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Research Article

# Safety of Safil® Polyglactin Mesh in Implant-based Breast Reconstruction: A Single-center Retrospective Analysis

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## Abstract

Synthetic absorbable meshes have emerged as a viable alternative to acellular dermal matrices (ADMs) in prosthetic breast reconstruction, offering potential advantages in safety, cost, and handling. Safil® Mesh, a synthetic absorbable polyglactin mesh, has been increasingly adopted in clinical practice; however, real-world data on its performance remain limited. This study aimed to evaluate the safety and clinical performance of Safil® Mesh in breast reconstruction procedures performed at Hospital Universitario de Salamanca. Most patients were classified as ASA II. Safil® Mesh was predominantly used for post-mastectomy breast reconstruction, accounting for 92.2% of cases, with breast cancer as the primary indication in 89%. The mean operative time was approximately 200 minutes, and no intraoperative complications were reported. During follow-up, postoperative complications occurred in 13.6% of surgeries, most commonly prosthesis extrusion (3%), infection (2%), and hematoma (2%), with no complications directly attributed to the mesh. Surgical reintervention was required in 8% of patients, mainly due to implant-related issues. These findings are consistent with previously published long-term observational data on synthetic absorbable meshes, which demonstrate comparable or lower complication rates relative to ADM-based reconstructions. Overall, Safil® Mesh demonstrated a favorable safety profile, with no intraoperative complications and a low incidence of postoperative adverse events. The absence of mesh-related complications and outcomes comparable to those reported in the literature support Safil® Mesh as a reliable alternative to ADMs. Further prospective, multicenter studies are warranted to confirm these findings and assess long-term outcomes.

## Keywords

Breast Reconstruction, Safil® Mesh, Absorbable Mesh

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# 1. Introduction

Breast reconstruction following mastectomy is a central component of comprehensive breast cancer care, with its utilization steadily increasing over recent decades as oncological safety has been well established and reconstructive options have expanded. Implant-based breast reconstruction now represents the predominant modality in many Western healthcare systems. In Europe, longitudinal institutional data demonstrate that implant-based immediate breast reconstruction accounts for approximately 60–75% of such procedures, with one major UK center reporting an increase from 61.3% to 76.5% over a decade. Moreover, broader regional analyses confirm that in Western Europe, implants constitute the most frequently used method of immediate reconstruction among the more than 40% of mastectomy patients who undergo reconstructive surgery. Similarly, in the United States, national procedural data from the American Society of Plastic Surgeons show that implant-based techniques—particularly tissue-expander-to-implant and direct-to-implant reconstruction—far outnumber autologous methods, underscoring their position as the most commonly performed reconstructive approach nationwide [1].

The choice of materials and techniques used in reconstructive surgery plays a pivotal role in determining both aesthetic outcomes and overall patient safety. In this setting, the use of absorbable meshes has become increasingly common as an adjunct in breast reconstruction procedures.

The literature reports positive aesthetic outcomes associated with the use of acellular dermal matrices (ADMs), and comparable aesthetic results have also been described with synthetic matrices. However, the use of matrices in breast reconstruction has been associated with a wide range of complications. Patient-related factors have been consistently linked to increased complication rates in breast reconstruction, regardless of whether matrices are used.

Infection remains one of the most frequent complications observed with both biological and synthetic meshes in implant-based breast reconstruction, and when severe, it can precipitate tissue necrosis and may ultimately require revision surgery, explantation, or complete implant loss [2, 3]. Seroma and haematoma also represent common postoperative events and are recognized contributors to increased risk of infection and subsequent tissue necrosis [2-4]. Evidence from recent meta-analyses indicates that synthetic meshes are associated with lower rates of seroma compared with acellular dermal matrices (ADMs), a finding attributed to differences in surface characteristics that may promote more rapid interaction with subcutaneous tissue and reduce implant fluctuation, thereby decreasing fluid accumulation [2, 4]. Notably, most available comparative studies report similar—or in some cases lower—rates of implant loss when synthetic meshes are used instead of biological matrices [3, 4]. Although numerous publications have extensively described the advantages and limitations of ADMs, the amount of high-quality evidence specifically addressing synthetic meshes remains more limited, with several reviews highlighting the need for further direct comparative research [2, 5].

