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Early post-operative outcome of pre-pectoral implant-based immediate total breast reconstruction with Polyglactin 910 (Vicryl™) mesh – low cost solution for a low-middle income country

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Abstract

Background The incidence of breast cancer in Pakistan has been rising with approximately one third of these patients requiring mastectomy. Among breast reconstruction treatment options, the use of Acellular Dermal Matrix (ADM) for pre-pectoral breast implant surgery has proven effective with improved cosmetic outcome. However, due to high cost it cannot be regularly implemented in a developing country like Pakistan. An alternative to ADM, Polyglactin 910 (Vicryl™, Ethicon) mesh has been introduced in pre-pectoral breast reconstructive surgery which has shown to be almost 10 times lower in cost. We set out to determine the frequency of early postoperative complications when using Polyglactin 910 mesh for pre-pectoral implant-based breast reconstruction surgery.

Methods A single centre, retrospective, chart review was conducted, and a total 28 women were included in the study. Thirty-two pre-pectoral implant-based mastectomies with Polyglactin 910 mesh were performed. Early post-operative outcomes (within 12 months of procedure) including duration of antibiotic use, post-operative infection, implant displacement, flap necrosis, seroma formation, wound dehiscence, hematoma formation, capsular contracture and reconstruction failure, were recorded.

Results Only 4 (12.5%) women experienced early post-operative morbidity. One patient developed a wound dehiscence, which eventually led to reconstruction failure and removal of the implant. Another patient had seroma formation and flap necrosis. None of the patients developed postoperative implant displacement, hematoma formation or capsular contracture in the early post-operative period.

Conclusion This study reveals that early post-operative outcomes with Polyglactin 910 mesh in breast reconstructive surgery are few, thus making it a cost effective, reliable, and safe treatment option, especially in developing countries like Pakistan.

Keywords Implant-based mastectomy, Polyglactin 910 (Vicryl™, Ethicon) mesh, Immediate breast reconstruction

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Background

In Pakistan, the lifetime risk of being diagnosed with breast cancer has increased to one in every nine women [1]. Among the Asian countries, Pakistan has one of the highest age-standardized incidence rate of breast cancer [2], with an estimated increase of 23.1% from 2015 to 2020 [3]. At present, there is no national screening program for breast cancer and as a result patients often present late with advanced disease and poor outcomes [4]. However, breast cancer has a good prognosis with the National Cancer Institute of America reporting up to a 90% survival rate among all patients diagnosed with breast cancer [5].

Surgery is an essential component of the treatment of breast cancer with approximately one-third of affected women requiring mastectomies [6].The initial subcutaneous and submuscular implant placement had poor aesthetic outcomes, thus other techniques were explored over time [7, 8]. Improved results of reconstruction were seen with the use of acellular dermal matrix (ADM), a biomaterial derived from human and animal sources [9]. The ADM has been used to complete the subpectoral pocket, which gives the breast a more natural teardrop appearance [10]. It could integrate into the surrounding tissue and revascularize, thus providing a stable permanent cover with reduced capsular fibrosis [11, 12]. Furthermore, the occurrence of capsular contracture is reduced as there is minimal scar formation [13]. Based on these properties of ADM, in 2014, Berna et al. introduced a new breast reconstruction method, whereby the pectoralis major muscle is completely preserved. The implant is wrapped in a pre-shaped ADM and placed in the pre-pectoral, subcutaneous plane [14].

Despite its' strengths, a major drawback of ADMs is its high cost. As an example, a 6×16 cm mesh of AlloDerm costs $ 3,700 USD (PKR 560,000), and meshing of AlloDerm has been done to make it more cost-effective [15], however, this is too steep a cost to add to the multipronged breast cancer treatment regime for most patients in a developing country like Pakistan. As an alternative to ADM, Polyglactin 910 (Vicryl™, Ethicon) mesh is being used in breast reconstructive surgery. When compared to ADM, the cost of Polyglactin 910 mesh has been shown to be 7 to 10 times lower, and retrospective studies have proved it to be a reliable, safe, effective, and economical alternative for implant-based breast reconstruction [16, 17]. Polyglactin 910 mesh is considered cost-effective primarily due to its lower material costs compared to alternatives like ADMs. Synthetic in nature, Polyglactin 910 mesh is more affordable to produce and procure, making it accessible in resource-limited settings where budget constraints are significant.

