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Reconstructive breast surgery with partially absorbable bi-component Seragyn® BR soft mesh: an outcome analysis

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Abstract

Objective Synthetic meshes and acellular dermal matrices are increasingly used in implant-based breast reconstruction. The objective of this study was to determine the incidence and severity of complications following the implantation of the partially absorbable bi-component soft mesh SERAGYN® BR and assess risk factors for adverse operative outcomes.

Methods A retrospective clinical study was performed: The SERAGYN® BR soft mesh was utilized in 148 operations (skin-sparing mastectomy, nipple-sparing mastectomy, breast-conserving surgery, and secondary reconstruction after mastectomy) in four different institutions in Germany from June 2012 to February 2014. We analyzed whether the results were affected by tumor morphology (e.g., grading), patient characteristics and comorbidities, previous surgery or therapies, and use of alloplastic materials.

Results The SERAGYN® BR soft mesh was successfully implanted in 131 of 148 operations. The rate of reconstructive failure was 11.5%. The most common complication was seroma (25.7%), followed by hematoma and skin infection (each 14.2%). Wound-healing issues were detected in 13.5% cases, secondary wound infections in 10.8%. 83.8% of operations had no severe complications. Independent predictors for reconstructive failure were wound-healing issues, nipple- or skin necrosis, wound- or skin infections, a high volume of excised tissue, hematomas, seromas, and sentinel lymph node excisions. A higher body mass index was correlated with a higher rate of infection.

Conclusion SERAGYN® BR mesh can be used successfully in breast reconstructive surgery. Rates of major complications or reconstructive failure are comparable to the use of other synthetic or biological meshes.

Keywords Breast · Surgery · Mesh · Reconstruction · Cancer

Abbreviations

DIEP	Deep inferior epigastric perforators
ADM	Acellular dermal matrix
TRAM	Transverse rectus abdominis muscle
GCP	Good clinical practice
SLNE	Sentinel lymph node excision
LNE	Lymph node excision

Introduction

The recommendations for diagnosis and treatment of breast cancer in Germany are summarized in the S3 guidelines (AWMF) [1]. They state that patients undergoing breast surgery should be informed about potentially feasible available reconstructive techniques. Modern breast surgery can offer autologous breast reconstruction as well as

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alloplastic implant-based techniques to patients following a mastectomy.

The beginning of autologous breast reconstruction was described at the end of the 19th century. In 1896, Iginio Tansin reported on the first autologous muscle flap reconstruction, where he used a muscle–skin flap of the Latissimus dorsi muscle [2].

Autologous reconstruction including pedicled and microsurgical techniques and perforator-based flaps is now standard surgical procedures in Europe and the United States [3]. To reconstruct or remodel the breast, muscle flaps as well as muscle sparing- and muscle-free flaps are used. The transplantation of the tissue can be conducted as free- or pedicled flaps. Techniques in breast reconstruction which utilize abdominal tissue are, for example, the DIEP (deep inferior epigastric perforators) and TRAM (transverse rectus abdominis muscle) flaps. Skin and subcutaneous fat and vessels are removed from the lower abdominal wall to rebuild the breast as a free and muscle-free flap. Vessels are microsurgically reconnected to vessels of the thoracic wall. In contrast, the TRAM flap consists of both skin and abdominal subcutaneous fat in addition to a part of the Musculus rectus abdominis. Another muscle transferring flap is the Latissimus dorsi flap, where the muscle is removed from the back to reconstruct the ipsilateral breast (pedicled flap) [4].

Autologous breast reconstruction is commonly used as modality of breast reconstruction following mastectomy. Over the last 20–30 years, there has been a shift towards higher rates of primary and secondary reconstructive procedures [5, 6]. The number of implant-based reconstructions increased significantly and surpassed the above described autologous methods as the leading reconstructive modality in the United States in 2002 [5].

The safety and choice of shapes, textures, and styles of implants have improved enormously and provide a variety of choices for the patients. Implants and expanders are used for one- or two-stage post-mastectomy breast reconstruction and in skin-sparing or nipple-sparing mastectomy which have been recently proven to be in accordance with oncological guidelines [6].