Among the various absorbable synthetic materials available, Safil® Mesh has emerged as a promising option due to its biocompatibility and mechanical properties. Polyglycolic acid (PGA) mesh, in particular, has been widely used in implant based breast reconstruction. Its absorbable nature makes it an attractive option for providing temporary support during early healing. Studies have shown that PGA mesh can provide adequate reinforcement while minimizing long term foreign body reactions [6]. As the material gradually degrades, it eliminates the need for removal surgery and has demonstrated good tolerability [3], reducing the risk of chronic inflammation and foreign body responses [5].

In contrast to ADMs, synthetic meshes demonstrate several clinically meaningful advantages in breast reconstruction. Notably, they have been associated with lower infection rates compared with ADMs [2] Additionally, their use has been linked to reduced incidences of skin necrosis and implant explantation, contributing to improved postoperative outcomes [3] Although ADMs offer the benefit of integrating into host tissue [7], the emerging evidence underscores the favorable complication profile of synthetic meshes, highlighting their growing relevance in reconstructive surgery.

Despite the expanding use of absorbable synthetic meshes, robust clinical evidence specifically supporting the safety and effectiveness of Safil® Mesh in breast reconstruction remains limited. This study aims to address this gap by conducting an observational, retrospective, single-center analysis of the safety profile of Safil® Mesh in patients undergoing breast reconstruction. By evaluating a broad patient population, this study seeks to generate comprehensive insights into the clinical outcomes associated with Safil® Mesh use.

The primary objective of this study is to assess the incidence of complications and adverse events related to Safil® Mesh. Secondary objectives include evaluating long term outcomes and overall patient satisfaction with the reconstructive results. Through this analysis, we aim to contribute meaningful evidence to ongoing efforts to optimize breast reconstruction techniques and improve patient care.

# 2. Material and Methods

## 2.1. Subjects and Indications for Surgery

The study has been designed as single centre, single-arm retrospective case-note series. The trial was registered before the study was initated (January 19, 2021) in clinicaltrials.gov under the registration number NCT04947202. Ethics approval was obtained by the Ethical and Research with medication in Health area of Salamanca assistance complex of Salamanca university, study code: SAFIL MESH STUDY E.O. 20/702 on 19 Janyary 2021. The inclusion criteria were only adult

(≥18 years old) female patients operated between January 2019 - November 2020 at the Hospital Universitario de Salamanca (Salamanca, Spain) for breast reconstruction and received Safil® Mesh (B. Braun Surgical S. A. Rubi, Spain) for soft tissue reinforcement. No specific exclusion criteria were applied, meaning that all consecutive patients meeting the surgical indication during the study period were included.

A total of 76 patients were included in the study. Among them, 24 patients (31.6%) underwent bilateral procedures. For analytical purposes, each breast was considered an independent unit; therefore, a total of 100 breast surgeries were included in the analysis.

Complications such wound dehiscence, wound infection, seroma, fistula, abscess formation, haematoma, tissue reaction, allergic reaction, inflammation and the need for mesh removal were considered within the first 90 days after surgery.

### 2.2. Device Description

Safil Mesh® is made of the synthetic, absorbable homopolymer polyglycolic acid, uncoated and undyed filaments of the same composition as Safil® suture material. It is designed to mechanically strengthen the newly formed tissue temporarily during the healing phase, it provides a temporary augmentation of the wound and is absorbed after the wound has healed. Safil Mesh® is metabolized in the body through hydrolysis into glycolic acid, the mesh is considered to have direct contact with tissue and organs for between 60-90 days (>30 days). Complete mass absorption occurs gradually over 90 days, ensuring adequate tissue support during the critical healing period.

