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Retrospective Study of Radiotherapy Impact on the Outcome of Material-assisted Implant-based Subpectoral Breast Reconstruction

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Abstract. *Background/Aim: Synthetic meshes (SMs) and acellular dermal matrices (ADMs) are used in reconstructive breast surgery. In the absence of prospective comparative studies, the identification of differences relies on retrospective analyses. Patients and Methods: Our analysis focused on the impact of pre- and postoperative radiotherapy (RTX) and material-related differences. The analysis included 281 breast cancer patients (362 breasts) after nipple- and skin-sparing mastectomy with subpectoral implant insertion. Results: Overall, the implant loss rate was 23.1% using porcine ADM, 7% using partially resorbable SM (prSM), and 5.6% using non-resorbable SM (nrSM). After RTX, the implant loss rate was 56.3% with ADM, 13% with prSM and 13.2% with nrSM. The ADM group showed a significant effect of RTX on the postoperative seroma rate, wound infections, and implant loss rate. When prSM was used, RTX showed no significant effect. When using the nrSM, RTX significantly influenced complication rates regarding wound infections and implant loss. Conclusion: In material-assisted breast reconstructions with pre- or post-operative RTX, there is a significantly higher implant loss rate when using porcine ADM compared to SM.*

In reconstructive breast surgery, heterologous materials, acellular dermal matrices (ADM), and synthetic meshes (SM) with different resorption behaviors are used to improve implant stability and create a protective or covering layer between the implant and the skin (1, 2).

Since 2011, the guidelines of the Gynecologic Oncology Working Group (Arbeitsgemeinschaft Gynäkologische Onkologie, AGO) have considered the use of SM and ADM to be equally advisable for implant-based breast reconstruction after nipple-sparing subcutaneous mastectomy (NSM/SSM) (AGO +, LoE 2b, GR B). Because of the lack of prospective comparisons of the materials, which differ greatly in their properties, no material-specific recommendations for use are given. The participation in studies or registries is recommended (3).

For years, subpectoral implant placement was considered the standard procedure for implant-based reconstructions (2, 4, 5). Only with newly developed material forms such as the pocket forms of ADM and SM, and in response to the intensive discussion about the BIA-LCAL problem and the associated change to smooth-walled or microtextured implants, has there been a strong national and international trend toward a change to prepectoral implant placement (6).

Surgical technique. The present evaluation refers exclusively to patients with subpectoral implant placement. The surgical technique for subpectoral implant placement is to dissect the pectoralis muscle caudally and partially at its medial insertion and to cover the implant cranioventrally by the muscle. To cover primarily the caudolateral pole, various ADMs or SMs are used as interposition devices.

If primary reconstruction is not possible or not desired, secondary reconstruction can be performed as delayed-immediate or interval reconstruction. In delayed-immediate reconstruction, an expander is initially used, with a later change to the final implant. In interval reconstruction, the breast is reconstructed only after any adjuvant therapy has been performed.

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Key Words: Breast reconstruction, implant-based, radiotherapy, acellular dermal matrices, synthetic meshes.

Materials. The purpose of this analysis was to highlight relevant material-related differences in otherwise identical surgical techniques with the aim of progressively improving reconstructive breast surgery procedures. Implants from Allergan (n=91), Mentor (n=31), Polytech (n=14), and Sebbin (n=226) were used. One ADM and two synthetic SMs that differed in their resorbability, which were used in the Greifswald University Women's Hospital during the study period, were retrospectively analyzed:

– the porcine acellular dermis Strattice (Allergan (LifeCell™ in the past), Illinois, U.S.A.)
– the pr two-component mesh SERAGYN® BR (SERAG-WIESSNER, Naila, Germany)
– the nr polypropylene mesh TiLOOP® Bra (pfm medical ag. Cologne, Germany)

The interposition device Strattice is made of porcine starting cell clusters. Cellular elements such as the alpha-galactose antigen were minimized, and DNA components were removed. This should lead to a reduction of xenogeneic rejection reactions while maintaining an intact matrix (7).

The prSM SERAGYN BR consists of a non-resorbable polypropylene and a resorbable polyglycolic acid – caprolactone – filament portion, which should be resorbed after 90 to 120 days. This reduces the mesh weight by one third, which should result in a softer implant bed (8).

