



# Implant Based Breast Reconstruction Using a Titanium-Coated Polypropylene Mesh (TiLOOP® Bra): A Systematic Review and Meta-analysis



Tingjian Zhang<sup>1</sup> · Jing Ye<sup>2</sup> · Tian Tian<sup>1</sup>

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## Abstract

**Background** Implant-based breast reconstruction (IBBR) can be performed using a variety of biological and synthetic meshes. However, there has yet to be a consensus on the optimal mesh. This study investigates the safety and patient satisfaction of using TiLOOP® Bra in IBBR and compares its postoperative complication risk with that of porcine acellular dermal matrix (ADM) and SERAGYN® BR.

**Methods** The literature review was performed via PRISMA criteria, 23 studies met the inclusion criteria for the TiLOOP® Bra review, and 5 studies met the inclusion criteria for the meta-analysis. Patient characteristics and per-breast complications were collected. Data were analyzed using Cochrane RevMan and IBM SPSS.

**Results** In 3175 breasts of 2685 patients that underwent IBBR using TiLOOP® Bra, rippling was observed as the most common complication, followed by seroma and capsular contracture. No significant difference in the overall complication rate between pre- and sub-pectoral IBBR using TiLOOP® Bra. However, the meta-analysis showed that the TiLOOP® Bra group had significantly lower odds of implant loss, seroma, wound dehiscence, and

the need for reoperation or hospitalization than the ADM group. Additionally, the TiLOOP® Bra group had a significantly lower seroma rate compared to the SERAGYN® BR group, while the other outcome indicators were similar between the two groups.

**Conclusion** TiLOOP® Bra has become increasingly popular in IBBR in recent years. This review and meta-analysis support the favorable safety profile of TiLOOP® Bra reported in the current literature. The meta-analysis revealed that TiLOOP® Bra has better safety than ADM and a comparable risk of complications compared to SERAGYN® BR. However, as most studies had low levels of evidence, further investigations are necessary.

**Level of Evidence III** This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors [www.springer.com/00266](http://www.springer.com/00266).

**Keywords** Implant-based breast reconstruction (IBBR) · Complication · Titanium-coated polypropylene mesh (TiLOOP® Bra) · Acellular dermal matrix (ADM) · SERAGYN® BR

✉ Tian Tian  
tiantianis@163.com

Tingjian Zhang  
ztj199706@163.com

Jing Ye  
224132184@qq.com

<sup>1</sup> General Surgery Department, Yongchuan Hospital of Chongqing Medical University, No. 439, Xuanhua Road, Yongchuan District, Chongqing 402160, China

<sup>2</sup> Department of Surgery, Maternal and Child Health Hospital of Yongchuan, Chongqing 402160, China

## Introduction

Breast cancer has become the most prevalent cancer worldwide, surpassing lung cancer in incidence [1]. Although advanced treatment methods have improved survival rates, breast removal surgery's psychological and social impacts on patients are substantial [2]. Breast reconstruction technology has become a critical means of restoring breast appearance and enhancing psychological health and overall quality of life. And use of implants for

breast reconstruction has become a main option for post-mastectomy reconstruction due to its minimal surgical trauma and satisfactory outcomes [3, 4].

In addition, introducing ADM and synthetic meshes can help to expand the space between chest muscles, increase implant coverage, and broaden the indications for breast reconstruction [5]. The development of meshes enabled a single-stage breast reconstruction and facilitated the advancement of prepectoral breast reconstruction techniques that are more anatomically conforming [6]. ADM, a representative of biogenic meshes, can be derived from human, porcine and bovine skin tissue. This material preserves the soft tissue skeleton while removing highly immunogenic cellular components, thus significantly reducing the risk of immune rejection [7]. ADM also has excellent biocompatibility and can address the issue of insufficient soft tissue coverage in prosthetic reconstruction, leading to improved cosmetic outcomes [8]. Porcine-derived ADM has been widely used in Europe since 2008 and remains the most commonly used ADM in the United Kingdom [9]. However, whether it increases the incidence of postoperative complications and the risk of reconstruction failure remains uncertain [10]. Furthermore, the high cost of ADM and religious beliefs have hindered its application in certain countries and regions. Titanium-coated polypropylene mesh (TiLOOP® Bra) is a possible substitute for ADM because it is soft, thin, mechanically robust, inexpensive, and can effectively support the implant and tissue connection. It is made of non-absorbable, titanized, lightweight polypropylene with a monofilament structure. It has been approved for breast reconstruction since 2008 and is widely used in clinical practice [11–13]. Currently, the benefits, risks, and clinical outcomes of for TiLOOP® Bra breast reconstruction are actively being studied.

