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Review

Breast reconstruction with TiLOOP® Bra: Another arrow in plastic surgeons' quiver?

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Summary *Background:* The use of lower-pole sling products has made immediate breast reconstruction a feasible option in women undergoing skin-nipple sparing and skin-reducing mastectomies. To date, available data on the comparative efficacy of biological and synthetic meshes regarding postoperative complications are scattered and limited.
Methods: A systematic literature search was performed to screen three different databases (PubMed, Web of Sciences, and Embase) using the following keywords: "breast reconstruction" AND "TiLOOP®" OR "Titanium-Coated Polypropylene Mesh" OR "TCPM". The perioperative and demographic characteristics of patients, complications profiles, and patient-reported outcomes were considered.
Results: We initially identified 234 articles, of which only 41, including 3923 patients and 5042 reconstructed breasts, fully satisfied the inclusion criteria.
Conclusion: TiLOOP® Bra could be considered a safe and aesthetically valid alternative to Acellular Dermal Matrices (ADMs) in non-smokers patients undergoing skin-nipple sparing and skin-reducing mastectomies and immediate reconstruction. In such populations, complications are more likely to develop in patients with extreme body mass index values. The incidence of seroma with TiLOOP® Bra is comparable to that of ADMs as it is the beneficial effect in radiated patients, where TiLOOP® Bra seems superior to implant alone reconstruction. It has a good

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bio-integration with host tissues and resistance to infections in patients with a weakened immune system as a consequence of oncologic perioperative treatments.

Contents

Although autologous breast reconstruction remains the gold standard, the most widely used technique is reconstruction with implants.[1]

To reduce the psychological burden of the classical two-stage approach, the current trend is to perform immediate reconstruction with implants of the desired size placed either above or partially under the pectoralis major muscle (PMm).[2,3] In either case, the use of meshes is advantageous, as it provides an additional coating to the implant in the former case and enlarges the subpectoral pocket in the latter, where it is sutured to the lower edge of the muscle, acting as a hammock.[2,3].

Among synthetic meshes, TiLOOP® is the most widely used.[4] It is a titanium-coated polypropylene mesh (TCPM) approved for breast reconstruction in Europe in 2008.[1] The hydrophilic and tetanized surface of TiLOOP®, combined with its light weight (16–35 g/m^2) and pyrogen-free sterilization process, have been associated with less pronounced inflammatory reactions, reduced connective tissue-like scar formation, and significantly less shrinkage compared to non-TCPMs.[5] These advantages, already known in the use of titanized mesh implants for hernia surgery, enable tissue ingrowth and vascularization and ensure optimum capsule quality.[6] Another advantage of TiLOOP® lies in its mosquito framework, which allows continuous drainage of secretions, dampening the risk of seromas between skin envelope and mesh, a known complication of Acellular Dermal Matrix (ADM)-assisted breast reconstruction.[7]

TiLOOP® is available in 2 preshaped configurations: TiLOOP® Bra (crescent-shaped, cut out for being sutured to the lower edge of the PMm and serving as a direct muscular extension in dual plane reconstruction) and TiLOOP® Bra Pocket (pocket-shaped, planned for implant accommodation in pre-pectoral reconstruction).[6]

This is a systematic review of available literature about the use of TiLOOP® Bra in breast reconstruction. The aim of this study was to determine the target population of women in which this device can be offered as a safe and valid adjunct in alloplastic breast reconstruction.

Materials and methods

On March 3, 2023, a literature search in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines was conducted using PubMed, Web of Sciences, and Scopus databases to identify relevant articles on breast reconstruction with synthetic meshes (Figure 1).

The search algorithm included the following keywords: “breast reconstruction” AND “TiLOOP®” OR “Titanium-Coated Polypropylene Mesh” OR “TCPM”.

The inclusion criteria were clinical trials, case series, and TiLOOP® Bra-assisted reconstruction.

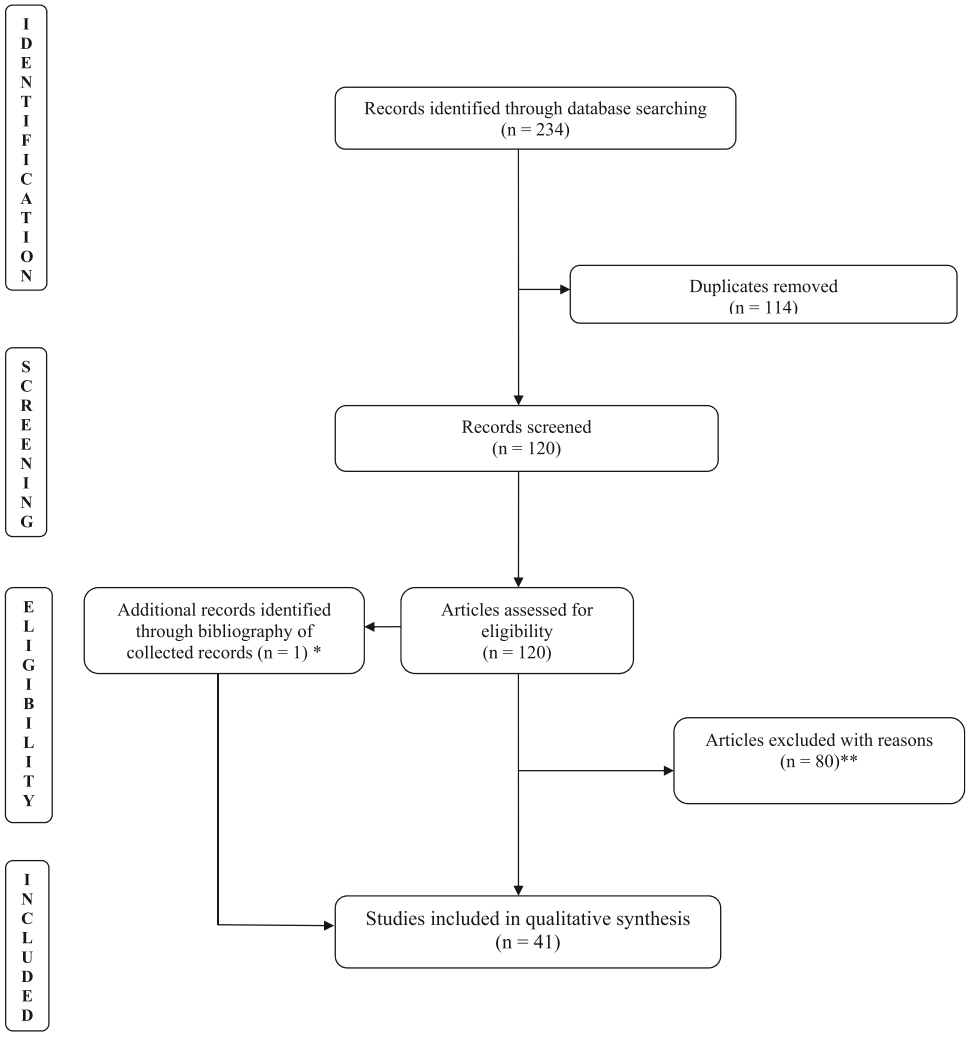

Figure 1 PRISMA flowchart. A total of 234 studies were identified through database searching: 41 articles were selected and included in qualitative synthesis. * The reference list of analyzed studies was scrutinized to retrieve additional articles eligible for inclusion. One additional article was identified and included. ** Among these, we decided to exclude also one article[64] in which a technique of implant salvage was described in four cases of implant exposure after DTI breast reconstruction with TiLOOP® Bra, two articles[65,66] whose purpose was a socio-economical rather than clinical analysis about mesh distribution across China and UK and one article[15] in which the personal experience of authors with TiLOOP® Bra was described from a technical rather than a clinical viewpoint.