An implants' cranial- and medial segments is usually covered by the pectoralis muscle, whilst the lower and lateral segments are only covered by skin and thinned out subcutaneous fat. The result can be impaired by instability of the implant and skin erosion [7]. Solutions for stabilization of the lower segment are biological- and synthetic meshes which are utilized as additional coverage. These meshes are fixed on the lower edge of the pectoralis muscle. These meshes are either it is fixed to the thoracic wall in the inframammary fold or are draped around the implant [8].

Besides biological matrices made out of porcine-, bovine-, or human-derived material, different synthetic meshes are available. The meshes differ in material, strength, weight, elasticity, and rate of resorption [7]. Biological- and synthetic meshes are increasingly used in reconstructive breast surgery. Rates of complications using these matrices and meshes vary between 12 and 50% [9–11]. Most reported complications are seromas, hematomas, infections, skin or nipple necrosis, and capsular contractures which may result in reconstructive failure.

This study was initiated to evaluate the application of SERAGYN® BR (SERAG-WIESSNER GmbH & Co. KG, Naila, Germany) bi-component soft mesh in (implant-based) breast surgery and reconstruction. The aim of this surgical trial was to answer questions concerning the quantity and the severity of complications, to identify patient related risk factors and to evaluate successful applications of SERAGYN® BR in reconstructive breast surgery.

SERAGYN® BR mesh is part absorbable polyglycol acid–caprolactone (resoprtion within 90–120 days) and part non-absorbable polypropylene. In in vitro investigations, SERAGYN® BR mesh showed good biocompatibility and no relevant cytotoxicity [12]. This post-market study records a basic and multicenter data collection and discusses the complications and limitations of SERAGYN® BR to guide patient selection.

Patients and methods

This retrospective cohort study evaluates the partially absorbable bi-component SERAGYN® BR soft mesh (SERAG-WIESSNER GmbH & Co. KG, Naila, Germany) in implant-based breast surgery and reconstruction. The study was conducted in line with good clinical practice (GCP) and declaration of Helsinki.

Seragyn® BR

SERAGYN® BR is a soft mesh implant made of polypropylene and polyglycolic acid–caprolactone. It is placed into the breast following surgical procedures, thereby interrupting its natural integrity and allowing for greater postoperative stability whilst stimulating healing. Following the resorption of hydrophilic polyglycolic acid–caprolactone after 90–120 days, only the polypropylene filaments remain [13].

Study design and patient selection

This retrospective cohort study was performed at four German breast centers under the supervision and care of four fellowship-trained surgeons. The institutions were the St. Gertrauden Krankenhaus Berlin, the Universitätsmedizin Greifswald, the Kreiskrankenhaus Grevenbroich, and the Klinikum rechts der Isar Munich. Data were reviewed from a retrospectively mined databases of all patients who received SERAGYN® BR from June 2012 until February 2014 at

these institutions. Adult female patients between the age of 18–77 years with an ECOG performance status from 0 to 2 and surgical clearance were considered viable study candidates. Patients with metastatic breast cancer, two or more prior breast surgeries, a diagnosis of an infectious disease, untreated diabetes, a low platelet count (< 100.000/µl), low hemoglobin (< 9.5 g/dl) or neutropenia (< 1.500/µl) as well as pregnant or breast feeding women were excluded.

Surgery

Indication for the reconstructive procedure with SERAGYN® BR was based on the guidelines of the German consortium of gynecologic oncology ('Arbeitsgemeinschaft gynäkologische Onkologie e.V.') [14]. Depending on the oncologic and anatomic predispositions of the individual patient and their expectations, a variety of primary operations were undertaken. Depending on the sub-pectoral or epi-pectoral implant placement, SERAGYN® BR covered the implant partially (sub-pectoral placement) or in its entirety (epi-pectoral placement). In women who received either breast-conserving surgery or a reduction mammoplasty, SERAGYN® BR was utilized as a supportive layer for the remaining breast tissue.

The study evaluated postoperative seroma, hematoma, skin infection, skin necrosis, nipple necrosis, wound-healing issues, implant dislocation, secondary wound infection, and capsular fibrosis. Complications were classified as follows:

1. Minor complication if treatment was conservative.
2. Moderate complication if intervention was needed.
3. Major complication if surgical revision was needed.

