A Retrospective Head-to-head Comparison Between TiLoop Bra/TiMesh® and Seragyn® in 320 Cases of Reconstructive Breast Surgery

CHRISTIAN EICHLER¹, CAROLIN SCHULZ², FABINSHY THANGARAJAH¹,
WOLFRAM MALTER¹, MATHIAS WARM^{1,2} and KLAUS BRUNNERT³

¹Department of Gynecology and Obstetrics, Medical Faculty, University of Cologne, Cologne, Germany;

²Breast Cancer Center, Municipal Hospital Holweide, Cologne, Germany;

³Department of Senology, Clinic for Senology, Osnabrueck, Germany

Abstract. *Background/Aim:* Clinical data concerning synthetic meshes in comparison to acellular dermal matrices (ADMs) in breast reconstruction are limited. Also, direct comparisons between titanium-coated polypropylene mesh and partially absorbable polypropylene mesh have not yet been reported. *Materials and Methods:* This analysis represents a retrospective, single-surgeon, multi-center study of 320 cases using either TiLoop Bra/TiMesh® (n=192) or Seragyn® (n=128) in breast reconstruction. Results were compared with ADM-based reconstructions (Epiflex® and SurgiMend®). *Results:* Major complication rates (i.e. revision surgery) occurred in 3.9% (Seragyn®) and 8.3% (TiLoop Bra/TiMesh®) of all cases. Minor complications occurred in 18% (Seragyn®) and 8.9% (TiLoop Bra/TiMesh®). Subgroup analysis showed red breast syndrome to occur more often in the Seragyn group (3.9% Seragyn® vs. 0.5% TiLoop Bra/TiMesh®, $p<0.05$). *Conclusion:* TiLoop Bra/TiMesh® and Seragyn® do not differ significantly in complication rates. There was no difference in performance when compared to ADMs.

Breast reconstruction in a post-oncological intervention scenario may either be performed via an autologous or implant-based approach. For skin-sparing mastectomies (SSM)/nipple sparing mastectomies (NSM) literature states a shift from autologous breast reconstruction towards implant-based reconstruction. Recent data from the United States demonstrated that implant-based breast reconstruction is used in 37% of breast cancer patients. Performing implant-

based surgeries, even if acellular dermal matrices (ADMs) or synthetic meshes are required, has a variety of advantages when compared to autologous reconstruction (1-5). Most importantly, overall patient morbidity is decreased since implant-based reconstruction is a far less invasive procedure. Additionally, factors such as a decrease in the donor site morbidity, more cost-effective surgical procedures and improved implant materials play an important role in the general shift towards implant-based reconstruction. In addition to simply using an implant, overall cosmetic outcome may also be improved by using ADMs or synthetic meshes for implant stabilization (6-10). Over the past decades we have seen a steep increase in the use of ADMs in epi-pectoral and sup-pectoral implant driven breast reconstruction and recent meta-analyses showed the use of ADM's to be particularly beneficial in reducing implant malrotation/malpositioning and capsular contracture (11-13). While this may be the case, the increasing use of ADM's causes a severe increase in healthcare costs with ADM's costing up to \$3,000. There are currently only minimal data available regarding whether this improvement in overall outcome may also be achieved by replacing an ADM with a synthetic mesh. This would be prudent as synthetic meshes are cheaper than ADMs by an order of magnitude. This work aimed at retrospectively evaluating the postsurgical complication rates, i.e. outcome of two synthetic meshes (Seragyn® and TiLoop Bra/TiMesh) in both aesthetic and oncoplastic surgery in a head to head manner. In addition, the outcome data were then compared to available data by the same surgeon using ADM's instead of synthetic meshes for the same types of surgeries.