In our setting, due to the financial constraints of breast cancer treatment and the lack of availability of ADMs, we have been using Polyglactin 910 mesh as an alternative to ADM for pre-pectoral implant-based breast reconstruction surgeries. With the rising cost of living and the increasing incidence of breast cancer among younger women, globally, there is a greater emphasis of the need for cost-effective treatment, as well as the need for an aesthetically pleasing result to the outcome of breast cancer management. We reviewed a single-center, single surgeon's experience of using Polyglactin 910 mesh, and the early post-operative outcomes post breast reconstruction surgery among women undergoing a mastectomy with pre-pectoral breast reconstruction.

Methodology

This single-centre, retrospective, single group chart review was conducted at the Department of Surgery, Aga Khan University Hospital, Karachi. Approval was attained from the Ethical Review Committee (ERC 2021–6789-19282).

Women aged 18 to 70 years who underwent a pre-pectoral implant-based mastectomy with Polyglactin 910 mesh from January 2016 to June 2021 were included in the study. These women included those treated for breast cancer that underwent either nipple sparing or skin sparing mastectomy and also those who had reconstruction after prophylactic mastectomy in the same setting. Patients who had reconstruction with latissimus dorsi flaps and those patients who had subpectoral reconstruction were excluded from the study.

The data variables including demographics, surgical details, pathological staging of the disease were collected from the patient charts, clinic notes, surgical notes, and discharge summaries on a structured questionnaire. Outcomes including duration of antibiotic use, post-operative infection, implant displacement, flap necrosis, seroma formation, wound dehiscence, hematoma formation, capsular contracture and reconstruction failure were collected from the post-surgical clinic follow-up notes that took place within 12 months post-surgery.

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 22.0 for Windows. Age, height, weight and body mass index (BMI), duration of surgery, has been reported as mean ± standard deviation (SD), while qualitative variables like co-morbidities, surgical details and postoperative complications have been reported as frequency and percentages (Tables 1, 2 and 3).

Significance testing was performed to determine the association of patient and treatment factors (BMI, comorbidities, neo-adjuvant chemotherapy) with early post-operative complications using chi-square test with

Table 1 Demographics

Age (*n* = 28)	Mean ± SD	43.25 ± 9.98 years
Comorbid	Yes	50.0% (14)
Hypertension	Yes	29.0% (9)
Diabetes mellitus	Yes	10.7% (3)
Hypothyroidism	Yes	7.1% (2)
Polycystic ovarian syndrome	Yes	7.1% (2)
Weight	Mean ± SD	72.1 ± 11.4 kg
Height	Mean ± SD	157.4 ± 4.5 cm
BMI	Normal	17.9% (5)
	Overweight	42.9% (12)
	Obese	39.3% (11)

alpha at 0.05 (Table 4). The sample size was too low for multivariate analysis.

A urine culture was performed for all patients within a week of surgery and all patients received a single dose of preoperative prophylactic antibiotic. The surgical procedure followed the standard raising of the skin flaps and removal of the breast tissue off the pectoralis major muscle. The specimen was weighed intra-operatively, the dimensions of the cavity measured and the volume of the implant selected was 50-60 ml less than the measured mastectomy volume. A sizer was also used to determine the volume of implant. The corresponding implant was then selected and placed pre-pectoral within the skin flaps after ensuring hemostasis. To prevent movement of the implant a standard 15 × 15 cm Polyglactin 910 mesh was placed over the implant and sutured in place to the pectoralis major muscle in 4 corners using Polyglactin 910 3–0. A 10 Fr redivac drain was inserted and the dermis and epidermis closed in 2 layers with absorbable sutures.

