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ORIGINAL PAPER

Immediate implant reconstruction using absorbable TIGR mesh after nipple-sparing mastectomy

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Abstract

Backgound Nipple-sparing mastectomy with immediate implant reconstruction is an increasingly popular technique for both treatment of breast cancer and risk-reducing surgery, with an evolving body of evidence confirming low complication rates and satisfactory patient outcomes. Immediate implant reconstruction usually requires use of one of many available meshes for complete implant coverage. The aim of this study was to assess outcomes after nipple-sparing mastectomy using synthetic absorbable TIGR mesh.

Methods A retrospective review of a prospectively maintained database of 164 skin and nipple-sparing mastectomies with immediate implant reconstruction using TIGR mesh was performed. Data was retrieved and cross-checked with electronic patient records. Data was analysed with regard to patient demographics, indications for surgery, surgical procedure, complication rates and locoregional recurrence rates.

Results Of 164 implant reconstructions, forty-three were performed after nipple-sparing mastectomy. No differences in outcomes were seen between the two groups except for a higher incidence of skin or nipple necrosis in the nipple-sparing group (12% versus 2%). There was no nipple loss in this cohort. Infection rate in the nipple-sparing group was 9% versus 11% in the skin-sparing group, with implant loss rates of 9% and 6%, respectively. Mean follow-up was 23.6 months.

Conclusions Our study has shown that immediate implant reconstruction after nipple-sparing mastectomy using TIGR mesh is safe and feasible, with low rates of early and medium-term complications.

Level of evidence: Level III, therapeutic study.

Keywords Mastectomy · Breast reconstruction · Implant · TIGR mesh

Introduction

Nipple-sparing mastectomy (NSM) with immediate breast reconstruction is increasing in popularity [1]. NSM has been shown to be safe, both as a therapeutic modality for breast cancer [2–5] and in risk-reducing surgery [6, 7]. Subsequent need for nipple excision, based on histopathology, is as low as 1.2% [8]. NSM is associated with good cosmetic outcomes, which has added to its popularity, along with a low rate of complication when performed in appropriately selected patients [1, 8, 9]. The best outcomes are seen in patients with B or smaller cup sizes, non-smokers and patients with lower body mass index [10, 11]. However, the only absolute contraindications to NSM are inflammatory breast cancer, nipple-areola complex involvement by disease, locally advanced breast cancer with skin involvement and bloody nipple discharge [11].

Patients undergoing NSM are usually suitable for direct-to-implant–based reconstruction and experience with this has increased in recent times [1, 8]. Implant placement is submuscular, with or without addition of mesh to complete lower and lateral pole coverage of the implant [8, 12]. Lower pole coverage can be achieved through use of human or animal acellular dermal matrices (ADMs), absorbable synthetic mesh or non-absorbable mesh [12]. This avoids the requirement to mobilise the serratus anterior, thus reducing postoperative pain and increasing the size of the pocket available in which to place the implant. Use of mesh to cover the inferior pole also allows generation of pseudoptosis and better inferior pole projection, to match the native contralateral breast [13].

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In general, NSM has been shown to have low rates of complications [1]. However, concerns do exist in relation to skin and nipple necrosis, infection and potential implant loss [9, 14]. A recent systematic review of NSM versus skin-sparing mastectomy (SSM) has shown a higher overall complication rate in NSM, mainly due to the risk of nipple necrosis [9]. Addition of further foreign material, in the form of mesh, may contribute to the potential for infection and implant loss [15–17].

Mesh used in implant reconstruction can have its own complications. Issues identified with the use of ADMs include increased risk of infection, seroma formation and implant loss [13, 18]. Commonly used synthetic surgical meshes such as polytetrafluoroethylene (PTFE) and Vicryl® also have their issues when it comes to breast reconstruction [19]. PTFE, a permanent synthetic mesh, may be too rigid whereas Vicryl may be absorbed too rapidly, which can result in "bottoming out" of the implant. Recently, interest has been increasing in the use of longer term absorbable synthetic meshes in breast reconstruction, such as TIGR® matrix (Novus Scientific AB, Sweden) mesh [19]. A recent cohort study of TIGR mesh compared with biological mesh has shown fewer overall complications (29% versus 36%) and lower implant loss rates (4.9% versus 22%) with TIGR mesh [20]. However, whilst TIGR use has been studied in conjunction with skin-sparing mastectomy (SSM), there is minimal data available regarding its use in NSM.