The nrSM interposition device TiLOOP BR consists of monofilament polypropylene threads with a covalent coating of titanium oxide. This is expected to result in improved biocompatibility, reduced rejection, and accelerated wound healing (9).

RTX and reconstruction. RTX has been reported in the literature as a risk factor for postoperative complications associated with breast reconstruction after mastectomy. Currently, studies on the impact of RTX on postoperative complications are available for the Strattice interposition device (n=8) (5, 10-16) and for the SM (n=2) (5, 17). Since no comparative study exists to date between the three interposition devices regarding the impact of preoperative RTX (after breast-conserving therapy) and postmastectomy RTX on the outcome of breast reconstructions, the aim of this retrospective analysis was to explore this relationship.

Patients and Methods

Between 11/2010 and 7/2017, 281 patients at the Breast Center of University Medicine Greifswald underwent nipple- and skin-sparing mastectomy with immediate reconstruction with subpectoral material-assisted implant insertion. The parameters defined for the evaluation were retrospectively obtained from patient records and analyzed with SPSS version 22, IBM, at the Institute of Community Medicine in Greifswald. The significance level was set at $p<0.05$. This retrospective data analysis was performed after approval was granted by the Ethics Committee of the University of Greifswald based on the Declaration of Helsinki (18).

Patient data were analyzed regarding complication rates, as differentiated between the materials and the RTX. In addition, for certain questions, patients who had received RTX were subdivided by timing of RTX in relation to the reconstructive surgery. RTX prior to reconstruction occurred after prior breast-conserving therapy, which dated back an average of 5.3 years (1 to 15 years) for patients treated with an ADM, 5.9 years (1 to 14 years) for prSM, and 6.3 years (0.9 to 18 years) for nrSM.

Indications for RTX after mastectomy in our study population were more than three affected axillary lymph nodes, a T3 stage with the risk factors of lymphangiosis, G3, age <50 years, and premenopausal (19). Postoperative RTX was performed from postoperative week 6 according to our data.

Demographic factors, patient characteristics, comorbidities, and factors characterizing the surgery were considered (Table I). The focus was on the detection of material differences between the acellular matrix and the SMs overall and within the group of SMs based on their different resorbabilities. Complications were divided into major and minor according to the internationally accepted differentiation criteria depending on the degree of invasiveness (20).

At Greifswald University Hospital, 362 material-assisted breast reconstructions were performed during the period under review (Table I); in 264 cases (72.9%) as primary and in 98 cases (27.1%) as secondary reconstruction. ADM was used in equal distribution in primary and secondary reconstructions ($p=0.213$), whereas SMs were used significantly more often in primary reconstructions ($p<0.001$).

Methodological critique. This study was a purely descriptive retrospective non-randomized single-center study.

Results

Implant loss rate (reconstructive failure). Overall, the implant failure rate was 23.1% (n=12) with ADM, 7.0% (n=8) with prSM, and 5.6% (n=11) with nrSM. Among patients who received RTX (pre- and post-operative), the implant loss rate was 56.25% (n=9) with ADM, 13% (n=3) with prSM, and 13.2% (n=5) with nrSM.

Complication rate. Overall, major complications occurred in 28.8% and minor complications in 26.9% when ADM was used. When using the prSM, major complications occurred in 14.7% and minor complications in 15.7%, and with the nrSM, major complications occurred in 15.4% and minor complications in 11.7%. Thus, the rates of major and minor complications with the use of ADM are approximately twice as high as with the SMs, which are similar to each other. The distribution of major and minor complications with RTX is shown in Table II.

The distribution of individual complications in the overall patient population is shown in Table III. In the more detailed observation of postoperative complications, the group treated with ADM showed a significant effect of RTX on seroma rate ($p=0.014$), wound infection rate ($p<0.001$), and implant

Table I. *Patient characteristics*.