The exclusion criteria were partial resorbable/resorbable mesh usage, previous reviews and meta-analyses,[4,8-12] case reports,[13,14] expert opinion articles,[15-17] and animal studies.[18]

Data on peri-operative characteristics and patient demographics (reported in Tables 1 and 2, respectively) were collected. We also recorded all acute and chronic complications following surgery (Table 3) and Patient-Reported Outcomes (PROs) (Table 4). When reported by authors, complications were categorized as minor (Mn) or major (Mj). Table 5 refers to the configuration of TiLOOP® (TiLOOP® Bra vs TiLOOP® Bra Pocket) used in different studies.

In some studies, TiLOOP® was the only mesh considered, while in others, it was compared either with animal-derived or other synthetic devices or implant alone reconstruction, possibly interfering with the conclusions of this study. To reduce any risk of bias, we have summarized the results of the articles in which the population was segmented between patients reconstructed with TiLOOP® Bra and patients reconstructed with ADM/other mesh or implant alone in Figure 2 and Table 6.

Data were recorded and tabulated using Microsoft Excel (Version 2210, Microsoft Corp., Redmond, Washington,).

Quality assessment

The risk of bias of each study is reported in Supplementary Table 7.

Results

We identified 234 articles through database searching. After removing duplicates (n = 114) and articles that did not meet the inclusion criteria (n = 80), we collected 40

Table 1 Summary of perioperative characteristics of included studies.

Author	Type of study	Patients (breasts)	Mastectomy	Indication for surgery	Breast weight (g)	Implant pocket	Dermal sling (yes/no)	Implant characteristics/TE	Timing of reconstruction	Implant size	SLNB (%) - ALND (%) [during surgery]	(Homolateral) previous breast surgery	Drainage duration (days)	Number of vacuum drains
Bernini, 2015	prospective, non-randomized single-center study	29 (34) [dual plane]; 34 (39) [pre-pectoral]	SSM (15% dual plane; 8% pre-pectoral), NSM (85% dual plane; 92% pre-pectoral)	therapeutic (100%)	N/A	dual plane (46.6%) and pre-pectoral (53.4%)	no	implant (N/A)	immediate (DTI)	N/A	ALND (26% dual plane, 33% pre-pectoral)	0%	N/A	N/A
Casella, 2014	prospective non-randomized, single-center study	29 (34) [dual plane]; 34 (39) [pre-pectoral]	SSM, NSM	therapeutic (100%)	N/A	dual plane (46.6%) and pre-pectoral (53.4%)	no	implant (N/A)	immediate (DTI)	N/A	N/A	0%	N/A	2 (dual plane group); 1 (pre-pectoral group); +1 drain in ALND cases
Casella, 2015	case series	25 (25)	SSM, NSM	therapeutic (100%)	N/A	pre-pectoral	no	tissue expander	immediate (TE)	N/A	SLNB (N/A %) - ALND (N/A%)	0%	N/A	N/A
Casella, 2018	retrospective, single-center, observational study	46 (92)	NSM	prophylactic mastectomy (100%)	N/A	pre-pectoral	no	implant (N/A)	immediate (DTI)	N/A	0%	0%	mean (range): 6.5 (4–9)	1
Casella, 2019 (n°1)	prospective, single-center non randomized study	179 (250)	SSM, NSM	therapeutic (56%) and prophylactic (44%)	N/A	pre-pectoral	no	implant (anatomical)	immediate (DTI)	range: 270—470 cc	SLNB (39.2%) - ALND (10.4%)	20.1% (wide local excision: 11.7%; ipsilateral QUART: 5%; breast augmentation: 3.3%)	mean (range): 4.2 (2–9)	1
Casella, 2019 (n°2)	retrospective, single-center observational study	397 (521)	SSM, NSM	therapeutic (76.1%), prophylactic (23.9%)	N/A	pre-pectoral	no	implant (N/A), tissue expander	immediate (DTI: 54.5%; TE: 45.5%)	N/A	SLNB (37.4%) - ALND (10.4%)	28.5% (N/A)	N/A	1
Casella, 2019 (n°3)	prospective, single-center study	187(237)	SSM, NSM	therapeutic (82.4%) and prophylactic (17.6%)	N/A	pre-pectoral	no	tissue expander	immediate (TE)	N/A	SLNB (40.6%) - ALND (10.5%)	18.2% (wide local excision, QUART, previous augmentation)	N/A	1
Casella, 2021	retrospective single-center observational study	352 (467)	SSM, NSM	therapeutic (75.3%), prophylactic (24.7%)	N/A	pre-pectoral	no	implant (anatomical), tissue expander	immediate (DTI: 30.8%; TE: 69.2%)	N/A	SLNB (38.5%) - ALND (9.4%)	20.7% (wide local excision: 11%; QUART: 7.1%; breast augmentation: 2.6%)	mean (range): 4.2 (2–9)	1
Casella, 2022	retrospective single-center observational study (pts randomized for contralateral symmetrization: immediate vs delayed)	84 (84)	SRM	therapeutic (100%)	N/A	pre-pectoral	yes	tissue expander	immediate (TE: 100%)	N/A	SLNB (100%) - ALND (25%)	0%	N/A	N/A

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Table 1 (*continued*)

Author	Type of study	Patients (breasts)	Mastectomy	Indication for surgery	Breast weight (g)	Implant pocket	Dermal sling (yes/no)	Implant characteristics/TE	Timing of reconstruction	Implant size	SLNB (%) - ALND (%) [during surgery]	(Homolateral) previous breast surgery	Drainage duration (days)	Number of vacuum drains
Casella, 2023	prospective, single-center observational study	46 (46)	SSM (DACI)	therapeutic (100%)	N/A	pre-pectoral	no	tissue expander	immediate (TE: 100%)	N/A	N/A	17.3% (N/A)	N/A	N/A
Chen, 2019	retrospective single-center observational study	10 (14)	SSM, NSM, mRM	therapeutic (71.4%) and prophylactic (28.6%) mastectomy	N/A	dual plane	no	implant (N/A)	immediate (DTI)	mean, SD (range): 255, 26 (200-280 cc)	SLNB (N/A %) - ALND (N/A%)	0%	mean, SD (range): 7.6, 2.6 (3-11)	2
Delmond, 2020	abstract of retrospective single-center study	209 (260)	SSM, NSM, SRM	therapeutic (N/A%) and prophylactic (N/A%)	N/A	dual plane	yes (9.2% of reconstructions)	implant (N/A)	immediate (DTI)	N/A	SLNB (N/A %) - ALND (N/A%)	N/A	N/A	N/A
Dieterich, 2012	prospective, single-center observational study	42 (45)	SSM, NSM	therapeutic (85.7%), prophylactic (7.1%), revision of previous surgery (7.2%)	N/A	dual plane	no	implant (anatomical), tissue expander	immediate [DTI: N/A%;TE: N/A%] (86.7%) and delayed (13.3%)	median (range): 215 84 cc (135-480	SLNB (66.7%) - ALND (21.4%)	86.7% (BCT: 28.2%; mRM: 5.1%; SSM + implant reconstruction: 15.4%; BCT + SLNB: 23%; mRM + autologous reconstruction: 2.6%; SLNB/ALND: 20.5%; breast augmentation: 5.1%)	median, IQR (range): 6, 2.4 (3-14)	N/A
Dieterich, 2013	retrospective, multicenter observational study	207 (231)	SSM, NSM, mRM	therapeutic (74.9%) and prophylactic (25.1%)	N/A	dual plane	no	implant (anatomical, round), tissue expander	immediate [DTI: N/A%, TE; N/A%] (87.4%) and delayed (12.6%)	N/A	N/A	yes (N/A%)	N/A	2
Dieterich, 2015 (n°1)	prospective, single-center observational study	34 (34)	SSM, NSM, SRM	therapeutic (94.1%) and prophylactic (5.9%) mastectomy	mean, SD (range): 240.9 g, 136.6 (100-609)	dual plane	yes (20.6% of reconstruction)	implant (N/A)	immediate (DTI) (94.1%) and delayed (5.9%)	mean, SD (range): 225.4, 72.6 (135-475)	SLNB (26.5%) - ALND (0%)	11.8% (BCT: 11.8%, SLNB alone: 20.6%, BCT + SLNB/ALND: 44.1%)	N/A	1
Dieterich, 2015 (n°2)	retrospective, single-center observational study	48 (51)	SSM, NSM, SRM	therapeutic (91.7%) and prophylactic (8.3%)	mean, SD (range): 232.4, 130.5 (100-609)	dual plane	yes (15.7% of reconstructions)	implant (anatomical), tissue expander	immediate (DTI)	mean, SD (range): 228.1, 130.5 (135-475)	SLNB (22.9%) - ALND (0%)	79.2% (BCT: 14.6%, SLNB alone: 22.9%, BCT + SLNB: 41.7%, BCT + ALND: 0%)	N/A	1 (66.7%); 2 (33.3%)
Eichler, 2019	retrospective single-surgeon multicenter observational study	142 (192)	SSM, NSM	"oncologic" mastectomy (64.6%) and aesthetic surgery (contralateral symmetrization) (35.4%)	N/A	dual plane	no	implant (N/A)	immediate (DTI) (N/A%) and delayed (N/A%)	implant (N/A)	N/A	N/A	mean, SD (range): 3.2, 1.8 (1-9)	1