The aim of this study was to evaluate outcomes following use of TIGR mesh in the context of NSM, compared with SSM, with immediate implant reconstruction.

Methods

All patients undergoing immediate breast reconstruction with use of TIGR mesh between January 2015 and April 2019 at a tertiary referral breast cancer centre were identified from prospectively maintained electronic theatre records. Patients undergoing immediate postmastectomy implant or expander reconstruction, in the form of either nipple-sparing mastectomy (NSM) or skin-sparing mastectomy (SSM), were included. Excluded were patients undergoing delayed reconstruction, flap-based reconstruction and wide local excision procedures.

SSM or NSM was performed via an incision of the surgeon's choice. Following mastectomy, sentinel node biopsy or axillary lymph node dissection was completed via the same incision, if indicated. In a NSM, the site of the dissection from the nipple base was marked with a suture to aid histopathological analysis. An additional tissue specimen from the nipple base was also sent separately for histopathological analysis, to ensure no disease proximity to the nipple. Pectoralis major was then mobilised laterally and inferiorly to create a submuscular pocket and all implants were placed posterior to the muscle. TIGR mesh was then sutured in place along the inframammary fold and laterally to fascia overlying the serratus anterior before being sutured along the inferior free border of pectoralis major to complete coverage of the implant. The TIGR mesh used was either 10 × 15cm or 15 × 20cm, depending on the size required for each individual patient and was cut to size, where appropriate. All patients had drains placed and closure in two layers with absorbable sutures. Complete muscle coverage techniques for implant or tissue expander insertion are no longer routinely practiced in our unit, due to the increased pain and poorer lower pole projection associated with this technique [13]. During the timeframe of this study, prepectoral implant reconstructions were also not performed in our unit. We have subsequently used TIGR mesh for prepectoral reconstruction but it is outwith the scope of this study.

Anonymous data were collected in relation to indication for mastectomy, breast cancer stage, specimen weight, type of reconstruction, immediate postreconstruction complications, implant loss, adjuvant therapies, comorbidities including obesity and smoking status, disease recurrence and length of follow-up. A diagnosis of infection was made if a patient developed clinical signs of erythema, warmth and tenderness and antibiotics were prescribed. Cultures were not required to make the diagnosis. These data were collected from electronic patient charts as well as histopathology and radiology electronic records.

Data was collected and analysed using Microsoft Excel (Microsoft, US) and Graph Pad Quickcalcs (Graphpad, US).

Results

Between January 2015 and April 2019, 164 immediate implant/expander based reconstructions using TIGR mesh were performed, in 131 patients. Thirty-three patients underwent bilateral procedures. Of these, forty-three breasts (26%) were reconstructed after NSM. Examples of cosmetic outcomes post-bilateral NSM with TIGR are shown in Fig. 1. Surgical and disease characteristics are summarised in Tables 1 and 2. As would be expected, more patients in the NSM group underwent risk-reducing mastectomy rather than therapeutic mastectomy, compared with the SSM group (24/43 versus 10/121, $p < 0.001$). In the NSM group, just four patients underwent radiotherapy; two had had prior exposure and two underwent postmastectomy radiotherapy. All NSM were performed through radial or inframammary incisions. No patient in the NSM group required nipple excision for oncological reasons following histopathological analysis; all separate operative nipple biopsies were negative for malignancy.