Results

A total of 28 patients were included in the study who underwent a total of 32 pre-pectoral implant based mastectomies altogether. Table 1 describes the demographic details of the patients. All patients were women with a mean age of 43.25 ± 9.98 years. Only 5 (17.9%)

Table 3 Early post-operative complications

Duration of antibiotics	Median + IQR	7 days (6—11)
Post-operative complications	No	87.5% (28)
	Yes	12.5% (4)
Flap necrosis		3.1% (1)
Wound dehiscence		6.3% (2)
Seroma formation		6.3% (2)
Wound infection		0.0% (0)
Implant displacement		0.0% (0)
Reconstruction failure		3.1% (1)
Hematoma formation		0.0% (0)
Capsular contracture		0.0% (0)

Table 2 Surgical details

ASA (*n* = 28)	I	25.0% (7)
	II	67.9% (19)
	III	7.1% (2)
Neoadjuvant chemotherapy (28)	No	78.6% (22)
	Yes	21.4% (6)
Surgical procedure	Skin sparing mastectomy	78.1% (25)
	Nipple sparing mastectomy	21.9% (7)
Axillary clearance	No	75.0% (24)
	Yes	25.0% (8)
Duration of surgery	Mean ± SD	207.2 ± 74.0 min
Implant volume	Median + IQR	445 ml + (400–450)
Therapeutic mastectomy		84.4% (27)
Prophylactic mastectomy		15.6% (5)
Pathological staging	DCIS	15.6% (5)
	Ia	9.4% (3)
	Ib	3.1% (1)
	IIa	34.4% (11)
	IIb	6.3% (2)
	IIIa	6.3% (2)
	Complete pathological response	6.3% (2)

patients had a normal body mass index (BMI) with the majority of women, 23 (82.1%), being overweight or obese.

Table 2 describes the surgical details. Only 6 (21.4%) women had received neoadjuvant chemotherapy and among them axillary clearance was done 8 (25.0%) times. The women underwent either a skin sparing mastectomy 25 (78.1%) or a nipple sparing mastectomy 7 (21.9%). The median implant volume was 445 ml (IQR: 400–450). The mean duration of surgery was 207.2 ± 74.0 min.

Twenty-seven (84.4%) therapeutic mastectomies were performed and the most common pathological stage was stage IIa in 11 (34.4%) women. All patients received post-operative antibiotics for a median duration of 7 days (IQR: 6–11). Early post-operative complications, within 12 months post-operatively were recorded (Table 3).

While the majority of women had a good early outcome (Fig. 1), 4 (12.5%) women experienced early post-operative morbidity, among whom 1 patient developed a wound dehiscence which eventually lead to reconstruction failure and removal of the implant (Fig. 2), while another patient had seroma formation and flap necrosis (Fig. 3). None of the patients developed post-operative implant displacement, capsular contracture or hematoma formation in the early post-operative period. It was observed that all four patients who developed post-operative complications had a BMI of ≥ 30.0 kg/m^2 (p-value 0.053). A patient with an existing comorbidity (diabetes mellitus/ hypertension/ hypothyroidism/ polycystic ovarian syndrome (PCOS) had a significant risk of developing early post-operative complications (p-value 0.033) (Table 4). There was no statistically significant association between individual comorbidities (eg. diabetes mellitus) and postoperative outcomes.