### 2.3. Statistical Analysis

All patients meeting the eligibility criteria who underwent breast reconstruction and received Safil® Mesh were included in the analysis. The patient data was identified by the patient ID assigned during data entry, which incorporates the study center ID and a consecutive patient number. Study variables are presented absolute frequencies and percentages for qualitative variables.

## 3. Results

### 3.1. Patient Demographics and Other Baseline Characteristics

A total of 76 patients were included in the study, all patients received breast reconstruction surgery at Hospital Universitario de Salamanca. A summary of patient demographics and baseline characteristics are described in Table 1. As can be seen in the table, the mean age ± standard deviation of patients included in the study was 49.3±8.7 years and mean weight of 64.4±13.9 Kg, corresponding to a BMI of 24.7±5.09. From all patients that data was available (N=76) 40.79% of the patients were classified as normal healthy patients in the ASA scale, and only 5 patients were classified as ASA III, defined by having a severe systemic disease. The rest of the patients (59.21%) were classified as ASA II, patients with mild systemic disease. Most of the patients had unilateral surgery and 31.6% had bilateral surgery (counted as separate cases).

When considering the risk factors and concomitant diseases of the patients, no diabetic patient nor patient with previous aortic aneurism was included in the study sample of the Hospital Universitario de Salamanca. Only 3.1% of patients had previous pulmonary disease, 9.4% and 7.8% of the patients were in immunosuppressive or coagulation disorder treatments respectively. Additionally, most of the patients had undergone previous surgeries (67.2%) and did not present other concomitant diseases such as Chron's (87.3%). Finally, 20.3% of the patients were smokers or ex-smokers.

***Table 1.*** *Demographics data.*

| | **Salamanca (N=76 patients)** |
|---|---|
| Age | |
| N | 76 |
| Mean (SD) | 49.3 (8.7) |
| CI 95% | (47.3; 51.3) |
| Median (Min; Max) | 49.0 (30.0; 68.0) |
| P25; P75 | 43.5; 55.0 |
| Weight (Kg) | |
| N | 76 |
| Mean (SD) | 64.4 (13.9) |
| CI 95% | (61.28; 67.58) |
| Median (Min; Max) | 61.0 (46.0; 121.0) |
| P25; P75 | 61.29; 67.58 |
| Gender | |
| N | 100 |
| Female | 100 (100.0%) |
| Male | 0 (0.0%) |
| Height (cm) | |
| N | 76 |
| Mean (SD) | 161.4 (5.2) |
| CI 95% | (160.2; 162.5) |
| Median (Min; Max) | 161.0 (150.0; 172.0) |
| P25; P75 | 158.3; 164.0 |
| BMI | |
| N | 76 |

| | Salamanca (N=76 patients) |
|---|---|
| Mean (SD) | 24.7 (5.09) |
| CI 95% | (23.56; 25.86) |
| Median (Min; Max) | 23.71 (18; 44.9) |
| P25; P75 | 21.0; 27.3 |
| ASA | |
| N | 76 |
| P1 | 31 (40.79%) |
| P2 | 45 (59.21%) |
| P3 | 5 (6.58%) |
| P4 | 0 (0.0%) |

N= number of patients

## 3.2. Surgical Details and Intraoperative Complications

In most of the cases (86.9%), Safil Mesh was used for breast reconstruction following mastectomy due to breast cancer diagnosis. Open surgery was the procedure used in all patients, and all cases included in the study were elective surgeries. Mean surgery duration ± SD, considering each mama as an individual case, was 199.5 ±62.6 min [range 75 - 325 min]. Antibiotics were used in all cases in which this information was collected.

Number of Safil Meshes used is one in 60% of the cases, and two in the rest of the cases. Safil Mesh was applied in 15.9% of the cases together with a breast expander and was sutured with absorbable suture in almost every patient (97.6%).

No intraoperative complications were observed, and mean hospitalization time was 1.7 ±1.2 days [range 1 – 7 days]. Blocks and morphic drugs were used in 44.4% and 51.9% of the patients, respectively.