This study aims to conduct a comprehensive and up-to-date review of TiLOOP® Bra's application in breast reconstruction, including a meta-analysis comparing the safety of TiLOOP® Bra and porcine ADM (Strattice™ & Protexa®). This study also compared the safety of SERAGYN® BR and TiLOOP® Bra for breast reconstruction. The SERAGYN® BR is a bi-component mesh made of polypropylene and absorbable polyglycolic acid employed in breast reconstruction since 2011. Our objective is to provide patients with valuable information on selecting the most suitable mesh for breast reconstruction.

## Methods

### Search Strategy and Eligibility Criteria

In January 2023, a comprehensive search of PubMed, Embase, Web of Science, and Cochrane Library was

conducted to retrieve literature on implant-based breast reconstruction using TiLOOP® Bra. The search was performed according to the PRISMA guidelines, using the MeSH term “Mammoplasty” combined with free terms such as “Breast reconstruction” and “Mammoplasties,” as well as keywords such as “TiLOOP,” “TiMesh,” and “Titanium-coated polypropylene mesh.” Inclusion criteria: (1) female patients aged 18–75 who underwent breast reconstruction using both implants and TiLOOP® Bra mesh; (2) only the study with the most cases or the one that presented the data in more detail was chosen when multiple studies from the same institution overlapped in time. (3) English-language articles. Exclusion criteria: (1) literary reviews without original data, abstracts, case reports, brief reports, surgical techniques, animal experiments, and anatomical studies; (2) sample size < 20 breasts (3) full-text articles that did not provide sufficient information.

### Data Extraction

Data were independently extracted and input into a standard Microsoft Excel data collection template by two authors. The collected information included study design types, reconstruction types (Table 1), patient characteristics (Table 2), and patient outcomes (Tables 3 and 4). The Newcastle-Ottawa Scale and Jadad Scale were used to assess the quality of the studies (Table 5). When disagreements arose, the three authors discussed and resolved them jointly.

### Statistical analysis

Data analysis was performed using the Cochrane RevMan Version 5.4 (Cochrane Collaboration, Copenhagen) and IBM SPSS Version 26 (IBM Corp., Armonk, N.Y.). All *p*-values and 95% confidence intervals (CI) were two-sided, and *p* < 0.05 was considered as statistically significant. The demographic and clinical characteristics data of patients undergoing IBBR using TiLOOP® Bra were collected and presented as weighted means/proportions. For studies that

**Table 1** Study design and type of reconstruction

Study design/type of reconstruction	No. studies
Prospective cohort	8
Prospective randomized	1
Retrospective cohort	14
Prepectoral reconstruction	9
Subpectoral reconstruction	12
Both reconstruction	2

**Table 2** TiLOOP® Bra patient characteristics by patient

Characteristic	No. studies	TiLOOP® Bra (%)
Number of patients	23	2685
Number of breasts	23	3175
Mean age, years	16	50.89
Mean BMI, kg/m <sup>2</sup>	14	24.15
Smoking	18	468 (19.61)
Diabetes	12	54 (3.91)
Neoadjuvant chemotherapy	9	138 (21.70)
Adjuvant chemotherapy	8	124 (23.05)
Preoperative RTx	18	264 (11.60)
Postoperative RTx	13	173 (11.50)
Prepectoral reconstruction	11	1655 (94.68)
Subpectoral reconstruction	14	1520 (94.47)
Primary reconstruction	21	2825 (96.15)
Secondary reconstruction	6	113 (3.85)
Mean drainage duration	9	6.62 (days)

only reported results per patient rather than per reconstructed breast, we assumed that the number of reconstructed breasts was equal to the number of patients, as each patient had at least one breast reconstructed. In addition, since the total number of breasts was difficult to determine without laterality information, and the overwhelming majority of reconstructions in our dataset were unilateral, assuming bilateral reconstruction was inappropriate. The rate of complications in IBBR using TiLOOP® Bra was meta-analyzed separately from those in IBBR using ADM and SERAGYN® BR. The chi-square test was used to calculate the differences in patient characteristics between groups. The Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated using the Mantel-