	ADM (Strattice™) (n, %)	Partially resorbable SM (SERAGYN BR®) (n, %)	Non-resorbable SM (TiLOOP Bra®) (n, %)	*p*-Value
Patients n=281 (%)	43 (15.3)	95 (33.8)	143 (50.9)	<0.001
Breasts n=362 (%)	52 (14.4)	115 (31.8)	195 (53.9)	<0.001
Age (years)	49.9	51.6	47.4	0.037
Min - max	33-69	26-74	21-77	
Primary reconstruction (n=264)	23 (44.2)	87 (75.7)	154 (79.0)	<0.001
Secondary reconstruction (n=98)	29 (55.8)	28 (24.3)	41 (21.0)	<0.001
Ablated material weight (g)	332.5	407.1	381.3	0.652
Min - max	66-1,002	76-1,290	27-1,095	
Implant size (ml)	309.8	384.1	381.0	0.001
Min - max	160-585	125-660	135-660	
Duration of hospitalization (d)	6.3	7.5	7.2	0.001
Min - max	4-14	3-12	3-15	
Drain retention (d)	6.1	7.4	7.1	<0.001
Min - max	3-11	3-15	3-13	
Total drained volume (ml)	371.3	523.3	530.7	<0.001
Min - max	80-975	50-1,750	40-1,870	
Follow up (months)	42.8	27	27	0.005
Min - max	3-80	0.5-61.5	0.5-61	
Radiotherapy before reconstructive surgery (n=42)	10 (19.2)	12 (10.4)	20 (10.3)	0.306
Radiotherapy after reconstructive surgery (n=35)	6 (11.5)	11 (9.6)	18 (9.2)	0.897
Neoadjuvant chemotherapy (n=93)	11 (21.2)	39 (33.9)	43 (22.1)	0.082
Adjuvant chemotherapy (n=67)	16 (30.8)	22 (19.1)	29 (14.9)	0.069
Nicotine abuse (n=100)	15 (28.8)	30 (26.1)	55 (28.2)	0.984
BMI	23.4	26.5	25.7	<0.001
Min - max	15.2-38	19.3-46.9	17.9-40.2	
BMI <18.5 (n=27)	12 (23.1)	1 (0.9)	14 (7.2)	0.002
BMI 25-30 (n=101)	7 (13.5)	43 (37.4)	51 (26.2)	0.033
BMI >30 (n=29)	2 (3.8)	6 (5.2)	21 (10.8)	0.120

loss rate (p=0.001). In contrast, RTX had no effect on the complication rate for reconstructions using the prSM. When the nrSM was used, RTX significantly influenced the complication rates in terms of wound infections [15.8% with RTX (n=6) and 3.2% without RTX (n=5), p=0.006] and implant loss [13.2% with RTX (n=5) and 3.8% without RTX (n=6), p=0.037] (Table IV).

Discussion

The analysis presented here examines the complication rates as well as the possible differences between different materials approved for breast reconstruction, with a focus on the study performed at the Breast Center of the University Medicine Greifswald.

Comparing the different interposition devices, the seroma rate was significantly higher with ADM (Strattice™) than with SMs (ADM 21.2%, prSM 5.2%, nrSM 3.1%; p=0.005). One reason for this could be the incorrect statement of seemingly good RTX tolerance of the porcine acellular dermis communicated by the company LifeCell up until the safety notice (21). The seroma rate in our study, independent of the RTX context, was 21.2% and thus, significantly higher than in other studies (4, 10-12, 22-24).

The occurrence of seromas after reconstructions with ADM following RTX was 43.8% in our study. The only comparable study in German-speaking countries reported a similar conclusion with a seroma rate of 35% (10). Seromas after RTX occurred in 4.3% of patients with prSM and in 7.9% of patients with nrSM. Comparative values to SMs are not available in the literature.

Secondary wound complications are a relevant complication after reconstructive surgery. The incidence of wound healing disorders was 5.2% with prSM, 3.6% with nrSM, and 13.5% with ADM.

In the context of preoperative RTX, wound healing disorders occurred in 30% with ADM, 16.7% with prSM, and 10% with nrSM. In the context of postoperative RTX, it was 16.7% for ADM and 5.6% for nrSM; no wound healing disorders occurred when prSM was used.