*Table 2. Surgery details.*

| | (N=100 Breasts) |
|---|---|
| Diagnosis | |
| N | 100 |
| Breast cancer | 89 (89%) |
| Preventive mastectomy | 5 (5%) |
| Prosthesis extrusion | 2 (2%) |
| Prosthesis infection | 1 (1%) |
| Replacement of expander for prosthesis | 3 (3%) |
| Type of surgery | |
| N | 100 |
| Elective | 100 (100.0%) |
| Urgent | 0 (0.0%) |
| Type of access | |
| N | 100 |
| Open surgery | 100 (100.0%) |
| Laparoscopic converted to open | 0 (0.0%) |
| Laparoscopic | 0 (0.0%) |

N= number of surgeries performed

## 3.3. Compliance with Study Protocol

No protocol deviations occurred during this study.

## 3.4. Postoperative Complications

Although during surgery, no complications occurred, during the follow-up, only in 11 surgeries (11%), involving 10 patients, some complication was observed within the first 90 days after surgery. No particular complication was repeatedly observed. Specifically, three cases presented prosthesis (breast implant) extrusion (3%), in two cases hematoma was observed (2%) and one patient operated for a bilateral mastectomy required transfusion (2%). Axillar cellulitis, fever and pain and erythema, prosthesis infection and NAC (nipple-areolar complex) infiltration were reported as single events.

Of note, no complication was related to the mesh by the healthcare professionals.

Reintervention was deemed necessary in 7% (7/100) of the patients, mainly due to implant infection or extrusion, not involving any mesh removal or repositioning. Only in one case (1.2%), it was reported that prosthesis was required to be changed.

*Table 3. Postoperative complications.*

| | Salamanca (N=100 Breasts) |
|---|---|
| Postoperative complications (within 90d FU) | |
| N | 100 |
| No | 87 (87%) |
| Yes | 13 (13%) |
| Type of complication | |
| N | 100 |

| | Salamanca (N=100 Breasts) |
|---|---|
| None | 88 (88%) |
| Prosthesis extrusion | 3 (3%) |
| Transfusion | 2 (2%) |
| Hematoma | 2 (2%) |
| Prosthesis infection | 2 (2%) |
| NAC (nipple-areolar complex) infiltration | 1 (1%) |
| Axillar cellulitis | 1 (1%) |
| Fever, pain and erythema requiring change of prosthesis | 1 (1%) |

## 4. Discussion

The present study aimed to evaluate the safety and efficacy of Safil® Mesh in breast reconstruction surgeries performed at Hospital Universitario de Salamanca. In this center, Safil® Mesh is primarily used for post-mastectomy breast reconstruction, accounting for 92.2% of all cases. While a single-arm retrospective study can provide valuable preliminary safety data, it lacks a control group, limiting the ability to draw causal inferences or compare outcomes against standard treatments. Additionally, its retrospective nature may introduce selection bias and incomplete data collection. Consequently, findings should be interpreted with caution and ideally confirmed through prospective, controlled studies.

The study included 76 patients, with a mean age of 49.3 years and a mean BMI of 24.2. The majority of patients were classified as ASA II, indicating mild systemic disease, with a smaller proportion classified as ASA I and ASA III. This distribution reflects a typical patient population undergoing elective breast reconstruction, suggesting that the findings are generalizable to similar clinical settings [8].

Safil® Mesh was predominantly used for breast reconstruction following mastectomy due to breast cancer, accounting for 89% of cases. The mean surgery duration was approximately 200 minutes, and antibiotics were administered in all cases where data was available. The use of Safil® Mesh in combination with a breast expander was noted in 15.9% of cases, and absorbable sutures were used in nearly all patients. Importantly, no intraoperative complications were observed, indicating that the use of Safil® Mesh is safe and does not increase the risk of complications during surgery.

From a health economics and institutional perspective, these safety outcomes are particularly relevant. In environments focused on cost containment and efficient resource allocation, synthetic meshes represent a potentially advantageous alternative to ADMs, which are associated with substantially higher acquisition costs. Demonstrating low complication rates—including infection, implant loss, and reintervention—is critical, as these events directly influence overall treatment costs, length of hospital stay, and the need for additional procedures [9-12]. Therefore, a favorable safety profile supports the use of synthetic meshes as a cost-effective option without compromising patient outcomes.