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Table 1 (*continued*)

Author	Type of study	Patients (breasts)	Mastectomy	Indication for surgery	Breast weight (g)	Implant pocket	Dermal sling (yes/no)	Implant characteristics/TE	Timing of reconstruction	Implant size	SLNB (%) - ALND (%) [during surgery]	(Homolateral) previous breast surgery	Drainage duration (days)	Number of vacuum drains
Esposito, 2017	(abstract of) retrospective, single-center, observational study	N/A (69)	N/A	therapeutic (100%)	N/A	dual plane	N/A	implant (N/A)	immediate (DTI)	N/A	N/A	N/A	N/A	N/A
Gao, 2022	retrospective, single-center observational study	37 (55)	SSM, NSM	therapeutic (100%)	N/A	dual plane	no	implant (anatomical)	immediate (DTI)	median (range): 245 (215-280)	SLNB (91.9%) - ALND (8.1%)	0%	median (range): 20.9 (15.0-25.0)	2
Gentile, 2021	retrospective observational study	276 (328)	SSM, NSM, SRM	therapeutic (81.4%) and prophylactic (19.6%)	N/A	pre-pectoral	yes	implant (anatomical, round), tissue expander	immediate [DTI: 58.5%; TE with TCPM: 30.8%; TE w/o TCPM: 10.7%] immediate [DTI: 65.5%; TE: 34.5%]	implant (range): 270-470 cc; expander (range): 250-500 cc	SLNB (31.1%) - ALND (11.3%) - both: 6.7%	22.9% (wide excision: 10.4%; QUART: 10.4%; breast augmentation: 2.1%)	mean (range): 4.2 (2-9)	N/A
Gschwantler-Kaulich, 2016	prospective, open, 2-arm, multicenter, pilot study	25 (25)	SSM, NSM	therapeutic (60%), prophylactic (24%), both (16%)	N/A	dual plane	no	implant (anatomical)	immediate (DTI)	mean: 390.32 cc	SLNB (52%) - ALND (20%)	0%	mean: 10.44	1
Guanglei Chen, 2019	case series	27 (27)	NSM	therapeutic (100%)	N/A	dual plane	no	implant (N/A)	immediate (DTI)	range: 155-280 cc	N/A	N/A	N/A	N/A
Klein, 2012	(abstract of) prospective study	87 (N/A)	SSM	therapeutic (82.8%) and prophylactic (17.2%)	mean (range): 307.8 g (181-820)	dual plane	no	implant (N/A)	immediate (DTI)	median (range): 327 cm^3 (125-680)	N/A	N/A	median: 4.7	N/A
Krivorotko, 2021	retrospective single-center study	103 (112)	SSM, NSM	therapeutic mastectomy (100%)	N/A	dual plane	no	implant (N/A)	immediate (DTI)	N/A	N/A	N/A	N/A	N/A
Lo Torto, 2020	prospective, single-center observational study	18 (22)	SSM, NSM	therapeutic (77.8%) and prophylactic (22.2%)	N/A	pre-pectoral	no	implant (anatomical), tissue expander	immediate [DTI: 18.2%; TE: 81.8%]	tissue expander, mean (range): 500 (400-600)	N/A	N/A	mean (range): 6.5 (4-10)	1
Marcasciano, 2018	case series	12 (17)	SRM	therapeutic (N/A%) and prophylactic (N/A%)	N/A	pre-pectoral	yes	implant (anatomical)	immediate (DTI)	range: 275-410 cc	N/A	N/A	N/A	N/A
Marcasciano, 2023	case series	25 (27)	NSM	therapeutic (100%)	N/A	pre-pectoral	no	tissue expander	immediate (TE)	range: 275-600 cc	N/A	N/A	N/A	1
Michno, 2022	subgroup analysis of a prospective, single-arm, multicenter observational study	258 (345)	SSM, NSM, mRM	therapeutic (94%), prophylactic (5%)	mean 360 g	dual plane	no	implant (N/A), tissue expander	immediate [DTI: 90%;TE: 10%] (98%) and delayed (2%)	N/A	N/A	30% (BCT: 28%; prior mastectomy/ secondary reconstruction: 2%)	mean (range): 8 (0-21)	N/A

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Table 1 (*continued*)