Every complication was individually documented.

Radiotherapy

The indications for radiotherapy were based on the guidelines of the German consortium of gynecologic oncology [14].

Chemotherapy

The indications for chemotherapy were based on the guidelines of the German consortium of gynecologic oncology [14]. Chemotherapy was either neoadjuvant or adjuvant.

Data collection

The following data points were collected: patient demographics, smoking status, past surgical history, comorbidities, and surgical details. The tumor grade, TNM classification, tumor size, lymph node status, and surgical margins were documented. The details of pre- and postoperative care with regard to radio- and chemotherapy were recorded. If wound drainage was required in the postoperative period, the length of time it remained was documented.

The primary outcomes collected for this study were the rates of complications and implant removals. Complications were defined as a postoperative diagnosis of any of the following: seromas, hematomas, post-surgical bleeding, wound-healing impairments, skin and wound infections, skin or nipple necrosis, implant dislocations, and capsular fibrosis. The treatment and results of these adverse outcomes were recorded. If implant removal became necessary, the patient's outcome was defined as reconstructive failure.

Statistical analysis

The non-parametric Mann–Whitney *U* test and Fisher's exact test were used for comparison between the groups of patients. Univariate analysis for all potential risk factors was conducted using two-tailed independent student's *t* tests for continuous variables and Chi-square or Fisher's exact test for categorical and discrete variables. If more than three groups were compared, a *p* value correction after Benjamini and Hochberg was performed. A multivariate binary logistic regression was used to assess confounding factors and distinguish independent predictors of primary and secondary outcomes. In analyses of variance (ANOVA) with metric, normally distributed target variables and several states of expression, post hoc tests were performed. Bonferroni correction was carried out if more than three groups were compared. Statistical analysis was performed using SPSS 20.0 (IBM, Armonk, New York).

Results

Patient characteristics

In 119 patients, SERAGYN® BR was implanted as a part of breast surgery from June 2012 until February 2014 at the four participating institutions. A total of 148 breasts were operated on. The median follow-up was 7 months (range 0.5–28). The median age of the patients was 49 years (range 18–77 years). The median BMI was 24 kg/m^2 (range 19–44). 15.1% of the patients were active smokers. 14.3% were diagnosed with hypertension, 10.1% with a psychiatric depression, 3.4% with diabetes mellitus, 2.5% with hemostasis disorders, and 1.7% with coronary heart disease. The patient characteristics and the comorbidities are listed in Table 1.

In 42.6% of all cases, the previous breast operations had been performed, and the majority of which were breast-conserving surgeries. 17.8% of cases had previously received a sentinel lymph node excision and 4.8% an axillary lymph

Table 1 Patient characteristics and comorbidities

Patients characteristics and comorbidities	Value	
Number of patients	119 patients	(100%)
Number breast surgeries	148	
Follow-up in months	7	(Range 0.5–28.0)
Age in years median	49	(Range 18–77)
BMI (body mass index) kg/m^2 median	24	(Range 19–44)
Smokers	18 patients	(15.1%)
Arterial hypertension	17 patients	(14.3%)
Psychiatric depression disease	12 patients	(10.1%)
Coronary heart disease	2 patients	(1.7%)
Impaired hemostasis	3 patients	(2.5%)

Table 2 Indications for surgical therapy

Indication for surgical therapy	Surgeries	
Therapeutic	112	(75.7%)
Prophylactic	20	(13.5%)
Aesthetic	16	(10.8%)
Total	148	(100%)

node dissection. 13.5% of cases had received neoadjuvant chemotherapy and 4.1% prior radiotherapy. 6.1% of cases had previously received a tissue expander.

Treatment details

The indication for surgery was primarily breast cancer (75.5%). 13.5% of all cases underwent a mastectomy prophylactically due to BRCA-1 or BRCA-2 mutations. 10.8% of cases received cosmetic breast surgery (Table 2). Of these 16 cases of aesthetic procedures, there were 12 primary, three secondary, and one tertiary reconstruction.

