

Polypropylene Mesh in Nipple-Sparing Mastectomy and Immediate Implant-based Breast Reconstruction in Vietnamese Early Breast Cancer Patients: Safe and Feasible

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Abstract

Background: Breast cancer is the most common malignancy in women worldwide, and breast reconstruction following mastectomy is an integral part of patient care to improve quality of life and aesthetic outcomes. Nipple-sparing mastectomy (NSM) combined with immediate breast reconstruction (IBR) with implant is becoming increasingly preferred due to its ability to preserve breast aesthetics. Acellular dermal matrix (ADM) is commonly used in these procedures, but is often prohibitively expensive, particularly in resource-limited settings like Vietnam. Polypropylene mesh (PPM) has emerged as a more affordable alternative; however, its safety and effectiveness in NSM and IBR remain unknown, especially in low-resource healthcare environments. **Methods:** This retrospective single-arm study included early breast cancer (EBC) patients who underwent NSM followed by IBR with PPM at a single institution between January 1, 2022, and January 31, 2024. The inclusion criteria were EBC stage 0, I, or II, with no prior neoadjuvant therapy or chest wall radiotherapy. Descriptive statistics were applied, and chi-square or Fisher's exact tests were used to assess associations between clinical variables and postoperative complications. **Results:** Among the 37 patients, the mean age was 40.9 years (range: 25–57). Most (70.3%) had invasive carcinoma, and 73.0% were luminal/HER2-negative. High-profile implants were used in 76.7% of cases. Two patients (5.4%) experienced mild-to-moderate complications, including infection (2.7%) and nipple-areolar necrosis (2.7%). Both were treated successfully with medical therapy. No cases of implant loss occurred, and no significant associations were found between complications and clinical variables ($p > 0.05$). **Conclusion:** PPM use in IBR after NSM for EBC patients is a safe and viable option, with low complication rates. PPM may serve as a cost-effective alternative to ADM, particularly in resource-constrained settings, such as Vietnam. Larger studies are recommended to confirm these results and assess long-term outcomes.

Keywords: breast neoplasms- breast reconstruction- mastectomy- breast implant- polypropylenes

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Introduction

Breast cancer (BC) is the most common malignancy in women worldwide, accounting for about 25% of all female cancer cases in 2020 [1]. In Vietnam (VN), is the most frequently diagnosed cancer, with 24,563 new cases reported in 2020 [2]. Advances in screening and treatment have significantly improved overall survival, with more than 90% of early-stage breast cancer (EBC) patients surviving beyond five years [3].

Breast reconstruction (BR) after mastectomy is increasingly considered a critical part of the treatment for EBC patients. However, no single BR method has been universally accepted as the standard of care. Immediate BR (IBR) is often preferred over delayed reconstruction to achieve optimal outcomes. Nipple-sparing mastectomy (NSM) has gained popularity due to its ability to preserve breast skin and aesthetics, enhancing the appearance and

quality of life for BC patients. Compared to autologous tissue reconstruction (ATR), implant-based IBR offers advantages such as reduced surgery time, fewer scars, and less recovery time, making it a preferred option for many patients seeking better cosmetic outcomes without additional donor-site surgeries [4-7].

A challenge in implant-based IBR is ensuring adequate coverage of the implant, particularly its lower anterior aspect, which may remain uncovered due to limited skin and muscle tissue. This uncovered area increases the risk of complications, such as implant displacement, capsular contracture, or poor aesthetic outcomes. One approach to address this problem is using tissue expanders (TE_x) to create a larger pocket for the implant. However, TE_x involves a two-stage surgical process and delays final reconstruction for several months, increasing the risk of complications like infection or implant failure. Grafts and meshes, on the other hand, offer a more efficient

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solution by providing immediate support to the implant pocket, allowing for better tissue expansion, lower pole projection, and potentially improved long-term aesthetic outcomes [8, 9].

Acellular dermal matrix (ADM), derived from human or animal tissue, has become a leading biological mesh option for BR due to its ability to integrate with surrounding tissues and promote healing. ADM provides additional support and coverage for the implant, reducing the risk of displacement. However, its high cost and limited availability make it less accessible in developing countries. As a result, synthetic alternatives such as polypropylene mesh (PPM) are increasingly being used. PPM offers a more cost-effective solution, with some studies suggesting comparable safety and outcomes to ADM. PPM is easier to manufacture, more readily available, and significantly cheaper, making it a feasible option in resource-limited settings like Vietnam, where ADM may not be a practical choice for most patients [6-11].