The literature consistently reports favorable aesthetic outcomes with the use of acellular dermal matrices (ADMs) in breast reconstruction, and growing evidence indicates that synthetic meshes can achieve comparable, high-quality aesthetic results, as demonstrated by [13].

During the follow-up period, postoperative complications were observed in 13.6% of surgeries, involving 10 patients. The most common complications included prosthesis extrusion (3%), infection (2%) and hematoma (2%). Notably, no complications were directly attributed to the use of Safil® Mesh, and reintervention was required in 8% of patients, primarily due to implant-related issues rather than mesh-related problems. These findings suggest that Safil Mesh is a reliable material for breast reconstruction, with a low incidence of mesh-related complications.

In the largest long-term observational study to date involving patients who underwent single-stage direct-to-implant reconstruction with a synthetic absorbable mesh, the authors concluded that synthetic absorbable mesh represents a safe alternative to ADMs in prosthetic breast reconstruction and provides stable outcomes with significant cost savings. In their cohort of 227 patients (376 mastectomies) [13] reported an infection rate of 2.1%, similar to the 2% reported in the present study, a capsular contracture rate of 4.8% (1% in the present study), and an implant loss (removal without replacement) rate of 4.5% (3% in the present study). Therefore, the complication rates associated with absorbable polyglactin mesh in prosthetic single-stage breast reconstruction in that study fall at the lower end of the ranges reported for ADM-based reconstructions in the literature.

The results of this study are consistent with previous research indicating that absorbable meshes, such as Safil® Mesh, provide adequate support during the early stages of healing while minimizing long-term foreign body reactions [12, 14]. The absence of intraoperative complications and the low rate of postoperative complications further support the safety profile of Safil® Mesh. Additionally, the use of absorbable sutures aligns with current best practices in reconstructive surgery, promoting optimal healing and reducing the risk of chronic inflammation.

## 5. Conclusion

In conclusion, the use of Safil® Mesh in breast reconstruction surgeries at Hospital Universitario de Salamanca demonstrated a favorable safety profile, with no intraoperative complications and a low incidence of postoperative complications. These findings support the continued use of Safil® Mesh as a viable option for breast reconstruction, contributing to improved patient outcomes and advancing the field of reconstructive surgery. Further research is warranted to confirm

these results in larger, multi-center studies and to explore long-term outcomes.

## Abbreviations

| | |
|---|---|
| ADMs | Acellular Dermal Matrices |
| PGA | Polyglycolic Acid |
| NAC | Nipple-Areolar Complex |

## Author Contributions

**Pedro Antonio Montalban-Valverde:** Investigation, Writing – review & editing

**Monica Pujol-Canadell:** Formal Analysis, Writing – original draft

**Marta Valor-Soteras:** Project administration, Writing – original draft

**Irene Fita-Esteban:** Project administration, Writing – review & editing

**Marta Eguia-Larrea:** Investigation, Writing – review & editing

**Luis Munoz-Bellvis:** Conceptualization, Investigation, Writing – review & editing

## Conflicts of Interest

Monica Pujol-Canadell, Marta Valor-Soteras, and Irene Fita-Esteban are employees of B. Braun Surgical S. A., the manufacturer of the device evaluated in this study. MPC, MVS and IFE declare this potential conflict of interest.