**Table 3** TiLOOP® Bra complication rates, by breast

Complication	No. studies	TiLOOP® Bra (%)
Number of breasts	23	3175
Implant loss	15	71 (3.52)
Capsular contracture	11	83 (4.94)
Seroma	18	126 (4.94)
Hematoma	19	74 (2.81)
Skin-nipple necrosis	16	106 (3.88)
Infection	22	138 (4.46)
Wound dehiscence	13	58 (2.75)
Rippling	4	125 (11.67)
Need reoperation or hospitalization	11	193 (8.81)
Prepectoral reconstruction	12	278 (20.39)
Subpectoral reconstruction	11	328 (22.56)
Total	20	606 (21.33)

**Table 4** Patient-reported outcomes by breast

BREAST-Q dimension	No. studies	TiLOOP® Bra
Satisfaction with breast ± SD	8	70.08 ± 16.17
Psychosocial well-being ± SD	8	76.15 ± 15.18
Sexual well-being ± SD	8	59.97±16.01
Physical well-being ± SD	9	73.55±15.44
Satisfaction with outcome ± SD	6	75.08±13.17

**Table 5** Newcastle–Ottawa Grading Scale/Jadad Scale

Study	Score
Gschwantler (2016)*	5
Olinger (2021)	7
Katharina (2021)	7
Gao P (2022)	8
Eichler (2019)	6

\*RCT (Jadad scale)

Haenszel test. Cochrane  $Q$  statistics and  $I^2$  tests were used to assess potential heterogeneity across the studies, with  $p < 0.1$  or  $I^2 > 50\%$  indicating heterogeneity. A fixed-effect model was used for homogeneous datasets, and a random-effects model was used for heterogeneous datasets. Sensitivity analysis was performed for all outcomes. Importantly, postoperative outcomes were analyzed for complications reported in at least two studies. In addition, we evaluated the patient's quality of life by recording and analyzing patient-reported outcomes using the BREAST-Q score.

## Results

### Study Characteristics

A total of 196 studies were identified in the database search. After excluding duplicates, the titles and abstracts of the remaining 107 articles were screened. After that, 32 full-text articles were selected for evaluation based on inclusion/exclusion criteria. Finally, 23 articles were included, of which 4 contained comparative data between TiLOOP® Bra and ADM for IBBR, and 3 contained comparative data between TiLOOP® Bra and SERAGYN® BR for IBBR (Fig. 1). The 23 studies included 3135 patients, where 2685 patients (85.6%) (3175 breasts) underwent reconstruction using TiLOOP® Bra. Among these, 1655 breasts received pre-pectoral IBBR, and 1520 breasts received sub-pectoral IBBR. Immediate reconstruction was performed in 96.15% of cases, while delayed reconstruction was performed in 3.85%. The mean age was 50.88 years, and the mean BMI was 24.14. It is worth noting that 11.60% of patients had received radiotherapy before surgery, approximately 21.70% received neoadjuvant chemotherapy, and approximately 19.61% were current or past smokers.

### Systematic Review of Using TiLOOP® Bra in IBBR Complications

The overall complication rate for breasts undergoing IBBR using TiLOOP® Bra was 21.33%. The most common postoperative complication was rippling (11.67%), followed by seroma (4.94%) and capsular contracture (4.94%) for IBBR using TiLOOP® Bra, while the less frequent complications were wound dehiscence (2.75%) and hematoma (2.81%). Approximately 8.81% of postoperative complications required secondary surgical intervention or hospitalization. Furthermore, the total incidence of complications for pre-pectoral IBBR using TiLOOP® Bra was 20.39%. In contrast, it was 22.56% for sub-pectoral implant placement, and there was no statistically significant difference between the two groups.

### Quality of Life

Nine studies utilized the BREAST-Q questionnaire to assess subjective outcomes in patients, with six studies using the complete BREAST-Q questionnaire, which includes measurements of breast satisfaction, satisfaction with outcomes, psychological well-being, physical well-being, and sexual well-being. Physical well-being was evaluated in all nine studies, with an average Q-score of

$73.55 \pm 15.44$  among the 1130 patients. Table 3 presents the statistical data for other dimensions of the BREAST-Q.