In the literature, data related to RTX can only be found for ADM. Here, the values with RTX treatment were between

Table II. *Distribution of major and minor complications with preoperative and postoperative RTX.*

	Strattice™ (n=52)	SERAGYN BR® (n=115)	TiLOOP Bra® (n=195)
Major complications in patients with preoperative RTX (n=16, %)	7/10 (70)	3/12 (25)	6/20 (30)
Major complications in patients with postoperative RTX (n=6, %)	1/6 (16.7)	2/11 (18.2)	3/18 (16.7)
p-Value	0.050	0.693	0.340
Minor complications in patients with preoperative RTX (n=14, %)	6/10 (60)	4/12 (33.3)	4/20 (20)
Minor complications in patients with postoperative RTX (n=6, %)	3/6 (50)	1/11 (9.1)	2/18 (11.1)
p-Value	0.697	0.185	0.459

Table III. *Overall distribution of individual complications.*

	Strattice™ (n=52)	SERAGYN BR® (n=115)	TiLOOP Bra® (n=195)	*p*-Value
Seroma (n=23, %)	11 (21.2)	6 (5.2)	6 (3.1)	0.005
Suture dehiscence (n=30, %)	9 (17.3)	11 (9.6)	10 (5.1)	0.056
Wound healing disorder (n=20, %)	7 (13.5)	6 (5.2)	7 (3.6)	0.138
Wound infection (n=22, %)	5 (9.6)	6 (5.2)	11 (5.6)	0.616
Necrosis (n=16, %)	5 (9.6)	4 (3.5)	7 (3.6)	0.299
Hematoma (n=15, %)	3 (5.8)	5 (4.3)	7 (3.6)	0.792
Capsular fibrosis (n=15, %)	4 (7.7)	4 (3.5)	7 (3.6)	0.581
Implant loss (n=31, %)	12 (23.1)	8 (7)	11 (5.6)	<0.001

3.8% and 6.2% when timing was not considered and between 4.3% and 12.9% when RTX was performed postoperatively (20, 25-27). Without RTX, wound healing problems occurred most frequently with ADM (8.3%) and to a lesser extent with pr- and nrSM (4.3% and 2.5%, respectively). Since wound healing disorders occur more frequently in the context of RTX, the different material groups were studied separately (10, 15). RTX seems to have the strongest influence on ADM-assisted surgery. Comparative values can be found in the literature only for ADM and prSM. Here, the rates of wound healing disorders after RTX were 3.1% for ADM and 13.5% for prSM (10, 25). For postoperative RTX, the rate of wound healing disorders was between 12.5% and 25% for ADM (10, 13).

In this study, suture dehiscence was assessed and analyzed separately as a manifestation of the general wound healing disorder. No significant difference was seen between the different materials. Similarly, RTX did not result in increased suture dehiscence regardless of the timing of RTX.

The incidences for the occurrence of postoperative hematomas in pre-irradiated breasts in ADM patients are 0.6 to 2.7% in the literature (4, 10-12, 22, 28). The figures of the Greifswald study are only slightly higher with 5.6%. The value for reconstructions with SMs, 3.6%, is also below those described in the literature (5%, 7.1%, 9.5%, 14.2%) (2, 25, 29, 30). In the preoperative RTX group, hematoma occurred in 10% of breasts in patients treated with ADM or nrSM and 8.3% of breasts in patients treated with prSM. With postoperative RTX, 16.7% of patients with ADM had a hematoma.

In the study conducted at the University of Greifswald, the incidence of wound infections in surgeries with the nr- or prSM was 5.2% and 5.6%, respectively. These data are lower than those reported in the literature (14.2% or 26% for prSM; 5.6% to 28.6% for nrSM) (5, 25, 29-32). In patients who received ADM, it was 9.6%. These figures are within the range reported in the literature (5, 10-12, 23, 28, 33, 34). Notably, in the RTX group, wound infections in breasts with preoperative RTX occurred in 50% with ADM and 20% with nrSM. For the prSM, it was 8.3%. With postoperative RTX for nrSM, wound infection occurred in 11.1% of patients. There was a significant influence of RTX on postoperative wound infections in ADM ($p<0.001$) and nrSM ($p=0.006$). A significant influence of RTX on postoperative wound infections is also reported in the literature (35).