Author	Type of study	Patients (breasts)	Mastectomy	Indication for surgery	Breast weight (g)	Implant pocket	Dermal sling (yes/no)	Implant characteristics/TE	Timing of reconstruction	Implant size	SLNB (%) - ALND (%) [during surgery]	(Homolateral) previous breast surgery	Drainage duration (days)	Number of vacuum drains
Ng, 2021	retrospective, single-center observational study	80 (109)	NSM	therapeutic (87.2%) and prophylactic (12.8%)	mean (range): 265 g (110-580) [pre-pectoral]; 218 g (150-530) [dual plane]	pre-pectoral (45.9%) and dual plane (54.1%)	no	implant (anatomical, round)	immediate (DTI)	mean (range): 378 cc (125-555) [pre-pectoral]; 340 cc (120-555) [dual plane]	N/A	N/A	N/A	1
Nguyen-Strauli, 2022	retrospective, single-center observational study	43 (63)	SSM, NSM	therapeutic (74.4%) and prophylactic (9.3%) and other (16.3%)	mean, SD (range): 241 g, 142 (47-783)	pre-pectoral	no	implant (anatomical, round), tissue expander	immediate [DTI: 84.2%; TE: 3.2%] (90.5%) and delayed (6.3%)	mean, SD (range): 380, 128 cc (120-775)	SLNB (33.3%) - ALND (1.6%) - both (3.2%)	N/A	mean (range): 4 (1-11)	2
Ohlinger, 2021	retrospective, single-center observational study	143 (195)	SSM, NSM	therapeutic (100%)	mean (range): 381.3 g (27-1095)	dual plane	no	implant (N/A)	immediate (DTI) (79%) and delayed (21%)	mean (range): 381 cc (135-660)	N/A	N/A	mean (range): 7.1 (3-13)	N/A
Quah, 2019	retrospective, single-center observational study	120 (179)	SSM, NSM	therapeutic (80%) and prophylactic (20%)	N/A	dual plane	no	implant (anatomical)	immediate [DTI: 79%;TE: 21%]	mean: 390.32 cc	N/A	N/A	N/A	2
Rathinaezhil, 2015	case series	5 (7)	SRM	therapeutic (100%)	range: 454-107-1	dual plane	yes	implant (anatomical)	immediate (DTI)	N/A	SLNB (100%) - ALND (0%)	N/A	range: 7-10	2
Rezai, 2016	retrospective, single-center observational study	78 (272)	SSM, NSM	therapeutic (N/A%) > prophylactic (N/A%)	N/A	dual plane	no	implant (N/A)	immediate (DTI)	N/A	N/A	N/A	N/A	N/A
Rulli, 2013	case series	4 (5)	SSM, NSM	therapeutic (100%)	N/A	dual plane	no	implant (N/A), tissue expander	immediate (DTI: 60% N/A%, TE: 40%)	N/A	SLNB (20%) - ALND (40%)	60% (BCT+SLNB: 60%)	N/A	N/A
Schüler, 2021	retrospective single-center observational study	75 (94)	SSM, NSM	therapeutic (85.1%) and prophylactic (14.9%) mastectomy	mean, SD (range): 399.4 g, 244.2 (27-1095)	dual plane	no	implant (anatomical)	immediate (DTI) (55.3%) and delayed (29.8%)	mean, SD (range): 457.3106 (135-580 g)	N/A	N/A	mean, SD (range): 7.3, 2.1 (3-13)	2
Thill, 2020 (n°1)	(abstract of) retrospective, single-center, observational study	57 (N/A)	NSM	therapeutic (N/A%), prophylactic (N/A%)	N/A	pre-pectoral	no	implant (N/A)	immediate (DTI)	N/A	N/A	N/A	N/A	N/A

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Table 1 (*continued*)

Author	Type of study	Patients (breasts)	Mastectomy	Indication for surgery	Breast weight (g)	Implant pocket	Dermal sling (yes/no)	Implant characteris-tics/TE	Timing of recon-struction	Implant size	SLNB (%) - ALND (%) [during surgery]	(Homolateral) previous breast surgery	Drainage duration (days)	Number of vacuum drains
Thill, 2020 (n°2)	prospective, single-arm, multicenter study	210 (290)	SSM, NSM, mRM	therapeutic (72.9%) and prophylactic (27.1%)	N/A	dual plane (N/A%) and pre-pectoral (N/A%)	no	implant (N/A), tissue expander	immediate [DTI: N/A%, TE: N/A%] (97.1%) and delayed (2.9%)	N/A	0% (see homolateral previous surgery: SLNB: 22.4% - ALND: 8.1%)	81% (segment resection: 22.4%; quadrant resection: 6.2%; sentinel lymphade-nectomy: 22.4%; core biopsy: 21.9%; axillary dissection: 8.1%)	N/A	N/A
Xiao, 2022	retrospective, single-center observational study	40 (40)	NSM	therapeutic (100%)	N/A	dual plane	no	implant (N/A)	immediate (DTI)	N/A	N/A	N/A	mean, SD: 9.0, 1.4	N/A
Yang, 2019	retrospective, single-center observational study	26 (26)	SSM, NSM	therapeutic (100%)	N/A	dual plane	no	implant (N/A)	immediate (DTI)	N/A	SLNB: 100%	N/A	range: 10-14	N/A
Yao, 2019	retrospective, single-center observational study	40 (40)	SSM, NSM	therapeutic (100%)	N/A	dual plane	no	implant (N/A)	immediate (DTI)	62.5% ≤250 cc; 37.5% 255-390 cc	SLNB: 100%	N/A	N/A	2

Abbreviations: ALND = axillary lymph node dissection; BCT = breast conserving therapy; DACI = double asymmetric circular incision; DTI = direct-to-implant; IQR = interquartile range; mRM = modified radical mastectomy; N/A = not available; NSM = nipple sparing mastectomy; pts = patients; QUART = quadrantectomy, radiotherapy and axillary dissection; SD = standard deviation; SLNB = sentinel lymph node biopsy; SRM = skin reducing mastectomy; SSM = skin sparing mastectomy; TE = tissue expander; TCPM = titanium-coated polypropylene mesh; w/o = without.

Legend of symbols used:

n° = number (progressive number of studies published by a group with the same first author, tabulated in chronological order according to year/month of publication).

Table 2 Summary of demographic characteristics of analyzed patients.