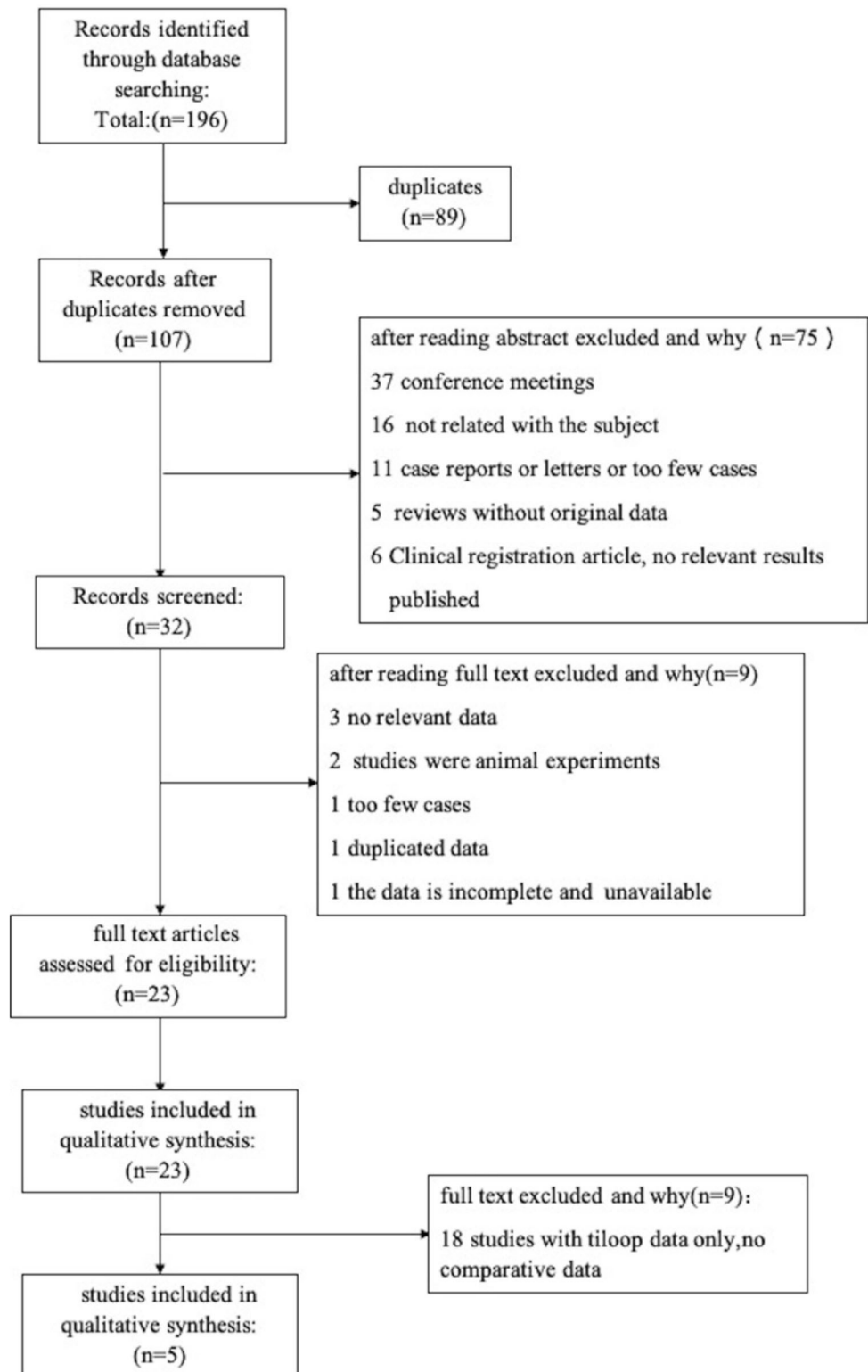
### TiLOOP® Bra versus ADM

Four studies directly compare the postoperative complications of using TiLOOP® Bra and ADM in IBBR. Of these, 351 breasts were reconstructed with TiLOOP® Bra, 194 breasts were reconstructed with ADM (porcine-derived), and all breasts underwent subpectoral reconstruction (Table 6). Only one of these studies was a randomized controlled trial, showing a higher ADM reconstruction failure rate. However, the sample size was small, and more experimental data are needed to validate this conclusion [14]. Although one of these retrospective studies demonstrated that radiotherapy significantly affected the incidence of wound infections and implant loss in both the TiLOOP® Bra and ADM groups [15], our study found no statistically significant difference in the proportion of patients who received pre- or postoperative radiotherapy between the two groups. Additionally, no significant difference was noted in the proportion of patients who received neoadjuvant chemotherapy between the two groups (Table 7). Meta-analysis was conducted on the incidence of seroma, implant loss and infection in four studies, as well as the incidence of hematoma, wound dehiscence, skin-nipple necrosis, and the need for secondary surgery or hospitalization in three studies. No heterogeneity was found in all analyses (all  $I^2 = 0$  &  $P > 0.1$ ). Therefore, a fixed-effect model was used. The results of the meta-analysis indicated that the TiLOOP® Bra group exhibited significantly lower rates of seroma, implant loss, and wound dehiscence, as well as lower rates of secondary surgery or hospitalization compared to the ADM group. At the same time, the risks of hematoma, infection, and skin-nipple necrosis did not significantly differ between the two groups (Tables 8 and 9).