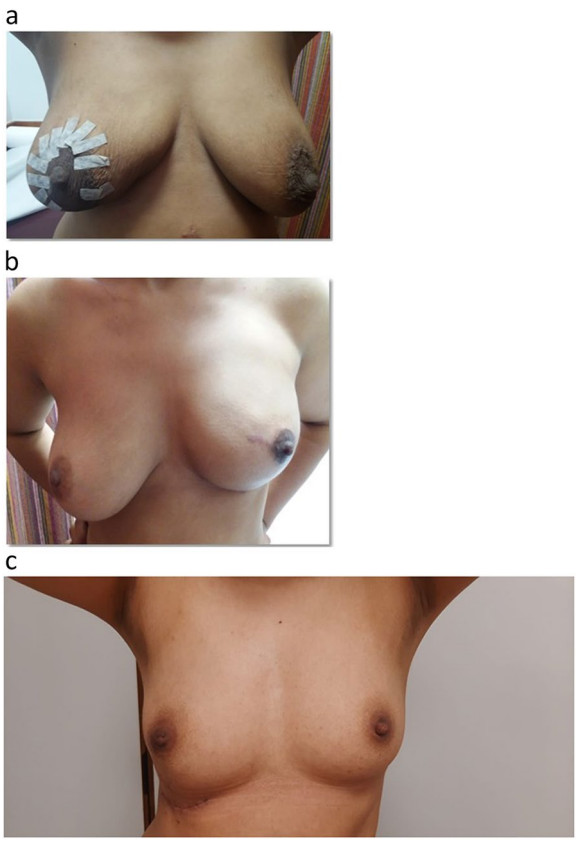

Fig. 1 **a**, **b**, **c** Pre-pectoral implant-based immediate total breast reconstruction with Polyglactin 910 (Vicryl) mesh. **a** Right nipple sparing pre-pectoral implant based mastectomy. **b** Left nipple sparing pre-pectoral implant based mastectomy. **c** Right nipple sparing pre-pectoral implant based mastectomy – Infra-mammary incision.

Discussion

It is important to understand the benefits of reconstructive surgery in this context. Reconstruction has been shown to improve body image, self-esteem, well-being, and even a possible life expectancy advantage [18]. There have been reports of subjective femininity loss, mental illness development, and marital/sexual dysfunction in women who do not undergo reconstructive procedures post mastectomy [18].

Literature has described that the use of ADM improves the definition of the breast contours, thereby improving aesthetic outcomes and may simplify direct-to-implant procedures [19]. Short term follow-up has revealed its ability to reduce capsular contracture, and reduce the incidence of implant migration, thus supporting the need for a covering mesh over the implant [19, 20].

There are two main categories of acellular dermal matrices: human derivatives (FlexHD and Alloderm)

Fig. 2 Left nipple sparing implant based mastectomy – wound dehiscence with eventual reconstruction failure

Fig. 3 Bilateral skin sparing mastectomy. Left flap necrosis – managed conservatively

and animal derivatives (Surgimend, Braxon). The most frequently used ADM is reported to be alloderm; however, cost is a major deterrent, especially in a third world nation like Pakistan. The price of Alloderm ranges from $3536 to $4856 per breast [21]. The setback with the Braxon ADM is that it is a porcine derivative which could pose religious issues in Pakistan. Swine are amongst the animals that are non-permissible to consume in Islamic law. This makes it challenging to obtain all their parts and derivatives for pharmaceutical use in a Muslim-majority country. Since Polyglactin 910 mesh is synthetically produced, it does not face the same religious concerns as ADM.

Because of aforementioned cost and availability problems, early-stage breast cancer patients who were unlikely to need adjuvant radiation therapy were offered immediate pre-pectoral implant-based mastectomy with Polyglactin 910 mesh.

The results of this study indicate that Polyglactin 910 mesh is a cost-effective alternative to ADM for immediate pre-pectoral implant-based mastectomy, particularly in a resource-limited setting like Pakistan. The overall complication rate was 12.5% ($n=4$), with only one patient experiencing implant loss due to infection. These results align with a Harvard Medical School study, which reported a 6.6% complication rate and 1.3% implant loss due to Serratia infection over a similar follow-up period [17]. It was also noted that $172,000 was saved in ten months as direct material cost saving. A study with a longer follow-up of 43 months reported a 15.2% complication rate with Polyglactin 910 mesh, indicating that while short-term outcomes are promising, long-term data is crucial for a comprehensive assessment [22].

Another study conducted in 2015 saw a 7% incidence of postoperative hematomas, 7% infection, and 23% seroma formation in their population [23]. The setback with this 2015 study is that their population size was merely 13 patients. It does, however, exhibit significant complication findings worth mentioning. The seromas resolved uneventfully, and the infection occurred in a morbidly obese patient post radiotherapy [23]. In our study, it was observed that all four patients who developed post-operative complications had a BMI of ≥ 30.0 kg/m^2. Due to the small sample size we were unable to further stratify the population for a more detailed analysis.