Patient characteristics are summarised in Table 3, with comparisons shown between patients in the NSM and SSM

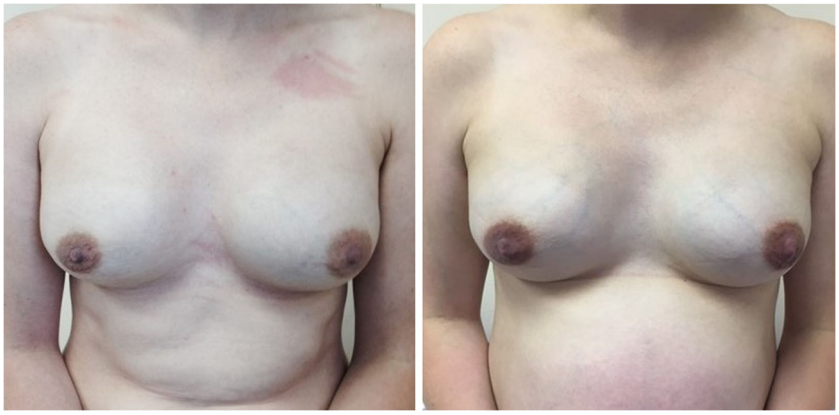

Fig. 1 Postoperative outcomes in two patients after bilateral nipple-sparing mastectomy with subpectoral implant reconstruction using TIGR mesh for inferior pole coverage

groups. Comparisons of outcomes between the two groups are shown in Table 4. No differences in key outcomes were seen, other than for a higher incidence of ischaemic complications in the NSM group. Ischaemic complications included skin flap or nipple ischaemia or necrosis. All ischaemic complications in both cohorts were superficial only, with no cases of full-thickness necrosis in either group. No patient required surgical intervention for necrosis and all were successfully managed conservatively with dressings and topical antibiotic gel. All infections were treated with oral or intravenous antibiotics at the onset of clinical features of cellulitis. Cultures were not always obtained in advance of antibiotic treatment and no specific organism was identified in most cases. One case of methicillin-resistant *Staphylococcus aureus* was identified, requiring implant explantation.

Implant loss rate in the NSM group was 9% versus 6% in the SSM group. In the NSM group, infection in 3 patients required immediate implant removal. The fourth patient had clinical cellulitis initially treated successfully but subsequent wound breakdown and implant exposure necessitated removal. In the SSM group, six patients were successfully treated for wound infections without implant loss. One patient required immediate implant removal due to severity of infection. Four implants were removed to facilitate wound healing in order to commence adjuvant chemotherapy in a timely fashion. Two further patients developed delayed infections during adjuvant chemotherapy, requiring implant removal. Mean follow-up was for 23.6 months (range 1–53 months, 23.4 months in the NSM group versus 23.8 months in the SSM group).

Table 1 Surgical characteristics of included procedures

	Number (%)
Mastectomy type	
Nipple-sparing	43 (26)
Skin-sparing	121 (74)
Reconstruction type	
Tissue expander	44 (27)
Direct-to-implant	120 (73)

There were two disease-related deaths during follow-up (1.5%).

Discussion

Our study has shown that TIGR mesh used in immediate implant- or expander-based reconstruction after both NSM and SSM is associated with low rates of complications. In our cohort of NSM, there was a postoperative infection rate

Table 2 Disease characteristics of patients included in the cohort

	Number (%)
Indication for surgery ($n = 164$)	
Risk reducing	34 (21)
In situ disease	29 (17)
Invasive carcinoma	98 (60)
Other	3 (2)
Tumour stage ($n = 125$)	
pTis	29 (23)
ypT0	3 (2)
pT1	43 (36)
pT2	34 (27)
pT3	15 (12)
pT4	0 (0)
Nodal stage ($n = 115$)	
N0	87 (70)
N1	20 (24)
N2	7 (5)
N3	1 (1)
Multifocal carcinoma	19 (15)
Mean tumour size (range)	50.3 mm (2.5-140 mm)
Receptor status ($n = 104$)	
ER positive	97 (93)
PR positive	89 (89)
HER2 positive	18 (18)