### TiLOOP® Bra versus SERAGYN® BR

A total of 778 reconstructed breasts from three retrospective studies were analyzed, with 481 IBBR using TiLOOP® Bra and 297 using SERAGYN® BR; all breasts underwent subpectoral reconstruction (Table 6). The meta-analysis calculated odds ratios for seroma, wound dehiscence, infection, implant loss, and secondary surgery or hospitalization rates. No heterogeneity was found in all analyses (all  $I^2 < 10\%$  &  $P > 0.1$ ), and the fixed effects model showed that the TiLOOP® Bra group had a significantly lower incidence of seroma than the SERAGYN® BR group. At the same time, no significant difference was found in the risks of other complications between the two groups (Tables 10 and 11).

**Fig. 1** Flowchart demonstrating selection process for included studies. Meta-analysis data were collected following the PRISMA (preferred reporting items for systematic reviews and meta-analyses) guidelines



### Sensitivity Analysis

The robustness and dependability of the pooled results were assessed in the current meta-analysis using sensitivity

analysis. The sensitivity analysis results showed that excluding each study had no significant effect on the results, and the consequences of this meta-analysis were reliable and stable (Supplementary material).

**Table 6** Characteristics of comparative studies

Studies (author, year)	Design	Reconstructive types (prepectoral/subpectoral/mixed)	Kind of mesh used	No. of Patient	Age, *year	BMI,* kg/m <sup>2</sup>	Preoperative RTx	Postoperative RTx	Follow-up Period (months)
Gao, P (2022)	Retrospective cohort	Subpectoral	TiLOOP® Bra	37	42.7 ± 8	21.5 (20.5–23.9)	0	4	17 (15–21)
Gschwamntler (2016)	Randomized controlled	Subpectoral	ADM	79	41.1 ± 7.0	21.4 (20.3–22.7)	0	16	17 (13–22)
Ohlinger, R (2021)	Retrospective cohort	Subpectoral	TiLOOP® Bra ADM	25 23	48.07 47.12	23.42 25.21	0 0	0 4	> 6 > 6
Katharina (2021)	Retrospective cohort	Subpectoral	TiLOOP® Bra ADM SERAGYN®BR	143 43 95	47.4 49.9 51.6	25.7 23.4 26.5	20 10 12	18 6 11	27 42.8 27
Eichler (2019)	Retrospective cohort	Subpectoral	TiLOOP® Bra ADM SERAGYN®BR	75 34 48	48.1 ± 10.3 52.3 ± 5.9 53.5 ± 10.7	25.7 ± 4.4 24.6 ± 4.3 26.2 ± 4.5	18 8 2	23 6 8	9.2 ± 9 17.8 ± 0.4 11.3 ± 7.1
			SERAGYN®BR	192	49.1 ± 11.7	23.6 ± 3.5	–	–	–
			SERAGYN®BR	128	48.8 ± 13.5	23.5 ± 3.3	–	–	–

#Data presented as mean, mean ± standard deviation or median (IQR; range)

**Table 7** Comparison of treatment received by patients (TiLOOP® Bra group vs. ADM group)

Study characteristic	No. studies	TiLOOP® Bra (%)	ADM (%)	<i>P</i>
Number of patients	4	280	179	
Neoadjuvant chemotherapy	3	46 (16.43)	25 (13.97)	0.4770
Adjuvant chemotherapy	3	53 (18.93)	65 (36.31%)	< 0.0001
Postoperative RTx	4	45 (16.07)	32 (17.88)	0.6140
Preoperative RTx	4	38 (13.57)	18 (10.06)	0.2617