Materials and Methods

This work evaluated a multicenter, single surgeon experience over the course of 14 years with a total of 320 cases (Seragyn®, n=128; TiLoop Bra/TiMesh®, n=192) (Figure 1). All procedures were

Correspondence to: Dr. med. Christian Eichler, Brustzentrum der Universitätsfrauenklinik Köln, Kerpener Straße 34, 50931 Köln, Germany. Tel: +49 1635050614, e-mail: ceichler@gmail.com, eichlerc@kliniken-koeln.de

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subcutaneous mastectomies with or without prior radiation treatment or reduction-mastopexy with internal bra fixation *via* a synthetic mesh. Most of the interventions were oncological interventions for both groups; Seragyn® (71 cases – 55.5%) and TiLoop Bra/TiMesh® (124 cases – 64.6%). If an SSM was performed, the contralateral side, if operated on to achieve symmetry, was considered to be an aesthetic procedure as it is treated as such by the German health care reimbursement system. Within the Seragyn® group, 35 cases did not receive implants (1 oncological and 34 aesthetic). Within the TiLoop Bra/TiMesh® group, 44 patients did not receive an implant (2 oncological and 42 aesthetic). This resulted in 93 implant-based Seragyn® reconstructions and 148 implant-based reconstruction for the TiLoop Bra/TiMesh® cohort. The median age for the Seragyn® group was 48.8 years (range=17-78) and the median age for the TiLoop Bra/TiMesh® group was 49.1 years (range=18-73; two-sided *t*-test $p>0.05$). The median BMI for Seragyn® group was 23.5 (range=17-37) and 23.6 (range=17-32) for the TiLoop Bra/TiMesh® group (two-sided *t*-test $p>0.05$). Except for a slight difference in smoking habit, age, BMI, received chemotherapy and received radiation therapy did not differ in both cohorts (Table I).

Seragyn® (Serag-Wiessner GmbH & Co. KG, Naila, Germany). This is a soft mesh partially resorbable implant [polypropylene (non-resorbable) and polyglycolic acid-caprolactone (resorbable)]. According to the manufacturer, it is designed to support and bridge weakened or damaged tissue. It is pre-cut to meet the anatomical requirements. The mesh is incorporated into the breast tissue and cell structures are able to grow into it. Most of it dissolves within about 90-120 days. Only a minimal residue remains permanently in the body. This ensures sustained stability.

TiLoop Bra/TiMesh® (pfm medical ag, Köln, Nordrhein-Westfalen, Germany). This product is a titanized mesh (polypropylene with covalently bonded, titanized surface). The manufacturer states that: compared to simple polypropylene, the hydrophilic and titanized surface carries a reduced risk of inflammation and thus a reduced tendency towards the formation of connective tissue-like scars and shrinkage: combined with a minimal weight, this yields ideal conditions for a permanent, stable result as well as adequate tissue ingrowth and a vascularized, flexible, and therefore optimum capsule quality. TiMesh® is the same material as TiLoop Bra® although it was being used off-label in breast reconstruction.

Endpoints. The endpoints of this analysis are major and minor complication rates. Major complications are defined as any event leading to revision surgery with implant loss or revisions surgery alone (if no implant was used), since both cases represent a rare, but severe impact on patient morbidity and cost to the health care system. Reasons for revision surgery included: implant loss or revision due to severe wound dehiscence, hematoma, antibiotic resistant infection, implant malrotation, capsular contracture *etc.*

Minor complication rates included seroma requiring aspiration, infection requiring *i.v.* antibiotics and wound dehiscence without revision. In addition, post-surgical red breast syndrome (RBS – a non-infections inflammatory response exceeding normal postoperative redness) was also recorded. Although this type of event is usually a problem of ADM application, it may also occur in synthetic mesh interventions. It should again be mentioned that this reaction is often mistaken for an infection and unnecessarily

treated with antibiotics although this hypersensitivity better responds to corticosteroids (14). In addition, time to surgical drain removal was also recorded.

Surgical technique. Surgery was performed according to the gold standard for SSM/NSM immediate or secondary implant-based reconstruction and or reduction-mastopexy procedures. All surgeries were performed by an experienced sonological surgeon. All materials were handled according to the manufacturer's specifications. Antibiotics were administered during surgery. No antibiotics were given after surgery unless required by clinical parameters. Drains were not removed within the first 24 h post-surgical period. Thereafter, a threshold of 30 ml/24 h was used as a cutoff for maintaining drainage. TiMesh® was used in an off-label application. Surgical compression bras were applied immediately after surgery and worn by the patient for at least a 6-week period.

Informed consent. Written informed consent was obtained from all patients. A copy of the written consent is available for review by the Editor-in-Chief of this journal. This study was conducted in accordance with the institutional review board standard operating procedures.

Statistics. Statistical analysis was performed using the VassarStats® (Vassar College, Poughkeepsie, NY, USA) statistics program. ANOVA analysis and *t*-tests were used in order to evaluate significances when appropriate.

