were determined to be where there were implant loss, haematoma formation, flap necrosis or infection of the implant requiring hospital re-admission. Minor complications were deemed as seromas requiring drainage, local infection of the surgical site requiring oral antibiotics, or issues managed in the outpatients such as post-operative pain. Any complications were documented and discussed at monthly morbidity conferences conducted within the hospital. Results were compiled in a prospective database, and retrospective analysis was performed on outcomes. Local institutional review board gave permission to proceed with this study.

Results

One hundred five reconstructive patients were recorded over an 18-month period from October 2014 to February 2016. Over this period, 56 patients were suitable for reconstruction using the surgical mesh and proceeded with surgery. The remaining 49 patients were deemed not suitable for reconstruction with the surgical mesh or opted for an alternative reconstructive procedure. The average age at the time of surgery of patients was 51, with a range of 36 to 80 years (Table 1). The average follow-up was 259 days. No patients were lost to follow-up. In total, there were 27 unilateral mastectomies with tissue expander insertions, 11 unilateral mastectomies with permanent implants, 9 bilateral mastectomies with tissue expanders and 9 bilateral mastectomies with permanent implants. In total there were 74 reconstructed breasts. There were 11 cases of confirmed BRCA mutation carriers, whereby risk reducing surgery in the form of bilateral either nipple-sparing or skin-sparing mastectomies were performed (Fig. 2). The remaining 52 reconstructed breasts were performed for primary invasive or in situ breast cancer. Radiation therapy was performed 14 patients. Adjuvant chemotherapy was prescribed to 22 patients as per multi-disciplinary

Fig. 2 Pre-operative and post-operative results using resorbable surgical mesh. Left image showing pre-operative marking for nipple sparring mastectomy with implant based reconstruction and use of resorbable surgical mesh. Right image showing post-operative results of the same patient

meeting discussion. Four patients were identified as active smokers.

Minor complications were seromas requiring drainage, local infection of the surgical site requiring oral antibiotics, or issues managed in the outpatients. There were 8 (n = 74; 10.8 %) reconstructed breasts where isolated wound infections occurred which required oral antibiotics, however these cases did not require any further intervention or result in any further morbidity. Culture and sensitivity of the wound was obtained where possible and antibiotic therapy was directed by hospital microbiological protocol. Of these 8 wound infection cases, 2 patients had radiation and chemotherapy treatment, 1 had chemotherapy alone, 2 were smokers and 4 had no chemo or radiation treatment and were non-smokers.

Major complications were classified as implant loss, haematoma formation, flap necrosis or infection of the implant requiring hospital re-admission. There were no reported instances of flap necrosis or haematoma formation in any of the cases (n = 74). Implant loss due to infection was experienced in 4 patients (n = 56, 7.1 %), with bilateral loss in one patient, resulting in an overall loss of implant in 5 reconstructed breasts (n = 74, 6.7 %). Of these patients where the implant was lost, the first patient was a current smoker who had previous radiation and was undergoing chemotherapy. The second patient was undergoing chemotherapy when the implant became infected and required removal. The third patient was not a smoker or had received radiation in the past and was not undergoing chemotherapy. The fourth patient, where both implants required removal, was a current smoker with no other risk factors. The overall complication rate including major and minor complications was 17.5 % (n = 13) (Table 1, Demographic of patients).

Discussion

Implant-based reconstruction remains the most widely used reconstructive option for women undergoing primary mastectomy or part of delayed reconstruction. The positive psychological benefits to women who undergo reconstruction have long been established. The feasibility of undergoing reconstruction at the time of mastectomy cannot always be undertaken. The need to perform a mastectomy, followed by tissue expander insertion and a change of expander to implant will require some patients to undergo up to three surgeries to complete their treatment.

Prior to use with the mesh there was a limit as to the size of expander and implant that could be inserted. This limitation is due to the physical limitations of the pocket required to place the implant (created by the pectoralis major and serratus anterior muscles). In some cases, the pectoralis major muscles were not fully developed which would prohibit the use of implants for those patients. The mesh allows the placement of an expander or a permanent implant at the time of surgery. The addition of the resorbable surgical mesh to the subpectoral pocket allows for added volume and translates into greater expansion at the time of surgery. This benefits the patient as fewer inflations are required post-operatively, thus reducing pain and shortening the time to definitive reconstruction with permanent implants.