**Table 8** Complication rates in comparative studies (TiLOOP® Bra group vs. ADM group) (%)

Study (author, year)	Group	No. breasts	Seroma	Hematoma	Implant loss	Infection	Wound dehiscence	Skin-nipple necrosis	Need reoperation or hospitalization
Gschwantler (2016)	TiLOOP® Bra	25	4.00	8.00	8.00	4.00	NR	NR	NR
	ADM	23	13.04	0.00	30.43	13.04	NR	NR	NR
Gao, P (2022)	TiLOOP® Bra	37	0.00	NR	0.00	2.70	0.00	0.00	0.00
	ADM	79	7.59	NR	6.33	5.06	2.53	2.53	6.33
Ohlinger, R (2021)	TiLOOP® Bra	195	3.08	3.59	5.64	5.64	5.13	3.59	15.38
	ADM	52	21.15	5.77	23.08	9.62	17.31	9.62	28.85
Katharina (2021)	TiLOOP® Bra	94	4.26	5.32	6.38	7.45	4.26	3.19	14.89
	ADM	40	27.50	7.50	27.50	5.00	12.50	5.00	27.50

NR, Not reported

**Table 9** Summative forest plot for primary post-operative endpoints (TiLOOP® Bra group vs. ADM group)

Complication	Odds ratio* (95% CI)	<i>P</i>	<i>I</i> <sup>2</sup> (%)	<i>Ph</i>
Seroma	0.13 (0.06–0.28)	< 0.001	0	0.92
Hematoma	0.87 (0.34–2.25)	0.780	0	0.45
Implant loss	0.19 (0.10–0.36)	< 0.001	0	1.00
Infection	0.66 (0.31–1.42)	0.290	0	0.64
Wound dehiscence	0.29 (0.13–0.62)	0.002	0	0.94
Skin-nipple necrosis	0.42 (0.16–1.10)	0.080	0	0.87
Need reoperation or hospitalization	0.43 (0.25–0.74)	0.002	0	0.83

*P*-values for ORs; *Ph* values of the Q-test for heterogeneity test; *I*<sup>2</sup> refers to the proportion of total variation due to between-study heterogeneity

\*Means the OR of the TiLOOP® Bra group/ADM group

## Discussion

Using meshes has opened up new prospects for implant-based breast reconstruction [16]. The meshes used in prosthetic breast reconstruction can provide excellent coverage for the lateral aspect of the breast, particularly the lateral pectoralis major muscle, thereby significantly improving the contour and aesthetics of the breast. However, the availability of multiple types of mesh has posed a challenge for breast surgeons in selecting the optimal mesh

for breast reconstruction. This study systematically reviewed the literature on the use of TiLOOP® Bra for IBBR and compared its incidence of postoperative complications with that of ADM and SERAGYN® BR. This investigation aimed to explore differences in the risk of complications following the use of these meshes in breast reconstruction.

This study reviewed 3175 cases of IBBR using TiLOOP® Bra, which included 1655 cases of prepectoral reconstruction and 1520 cases of subpectoral

**Table 10** Complication rates in comparative studies (TiLOOP® Bra group vs. SERAGYN® BR group) (%)

Study (author, year)	Group	No. breasts	Seroma	Hematoma	Implant loss	Infection	Wound dehiscence	Skin-nipple necrosis	Need reoperation or hospitalization
Eichler (2019)	TiLOOP® Bra	192	4.69	NR	8.33	2.60	1.04	NR	8.33
	SERAGYN® BR	128	9.38	NR	3.91	2.34	0.78	NR	3.91
Ohlinger, R (2021)	TiLOOP® Bra	195	3.08	3.59	5.64	5.64	5.13	3.59	15.38
	SERAGYN® BR	115	5.22	4.35	6.96	5.22	9.57	3.48	14.78
Schueler (2021)	TiLOOP® Bra	94	4.26	5.32	6.38	7.45	4.26	3.19	14.89
	SERAGYN® BR	40	17.50	10.00	5.00	5.00	2.50	0.00	15.00

NR, Not reported

**Table 11** Summative forest plot for primary post-operative endpoints (TiLOOP® Bra group vs. SERAGYN® BR group)

Complication	Odds ratio* (95% CI)	<i>P</i>	<i>I</i> <sup>2</sup> (%)	<i>Ph</i>
Seroma	0.45 (0.24–0.83)	0.01	0	0.75
Hematoma	0.77 (0.32–1.86)	0.56	0	0.87
Implant loss	1.39 (0.74–2.60)	0.31	10	0.33
Infection	1.17 (0.57–2.39)	0.67	0	0.68
Wound dehiscence	0.39 (0.34–1.53)	0.39	0	0.38
Need reoperation or hospitalization	1.34 (0.83–2.16)	0.23	0	0.47