A systematic review of incidence of complications in breast reconstruction using Polyglactin 910 mesh was conducted, and the results indicate that Polyglactin 910 mesh is a safe, effective, and a relatively inexpensive option. The study explored different papers and reviewed their results. They then compared those results to an earlier meta-analysis of ADMs and their efficacy. According to this paper, patients with mesh had an infection rate of 2.6% as opposed to patients with ADM had an infection rate of 5.7%. With regards to construction failure, 3.2% of patients with mesh experienced this as opposed to 5.1% of patients with ADM. Finally, seroma formation was found to have the most notable difference; 1.3% in mesh patients and 6.9% in ADM patients. Overall, it was noted that there was no statistical difference in complications between the methods available [24].

Table 4 Association of patient and treatment factors with early (within 12 months) post-operative complications

		Post-operative complications (n)		
		Yes	No	*p*-value
BMI	Normal	0	5	0.053
	Overweight	0	13	
	Obese	4	10	
Comorbid	Yes	4	12	0.033
	No	0	16	
Diabetes mellitus	Yes	0	3	0.492
	No	4	25	
Neo-adjuvant chemotherapy	Yes	1	7	> 0.999
	No	3	21	
	> 1	1	2	

Beyond cost considerations, Polyglactin 910 mesh has other potential limitations that need to be discussed. Long-term outcomes, including patient satisfaction and aesthetic results, remain less documented compared to ADMs. While early results are promising, comprehensive long-term studies are necessary to fully understand the durability and patient satisfaction associated with Polyglactin 910 mesh. None of the patients in our study developed capsular contracture in the early post-operative

period. Nonetheless, the impact of Polyglactin 910 mesh on tissue integration and the potential for late complications including capsular contracture need further exploration. As such, while Polyglactin 910 mesh presents a viable alternative in resource-limited settings, its long-term efficacy and patient satisfaction should be subjects of future research.

Some limitations to this study are the limited sample size and the follow-up period of 12 months. Long term follow-up studies are being conducted at our centre along with the assessment of patient perceptions and cosmetic outcomes. Another thing to note is that this option of pre-pectoral implant based mastectomy with mesh is only limited to patients with early breast cancer who are unlikely to require adjuvant radiation. This is to prevent radiotherapy associated adverse effects on the breast implant. Furthermore, a prospective, comparative study between Polyglactin 910 mesh and ADM in pre-pectoral implant-based mastectomy should ideally be conducted, however, due to the aforementioned financial and social limitations, this is not possible in our country.

Conclusion

Our study demonstrates that Polyglactin 910 mesh is a cost-effective, safe and viable option for pre-pectoral implant-based mastectomy for patients with early breast cancer, particularly in the early post-operative period. The key findings highlight its potential to reduce healthcare costs without compromising patient safety or immediate post-surgical outcomes. However, to validate these results and ensure comprehensive patient care, larger, long-term studies across multiple centres are necessary. These studies should focus on observing post-operative outcomes over an extended period. Comparative studies with ADMs are essential to determine the relative long-term effectiveness and cosmetic outcomes. Such research will help establish whether Polyglactin 910 mesh can be recommended for routine use in clinical practice. Future research should also explore specific complications and limitations associated with Polyglactin 910 mesh to provide a holistic understanding of its benefits and drawbacks.

Abbreviations

ADM	Acellular Dermal Matrix
ERC	Ethical Review Committee
SPSS	Statistical Package for the Social Sciences
BMI	Body mass index
IQR	Interquartile range
PCOS	Polycystic ovarian syndrome

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Not applicable.

Authors' contributions
The study concept, data interpretation and writing of the paper was contributed by LV. SV contributed to the data collection, interpretation, analysis and writing of the paper. HA and IA were responsible for the data collection and writing of the manuscript. SZ contributed to the study concept and writing of the paper. Figures 1-3 were prepared by LV and SV. All authors reviewed the manuscript.

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study was approved by the institutions Ethical Review Committee (ERC 2021–6789-19282).

Consent for publication
Informed consent was obtained from all individual participants included in the study.

Competing interests
The authors declare no competing interests.

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