The most common procedures were nipple-sparing mastectomies with implant placement (52.7%) followed by skin-sparing mastectomies (10.1%). 25.7% of all cases received a sentinel lymph node excision (SLNE), and 21.6% required axillary lymph node excision. The median amount of breast tissue removed was 292.5 g (range 0–1350 g).

Most operations (43.9%) showed no tumor containing breast tissue (prophylactic surgeries and aesthetic surgeries). Ductal carcinoma in situ (DCIS) was found in 14.2%. Tumor stage pT1a-c was found in 20.9%, and 12.2% of cases were stage pT2. Most cases were classified as pN0 (72.3%). The pN1 stage was diagnosed in 8.8%, whilst the lymph node status was unknown in an additional 10.8% of all cases. The grading of breast cancer was G1 in 7.1%, G2 in 28.5%, and G3 in 16%. In 8.8% of cases, reoperation due to tumor-positive surgical margins was necessary.

86.5% of cases ($n = 128$) received a primary reconstruction immediately following the mastectomy, whilst 12.2% ($n = 18$) received a secondary reconstruction in a separate procedure. In 1.4% ($n = 2$), breast reconstruction was performed in a third procedure. In 79.1% of cases implants (median volume of 360 cc), and in 7.4% of cases expanders (median volume of 310 cc) were used. Textured implants were used more commonly than smooth implants (73.8 vs. 1.9%). The most commonly used implants were manufactured by Allergan (38.4%) (Allergan, Frankfurt a.M., Germany), Mentor (34.5%) (Mentor Worldwide LLC, Santa Barbara, USA), Polytech (6.9%) (POLYTECH Health & Aesthetics GmbH, Dieburg, Germany), and Sebbin (1.4%) (SEBBIN Deutschland GmbH, Ratingen, Germany). In 13.5% cases, breast surgery was performed without implants or expanders.

In 80.3% of all cases, the SERAGYN® BR size was 22.5 × 14.5 cm. 3.4% of the nets were slightly larger at 28.5 cm × 17.5 cm, whilst in the remaining cases, nets were smaller.

In 35.2% of all cases, chemotherapy was performed. 14.3% of the cases had neoadjuvant chemotherapy; in 20.9% of the cases, chemotherapy was performed in the adjuvant setting.

A total of 17.6% received radiotherapy. 1.4% of all cases had deep hyperthermia treatments.

Complications

In 38 cases (25.7%), postoperative seroma was diagnosed, 11 (7.4%) of which had to be drained, and two (1.4%) of which needed surgical intervention.

In 21 cases (14.2%), a postoperative hematoma or bleeding occurred. Four of these cases (2.7%) needed interventions, whilst two cases (1.4%) required revision surgery. In 127 cases, no additional surgery (85.8%) was necessary.

We detected 21 postoperative skin infections (incidence of 14.2%). In this group, seven revision surgeries (4.7%) had to be performed. Eight cases (5.4%) were treated conservatively. Six cases (4.6%) underwent other interventions.

136 of all cases had no skin necrosis (91.9%). 10 revision surgeries (6.8%) were performed due to skin necrosis. Out of 15 (10.1%) documented nipple necroses, five (3.4%) were treated conservatively, and 10 (6.8%) had to undergo surgery.

In 20 (13.5%) of the documented cases in this study, wound-healing issues were detected. 16 had to undergo reoperation. In 128 cases (86.5%), no wound-healing issues were found.

In addition, 9 (6.1%) cases of postoperative implant dislocation which resulted in three (2.0%) reoperations were documented.

Capsular fibrosis was detected in two cases (1.4%) at an average follow-up of 7 months.

Overall, 22.9% of the cases required one (18.2%) or more reoperation. The SERAGYN® BR had to be removed due to infection in 11 cases (7.4%), due to skin necrosis in one case (0.7%), because of wound-healing issues in five cases (3.4%) and due to R1 resection in six cases (4.1%). As the explantation of SERAGYN® BR in R1 situation does not count as reconstructive failure, the rate of reconstructive failure amounts in 17 cases (11.5%) (Table 3).