Author	Age (years)	Diabetes	Smoking	Previous RHT	Adj RHT	Neoadj cht	Adj cht	BMI (kg/m^2)	Follow-up
Bernini, 2015	median (range): 51 (27-69) [dual plane]; 47 (31-76) [pre-pectoral]	0%	0%	0%	21% (dual plane), 26% (pre-pectoral)	3% (dual plane), 10% (pre-pectoral)	N/A	median (range): 23 (19-25) [dual plane]; 23 (19-24) [pre-pectoral]	median (range): 26 months (16-42) (dual plane); 25 (16-40) (pre-pectoral) [long term evaluation of the same cohort of patients evaluated by Casella et al. in 2014)
Casella, 2014	median (range): 51 (27-69) (dual plane); 47 (31-76) (pre-pectoral)	0%	0%	0%	N/A	7.9%	N/A	median (range): 23 (19-25) (dual plane group); 23 (19-24) (pre-pectoral group)	median (range): 13 months (3-29) (dual plane group); 12 months (3-27) (pre-pectoral group)
Casella, 2015	median (range): 60 (40-77)	0%	0%	0%	28%	32%	48%	median (range): 22 (19-24)	median: 14 months (after second stage)
Casella, 2018	mean (range): 43.2 (23—65)	6.5%	17.4%	0%	0%	0%	0%	mean (range): 28.4 (25-35)	2 years
Casella, 2019 (n°1)	mean (range): 56.3 (23—79)	7.8%	23%	19%	10.4%	N/A	N/A	mean (range): 22.6 (19.7-35)	mean (range): 38.5 months (24-60)
Casella, 2019 (n°2)	mean, SD (range): 46.5, 13.6 (23-80)	N/A	15.1%	17.9%	15.1%	N/A	N/A	mean, SD (range): 24.5, 3.9 (19-35)	mean: 38 months
Casella, 2019 (n°3)	mean (range): 55.5 (29-80)	6.4%	12.8%	15.5%	11%	N/A	N/A	mean (range): 24.9 (19-35)	mean (range): 36.5 months (1-6) after the second stage
Casella, 2021	mean (range): 55.9 (23—80)	7.4%	14.5%	13.4%	10.3%	N/A	N/A	mean, range: 23.75 (19-35)	mean (range): 37.5 months (12-60)
Casella, 2022	median: 55.5 ([a]) - 55.8 ([b])	0%	0%	N/A	N/A	9.5%	N/A	mean: 24.9 ([a]) - 25.3 ([b])	median (range): 22 months (1-4 years)
Casella, 2023	median (range): 57 (41-78)	N/A	N/A	10.8%	N/A	N/A	N/A	mean (range): 22.6 (19.7-35)	minimum 12 months
Chen, 2019	mean, SD (range): 44.4, 5.9 (34-54)	0%	0%	0%	N/A	N/A	N/A	mean, SD (range): 22.5, 2.4 (19.5—27.3)	mean, SD (range): 13.2, 3.1 months (8.1—19.8)
Delmond, 2020	median (range): 52.5 (25-84)	0%	26.3%	21.3%	N/A	N/A	N/A	N/A	N/A
Dieterich, 2012	N/A	4.8%	9.5%	16.7%	4.8%	19%	14.3%	median, IQR [range]: 22, 3.1 (17-32)	median, IQR (range): 20 months, 6.9 (7-33)
Dieterich, 2013	mean, SD (range): 47, 11.6 (24-74)	3.4%	16.4%	1.9%	0.1%	yes (N/A%)	yes (N/A%)	mean, SD [range]: 23, 3.5 (16-39)	mean (range): 14 months (1-41)
Dieterich, 2015 (n°1)	mean, SD (range): 49.4, 8.4 (35-67)	0%	29.4%	8.8%	2.9%	2.9%	23.5%	mean, SD [range]: 22.9, 2.8 (17.5—28.2)	mean, range: 17.5 months (1—83)
Dieterich, 2015 (n°2)	mean, SD (range): 49.3, 8.1 (35-67)	0%	77.1%	12.5%	2.1%	2.1%	33.3%	mean, SD (range): 23.1, 2.9 (17.5-32.0)	mean (range): 17.5 months (1—83)
Eichler, 2019	median (range): 49.1 (18-73)	0%	50%	N/A	N/A	N/A	N/A	median (range): 23.6 (17—32)	N/A
Esposito, 2017	N/A	N/A	N/A	N/A	37.7%	N/A	63.92%	N/A	N/A
Gao, 2022	mean, SD: 42.7, 8.0	0%	0%	0%	10.8%	5.4%	56.8%	median (range): 21.5 (20.5-23.9)	mean (range): 17.0 (15-21)
Gentile, 2021	mean, SD (range): 55, 10.33 (26-84)	2.9%	16.3%	14.1%	15%	9.1%	28.4%	mean, SD [range]: 28, 4 [16-40]	mean (range): 44 months (23-65)
Gschwantler-Kaulich, 2016	mean (range): 48.07 (25-72)	N/A	N/A	0%	0%	4%	12%	mean (range): 23.42 (19-30)	N/A
Guanglei Chen, 2019	59.5% of patients <40	N/A	0%	N/A	N/A	N/A	N/A	N/A	N/A
Klein, 2012	median (range): 45.6 (26-76)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Krivorotko, 2021	median: 42.5 (± 2)	N/A	N/A	N/A	16.5%	71.8%	30.1%	N/A	N/A
Lo Torto, 2020	mean (range): 52 (34-67)	0%	27.8%	N/A	N/A	N/A	N/A	mean (range): 29.2 (25-35)	mean (range): 12 months (11—15)
Marcasciano, 2018	mean: 43.5	0%	0%	0%	N/A	N/A	N/A	mean 22.5	mean (range): 18 months (12—24)
Marcasciano, 2023	mean (range): 47 (29-55)	0%	0%	N/A	N/A	N/A	N/A	mean (range): 24.3 (20-35)	last evaluation 1 year after the second step (TE -> I)
Michno, 2022	mean (range): 49 (19-77)	N/A	22.5%	9%	N/A	N/A	N/A	mean (range): 23 (17-40)	subgroup analysis focused on complications that arose up to 8 weeks postoperatively
Ng, 2021	mean, SD: 50.6, 9.8 (pre-pectoral); 48.5, 11.0 (dual plane)	0%	3.8%	6.4%	11%	12.8%	16.5%	mean, SD: 23.6, 2.9 [pre-pectoral]; 23.2, 2.6 [dual plane]	mean (range): 21.0 months (18.8-26.5) [pre-pectoral]; 26.5 months (19.0-33.0) [dual plane]
Nguyen-Strauli, 2022	median (range): 44 (26-72)	0%	0%	11.6%	18.6%	30.2%	9.3%	median (range): 22.3 (18-40)	mean: 12 months
Ohlinger, 2021	mean (range): 47.4 (21-77)	N/A	28.2%	10.3%	9.2%	22.1%	28.2%	mean (range): 25.7 (17.9-40.2)	mean (range): 27 months (0.5-71)
Quah, 2019	mean (range): 45 (24-72)	5.8%	5%	N/A	9.2%	7.5%	21.7%	N/A	mean: 12 months
Rathinaezhil, 2015	mean (range): 53 (42-62)	0%	40%	0%	42.9%	25%	40%	range: 22-33	range: 1-2 weeks
Rezai, 2016	N/A	N/A	N/A	0%	N/A	N/A	N/A	N/A	median (range): 3.5 years (0-13)
Rulli, 2013	range: 52-66	N/A	N/A	N/A	40%	N/A	25%	N/A	N/A
Schüler, 2021	mean, SD (range): 48.1, 10.3 (23-69)	yes (N/A%)	25.3%	24%	30.7%	N/A	N/A	mean, SD (range): 25.7, 4.4 (17.9-37.1)	mean, SD (range): 9.2, 9 (3.29-33)
Thill, 2020 (n°1)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Thill, 2020 (n°2)	mean (range): 49.3 (19—77)	1.9%	18.6%	10.1%	13.8%	27.6%	N/A	mean (range): 23 (17-40)	12 months
Xiao, 2022	median: 42	N/A	N/A	0%	N/A	0%	67.5%	N/A	3 months

(*continued on next page*)

Table 2 (*continued*)

Author	Age (years)	Diabetes	Smoking	Previous RHT	Adj RHT	Neoadj cht	Adj cht	BMI (kg/m^2)	Follow-up
Yang, 2019	mean (range): 46 (26-64)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	range: 5–21 months
Yao, 2019	67.5% of patients > 35	0%	0%	0%	0%	N/A	N/A	87.5% of patients < 28	data recorded immediately after surgery and 6 months after surgery

Abbreviations: Adj = Adjuvant; BMI =body mass index; cht =chemotherapy; I = implant; IQR = interquartile range; N/A = not available; Neoadj = Neoadjuvant; RHT = Radiotherapy; SD = standard deviation; TE = tissue expander.

Legend of symbols used:

n° = number (progressive number of studies published by a group with the same first author, tabulated in chronological order according to year/month of publication).

[a] Immediate symmetrization group.

[b] Delayed symmetrization group.

studies,[1,5,7,19-50] four of which were abstracts.[51-54] An additional article was found by scrolling the references list of the included articles.[55] Figure 1 shows the PRISMA checklist. Excluding studies that did not report the exact number of patients/breasts, 3923 patients and 5042 reconstructed breasts were analyzed.

Mastectomy

In all studies, the ablative surgery was performed in the form of: - skin sparing mastectomy (SSM), representing 34.4% of procedures; - nipple sparing mastectomy (NSM), representing 60.9% of procedures; skin reducing mastectomy (SRM), representing 4.7% of procedures. In 4 articles,[1,27,34,38] a modified radical mastectomy was described too. The timing of reconstruction was distributed as follows: immediate (97.4% of breasts) and delayed (2.6% of breasts). Two-stage reconstruction with a tissue expander (TE) represented 28% of immediate reconstruction procedures, whereas direct-to-implant (DTI) represented 72%. Both dual-plane (51.5%) and pure pre-pectoral (48.5%) breast reconstructions were described. Bernini et al.[55] found that pre-pectoral breast reconstruction was associated with a higher score in BREAST-Q domain "satisfaction with outcome" ($p = 0.03$), a higher Baker I capsular contracture ($p < 0.01$) and a better aesthetic outcome ($p < 0.01$). Ng et al.[39] found no statistically significant differences in complication rate between the 2 groups.