*Receptor status available for invasive carcinomas only

Table 3 Patient characteristics, with comparison between skin sparing mastectomy (SSM) and nipple-sparing mastectomy (NSM) groups

	SSM	NSM	
Mean BMI*	24.6	22	$p = 0.169$
Mean specimen weight	739.9 g (52–1149)	280.7 g (65–663)	$p < 0.001$
Smoking*	*N* (%)	*N* (%)	
Active/ex	20 (19)	5 (18)	
Never	59 (56)	13 (50)	
Unknown	26 (26)	8 (32)	
Radiotherapy			
Postoperatively	31 (27)	2 (8)	
Previously	6 (5)	2 (8)	
None	76 (67)	20 (84)	

*Data not available for all patients

of 9%, skin/nipple necrosis rate of 12% and implant loss rate of 9%. With the use of TIGR mesh, we had a direct-to-implant rate of 84% ($n = 35$). Patients undergoing NSM did have significantly smaller breast size and tended to have lower BMIs than those undergoing SSM, which reflects patient selection policy within our unit. Rates of smoking were similar between both groups. Only four patients in the NSM group had radiotherapy exposure.

NSM has increased in popularity in recent times, due to its demonstrated safety in both oncological resection and as a risk-reducing therapy [1]. It is particularly popular in the setting of risk-reducing surgery for a number of reasons; these surgeries are usually bilateral [1], allowing for better nipple symmetry at the time of reconstruction compared with unilateral surgery, and in the absence of malignancy, many patients are keen to keep their own nipple. Loss of the nipple has been shown to add to the psychological distress of mastectomy [21]. This is reflected in our cohort, where 56% of the NSM cohort were having risk-reducing surgery, compared with 9% of the SSM cohort.

However, NSM is not a suitable procedure for all patients, as better cosmetic results are achieved in patients with smaller, non-ptotic breasts [22, 23]. Again, this is reflected in our cohort, where patients selected for NSM has significantly smaller breast volumes than patients undergoing SSM. There have also been concerns about undertaking the procedure in smokers and those undergoing radiotherapy [8, 9, 24], due to flap or nipple necrosis and infection risks. However, our cohort included smokers and ex-smokers, in similar proportions to those undergoing SSM, without an increase in complication rate. Only one patient who developed postoperative necrosis was an active smoker. Whilst our cohort did also include patients who underwent radiotherapy, the numbers in the NSM group are too small to draw any meaningful conclusions. Other studies have shown that good outcomes can be achieved in the setting of radiotherapy [11]. However, the likelihood of complications increases if patients have additional risk factors such as older age, smoking, larger volume breasts and periareolar incisions [11].

Complication risks remain a concern when choosing patients for NSM. Nipple ischaemia or necrosis is a unique complication of NSM, with reported rates in the literature of 4.4–13% [1, 9, 14]. However, surgical intervention is rarely required and nipple loss rates are much lower at 1.9–3.3% [1, 6]. The risk of nipple necrosis may be reduced by avoiding periareolar incisions [1, 25]. In our cohort of NSM using TIGR mesh, no nipples were lost due to necrosis and periareolar incisions were not employed. Infection and implant loss rates also remain a concern for all implant-based reconstructions. Previous reports have shown low infective complication rates with TIGR mesh in SSM, with infection rates of 1.7–10% [26, 27] and implant loss rates of 3.6–6.7% [19, 20, 27, 28]. Our study supports those findings, with low complication rates in our SSM group (infection rate 11%, implant loss rate 6%). Additionally, we have shown equally low complication rates in the NSM setting with infection rates of 9% and implant loss rate of 9%. In a recent larger cohort study, NSM has not been shown to be associated with a higher risk of infection, reoperation or implant loss, compared with SSM [29]. However, previous studies have not specifically reported on these outcomes with TIGR mesh in NSM.