Our data show simultaneous appearance of two severe complications in eight cases (5.4%) and another eight cases showed 3 or more severe complications (5.4%). In 124 operations, there were no severe complications. Overall, 131 of 148 operations with SERAGYN were performed successfully (88.5%) (Table 3).

Risk-factor analysis

Women who were smokers had higher rates of skin necrosis (Spearman's ρ 0.190, $p < 0.05$). Other predictors for skin necrosis were skin infection, sentinel lymph node excision (SLNE), seroma, higher tumor grade, higher tumor stage, and higher volume of removed breast tissue. The median amount of removed breast tissue in the group with severe complications was 440 g. For comparison, in the whole study population, the median amount of removed tissue was 292.5 g. Occurrence of seroma correlated with the amount of time a drain was required (Spearman's ρ 0.165, $p < 0.05$), psychiatric depression disease (Spearman's ρ 0.161, $p < 0.05$), and SLNE (Spearman's ρ 0.337, $p < 0.005$). Cases with severe complications showed a drain duration of 10.1 days on average. Looking at the overall study population drains were removed after 6.2 days on average. SLNE was found to increase the appearance of all examined complications including reconstructive failure and reoperation. Lymph node excision increases the incidence for implant dislocation (Spearman's ρ 0.175, $p < 0.05$). Strong predictors for wound-healing problems were skin infection (Spearman's ρ 0.496, $p < 0.0001$), skin necrosis (Spearman's ρ 0.623, $p < 0.0001$), and nipple necrosis (Spearman's ρ 0.422, $p < 0.0001$).

Wound-healing problems and skin necrosis were strong predictors (Spearman's ρ 0.570, $p < 0.0001$ and 0.535, $p < 0.0001$) for reoperation. Skin infection ($p < 0.0001$), nipple necrosis ($p < 0.0001$), SLNE ($p < 0.005$), and wound-healing issues ($p < 0.0001$) also increased the incidence of reoperation significantly with a correlation coefficient Spearman's ρ between 0.3 and 0.4. The risk of hematoma or postoperative secondary bleeding was increased by a higher volume of removed tissue and SLNE (Spearman's $\rho = 0.178$, $p < 0.05$ and Spearman's $\rho = 0.164$, $p < 0.05$). Hematoma itself showed a correlation with wound-healing issues, secondary wound-healing issues, reoperation, and reconstructive failure. Independent predictors for skin infection were seroma, SLNE, volume of removed tissue, and BMI. Skin infection was found to be the strongest predictor for nipple necrosis (Spearman's $\rho = 0.34$, $p < 0.0001$). Overall, skin infection ($p < 0.0001$), skin necrosis ($p < 0.0001$), wound-healing issues ($p < 0.0001$) as well as secondary wound infection ($p < 0.0001$) significantly increased the risk of reconstructive failure (Spearman's ρ between 0.45 and 0.67).

Table 3 Major complications, reoperation, and reconstructive failure

Number of major complications per case		
No major complication	124	(83.8%)
1 major complication	8	(5.4%)
2 major complications	8	(5.4%)
3 or more major complications	8	(5.4%)
Removement of mesh in reoperation		
Reason for removement of mesh	23	(15.5%)
Infection	11	(7.4%)
Skin-/nipple necrosis	1	(0.7%)
R1 resection	6	(4.1%)
Wound-healing issues	5	(3.4%)
Reconstructive failure	17	(11.5%)

Discussion

Implant-based breast reconstruction is increasingly used in oncological, prophylactic, and aesthetic breast surgery. Meshes and biological matrices help to stabilize the implant pocket, avoid high-riding implants, cover the implant in the caudal segment, and define the mammary fold. There are already several studies showing the advantages and complication rates of acellular dermal matrices (ADM) in reconstructive surgery [15–18]. The reported infection rate in ADM use varies between 0 and 35.8% [8]. A meta-analysis by Kim et al. [19] found a 5.3% rate of infection in ADM use, whilst a large retrospective study by Ibrahim et al. [20] identified a 3.3% infection rate. In our study, the rate of skin infections that resulted in interventions or operations was 4.7%. A large study using a synthetic, non-absorbable mesh (TiLOOP) showed an overall infection rate of 6.1, 1.7% of which needed revision [21]. Our rates of reconstructive failure or major complications appear to be comparable to the results of this multicenter study. The rate of major complications was described with 13.4%, whilst 8.7% of the patients lost their implant [21]. Loss of implant for ADMs is reported in literature with a wide range between 0 and 33.3% [8].