In Vietnam, PPM has become a common alternative to ADM in clinical practice due to its lower cost and availability. Despite its widespread use, evidence regarding the safety of PPM in NSM followed by immediate implant-based IBR remains limited. The current study aims to evaluate the safety of PPM in EBC patients undergoing NSM and IBR with implant. Specifically, it focuses on the incidence and severity of postoperative complications and their association with various clinical and therapeutic factors.

Materials and Methods

Acknowledging Prior Publication of Preliminary Data

This study builds upon our earlier work [Bui DT, Pham XD, Le VQ. The safety of polypropylene mesh in nipple-sparing mastectomy and immediate implant-based breast reconstruction in early breast cancer patients. *TCNCYH*. 2024;179(06)], which analyzed 28 cases. In this study, we present an expanded cohort of 37 cases to enhance the reliability of the results previously reported.

Study Design

This was a retrospective, single-arm, single-institutional study conducted at the Oncology Hospital in Ho Chi Minh City (HCMC), VN. The study period spanned from January 1, 2022, to January 31, 2024. The study aimed to evaluate the safety of PPM in EBC patients undergoing NSM followed by implant-based IBR.

Ethical Statement

Ethical approval was obtained from the Institutional Review Board (reference number: 671/GCN-HDDDNCYSH-DHYHN), and the study was conducted in accordance with the Helsinki Declaration.

Study population

This study included female patients diagnosed with EBC (stages 0, I, or II) who met the following inclusion criteria, such as pathological diagnosis of breast carcinoma, preoperative tumor size ≤ 3 cm, no prior history of chest wall radiotherapy or neoadjuvant

therapy. Patients were excluded if they were pregnant, had recurrent breast cancer, a history of other primary cancers, or had undergone neoadjuvant therapy. Additionally, patients with advanced-stage disease, or those who had received previous chest wall irradiation, were not included in the study.

Surgical Procedure

All patients underwent NSM followed by IBR with PPM to cover the lower anterior aspect of the breast implant. The NSM procedure aimed to preserve the nipple-areolar complex (NAC), and a periareolar incision was performed in most cases. Sentinel lymph node biopsy (SLNB) was performed for axillary staging, and prophylactic antibiotics were administered in all cases. PPM was used to provide support to the implant, covering the lower anterior aspect of the implant, thereby expanding the implant pocket and preventing displacement.

Data collection

Patient demographic information, tumor characteristics, surgical details, and postoperative outcomes were retrospectively collected from medical records. The following variables were recorded: age at diagnosis, tumor size, histological subtype, clinical stage, implant volume, implant profile, incision type, antibiotic regimen, and surgical duration. Postoperative complications, including infection, necrosis, seroma, implant loss, and other adverse events, were assessed for up to 12 months after surgery. The severity of complications was classified as mild, moderate, or severe, according to "Common Terminology Criteria for Adverse Events, Version 5.0" published on November 27, 2017.

Statistical analysis

Data were analyzed using R-4.4.1 for Windows. Descriptive statistics were used to summarize the patient characteristics and surgical details. Chi-square or Fisher's exact tests were used to assess associations between clinical variables and postoperative complications, as the categorical variables. A p-value of less than 0.05 was considered statistically significant.

Results

This study found that postoperative complications were minimal, affecting only 5.4% of patients. Mild-to-moderate infections (2.7%) and nipple-areolar necrosis (NAN) (2.7%) were successfully treated with medical therapy. No cases of implant loss or severe complications occurred, and no significant associations were observed between complications and clinical variables.

Baseline characteristics

A total of 37 EBC patients included in this study. The mean age at diagnosis was 40.9 years (range: 25–57 years), with more than half of the patients (51.4%) aged 40 years or younger (Table 1). The clinical stage distribution showed that 27% were stage 0, 48.6% were stage I, and 24.3% were stage II. Tumor sidedness was nearly equally distributed, with 51.4% of tumors located in the left