Successful implant-based breast reconstruction aims to provide a natural appearing breast through the use of anatomically shaped implants. In order to achieve this, the implant has to be adequately placed in a pocket in order to keep its position, prevent rotation of the implant and reduce infection of the implant. Due to the anatomic and non-symmetric shape of implants, certain challenges exist. The position of the implant can sometimes drop below the natural infra-mammary

fold of the breast which is sometimes termed "bottoming out", or can sometimes sit higher on the chest wall which is termed "high riding". To counteract this "bottoming out" and "high riding" effects, various strategies have been employed. These range from attempting to re-suture the released pectoralis major muscle to the rectus abdominis fascia to the use of various techniques. In recent years, there has been an increase in the use of meshes or matrices, termed acellular dermal matrices (ADM) used in breast reconstruction. ADMs are a biologically derived scaffold prepared from various sources including human, porcine and bovine tissues, which through various propriety techniques have been shed their antigenic properties [13]. Meshes are synthetic porous sheets made from various materials which vary in their properties and their ability to be integrated. Both ADMs and meshes can be used at the inferior pole of the pocket containing the implant. This allows for reduced tension at the inferior pocket of the implant, thus reducing the tendency for the implant to be forced upwards. Meshes and ADMs also have the added benefit of reinforcing the inferior pole of the pocket, which prevents the implant from slipping below the inframammary fold and thus "bottoming out".

Apprehension in the use of meshes and ADMs have persisted mainly in relation to their adequacy to provide cover of the implant and in relation to infection. Higher rates of infection, seroma and explantation of implants have been reported, with some series experiencing an implant loss rate as high as 30 % [14, 15]. An advantage to the use of meshes and ADMs is that they allow for greater expansion of tissue expanders initially, thus decreasing the number for inflations required for full expansion [16]. The cost of ADMs is another reason why their use has been somewhat limited. ADMs can vary in price anywhere from $1825 to $4856 [17]. The use of ADMs to reduce the number of surgeries and competitive pricing with newer ADMs on the market have mitigated these costs. Compared to ADMs, the lower cost of synthetic resorbable meshes, which typically cost about $900 means it is a much more cost effective alternative [10]. In our experience, we observed excellent integration of the mesh into the capsule in patients who underwent two stage reconstructions, thus providing excellent implant coverage and protection. This excellent integration of the mesh we believe also occurs in patients undergoing direct to implant reconstruction. We also believe that the resorbable mesh acts as an autologous ADM, as they are integrated by the patient to leave a fibrotic capsule. As the mesh is soaked in antibiotic wash prior to insertion this may act as an antibiotic "sink" to reduce infection and implant loss rates.

In our initial experience with resorbable surgical mesh, excellent outcomes were achieved in the majority of cases. Minimal complications were encountered with the mesh. In this series of patients, major complications were limited to implant loss in 4 patients, with no flap necrosis and no hematoma formation. In the patients with implant loss, 2 of the 4 patients were smokers. In the smoking population, this increase in complications warrants prudent counselling of these patients to the potential risks with undergoing reconstructive surgery while they continue to smoke. Care and consideration should also be given to patients who have either had or are undergoing radiation therapy as this can also lead to increased risk of inadequate wound healing and risk of infection. The rates of infection and implant loss we have seen in this series of patients is low in comparison to other series of ADMs which report an overall complication rate as high as 36.2 % [18]. A 2012 meta-analysis looking at the use of human acellular dermis in tissue expander breast reconstruction found an overall complication rate of 15.4 % [19]. A 2012 MD Anderson study comparing the use of ADMs in non-irradiated and irradiated breasts found complication rates of 15.6 and 43.3 %, respectively [20]. In this series, the overall complication rate, in non-irradiated and irradiated breasts, was only 17.5 %.

Patients who are due to commence chemotherapy should also be aware of the potential risk of infection, particularly since the immunosuppression associated with treatment makes them a higher risk group which could result in failed reconstruction or delay their oncological treatment. These risks do not represent an absolute contraindication to the use of this surgical mesh or reconstruction; rather they are factors which the surgeon should consider when planning which operative strategies to employ. For patients not candidates for immediate reconstruction with this surgical mesh, due to anatomical or oncological concerns, then an alternative reconstructive strategy can be employed in the form of autologous tissue transfer, or as a delayed approach. This decision should be made on a case by case basis involving the patient and members of the multidisciplinary team.

Overall, this case series shows that a resorbable surgical mesh is an effective adjunct for use in breast reconstruction, providing excellent cosmetic outcomes with minimal complications.

Compliance with ethical standards

Ethical standards For this type of retrospective study formal consent from a local ethics committee is not required.

Conflict of interest Shiva Sharma, Susie Van Barsel, Mitchell Barry, 358 Malcolm R. Kell declare that they have no conflict of interest.

Patient consent Patients provided written consent before their inclusion in this study. Additional consent was obtained for the use of their images.

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