The risk of developing a capsular fibrosis is described to be lower in breast reconstruction using biological meshes than synthetic meshes [8]. In our study, the risk for capsular fibrosis is remarkably low at 1.4%. This may have resulted from the good biocompatibility of SERAGYN® BR [12]. Nevertheless, our relatively short follow-up has to be critically considered. Capsular fibrosis may develop after a long time period following the original surgery, making our relatively low median follow-up time too short to record a true incidence.

Seroma is the most common complication in our study (25.7%). Dieterich et al. [21] showed a rate of seroma in titanium-coated polypropylene mesh of 4.8%. Becker et al. [22] found seroma as a complication in their study using TIGR® Matrix Surgical Mesh in only 1.8%. Rates of seroma in use of ADMs range between 1.5 and 24.3%, with one large study with a rate of 4.8% [8, 19]. The rate of seroma in our study is comparatively higher. However, it is important to differentiate whether a seroma needs intervention or not. In our study, only 1.4% of seromas ended up requiring an intervention, which is comparable to the TiLOOP multicenter study of 2013 of Dieterich et al. [23] without a doubt, the variable definition of seroma in different centers plays a role. In addition, our study's high rate of SLNE and lymph node excision (LNE) may contribute to the relatively high incidence of this complication in our patient pool. Both SLNE and LNE are a known risk factors for seroma.

We detected a correlation between hematoma formation and an increased amount of tissue removed as well as SNLE. It is plausible that a larger wound surface increases the risk of a bleeding-related complication. The correlation between LNE and the development of hematoma has previously been described by Madsen et al. [24].

Sixteen patients in our study had 2 or 3 severe complications, and were subsequently more likely to suffer reconstructive failure. We hypothesize that more than two severe complications increase the risk of reconstructive failure. A decrease in the rate of complications through optimized perioperative management, including appropriate postoperative antibiotics, drainage, and compressive wound dressings may lead to a lower rate of implant loss.

We detected obesity as a risk factor for patient-associated complications, particularly for infections. Obesity is a known risk factor for infections in surgery. For this reason, select authors recommend reconstruction with autologous technique in obese patients or alternatively weight loss under a BMI of 30 kg/m^2 [25, 26]. On the other hand, the subcutaneous tissue in obese patients is generally thicker than in thin patients, allowing for better blood circulation. To gather data on this, it would be interesting to conduct a study measuring the thickness of the subcutaneous tissue intraoperatively and correlate them to patient outcomes.

Smoking was detected as a risk factor for skin necrosis in our study. Besides obesity and smoking, other known risk factors for higher rates of complication or even reconstructive failure such as diabetes or hypertension were not detected as independent risk factor in our study [27, 28]. This may have resulted from the relatively low number of patients with these diseases included in our study population.

The major shortcomings of this retrospective study are the relatively small sample size and the lack of a control group. Since a minimum of a 2-year follow-up has become the gold standard, the relatively short follow-up in our cohort is a major limitation. The multicenter approach of the study is to be seen as an advantage compared to single-surgeon reports. Well-designed prospective studies with control groups and longer follow-up periods should be performed.

Conclusion

In this analysis of bi-component SERAGYN® BR mesh, it proved to be a successful addition to breast reconstructive surgery. Rates of major complications or reconstructive failure were found to be comparable to similar materials in use, even though the rates of conservatively treated complications such as seroma were somewhat higher. Our evaluation may help guide future surgical decision making regarding the use of SERAGYN® BR mesh and improve patient selection and operative outcomes.

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Compliance with ethical standards

Conflict of interest JU Blohmer, A Machleidt, J Kueper, N Schmidt-Feuerheerd, G von Waldenfels, S Dittmer, and E Klein no conflict of interest. Ohlinger S and Paepke S Honoraria and support for traveling expenses and training until 2015 by SERAG-WIESSNER GmbH & Co. KG, Naila, Germany.

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