One of the benefits of using mesh in immediate reconstruction is the ability to perform a single-stage reconstruction, with direct implant placement rather than tissue expander [13]. We performed single-stage reconstruction in 73% of our total cohort and in 84% of our NSM patients. Single-stage reconstruction is attractive, where possible, as it removes the need for a planned second surgery [13, 30]. NSM is particularly suited to single-stage reconstruction due to preservation of the entire skin pocket [1]. Addition of mesh to the procedure allows creation of a large enough submuscular pocket for immediate implant placement at the required volume, although there is a limit to the size of breast that can be immediately reconstructed [13]. Our study confirms that a high rate of single-stage

Table 4 Surgical outcomes in nipple-sparing mastectomy (NSM) versus skin-sparing mastectomy (SSM) groups; NSM patients were more likely to experience skin or nipple necrosis but all cases in this cohort were managed conservatively

	NSM (43)	SSM (121)
Infection	4 (9%)	13 (11%)
Skin/nipple ischaemia*	5 (12%)	3 (2%)
Superficial	5	3
Full-thickness	0	0
Haematoma	0	1 (1%)
Implant loss	4 (9%)	7 (6%)
Capsular contracture	1 (2%)	8 (6%)

*Skin/nipple ischaemia included patients with nipple and/or skin flap ischaemia or necrosis in the NSM group and just skin flap ischaemia in the SSM group

reconstructions can be achieved with the use of TIGR mesh following NSM in small to moderate volume breasts.

Other meshes have been used following NSM with single-stage implant reconstruction. These include ADMs and other synthetic meshes. ADMs were initially popular but concerns have arisen with their use, due to both costs and complication rates. High implant loss rates of 17–22% have been reported [18, 20], with subsequent delays to adjuvant therapy a concern in cancer patients [18]. Whilst more recently infection, necrosis and implant loss in NSM with ADM have more acceptable reported rates of 12%, 11% and 4% [31], respectively, cost remains an issue [32, 33]. Alternative synthetic meshes have been employed in an attempt to offset the costs and complications of ADMs, including polypropylene [34, 35], Ultrapro® [36] and Vicryl® [37, 38]. Results in small series are promising with regard to infection and implant loss rates but additional disadvantages such as lack of incorporation into the body's own tissues with non-absorbable mesh, possible higher capsular contracture rates and possible poorer outcomes in the setting of radiotherapy have been identified [39]. The recent multicentre iBRA study of UK practice in 2081 patients suggested similar outcomes with biological and synthetic meshes in terms of infection (22% versus 26%) and implant loss (8% versus 10%) [29]. However, various different meshes were used in the study depending on surgeon preference, and follow-up was relatively short at just 3 months [29]. A recent study directly comparing TIGR with a biological mesh (Surgisis) has shown lower complication rates (29% versus 39%) and lower implant loss rates (4.9% versus 22.2%) in the TIGR group [20]. With these considerations in mind and on the basis of this data, TIGR offers a durable, relatively low-cost alternative, with a low complication rate.

Our study is the first to report on consecutive NSM cases with immediate implant reconstruction using TIGR mesh. Use of prospectively maintained electronic theatre records has ensured accurate capture of all such cases performed and allowed direct comparison with SSMs. Inclusion of smokers and patients undergoing radiotherapy has allowed assessment of outcomes in a cohort of patients akin to real-life practice. Electronic patient records have also allowed accurate data collection in relation to postoperative complication rates. Our results are limited by the relatively small numbers in the NSM cohort, which precludes statistical analysis of some subgroups of patients. Retrospective data collection has resulted in unknown smoking status and BMI in some patients. However, as there are similar amounts of unknown data between both groups, we do not believe this has introduced a significant bias to our results.

In conclusion, we have shown that NSM with immediate implant-based reconstruction using TIGR mesh is a safe and effective procedure, with comparable outcomes to SSM and to NSM using other forms of mesh. TIGR mesh allows single-stage reconstruction to be performed post NSM with a low complication rate.

Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

Ethical statement Due to the retrospective database audit analysis undertaken in this study, ethics committee approval and informed consent was not required.

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