Smoking

Eleven studies[7,19,20,26,29,31,34,37,40,50,55] considered active smoking as an exclusion criterion, whereas 21[1,5,21-25,27,28,30,32,36,38,39,41-44,46,47,51] did not. The proportion of smokers was 19.7%. Delmond et al.[51] found an increased risk of major complications (infection and delayed wound healing) in univariate and multivariate analyses. In contrast, Gentile et al.[32] found an increased risk of surgical failure only in the univariate analysis. A negative effect on physical well-being domain of BREAST-Q was reported by Dieterich.[28] ($p = 0.054$), with a higher necrosis rate by Michno et al.[38] (20.7% vs 5.5%, $p = 0.002$). Rezai et al.[44] did not detect a correlation between implant loss and history of smoking ($p = 0.363$); however, they found a negative impact of smoking on aesthetic outcome ($p = 0.007$). In Dieterich et al.[5] 2012 study, mesh removal was not statistically different between smokers and non-smokers, and in their 2013[1] analysis, smoking showed no significance for complications onset ($p = 0.495$). In Quah et al.[42] study, the number of smokers who did not develop complications was greater than that of those who did; however, the difference was not significant.

Diabetes

Seventy-nine (3.2%) women had diabetes. In the study by Quah et al.,[42] the number of patients with diabetes who developed postoperative complications was lower than that of patients who did not develop complications; however, the difference was not significant. A similar result was found by Dieterich et al. in two studies, in 2012[5] ($p = 1$) and

Table 3 Summary of complications among included studies.

Author	RBS	Seroma	Hematoma	Infection	Implant loss	Rippling	Capsular contracture (Baker grade III-IV)	Necrosis	Wound dehiscence/ poor wound healing	Atopic reaction versus prosthesis/ mesh	Implant displacement/ dystopia	Overall complications
Bernini, 2015	N/A	0%	3% Mn (pre-pectoral)	6% Mn (dual plane)	3% pre-pectoral; 0% dual plane	15% (dual plane), 9% (pre-pectoral)	Baker III, 6% (dual plane), 0% (pre-pectoral) at a median follow-up of 25 months after surgery	3% Mj (pre-pectoral)	3% Mn (dual plane)	0%	N/A	
Casella, 2014	N/A	0%	1.4% Mj (dual plane)	2.7% Mn (pre-pectoral)	0% (dual plane); 1.4% (pre-pectoral)	N/A	N/A	1.4% Mn (pre-pectoral)	1.4% Mn (dual plane)	0%	N/A	9% (dual plane group); 8% (pre-pectoral)
Casella, 2015	N/A	0%	4% Mn	12% [after first stage] and 4% [after second stage] Mn	0%	N/A	N/A	skin-nipple: 4% Mn	0%	0%	N/A	4% Mn
Casella, 2018	N/A	0%	0%	0%	2.2%	N/A	Baker III, 2.2% at 2 years follow-up	skin: 2.2% Mj	0%	N/A	N/A	19.6%
Casella, 2019 (n°1)	N/A	0%	0.4% Mj	0.8% Mj	1.2%	16.7%	Baker III, 2%; Baker IV, 2% 2 years after surgery	skin-nipple: 0.8% Mj	0.4% Mj	N/A	0%	2.4%
Casella, 2019 (n°2)	N/A	1% Mj	0.2% Mj	2.3% Mj	3.1% Mj	12.5%	Baker III/IV: 3.6%	skin/nipple: 1% Mj	1.3% Mj	N/A	0.8%	5.8% Mj
Casella, 2019 (n°3)	N/A	1.3% Mj and 3.8% Mn	0%	3% Mj	3.8%	11.8%	Baker III, 1.3%; Baker IV, 2.5% at 36.5 months of mean follow-up after 2 stage surgery	0.8% Mj	1.7% Mj	N/A	0.8%	14.8% of which 10.5% Mj and 3.8% Mn
Casella, 2021	N/A	2.3% Mj	1.1% Mj	1.7% Mj	2.8%	8.1%	Baker III, 2.1%; Baker IV, 2.6% 2 years after surgery	skin/nipple: 3.1% Mj	0%	N/A	N/A	8.2% Mj
Casella, 2022	N/A	2.4% Mj	0%	1.2%	3.6%	10.7%	Baker III (3.6%), Baker IV (1.2%) 12 months after surgery	skin-nipple: 1.2%	2.4%	N/A	N/A	26.2%
Casella, 2023	N/A	2.2% Mn	4.3% Mn	2.2% Mn	0%	N/A	N/A	0%	2.2% Mn	N/A	N/A	10.9% Mn
Chen, 2019	N/A	14.3% Mn	7.1% Mn	7.1% Mn; 21.4% Mj	21.4%	N/A	7.1% Mn	nipple: 0%; skin: 14.3% Mj	7.1% Mn; 7.1% Mj	N/A	N/A	42.9% Mn and 42.9% Mj
Delmond, 2020	N/A	NR	N/A	8.8%	N/A	N/A	N/A	skin/nipple: 2.7%	20.8%	N/A	N/A	34.6% of which 8.9% Mj and 25.7% Mn
Dieterich, 2012	N/A	4.8% (Mn)	4.8% (Mn)	4.8% Mj	6.7%	N/A	Baker (N/A), 2.4%	2.4% Mn	N/A	N/A	N/A	19%
Dieterich, 2013	N/A	3% Mn; 1.7% Mj	7.4% Mn; 2.2% Mj	4.3% Mn; 1.7% Mj	8.7%	N/A	Baker IV, 2.2%	skin: 1.3% Mn; 2.6% Mj; nipple: 2.6% Mn; 0.9% Mj; mastectomy flaps: 0% Mn; 0.4% Mj	0%	N/A	N/A	major: 13.4%; minor: 15.6%
Dieterich, 2015 (n°1)	N/A	0%	0%	0%	2.9%	0%	5.9% 5 months after surgery	N/A	N/A	N/A	N/A	8.8% vs 25.9% in the simple prosthesis group (control group)
Dieterich 2015 (n°2)	N/A	2.1% Mn	6.3%	6.3% Mj	16.7%	N/A	4.2%	nipple: 0%; skin: 4.2% Mj; mastectomy flaps: 0%	6.3% Mj	N/A	N/A	14.6% of which 85.7% Mj and 14.3% Mn
Eichler, 2019	0.5% Mn	4.7% Mn	0%	2.6% Mn	8.3%	N/A	0%	N/A	1% Mn	N/A	0%	17.2% of which 8.3% Mj and 8.9% Mn
Esposito, 2017	N/A	N/A	N/A	N/A	5.79%	N/A	N/A	N/A	N/A	N/A	N/A	30.76% of which 15.91% Mj and 10.14% Mn
Gao, 2022	N/A	0%	0%	2.7%	0%	N/A	0%	nipple: 0%; skin: 2.7%	0%	N/A	0%	5.4% Mn
Gentile,2021	N/A	0%	0.6% DTI; 1.8% TE	5% DTI; 14.3% TE	4.6%	6.3% DTI; 7.1% TE	Baker III, 2.5% DTI, 0.25% TE; Baker IV, 0.6% DTI; 7.1% TE	nipple: 3.1% DTI; 2.7% TE	3.8% DTI; 1.8% TE	N/A	N/A	13.1%
Gschwantler-Kaulich, 2016	0%	4% Mn	8%	4%	8%	0%	0%	8%	8%	N/A	N/A	24%
Guanglei Chen, 2019	N/A	N/A	3.7%	0%	0%	N/A	0%	0%	0%	N/A	N/A	
Klein, 2012	N/A	9.2% Mn	17.2%	10.3% Mn	0%	N/A	N/A	N/A	N/A	N/A	N/A	35.6%

