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Can we safely accommodate larger volume implants in inframammary fold nipple sparing mastectomy compared to nipple sacrificing mastectomy in implant-based reconstruction with acellular dermal matrix? ☆

John Mathew [a,b,*]

[a] *Peterborough City Hospital, North West Anglia NHS Foundation Trust, Edith Cavell Campus, Bretton Gate, Peterborough PE3 9GZ, United Kingdom*
[b] *Consultant Oncoplastic Breast Surgeon, Peterborough City Hospital, North West Anglia NHS Foundation Trust, Edith Cavell Campus, Bretton Gate, Peterborough PE3 9GZ, United Kingdom*

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ABSTRACT

Introduction: The aim of this study was to analyse if inframammary fold nipple sparing mastectomy (IMF NSM) could safely accommodate larger implants in relation to weight of the breast as opposed to nipple sacrificing mastectomy (NSacriM) in implant reconstruction with biological mesh.

Methods: A review of prospectively collected data of implant-based reconstruction using biological mesh between Nov 2016 and December 2019 by a single surgeon. The volume of the implant was measured against the weight of the breast. The data was analysed using Chi-squared test and independent *t*-test, and a *P* value of < 0.05 was considered significant.

Results: Sixty-five patients had 86 implant reconstructions during this period. Median follow-up was 18 months (1–38). There was

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* Correspondence to: Peterborough City Hospital, North West Anglia NHS Foundation Trust, Edith Cavell Campus, Bretton Gate, Peterborough PE3 9GZ, United Kingdom.
E-mail address: John.mathew4@nhs.net

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no statistical difference between IMF NSM and NSacriM with regard to smoking, obesity (BMI>30) and radiotherapy (P>0.05). The volume of the implants was more than the weight of the breast in IMF NSM group compared to the NSacriM group (22/34 vs 21/52; $P = 0.026$). Significantly more patients in IMF NSM group had an implant volume within 100 g of the mastectomy weight compared to NSacriM group (31/34 vs 33/52; $P = 0.003$). None of the 34 IMF NSM had wound necrosis or threatened wound compared to 7/52 in NSacriM group ($P = 0.025$); 4 were managed in the clinic and 3 were managed in theatre. One patient in the NSacriM group lost her implant post radiotherapy at 5 months, and another patient lost her implant at 3 years. Comparisons were made between IMF-NSM and skin sparing mastectomy (SSM) having fixed volume silicone implants. The analysis showed that 22/33 (67%) IMF-NSM, had a volume of the implant more than the weight of the breast compared to 15/35 (43%) having SSM, this was statistically significant. There was a statistical difference between these two groups with regard to ischemic complications in favour of IMF-NSM.

Conclusion: IMF NSM allows safer insertion of larger volume implants in relation to the weight of the breast as opposed to NSacriM.

Introduction

The commonest reason for implant loss in direct-to-implant breast reconstruction is wound ischemia.[1–3] In a large series by De Vita et al., major skin envelope necrosis has been reported as the aetiology for explantation in approximately 79% of implant based reconstructive failures following nipple sparing mastectomy.[2] Thus, good vascularity of mastectomy flap is paramount in all implant-based reconstructions to prevent complications and implant loss. Inframammary fold nipple sparing mastectomy involves a less conspicuous scar below the inframammary fold through which the mastectomy and subsequent reconstruction is performed. A separate incision in the axilla is needed in cancer patients to perform sentinel lymph node biopsy or axillary clearance.

Mastectomy specimen weight and volume are closely correlated, and surgeons often use mastectomy weight to choose the volume of implant to achieve symmetry.[4] The implant is usually limited by the tightness of the skin after any mastectomy,[5,6] It is probable that, the larger the volume of implant in relation to the weight of the breast, more will be the tension and higher the chance of ischemic complications. In Inframammary fold nipple sparing mastectomy (IMF-NSM), all the skin envelope of the breast is preserved, as opposed to nipple sacrificing mastectomy (NSacriM), and thus potentially allowing larger implants to be inserted without tension to achieve symmetry. Because there is no incision around the nipple or on the mastectomy flap itself, it is possible that IMF-NSM can safely accommodate larger volume implants in relation to the weight of the breast compared to NSacriM.