## References

[1] Morad, A., Johnson, K., Bate, S., Birkby, I., Schofield, S., & Harvey, J. (2024). Ten-year trend analysis of breast cancer, oncoplastic, and reconstructive breast surgery in a single institution (2010–2019): What has not changed? *Breast Cancer Research and Treatment, 206*, 155–162. https://doi.org/10.1007/s10549-024-07294-x

[2] Choi, Y. S., You, H. J., Lee, T. Y., & Kim, D. W. (2023). Comparing complications of biologic and synthetic mesh in breast reconstruction: A systematic review and network meta-analysis. *Archives of Plastic Surgery, 50*(1), 3–9. https://doi.org/10.1055/a-1964-8181

[3] Clark, R. C., Reese, M. D., Attalla, P., Camacho, J. M., Hirpara, M. M., DeLong, M. R., et al. (2024). A systematic review and meta-analysis of synthetic mesh outcomes in alloplastic breast reconstruction. *Aesthetic Surgery Journal Open Forum, 6*, ojae066. https://doi.org/10.1093/asjof/ojae066

[4] Hu, Y., Diao, W., Wen, S., Kpegah, J. K. S. K., Xiao, Z., Zhou, X., et al. (2024). The usage of mesh and relevant prognosis in implant breast reconstruction surgery: A meta-analysis. *Aesthetic Plastic Surgery, 48*, 3386–3399. https://doi.org/10.1007/s00266-024-03879

[5] Logan Ellis, H., Asaolu, O., Nebo, V., & Kasem, A. (2016). Biological and synthetic mesh use in breast reconstructive surgery: A literature review. *World Journal of Surgical Oncology, 14*, 236. https://doi.org/10.1186/s12957-016-0874-9

[6] Zhang, T., Ye, J., & Tian, T. (2024). Implant-based breast reconstruction using a titanium-coated polypropylene mesh (TiLOOP® Bra): A systematic review and meta-analysis. *Aesthetic Plastic Surgery, 48*, 925–935. https://doi.org/10.1007/s00266-023-03500

[7] Hackley, L. A. (2024). Bridging gaps in chest wall reconstruction: A retrospective comparative analysis of acellular dermal matrices and synthetic meshes. *Texas A&M Medical Student Grand Rounds Proceedings*.

[8] Amato, B., Moja, L., Panico, S., Persico, G., Rispoli, C., Rocco, N., et al. (2012). *Shouldice technique versus other open techniques for inguinal hernia repair*. Cochrane Database of Systematic Reviews, 123(2), 121. https://doi.org/10.1002/14651858.CD001543.pub4

[9] Sbitany, H., & Serletti, J. M. (2011). Acellular dermis–assisted prosthetic breast reconstruction: A systematic and critical review of efficacy and associated morbidity. *Plastic and Reconstructive Surgery, 128*(6), 1162–1169. https://doi.org/10.1097/PRS.0b013e318230c55b

[10] Tanna, N., Wan, D. C., Kawamoto, H. K., Bradley, J. P., & Griffin, M. F. (2013). Comparison of expander/implant breast reconstruction with and without acellular dermal matrix: A meta-analysis. *Plastic and Reconstructive Surgery, 132*(2), 256–265. https://doi.org/10.1097/PRS.0b013e31829586bc

[11] Hallberg, H., Rafnsdottir, S., Selvaggi, G., Strandell, A., & Samuelsson, A. (2019). Clinical outcomes and cost analysis of synthetic mesh versus acellular dermal matrix in implant-based breast reconstruction. *Journal of Plastic Surgery and Hand Surgery, 53*(2), 108–113. https://doi.org/10.1080/2000656X.2018.1516407

[12] Lo Torto, F., Ruggieri, M., Pagnoni, M., et al. (2020). The use of synthetic mesh in breast reconstruction: A systematic review. *Annals of Medicine and Surgery, 60*, 547–555. https://doi.org/10.1016/j.amsu.2020.11.003

[13] Faulkner HR, Shikowitz-Behr L, McLeod M, Wright E, Hulsen J, Austen WG Jr. (2020). The Use of AbsorbableMesh in Implant-Based Breast Reconstruction: A 7-Year Review. Plast Reconstr Surg. 146(6): 731e-736e. https://doi.org/10.1097/PRS.0000000000007384

[14] Deeken, C. R., & Matthews, B. D. (2012). Characterization of the mechanical strength, resorption properties, and histologic characteristics of a fully absorbable material (poly-4-hydroxybutyrate–P4HB) in a porcine model of hernia repair. *ISRN Surgery, 2012*, 238067. https://doi.org/10.5402/2012/238067