Results

Overall (major+minor) complication rates did not differ significantly through both cohorts with some form of postsurgical complication found in 21.8% (n=28) of the Seragyn® group and 17.2% (n=33) of the TiLoop Bra/TiMesh®. Overall complication rates did not differ significantly ($p=0.3$).

Major complications *i.e.* revision surgery with implant loss due to wound dehiscence, hematoma, antibiotic-resistant infection and short-term capsular contracture occurred in 3.9% (n=5) of the Seragyn® group and 8.3% (n=16) of the TiLoop Bra/TiMesh® cohort. Results include revision within the first 3 months after surgery and also did not differ significantly ($p>0.16$).

Overall minor complication rates were 18% (n=23) in the Seragyn® group and 8.9% (n=17) in the TiLoop Bra/TiMesh® cohort. These results differed significantly ($p=0.024$) although this significance could not be sustained within all minor complication rate subgroups (Table II). The most common minor complication in both groups was seroma requiring aspiration in 9.4% (n=12) of the Seragyn® group and 4.7% (n=9) of the TiLoop Bra/TiMesh® cohort. This difference is not significant ($p=0.11$). Further subgroup analysis showed RBS to occur significantly more often in the Seragyn group (3.9% Seragyn® *vs.* 0.5% TiLoop Bra/TiMesh®, $p<0.05$). A factor commonly not reported in ADM or mesh analysis is time to drain removal. As drain removal is generally dependent on the

Figure 1. Shown are left to right. 1.1 Seragyn®, 1.2 TiLoop Bra®, 1.3 Implementation of a pocket type situation using TiLoop Bra®.

amount of post-surgical fluid production, this parameter is often used to determine whether a new medical product interferes with wound healing (15-21). Due to the retrospective and long-term nature of this analysis, data were only available on 142 patients. On average, drains were removed after 3.9 days ($n=95$, range=7) in the Seragyn® group and 3.2 days ($n=47$, range=8) in the TiLoop Bra/TiMesh® cohort. This difference was not statistically different.

Discussion

Although the use of synthetic meshes and/or ADMs in implant-based breast reconstruction is currently *en-vogue*, we must continuously and critically question their use to maintain implant positioning or mastopexy shape. However, with the exception of using MPU (Micropolyurethane foam=Microthane®) coated implants, preventing implant malrotation in an epi-pectoral or sub-pectoral pocket situation currently still requires the use of an ADM and/or a synthetic mesh. The same is true for preventing capsular fibrosis (22, 23).

There are currently no data comparing these two types of meshes in a head-to-head manner. There are however, some publications available on TiLoop Bra/TiMesh® in an SSM scenario. A PubMed search in August of 2018 showed 14 publications with relevant data (4, 24-32). No head to head trials are published, especially no direct comparisons between the meshes evaluated here and commonly used ADMs. A prospective trial by Casella *et al.* evaluated patient reported outcomes and showed overall subjectively satisfactory results using TiLoop Bra® (26). Other work, comparing TiLoop® Bra to a corial flap, showed improved aesthetic results, as well as a decrease in implant dislocation favoring TiLoop® Bra over a corial flap (31). Dieterich *et al.* showed that major complications occurred in 13.4%, minor complications in 15.6%, and implant loss in 8.7% of patients (4). In comparison, our implant loss /revision rate was recorded at 8.3% in the TiLoop Bra/TiMesh® group, demonstrating that results gained from this trial are very well

comparable to those found in the literature. A reliable comparison of this product to the newer, less often used Seragyn® mesh is now possible. Seragyn® has so far only been evaluated in a single publication (33). Machleidt *et al.* showed in 131 cases a reconstructive failure of 11.5%. Our trial showed implant loss (*i.e.* reconstruction failure) in 3.9% of all evaluated cases. Again, we find excellent comparability of this new product to available literature although implant loss seems numerically lower in our analysis.

Overall, we were able to find very little quantitative data about either product in breast reconstruction. Although the body of evidence is growing and a more complete picture becomes available, large-number retrospective evaluations remain important in understanding the impact of these materials in breast reconstruction. In this trial, we were able to establish that no significant difference in the overall complication rate exists in the use of these meshes in 320 patients with a minimal numerical benefit regarding revision surgery for the Seragyn® group. Minor complication rates such as seroma, infection and wound dehiscence did not differ significantly in both groups and are rare occurrences. Thus, the deciding factor should be the cost for the health care system. As both products are similarly prized (actual product cost vary depending on procurement contracts) we conclude that it is possible to choose either one of the two meshes.