Methods

Review of a prospectively collected data of implant-based reconstruction using biological mesh between Nov 2016 and Dec 2019 by a single surgeon.

All patients were offered immediate implant reconstruction irrespective of age, BMI, smoking and potential need for radiotherapy. Cancer patients who were eligible for nipple sparing mastectomy

based on oncology (cancer 2 cm away from nipple) at MDT, were offered IMF-NSM and implant reconstruction provided they did not have 3rd degree ptosis (Regnault's classification).[7] Cancer patients with 2nd degree ptosis were offered nipple lift at the time of reconstruction. Risk reduction patients with 2nd or 3rd degree ptosis undergoing IMF NSM were offered nipple lift or reduction of skin with or without reduction of breast tissue, prior to risk reducing IMF NSM, done 2–3 months later. Since skin reducing mastectomy (SRM) was done in a separate group of patients with very ptotic breasts, and the intention from the onset in this group was to insert adjustable permanent implant expanders, analysis was also done after excluding patients having SRM and those having adjustable permanent implant expanders.

Surgical technique

1) *Incision* – Nipple sparing mastectomy was performed through a less conspicuous scar at the inframammary fold and an axillary incision was used in patients undergoing sentinel lymph node biopsy or axillary clearance. In skin sparing mastectomy (SSM), elliptical incision was made around the nipple areola complex. In skin reducing mastectomy, wise pattern incision was used.
2) *Hydro-dissection* –Flaps were infiltrated with 100–250 ml of normal saline with adrenaline (1/2 L of Normal saline containing 0.5 mg of 1/1000 adrenaline) depending on the size of the breast. In all 3 mastectomies, a combination of dissection with Nelson scissors and diathermy blade was used.
3) *Meshes* –3 types of biological meshes were used in subpectoral reconstruction (Strattice, Native, Surgimend) and 2 types of biological meshes were used in prepectoral reconstruction (Braxon, Surgimend Meshed).
4) *Mesh coverage and fixation*–
   a) Subpectoral reconstruction – The long border of the rectangular piece of ADM was first stitched to the lower border of the released pectoralis major muscle using continuous 2–0 monocryl following which the short lateral end of the rectangular piece of the ADM is stitched to the chest wall. The selected sizer was used to adjust the pocket by tucking in the ADM under the sizer and stitching the ADM to the periostium of the underlying ribs creating a hammock. Similarly, interrupted sutures were placed medially, tucking in the medial end of the ADM under the sizer. Finally, the selected implant was inserted from below replacing the sizer and a few interrupted sutures were inserted in the lower end.
   b) *Prepectoral reconstruction* –Mesh has a full coverage anteriorly and partial coverage posteriorly and 3 interrupted sutures with 2–0 monocryl were inserted inferiorly, 1 laterally and 1 in the upper pole for fixation.
5) *Antibiotics and drains* –All patients had IV Augmentin at induction. They were sent home with oral antibiotics, to be continued until the drains (1 or 2) were in place for a maximum of two weeks.
6) *Selection criteria for implants* –In IMF-NSM and SSM the intention was to insert fixed volume silicone Mentor implants. In selected cases where the vascularity of the mastectomy flap was in question, a decision was made to consider adjustable permanent implants (Becker implant expanders). In patients with very ptotic breasts especially those who were obese undergoing SRM, Becker implant expanders were often considered from the onset. In few selected patients with good vascularity of the flaps, a fixed volume silicone implants were inserted.

Statistical analysis

Chi-squared test was used to analyse difference between the groups with regards to risk factors, differences in implant volume in relation to the weight of the breast and complications between the two groups. Independent *t*- test was used for the analysis of weight of the breast between groups. Statistical difference was defined by p value < 0.05.

Table 1
Comparison of risk factors between IMF NSM and NSacriM and implant reconstruction.