(*continued on next page*)

Table 3 (*continued*)

Author	RBS	Seroma	Hematoma	Infection	Implant loss	Rippling	Capsular contracture (Baker grade III-IV)	Necrosis	Wound dehiscence/ poor wound healing	Atopic reaction versus prosthesis/ mesh	Implant displacement/ dystopia	Overall complications
Krivorotko, 2021	5.88%	4.8% Mn	9.5% Mn	6.1%	5.88%	N/A	Baker III-IV, 2.2% (17.65% after radiotherapy)	nipple-areola: 3.5%; skin: 3.9% Mn; total skin flap necrosis: 0.4%.	N/A	N/A	N/A	35.3% Mj
Lo Torto, 2020	N/A	11.1% Mn	0%	0%	0%	N/A	0%	0%	5.6% Mn	N/A	N/A	16.7%
Marcasciano, 2018	N/A	0%	NR	0%	0%	N/A	N/A	0%	8.3% Mn	N/A	N/A	8.3% Mn
Marcasciano, 2023	N/A	4% Mn	0%	4% Mn	0%	N/A	N/A	0%	4% Mn	N/A	N/A	11%
Michno, 2021	N/A	8.5%	4.7%	5.8%	0%	N/A	N/A	8.9%	6.2%	N/A	N/A	26.7%
Ng, 2021	N/A	10% Mn	2.8% Mn	7.3% Mj	8.3%	N/A	N/A	nipple: 0%; skin 0.9% Mj [*due to heat pack burn*]	N/A	N/A	0%	22% (pre-pectoral group), 14% (dual plane group) no significant difference in the rates of seroma, hematoma, implant migration, skin/nipple necrosis and periprosthetic infections, comparable rates of implant loss
Nguyen-Strauli, 2020	N/A	12.7% Mn	3.2% Mj	4.8% Mn	4.8%	3.2%	4.8%	nipple: 1.6% Mn and 1.6% Mj	3.2% Mj	N/A	rotation: 3.2%; cranialization: 4.8%	30.2% of which 11.1% Mj and 19% Mn
Ohlinger, 2021	N/A	3.1%	3.6%	5.6%	5.6%	N/A	3.6%	3.6%	5.1%; "wound healing disorders": 3.6%	N/A	N/A	major: 15.4%; minor: 11.7%
Quah, 2019	0%	1.7%	0.6%	2.8%	1.7%	N/A	N/A	nipple: 1.1%; skin 5%	0.6%	N/A	1.1%	10.1% of which 7.8% Mj
Rathinaezhil, 2015	N/A	0%	0%	0%	0%	N/A	N/A	14.3% Mn	0%	N/A	0%	14.3% Mn
Rezai, 2016	N/A	3.7%	6.3%	2.6%	0%	N/A	N/A	N/A	2.2%	N/A	0%	N/A
Rulli, 2013	100%	0%	0%	0%	0%	N/A	N/A	0%	0%	0%	0%	0%
Schüler, 2021	N/A	4.3%	5.3%; 3.2% "secondary hemorrhage"	9.3%; 1.1% abscess	6.4%	N/A	N/A	skin: 3.2%	8.5%	N/A	N/A	14.9% Mj, 9.6% Mn
Thill, 2020 (n°1)	N/A	61% Mn	12.3% Mj	1.8% Mn	5.3%	N/A	N/A	skin: 5.3% Mj	5.3% Mj	N/A	0%	80.7% of which 6.5% Mj and 93.5% Mn
Thill, 2020 (n°2)	N/A	10.7%	3.4%	7.9%	0%	N/A	11.4%	"necrosis": 7.9%	0.1%	N/A	0.3%	94.1%
Xiao, 2022	N/A	0%	22.5%	2.5%	0%	N/A	10%	skin-nipple: 10%; fat necrosis: 5%	N/A	N/A	N/A	50%
Yang, 2019	N/A	3.8% Mn	11.5% Mn	3.8% Mj	3.8%	N/A	N/A	N/A	3.8% Mn	N/A	N/A	23.1%
Yao, 2019	0%	0%	5%	0%	0%	N/A	0%	nipple: 2.5% Mn; mastectomy flap: 2.5% Mn	5% Mn	0%	N/A	15.0% vs 17.2% in the simple prosthesis group (control group)

Abbreviations: DTI = direct-to-implant; Mj = major; Mn = minor; N/A = not available; NR = not reported; RBS = red breast syndrome; TE = tissue expander.
Legend of symbols used:
n° = number (progressive number of studies published by a group with the same first authors, tabulated in chronological order according to year/month of publication).

Table 4 Summary of Patient Reported Outcomes (PROs).