Red breast syndrome in synthetic meshes. No data are available on RBS in this synthetic mesh/implant situation. Generally, this type of reaction is attributed to the immunogenic nature of ADMs (14). We showed that this type of reaction may also occur with synthetic material. Clinical management should not differ *i.e.* corticosteroid treatment. In our opinion the significant difference in the observed RBS (3.9% Seragyn® vs. 0.5% TiLoop Bra/TiMesh®, $p<0.05$) does not have enough of a clinical impact to influence the choice of material in everyday practice. It may however be attributed to TiLoop Bra/TiMesh's titanized surface which, according to the manufacturer, carries a reduced risk of inflammation.

Table I. Patient characteristics for both cohorts.

	SERAGYN® BR		TiLOOP® Bra/TiMesh®		p-Value*
		%		%	
Patients		128		192	
Oncological intervention	71	55.5	124	64.6	0.1016
Aesthetic surgery	57	44.5	68	35.4	
Smoking**	25	27.5	39	50	0.0026
Chemotherapy**	30	26.8	36	25.9	0.8625
Radiation**	7	6.1	13	8.3	0.4976
Average age	48.8±13.5		49.1±11.7		0.8182
Range	17-78		18-73		
Average BMI**	23.5±3.3		23.6±3.5		0.8808
Range	17-37		17-32		

*Pearson Chi-squared, Fisher's exact probability test, or *t*-test (two-tailed) whenever appropriate; **All percentage data was calculated excluding the missing data. (Smoking: Seragyn n=91, TiLoop/TiMesh n=78); (CTX: Seragyn n=112 TiLoop/TiMesh n=139); (RTX: Seragyn n=114 TiLoop/TiMesh n=156); (BMI: Seragyn: 123 TiLoop/TiMesh: 183).

Table II. Complication rates for both synthetic mesh products.

	SERAGYN® BR		TiLOOP® Bra/TiMesh®		p-Value*
		%		%	
MAJOR					
Revision surgery**	5	3.9	16	8.3	0.1661
MINOR	23	18	17	8.9	0.0239
Seroma requiring aspiration	12	9.4	9	4.7	0.1102
Infection requiring antibiotics	4	3.1	5	2.6	>0.5
Red breast syndrome/Rash	5	3.9	1	0.5	0.0395
Wound dehiscence	1	0.8	2	1	>0.5
Others	1	0.8	0	0	0.4
Overall	28	21.8	33	17.2	0.2965
Drainage					
Patients (available data n=142)	95		47		
Average time to removal in days	3.9±1.7		3.2±1.8		0.0217
Range	2-9		1-9		
List price by size***					
	\$ 505.16		\$ 369.46 ****		

*Pearson Chi-squared, Fisher's exact probability test, or *t*-test (two-tailed) whenever appropriate; **Revision surgery due to wound dehiscence, hematoma, capsular fibrosis, implant malpositioning *etc.*; ***listed price for a medium net (approximately 320 cm²), exchange rate (Euro to Dollar) from June 6th 2017: 1 €=1,196 \$, price varies depending on offer; ****referring to TiLoop Bra, TiMesh prices varies depending on strength and size from 80-505 \$; 300cm² TiMesh light costs 296 \$.

Time to drain removal. The authors report that this data point since seroma formation and drain placement is part of a continuous debate within the oncoplastic breast surgery community. There was no difference between the two meshes. Also, time to drain removal seems adequate with drains being removed after 3.9 days (Seragyn®) and 3.2 days (TiLoop Bra/TiMesh®).

Synthetic vs. ADM. This is the first work comparing synthetic meshes vs. ADMs by a single surgeon, using the same surgical technique in a multicenter, retrospective analysis with this level of recruitment. Some limited (n=48) work is available to this extent, essentially favoring the cheaper mesh alternative (34-36). Since previous work by this group (8) has evaluated oncological interventions

Table III. Complication rates for both synthetic mesh products and 2 ADM. The latter is taken from a previous analysis (33). All surgeries were performed by the same surgeon.