Necrosis is listed in many publications as a possible complication after prior surgery and RTX. The literature describes values of 1.4% to 20% for ADM (11, 22, 23, 28, 33, 34, 36) and 2.5% to 3.9% for nrSM (2, 29, 31), as well as 0.7% for prSM (25). With preoperative RTX, 20% of ADM patients had necrosis. With postoperative RTX, it was 16.7%, and here there was also an association with postoperative wound healing disorders. With preoperative RTX, the incidence was 8.3% for the prSM and 10% for the

Table IV. *Distribution of individual complications with RTX.*

After radiotherapy (n=77)	Strattice™ (n=52)	SERAGYN BR® (n=115)	TiLOOP Bra® (n=195)
Seroma			
Yes (n=11, %)	7/16 (43.8)	1/23 (4.3)	3/38 (7.9)
No (n=12, %)	4/36 (11.1)	5/92 (5.4)	3/157 (1.9)
p-Value	0.014	0.834	0.076
Suture dehiscence			
Yes (n=9, %)	4/16 (25)	3/23 (13.0)	2/38 (5.3)
No (n=21, %)	5/36 (13.9)	8/92 (8.7)	8/157 (6.1)
p-Value	0.334	0.417	0.962
Wound healing disorder			
Yes (n=9, %)	4/16 (25)	2/23 (8.7)	3/38 (7.9)
No (n=11, %)	3/36 (8.3)	4/92 (4.3)	4/157 (2.5)
p-Value	0.134	0.410	0.134
Wound infection			
Yes (n=12, %)	5/16 (31.3)	1/23 (4.3)	6/38 (15.8)
No (n=10, %)	0/36 (0)	5/92 (5.4)	5/157 (3.2)
p-Value	<0.001	0.810	0.006
Necrosis			
Yes (n=6, %)	3/16 (18.8)	1/23 (4.3)	2/38 (5.3)
No (n=10, %)	2/36 (5.6)	3/92 (3.3)	5/157 (3.2)
p-Value	0.168	0.818	0.497
Hematoma			
Yes (n=4, %)	2/16 (12.5)	1/23 (4.3)	1/38 (2.6)
No (n=11, %)	1/36 (2.8)	4/92 (4.3)	6/157 (3.8)
p-Value	0.208	0.991	0.740
Capsular fibrosis			
Yes (n=7, %)	3/16 (18.8)	1/23 (4.3)	3/38 (7.9)
No (n=8, %)	1/36 (2.8)	3/92 (3.3)	4/157 (2.5)
p-Value	0.093	0.800	0.052
Implant loss			
Yes (n=17, %)	9/16 (56.3)	3/23 (13)	5/38 (13.2)
No (n=14, %)	3/36 (8.3)	5/92 (5.4)	6/157 (3.8)
p-Value	0.001	0.213	0.037

nrSM. Sbitany *et al*. described in their study a much lower incidence of 3.2% in patients with postoperative RTX, compared to our results (26).

Capsular fibrosis occurred in 7.7% of cases using ADM, in 3.5% of cases using prSM, and in 3.6% of cases using nrSM, which is comparable to the data found in the literature. For the nrSM, these values range from 2.2% to 7.1% (29, 31), and for ADM, they range from 0.2% to 9% (4, 10, 12, 22, 24).

Capsular fibrosis is listed in the literature as the most common complication after RTX (14, 37, 38). In postmastectomy RTX in the Sinnott *et al*. study, 52.2% of breasts had capsular fibrosis when ADM was used (15). In our study, capsular fibrosis in the context of RTX occurred in 18.8% of cases with ADM, 4.3% with prSM, and 7.9% with nrSM. Patients undergoing breast reconstruction with nrSM and ADM who received preoperative RTX had capsular fibrosis in 15% and 20% of cases, respectively. With postoperative RTX, it was 16.7% for ADM and 9.1% for prSM. These values do not confirm the reduced risk of capsular fibrosis with ADM that was described in the study by Moyer *et al*. (39).

In the study conducted at the Breast Center of the University Medicine Greifswald, implant losses occurred in 31 cases. Implant losses were higher with ADM (23.1%) than with the other interposition devices (7% for the prSM, and 5.6% for the nrSM). The 23.1% occurring with ADM is within the range of 1.4% to 30.4% that is reported in the literature (4, 5, 11, 22, 23, 33, 36, 40). For the other two interposition devices, the values determined are slightly lower than those in the literature, which range from 10% to 15.5% for the prSM and from 6.7% to 10% for the nrSM (5, 25, 29, 31, 40).