Risk factors	IMF NSM 34 (%)	NSacriM 52 (%)	*P* value
Smokers	6 (18)	11 (21)	$P = 0.689$
BMI>30	2 (6)	11 (21)	$P = 0.053$
Radiotherapy	8 (24)	22 (42)	$P = 0.074$

Table 2
Volume of the implant in relation to weight of the breast in IMF NSM and NSacriM and implant reconstruction.

	IMF-NSM and implant reconstruction with ADM 34 (%)	NSacriM and implant reconstruction with ADM 52 (%)
Volume of the implants were more than the weight of the breast	22 (65)	21 (40)
Implant volume within 100 g of the mastectomy weight	31 (91)	33 (63)

Table 3
Complications in IMF NSM and NSacriM and implant reconstruction.

Complication median FU-18 months (1-38)	Nipple sparing mastectomy and implant recon with ADM (34)	Nipple sacrificing mastectomy and implant recon with ADM (52)
Post op haematoma requiring evacuation	1	1
Wound infection	1	0
Red reaction	3	6
Wound necrosis/threatened wound	0	7
Nipple necrosis	0	
Seroma needing aspiration	1	0
full flap necrosis/failure (implant loss)	0	2

$P = 0.237$.

Results

Sixty-five patients had 86 implant-based reconstructions during this period; 34 IMF-NSM and 52 NsacriM. Median age was 48 years (27–73). Among the 52 NSacriM, 40 had skin sparing mastectomy and 12 had skin reducing mastectomy. Median follow-up was 18 months (1–38). All patients except one patient in the (SSM group) completed a minimum of 3 months follow-up. There was no statistical difference between the two groups with regards to risk factors as shown in Table 1. There were 5 nipple repositioning's, 3 as initial nipple repositioning followed by delayed IMF-NSM and 2 at the time of cancer surgery. There were 24 sub pectoral reconstructions and 62 pre pectoral reconstructions.

Volume of the implant was more than the weight of the breast in 22/34 (65%) IMF-NSM compared to 21/52 (40%) in the NSacriM which was statistically significant ($P = 0.026$) as shown in Table 2. Significantly more patients having IMF-NSM had implant volume within 100 g of the mastectomy weight compared to NSacriM. There was no difference in overall complications between the two groups as shown in Table 3. However, significantly more patients in NSacriM had ischemic complications compared to IMF-NSM (7 vs 0, $P = 0.025$). None of the 34 IMF-NSM had nipple necrosis.

Median weight of NSaciM was 423 g (119-1771) which was significantly higher than IMF-NSM group, 354 g (112-674); $P = 0.0001$. However, when the 12 patients who had SRM were excluded, there was no significant difference in the weight of the breast between the two groups (skin sparing mastectomy weight 388 g (119-1188) vs IMF-NSM 354 g (112-674); $P = 0.098$.

Fixed volume implants were inserted in 33/34 patients in IMF NSM, 35/40 patients in SSM and 2/12 patients in SRM. There was no significant statistical difference between IMF NSM and SSM having fixed volume silicone implants with regard to risk factors as shown in Table 4. After excluding patients having adjustable permanent implant expanders, 22/33 (67%) having IMF-NSM with fixed

Table 4
Comparison of risk factors between IMF-NSM and SSM with fixed volume silicone implants.

Risk factors	IMF NSM with fixed volume implants 33 (%)	SSM with fixed volume 35 (%)	*P* value
Smokers	5 (15)	7 (20)	$P = 0.600$
BMI>30	2 (6)	3 (9)	$P = 0.691$
Radiotherapy	8 (24)	14 (40)	$P = 0.165$

Table 5
Comparison of volume of the implant in relation to weight of the breast in IMF NSM and SSM in patients with fixed volume silicone implant reconstruction and ischemic complications.