	SERAGYN® BR		TiLOOP® Bra/ TiMesh®		SurgiMend® (Bovine ADM)*		Epiflex® (Human ADM)*		p-Value**
	%		%		%		%		
Patients	128		192		63		64		
Oncological intervention	71	55.5	124	64.6	57	90.5	54	84.4	<0.0001
Aesthetic Surgery	57	44.5	68	35.4	6	9.5	10	15.6	
Complications									
TOTAL	28	21.9	33	17.2	7	11.1	26	40.6	<0.0001
MAJOR									
Revision surgery***	5	3.9	16	8.3	3	4.8	8	12.5	0.1301
MINOR	23	18	17	8.9	4	6.4	18	28.1	0.0003
Seroma requiring aspiration	12	9.4	9	4.7	1	1.6	3	4.7	0.159
Infection requiring iv antibiotics	4	3.1	5	2.6	0	0	6	9.4	0.0338
Red Breast Syndrome/Rash	5	3.9	1	0.5	3	4.8	9	14.1	<0.0001
Wound dehiscence	1	0.8	2	1	N/A		N/A		
Others****	1	0.8	0	0	N/A		N/A		
Cost by size									
List price****	\$ 505.16		\$ 369.46*****		\$ 2485		\$ 2230		

*Data used from a former study (8); **Pearson Chi-squared, Fisher's exact probability test, or *t*-test (two-tailed) whenever appropriate; ***Revision surgery due to wound dehiscence, hematoma, capsular fibrosis, implant malpositioning *etc.*; ****listed price for a medium net (approximately 320 cm²), exchange rate (Euro to Dollar) from June 6th 2017: 1 €=1,1196 \$, price varies depending on offer; *****referring to TiLoop Bra, TiMesh prices varies depending on strength and size from 80-505 \$; 300cm² TiMesh light costs 296 \$.

with two commonly used ADMs, we were now able to directly compare these synthetic mesh data to available ADM data in a total of 477 oncological and aesthetic interventions, making this the largest available body of data on this topic.

The two ADMs used were SurgiMend® PRS (TEI, Biosciences, Inc., Boston, MA, USA), which is derived from fetal bovine dermal type III collagen and Epiflex® (Deutsches Institut für Zell- und Gewebeersatz (DIZG) gGmbH, Berlin, Germany), which is derived from human skin and undergoes a complex decellularization process, leaving behind a collagen matrix with low residual levels of genomic material insufficient to provoke an immune reaction. Table III shows the summarized data for all four products. Note that there is a difference between these groups as there is a significant increase in oncological interventions in the ADM subgroups. This is largely due to the fact that if an SSM/NSM procedure was performed on one side, the contralateral side was counted as an oncological intervention in the ADM analysis. The percentage of oncological interventions for the SurgiMend® group was 90.5% and 84.4% for the Epiflex® group, leaving these two cohorts with patients with a higher morbidity *i.e.* more risk factors for implant failure. However, no significant difference between implant loss rates /revision surgery rates could be shown between all four subgroups (revision/implant loss → 3.9% Seragyn®,

0.5% TiLoop Bra/TiMesh®, 4.8% SurgiMend®, 12.5% Epiflex®). Minor complication rates differed significantly in some subgroups although the truly relevant endpoint is the implant loss rate (Table III). In our opinion, this means that we may, very carefully, assume that synthetic meshes perform as well as the much more expensive ADM alternative.

Conclusion

This retrospective analysis shows similar overall clinical complication rates for Seragyn® and TiLoop Bra/TiMesh® in oncological and aesthetic breast reconstruction. No significant difference in implant loss rates/revision surgery rates were shown between these materials. Thus, both meshes offer a viable option for oncoplastic surgery. More importantly, it seems that complication rates of these two synthetic meshes compare very well to implant loss rates of more expensive ADM options. This leads to the careful conclusion that ADMs may be replaced by synthetic meshes in the future.

Ethics Committee Approval

This study was conducted in accordance with institutional review board standard operating procedures. An ethics committee vote was procured. A written statement to this extent is available.

Conflicts of Interest

The Authors declare no conflicts of interest in this investigator-driven study.

Authors' Contributions

CE: Writing, editing, data collection, statistical analysis, trial development; CS: writing, editing, data collection, statistical analysis, trial development; FT: writing, editing; WM: writing, editing; MW: writing, editing; KB: writing, editing, trial development.

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