*P*-values for ORs; *Ph* values of the Q-test for heterogeneity test; *I*<sup>2</sup> refers to the proportion of total variation due to between-study heterogeneity

\*Means the OR of the TiLOOP® Bra group/SERAGYN® BR group

reconstruction. Since the introduction of the subpectoral implant technique in 1982 by Radovan, it has become a popular approach to IBBR. In contrast, prepectoral reconstruction was developed earlier [17]. Placing the implant in the prepectoral space can lead to a more natural breast shape and better aesthetic outcome, but it was not widely applied due to the high incidence of severe complications [18–20]. However, our study found a higher proportion of breasts reconstructed with prepectoral implants, and the update on recently accumulated data further exemplifies the resurgence of this technique. Notably, there was no significant difference in the overall incidence of complications between prepectoral (20.4%, 328/1609) and subpectoral (22.6%, 278/1232) IBBR ( $p = 0.16$ ). This analysis showed a favourable risk profile in TiLOOP® Bra for prepectoral reconstruction, with comparable complication rates to subpectoral implant reconstruction. However, this conclusion is based on something other than a direct comparison between the two techniques and thus has its limitations. Ostapenko et al. conducted a meta-analysis of

15 studies involving 3101 patients comparing prepectoral and subpectoral IBBR and arrived at the same conclusion as our study [21]. Notably, our study reported a lower overall complication rate of pre-pectoral IBBR (20.39%, 328/1609) than Ostapenko et al. (25.08%, 366/1459). This difference may be due to the use of TiLOOP® Bra, as only a small number of patients in Ostapenko et al.'s study underwent reconstruction with TiLOOP® Bra. Overall, our analysis supports the safety of TiLOOP® Bra in prepectoral IBBR.

According to our study, using ADM in IBBR results in a higher implant loss rate than TiLOOP® Bra (OR = 0.19). Implant loss is a severe complication that can significantly impact patient satisfaction, increase costs, and even cause delays in treatment, resulting in physical and psychological harm [22, 23]. Several risk factors for implant loss have been identified in previous studies, including radiotherapy, obesity, advanced age, and direct-to-implant reconstruction [24–26]. Although implant loss after IBBR is a multifactorial process, the only prospective randomized controlled

study by Gschwantler et al. on TiLOOP® Bra versus ADM, controlling for preoperative radiotherapy, age, obesity, surgical technique, and other variables, found that the use of ADM for IBBR significantly increased the rate of implant loss [14]. Despite the small sample size of only 48 patients, the results of this study were consistent with the conclusions drawn from our pooled analysis. Recently, a retrospective study by Katharina et al. showed that regardless of whether it is one-stage or two-stage reconstruction, ADM combined with implant reconstruction has a significantly higher rate of implant loss than TiLOOP® Bra [27]. Additionally, Lee et al.'s meta-analysis, which included 23 studies, calculated that the postoperative implant loss rate for ADM combined with implant reconstruction was 6.5% (166/2558) [28]. In contrast, in our study, the postoperative implant loss rate for TiLOOP® Bra combined with implant reconstruction was only 3.5% (71/2019). In summary, we believe that selecting TiLOOP® Bra for IBBR can significantly reduce the risk of implant loss.

Our study showed a significantly lower risk of seroma in breasts undergoing IBBR using TiLOOP® Bra than ADM. Seroma is a common complication of IBBR. However, it can lead to patient discomfort, unsatisfactory aesthetic outcomes, increased medical visits, and even more severe complications such as infection or implant loss [29]. A large-scale systematic literature review and meta-analysis by Sumanas et al. identified obesity, ADM, and preoperative radiotherapy as risk factors for seroma formation in IBBR. Moreover, the combined relative risk of ADM was 1.83 (95% CI 1.28–2.62) [30]. Our meta-analysis found that the TiLOOP® Bra group had a significantly lower incidence of seroma formation than the ADM group, and there was no significant difference in the incidence of preoperative radiotherapy between the two groups. Furthermore, according to our meta-analysis results, the TiLOOP® Bra group had a significantly lower incidence of seroma formation compared to the SERAGYN® BR group. Therefore, we conclude that TiLOOP® Bra is a better choice for reducing the risk of postoperative seroma in IBBR.