	IMF-NSM fixed volume silicone implants 33 reconstructions	SSM fixed volume silicone implants 35 reconstructions	
Volume of the implants were more than the weight of the breast	22 (67%)	15 (43%)	$P = 0.048$
Ischemic complications	0	4 (11%)	$P = 0.045$

volume implants had volume of the implant more the weight of the breast compared to 15/35 (43%) in the SSM with fixed volume implants which was statistically significant as shown in Table 5. There was statistical difference between the two groups with regard to ischemic complications in favour of IMF-NSM.

All patients except one completed a minimum follow up of 3 months and none lost their implants within 3 months of surgery. One patient who had SSM lost her implant due to cellulitis at 5 months of surgery and another patient lost her implant due to cellulitis following pneumonectomy for metastasis at 3 years. Both these patients who lost their implants had adjuvant radiotherapy.

Discussion

Meta-analysis has shown that it is oncologically safe to preserve the nipple during mastectomy.[8] For aesthetic reasons Nipple sparing mastectomy has become the operation of choice both in the risk reduction setting and in cancer cases where surgeon is confident to get a clear margin. However, nipple sparing mastectomy has resulted in increased complications mainly due to nipple necrosis as shown in the systematic review.[8] This could be due to operations involving incisions around the nipple and mastectomy flap which may compromise the blood supply leading to increased ischemic complications. This may also be the case in nipple sacrificing mastectomy where you excise the nipple during mastectomy. Here the most prominent part of the implant sits against the wound following the excision of nipple areola complex and this would further compromise the blood supply, and also larger the implant, the higher the chance of wound ischemia.

Surgeons often use mastectomy weight to select the volume of the implant in reconstruction.[4] In my series the volume of the implant was significantly higher in those having IMF-NSM compared to NSacriM. Significantly more patients having IMF-NSM had volume of the implant within 100 g of mastectomy weight compared to NSacriM. In spite of having significantly larger volume implants in relation to weight of the breast none of the 34 IMF-NSM had ischemic necrosis of the wound or nipple. Seven patients who underwent nipple sacrificing mastectomy had ischemic complications of the would edge which was statistically significant compared to those undergoing IMF-NSM. Four of the ischemic complications were dealt in the clinic treatment room and 3 in the theatre.

SRM was done in a separate group of patients with very ptotic breasts and since Becker implant expanders only provide 35% of the final volume when they are inserted, these patients were excluded in the subgroup analysis. This also showed that IMF-NSM can accommodate larger volume implants in relation to the weight of the breast with less ischemic complications compared to those having SSM.

Phase 2 of the iBRA study looked into the short-term safety of implant-based reconstruction.[9] It was a multicentre prospective study involving 81 centres in UK. Most of the patients in the study had implant-based reconstruction with mesh and although there was no difference in short term

safety between the type of mesh used (biological or synthetic), the study showed that the implant loss within 3 months after operation was approximately 9%. This does not meet the criteria set by the Association of Breast Surgeons and the British Association of Plastic Reconstructive and Aesthetic Surgeons which is less than 5%.[9] In this series of 86 implant reconstructions with ADM, all except one completed 3 months of follow-up and there was no implant loss within 3 months of surgery. Although seven out of 52 NSacriM had ischemic complications in my series, early intervention prevented further progression and implant loss. One patient with IMF-NSM had infection of axillary wound and this was successfully treated with oral antibiotics.

Limitation

This study has a relatively small follow-up (median FU-18 months). In a paper by Sinha et al. looking into infection in immediate implant-based reconstruction, late surgical site infection (31 days to a year) account for up to 71% of the surgical site infections.[10] Radiotherapy and obesity were significantly associated with late surgical site infection.[10] In this study, both the implants that were lost one at 5 months and the other at 3 years were post radiotherapy patients who developed delayed cellulitis.

In conclusion, this small series has shown that IMF NSM can safely accommodate larger volume implants in relation to weight of the breast as opposed to NSacriM patients undergoing immediate implant reconstruction with ADM. This was also true in the subgroup analysis between IMF-NSM and SSM after excluding patients having adjustable permanent implant expanders.

Declaration of Competing Interest

There is no conflict of interest.

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Ethical approval

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