RTX was characterized as a significant impact factor for the implant loss rate in the summary analysis of all implants and interposition devices ($p<0.001$). With preoperative RTX, the implant loss rate was 70% for ADM and 25% for each of the SMs; with postoperative RTX, the implant loss rate

was 33.3% for ADM; for SMs there were no cases. According to this study, the use of ADM resulted in a higher complication rate when radiation was applied. The LifeCell safety notice also stipulates careful consideration of the risk/benefit ratio associated with pre- or post-operative RTX to the breast (21). However, in the absence of accurate data prior to the safety notice (2008 through 2015), ADM was frequently used in the context of a pre-exposed skin soft tissue mantle.

The negative influence of RTX on the outcome of breast reconstructions is considered confirmed. With ADM, a significant influence of pre- and post-operative RTX on postoperative seromas (p=0.014), wound infections (p<0.001), and implant losses (p=0.001) was shown. In the case of nrSM, this negative influence was shown with pre- and post-operative RTX on wound infections (p=0.006) and implant losses (p=0.037). Comparable data have not been reported in the literature to date. In the case of prSM, no significant influence of RTX on postoperative complications could be demonstrated.

According to the AGO working group, the use of autologous material in reconstructive breast surgery in association with RTX of the thoracic wall would be the preferred solution (3). In the study conducted by Hughes *et al*., the rate of minor complications was 15% and the rate of major complications was 12.5% in association with RTX (41). In addition, the study published by Berbers *et al*. described no increase in the overall complication rate in relation to the timing of RTX. However, fewer fibroses occurred with preoperative than with postoperative RTX (42).

Conclusion

Although no similar studies comparing alloplast and dermis can be found in the literature to date, the comparability of the results is confirmed by separate studies on the individual interposition devices in other publications. The results of the study performed at the University Medicine Greifswald show a significantly higher major and minor complication rate for pre- and post-operative RTX with ADM. This is also shown in the guidelines published by the AGO working group (3). Of particular note is the negative impact on wound infections, seromas, capsular fibrosis, and implant loss. The assumption that ADM might be particularly suitable for reconstructions in pre-irradiated breasts cannot be substantiated by this study. While no negative influence of RTX was demonstrated with the prSM, it was evident with the nrSM regarding wound infections and implant losses. A careful indication, taking all risk factors into consideration, is mandatory to ensure that the therapy is tailored to the patient's needs. In this way, the complication rates can be reduced (27). International prospective randomized multicenter studies are needed to verify the results of this study.

Conflicts of Interest

Florian Nawroth, Thomas Kohlmann, Zaher Alwafai, Katharina Schüler, and Marek Zygmunt have no conflicts of interest to disclose. Stefan Paepke: Consultant of pfm medical ag, Cologne, Germany; Novusscientific, Sweden; Triconmed, Germany; Sysmex, Germany; Sysmex, Europe; Neodynamics, Sweden; MBN, Germany; Invitrocue Europe GmbH; Dynamesh, Germany; Scientific grants: RTI Surgical; pfm medical ag; Novusscientific, Sweden; AG, Germany; GBG, Germany; Support of workshops: Roche, Grenzach-Whylen; Sysmex, Germany; Philips GmBH; Triconmed, Germany; In the past: Consultant of Serag Wiessner AG (<5 years); Consultant of KCI (>3 years); DZIG, Berlin (<5 years); Allergan (>3 years). Ralf Ohlinger: Consultant and support of workshops of pfm medical ag, Cologne; Serag Wiessner AG, and KCI in the past.

Authors' Contributions

Marek Zygmunt planed the study and edited the paper. Ralf Ohlinger planed the study, recruited the patients, performed the surgery, analysed the data, wrote and edited the manuscript. Florian Nawroth recruited the patients, analysed the data, wrote and edited the manuscript. Stefan Paepke analysed the data, wrote and edited the manuscript. Zaher Alwafai recruited the patients, performed the surgery and edited the manuscript. Katharina Schueler recruited the patients and edited the manuscript. Thomas Kohlmann performed the statistical analysis and edited the manuscript.

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