Table 1. Patient's Preoperative Characteristics

Characteristics (N)		n (%)	95% CI
Age at diagnosis (N=37)	≤ 40	19 (51.4)	35.1 – 67.6
	41 – 59	18 (48.6)	32.4 – 64.9
Clinical stage (N=37)	0	10 (27.0)	13.5 – 40.5
	I	18 (48.6)	32.4 – 64.9
	II	9 (24.3)	10.8 – 40.5
Tumor sidedness (N=37)	Left	19 (51.4)	35.1 – 67.6
	Right	18 (48.6)	32.4 – 64.9
Tumor location (N=37)	Central	6 (16.2)	5.4 – 29.7
	Upper outer quadrant	9 (24.3)	10.8 – 40.5
	Upper inner quadrant	5 (13.5)	2.7 – 24.3
	Upper half	1 (2.7)	0.0 – 8.1
	Lower half	2 (5.4)	0.0 – 13.5
	Outer half	8 (21.6)	8.1 – 35.1
The number of tumors (N=37)	1	34 (91.9)	81.1 – 100
	2	3 (8.1)	0.0 – 18.9
The number of tumors (N=37)	Carcinoma in-situ	11 (29.7)	16.2 – 43.2
	Invasive carcinoma	26 (70.3)	56.8 – 83.8
Preoperative pathology (N=37)	Luminal/HER2-	27 (73.0)	56.8 – 86.5
	Luminal/HER2+	6 (16.2)	5.4 – 27.0
	HER2+	3 (8.1)	0.0 – 18.9
	TNBC	1 (2.7)	0.0 – 8.1

breast. The upper outer quadrant was the most common site (24.3%), followed by the outer half (21.6%) and the central region (16.2%).

Most patients (97.3%) underwent SLNB, with only one patient (2.7%) requiring axillary dissection due to axillary node metastasis (Table 2). The majority (73%) of patients underwent periareolar incisions, while radial (8.1%) and inframammary (10.8%) incisions were less frequently used. Prophylactic intravenous antibiotics were administered to all patients, with Zolifast being the most used (52.8%), followed by Amapower (30.6%). The mean duration of surgery was 157.24 ± 56.52 minutes (range: 60–300 minutes). The majority of patients (91.7%) had one surgical drain postoperatively, while 8.3% had two

drains.

Implant volume ranged from less than 200 mL to over 300 mL, with the majority (64.9%) of patients receiving implants in the 200–300 mL range (Table 3). High-profile implants were used in 76.7% of cases, while the remaining 23.3% had moderate-high profile implants. The mean implant volume was 284.46 ± 65.18 mL, and the mean surgical specimen volume was 232.57 ± 110.58 mL. The median tumor size was 1.8 cm, with a maximum size of 3 cm.

Postoperative complication characteristics

Of 37 patients, 5.4% of those experienced an infection, while 5.4% had NAN, both classified as mild to moderate

Table 2. Patient's Surgical and Postoperative Characteristics

Characteristics (N)		n (%)	95% CI
Axillary treatment (N = 37)	SLNB	36 (97.3)	91.9 – 100
	Dissection	1 (2.7)	0.0 – 8.1
Skin incision (N = 37)	Periareolar	27 (73.0)	59.5 - 86.5
	Radial	3 (8.1)	0.0 – 18.9
	Inframammary	4 (10.8)	2.7 – 21.6
	Other	3 (8.1)	0.0 – 16.2
Prophylactic intravenous antibiotics (N = 36)	Amapower	11 (30.6)	16.7 – 47.2
	Cephazolin	2 (5.6)	0.0 -13.9
	Unasyn	4 (11.1)	2.8 – 22.2
	Zolifast	19 (52.8)	33.3 – 69.4
The number of drains (N = 36)	1	33 (91.7)	80.6 – 100
	2	3 (8.3)	0.0 – 19.4

Table 3. Patient's Implant Characteristics

Characteristics (N)		n (%)	95% CI
Implant volume (N=37)	< 200 mL	4 (10.8)	2.7 – 21.6
	200-300 mL	24 (64.9)	48.6 – 78.4
	> 300 mL	9 (24.3)	10.8 – 40.5
Implant profile (N=30)	Moderate – High	7 (23.3)	10.0 – 40.0
	High	23 (76.7)	60.0 – 90.0

Table 4. Patient's Other Characteristics

Characteristics (N)	Mean ± SD	Median	Min	Max
Implant volume (mL) (N=37)	284.46 ± 65.18	300	150	450
Surgical specimen volume (mL) (N=37)	232.57 ± 110.58	250	100	600
Clinical tumor size (cm) (N=37)	1.962 ± 0.90	1.8	0.7	5
Duration of surgery (mins) (N=37)	157.24 ± 56.52	150	60	300

in severity (Table 4). All complications were successfully treated with medical therapy, including antibiotics and anti-inflammatory medications, and no major surgical interventions were required. Importantly, there was no case of implant loss. There was no statistically significant association between postoperative complications and patient age, clinical stage, surgical incision type, or antibiotic regimen ($p > 0.05$).