Our study also demonstrated that the TiLOOP® Bra has a lower incidence of wound dehiscence in IBBR when compared with ADM. Wound dehiscence is a severe complication that can be troublesome for the patient and the surgeon. A multicenter retrospective study by Wilson et al. compared 553 cases of ADM (Strattice™) combined with implant reconstruction to 242 cases of implant reconstruction alone. The study found that the use of ADM significantly increased the incidence of wound dehiscence (16.3% (n = 90) vs. 10.4% (n = 25),  $p = 0.03$ ) [9]. Furthermore, our study, which analyzed 13 studies, reported an incidence of wound dehiscence of only 2.75% for

TiLOOP® Bra combined implant reconstruction. The problem of wound dehiscence is challenging for patients and surgeons, as it may cause more severe postoperative complications and delay treatment. Choosing appropriate materials during reconstruction is, therefore, of utmost importance. Our research findings indicate that TiLOOP® Bra is better than ADM at reducing the risk of postoperative wound dehiscence in IBBR.

Safety is the primary concern when selecting a mesh for breast reconstruction, but the cost is also a significant factor for patients. Vidya et al. elaborated on a cost analysis comparing synthetic meshes with ADM, concluding that synthetic meshes were cheaper (synthetic meshes: €500 versus ADM £1800–3000) [7]. However, the cost of meshes varies across countries and regions. In the Eichler et al. study, a TiLOOP® Bra of approximately 320 cm<sup>2</sup> cost  $\times\times\times$  a SERAGYN® BR of the same size cost  $\times\times\times$  but an ADM of the same size cost over \$2000 [31]. In a national cross-sectional survey of 110 hospitals in China conducted by Guo R et al., half offered TiLOOP® Bra, while only one-third offered ADM. This study suggests that the high cost of ADM may be the main reason for its less prevalence [11]. As a result, patients may opt for synthetic meshes due to cost considerations.

One inherent limitation of our study is that we could not obtain individual-level data when extracting data from the reports. Consequently, we could not adjust for patient selection bias, and the reports did not provide adjusted estimates. Moreover, as many patient and biological factors influence post-operative outcomes after an IBBR, attributing cause and effect is challenging. In the meta-analysis of TiLOOP® Bra and ADM, we only excluded the influence of certain factors (reconstruction method, radiotherapy, and neoadjuvant chemotherapy). However, other factors such as smoking status, body mass index (BMI), diabetes, and type of implant, among others, could not be analyzed due to unavailable or limited data. This limitation was also observed in the meta-analysis of TiLOOP® Bra and SERAGYN® BR, which further restricts our ability to confirm the non-influence of these factors on our analysis results. Additionally, among the 23 articles included in our study, the case assignment of most studies was non-randomized, and the resulting selection bias limited their conclusions. Further well-designed, prospective, randomized controlled trials will be required to resolve this issue. Furthermore, only two studies conducted a comparative patient satisfaction analysis, but different evaluation methods were used. Therefore, we could not perform a meta-analysis on patient satisfaction and only conducted a safety assessment. Due to limited data on implant capsule contracture and rippling, this study did not provide relevant analyses. Moreover, ADM can be derived from bovine, human, and porcine, but our study only compared ADM

derived from porcine with TiLOOP® Bra. However, this is also an advantage of our study, as some studies have shown that ADMs from different sources have differences in safety [32, 33]. In addition, to the best of our knowledge, no studies have shown differences in the postoperative safety of these two types of porcine ADM (Protexa® & Strattice™). In the future, more well-designed prospective randomized controlled trials are needed to provide more accurate and comprehensive evidence for patients and breast surgeons when selecting meshes.

## Conclusion

This is the first large-scale review of IBBR using TiLOOP® Bra, analyzing 3666 breasts of 3135 patients. The statistical findings of this study support the favorable risk profile of TiLOOP® Bra in IBBR. Meta-analysis demonstrates that TiLOOP® Bra had better safety in IBBR when compared to ADM. Moreover, there are no significant advantages except for a lower risk of seroma in IBBR using TiLOOP® Bra than SERAGYN® BR. In the future, the expensive ADM may be replaced by cheaper synthetic mesh, especially TiLOOP® Bra. However, due to the limited comparative data and the fact that multiple factors may affect the results, further investigations are necessary to produce more solid conclusions.

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## Declarations

**Conflict of interest** The authors declare that they have no conflict of interest.

**Human and Animal Rights** This article does not contain any studies with human participants or animals performed by any of the authors.

**Informed Consent** For this type of study, informed consent is not required.

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