Discussion

This study demonstrates that PPM is a safe and effective alternative to ADM for implant-based IBR following NSM in EBC patients. The complication rate in this study was 5.4%, which is lower than several other studies that evaluated both synthetic and biological meshes in BR. Hansson et al. reported a complication rate of 19% using a biological mesh, and Blok et al. found a 14.7% complication rate with synthetic mesh [10, 12]. Our lower complication rate further supports PPM as a safe alternative, especially in resource-limited settings.

Notably, the complications observed, including mild-to-moderate infections (2.7%) and NAN (2.7%), were successfully managed with medical therapy, with no cases of implant loss or severe complications. The patient experienced partial NAN with mild-to-moderate severity, but this was also effectively treated with medical therapy. Multiple factors, including a large breast specimen volume (350 mL), periareolar incision, and the tumor's central location beneath the skin surface, likely contributed to the case of NAN. These factors may have negatively affected the NAC blood supply, which is likely the origin of the problem.

As compared to studies related to ADM, our results align with findings indicating that synthetic meshes, such as PPM, offer a comparable safety profile. Choi et al. reported that ADM carries a complication rate of 11.7%, which is significantly higher than the 5.4% observed in our study using PPM [11]. The high cost and lower availability of ADM, especially in developing countries such as Vietnam, make PPM a more practical and economically feasible alternative. The absence of severe complications

such as implant loss in this study is consistent with other reports, such as Blok et al., who found a 5.8% rate of implant loss in patients using synthetic mesh [10].

We did not find any statistically significant association ($p > 0.05$) between postoperative complications and clinical or therapeutic characteristics, such as age at diagnosis, clinical stage, operative procedure, or prophylactic antibiotic regimen. This lack of statistical significance is likely due to the limited sample size of 37 patients, which may have reduced the power of the analysis. Larger, multicenter studies are necessary to confirm the long-term safety and efficacy of PPM. Additionally, the current study did not evaluate patient-reported outcomes or aesthetic results, which are critical aspects of BR success. Santosa et al. has shown the importance of long-term patient satisfaction and quality of life in BR, areas that should be addressed in future studies [13].

Despite these limitations, the low complication rate observed in our study is promising and suggests that PPM is a viable and cost-effective option for implant-based reconstruction following NSM. The use of PPM in place of ADM could provide substantial cost savings without compromising safety, particularly in settings where healthcare resources are constrained. Future research should focus on long-term follow-up and patient-reported outcomes to further evaluate the role of PPM in breast reconstruction.

In conclusion, PPM is a safe and effective option for implant-based IBR following NSM in EBC patients. PPM demonstrates cost-efficiency compared to ADM, particularly given its low complication rate and accessibility in resource-constrained settings. Future studies should focus on larger populations and long-term patient outcomes to confirm these findings and further define the role of PPM in IBR.

Author Contribution Statement

Tung Duc Bui conceived and designed the study, collected and curated data, analyzed and interpreted the data, and drafted the manuscript; Dung Xuan Pham

provided essential materials, contributed to data analysis, and critically revised the manuscript; Nam Hoai Vo contributed to the the study design, assisted in data interpretation, visualize several key data, and critically revised the manuscript; Quang Van Le supervised the project, critically revised the manuscript, and approved the final version of the manuscript.

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Prior Publication of Preliminary Data

This study builds upon our earlier work [Bui DT, Pham XD, Le VQ. The safety of polypropylene mesh in nipple-sparing mastectomy and immediate implant-based breast reconstruction in early breast cancer patients. *TCNCYH*. 2024;179(06)], which analyzed 28 cases. In this study, we present an expanded cohort of 37 cases. Furthermore, this study constitutes part of the doctoral thesis of Tung Duc Bui, as the first author of this study, at Hanoi Medical University, Vietnam.”

The ethical issue

Ethical approval was obtained from the Institutional Review Board (reference number: 671/GCN-HDDDNCYSH-DHYHN), and the study was conducted in accordance with the Helsinki Declaration.

Availability of data

The data that support the findings of this study are available from the corresponding author upon reasonable request.”

Any conflict of interest

The authors declare no conflicts of interest regarding this manuscript.

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