Author	Use of scale other than BREAST-Q	Notes	BREAST-Q domains				
			Satisfaction with breasts (mean ± SD or median, IQR)	Satisfaction with outcome (mean ± SD or median, IQR)	Physical well being (mean ± SD or median, IQR)	Psychosocial well being (mean ± SD or median, IQR)	Sexual well being (mean ± SD or median, IQR)
Bernini, 2015[55]	/	Number of evaluated patients: -Dual plane: 29 -Pre-pectoral: 30 Median FU: 25 months	Dual plane implant location: Mean ± SD: 59 ± 21 Median (range): 58 (13-100) Pre-pectoral implant location: Mean ± SD: 57 ± 22 Median (range): 63(15-94) p = 0.81	Dual plane implant location: Mean ± SD: 84 ± 28 Median (range): 100 (0-100) Pre-pectoral implant location: Mean ± SD: 98 ± 9 Median (range): 100 (57-100) p = 0.03	Dual plane implant location: Mean ± SD: 92 ± 8 Median (range): 97 (69-100) Pre-pectoral implant location: Mean ± SD: 93 ± 11 Median (range): 95 (52-100) p = 0.71	Dual plane implant location: Mean ± SD: 70 ± 23 Median (range): 75 (25-100) Pre-pectoral implant location: Mean ± SD: 76 ± 25 Median (range): 85 (15-100) p = 0.22	Dual plane implant location: Mean ± SD: 54 ± 29 Median (range): 54 (0-100) Pre-pectoral implant location: Mean ± SD: 58 ± 31 Median (range): 54 (4-100) p = 0.45
Casella, 2015[20]		Number of evaluated patients: 25 Evaluation: 14 months post-op values expressed as mean ± SD or median (range)	Mean ± SD: 58 ± 23 Median (range): 64 (16-95)	Mean ± SD: 99 ± 9 Median (range): 100 (63-100)	Mean ± SD: 94 ± 12 Median (range): 96 (54-100)	Mean ± SD: 77 ± 26 Median (range): 87 (18-100)	Mean ± SD: 56 ± 31 Median (range): 53 (4-100)
Casella, 2018[21]		Number of evaluated patients: 46 Evaluation: 1 month prior to surgery and at 1 and 2 years FU points	Pre-op: 59.3 ± 12.2 Post-op (1 year): 72.5 ± 10.1 Δ = 13.2 p = 0.0033 Post-op (2 year): 73.7 ± 9.8 Δ = 14.4 p = 0.0145	Pre-op: - Post-op (1 year): 75.7 ± 12.3 Δ = - p = - Post-op (2 year): 79.7 ± 11.8 Δ = - p = -	Pre-op: 80.9 ± 10.4 Post-op (1 year): 77.6 ± 14.2 Δ = −3.3 p = 0.0984 Post-op (2 year): 80.6 ± 13.6 Δ = −0.3 p = 0.0846	Pre-op: 66.4 ± 13.7 Post-op (1 year): 78.4 ± 13.3 Δ = 12 p = 0.0132 Post-op (2 year): 78.6 ± 13.7 Δ = 12.2 p = 0.0193	Pre-op: 52.7 ± 14.4 Post-op (1 year): 58.8 ± 12.6 Δ = 6.1 p = 0.0253 Post-op (2 year): 59.4 ± 13.5 Δ = 6.7 p = 0.0179
Casella, 2019 (n°1)[22]	outcomes measured **at 2-year FU** using 5-point Likert scales from 1 (i.e., very poor result) to 5 (excellent result) (mean ± SD, p < 0.05): Breast symmetry 3.97 ± 0.63 Breast shape 4.16 ± 0.53 Breast scars 4.21 ± 1.15 Breast volume 4.03 ± 1.72 Position of IMF 3.7 ± 0.65 Overall aesthetic result 8.72 ± 1.25	Number of evaluated patients: 173 Evaluation: 1 month prior to surgery and at 2 years FU	Pre-op: 58.4 ± 11.3 Post-op: 72.5 ± 10.1 Δ = 14.1 ± 16 p = 0.0242	Pre-op: - Post-op: 73.8 ± 11.5 Δ = - p = -	Pre-op: 78.2 ± 11.3 Post-op: 75.4 ± 12.4 Δ = −2.8 ± 17 p = 0.134	Pre-op: 64.5 ± 14.3 Post-op: 77.7 ± 12.3 Δ = 13.23 ± 18.5 p = 0.0376	Pre-op: 56.7 ± 13.7 Post-op: 57.9 ± 14.1 Δ = 1.2 ± 19.9 p = 0.0345
Casella, 2019 (n°2)[23]	outcomes measured **at 2-year FU** using 5-point Likert scales from 1 (i.e., very poor result) to 5 (excellent result) (mean ± SD, p < 0.05): Breast symmetry: TE: 3.8 ± 0.6; DTI: 3.8 ± 0.4; p = 0.19 Breast shape: TE:3.9 ± 0.6; DTI: 4 ± 0.5; p = 0.06 Breast scars: TE: 3.9 ± 0.5 DTI: 4.1 ± 0.5; p = 0.16 Breast volume: TE: 4 ± 0.5; DTI: 4.1 ± 0.5; p = 0.11 Position of IMF: TE: 3.7 ± 0.5; DTI: 3.6 ± 0.5; p = 0.12 Overall aesthetic result: TE: 8.6 ± 0.6; DTI: 8.5 ± 1; p = 0.32	210 patients underwent DTI and 187 TE Evaluation: 1 month pre-op and 1 year post-op	TE Pre-op: 59.2 ± 11.8 Post-op: 72.2 ± 9.9 Δ = 13.1 ± 15.5 p < 0.01 DTI Pre-op: 59.4 ± 11.9 Post-op: 72.1 ± 19.8 Δ = 12.7 ± 5.4 p = <0.01 TE vs DTI p-value: 0.82	TE Pre-op: - Post-op: 74 ± 12 Δ = - p = - DTI Pre-op: - Post-op: 74.2 ± 12.1 Δ = - p = - TE vs DTI p-value: 0.87	TE Pre-op: 77.1 ± 11.7 Post-op: 75.4 ± 13 Δ = −1.7 ± 17.4 p = 0.18 DTI Pre-op: 77 ± 11.4 Post-op: 75.2 ± 12.8 Δ = −1.8 ± 17 p = 0.13 TE vs DTI p-value: 0.96	TE Pre-op: 64 ± 14 Post-op: 77.5 ± 11.9 Δ = 13.3 ± 18.5 p < 0.01 DTI Pre-op: 64.3 ± 13.9 Post-op: 77.2 ± 11.7 Δ = 13 ± 18.3 p < 0.01 TE vs DTI p-value: 0.86	TE Pre-op: 57.3 ± 14.5 Post-op: 61.6 ± 12.8 Δ = 4.2 ± 17 p < 0.01 DTI Pre-op: 56.9 ± 14.6 Post-op: 59.8 ± 13.2 Δ = 2.8 ± 19.5 p 0.03 TE vs DTI p-value: 0.45

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Table 4 (*continued*)

Author	Use of scale other than BREAST-Q	Notes	BREAST-Q domains				
			Satisfaction with breasts (mean ± SD or median, IQR)	Satisfaction with outcome (mean ± SD or median, IQR)	Physical well being (mean ± SD or median, IQR)	Psychosocial well being (mean ± SD or median, IQR)	Sexual well being (mean ± SD or median, IQR)
Casella, 2019 (n°3)[24]	outcomes measured **at 2-year FU** using 5-point Likert scales from 1 (i.e., very poor result) to 5 (excellent result) (mean ± SD, $p < 0.05$): Breast symmetry: 3.8 ± 0.6 Breast shape: 3.9 ± 0.6 Breast scars: 3.9 ± 0.5 Breast volume: 4 ± 0.5 Position of IMF: 3.7 ± 0.5 Overall aesthetic result: 8.6 ± 0.6	Number of evaluated patients: 187 Evaluation: 1 month pre-op and 1 year post-op	Pre-op: 59.2 ± 11.8 Post-op: 72.2 ± 9.9 Δ = 13.1 ± 15.5 p < 0.05	Pre-op: - Post-op: 74 ± 12 Δ = - p = -	Pre-op: 77.1 ± 11.7 Post-op: 75.4 ± 13 Δ = −1.7 ± 17.4 p > 0.05	Pre-op: 64 ± 14 Post-op: 77.5 ± 11.9 Δ= 13.3 ± 18.5 p = <0.05	Pre-op: 57.3 ± 14.5 Post-op: 61.6 ± 12.8 Δ= 4.2 ± 17 p = <0.05
Casella, 2021[25]		Number of evaluated patients: 352 Evaluation: 1 month pre-op and 1 year post-op	Pre-op: 58.9 ± 11.5 Post-op: 72.4 ± 9.9 Δ = 13.5 p = 0.0016	Pre-op: - Post-op: 74.2 ± 11.7 Δ = - p = -	Pre-op: 77.8 ± 11.3 Post-op: 75.3 ± 12.4 Δ= −2.5 p = 0.4861	Pre-op: 64.3 ± 14.1 Post-op: 77.6 ± 12 Δ = 13.3 p = 0.0078	Pre-op: 55.9 ± 12.1 Post-op: 65.1 ± 11.2 Δ = 9.2 p = 0.0303
Casella, 2022[26]		Number of evaluated patients: 84 Evaluation: 1 year post-op	Immediate contralateral symmetrization: 78 ± 11.9 Delayed contralateral symmetrization: 73 ± 10 p = 0.04	Immediate contralateral symmetrization: 75 ± 10.7 Delayed contralateral symmetrization: 73 ± 12.1 p = 0.42	Immediate contralateral symmetrization: 58.8 ± 11.8 Delayed contralateral symmetrization: 56.5 ± 13.2 p = 0.40	Immediate contralateral symmetrization: 79.2 ± 14.2 Delayed contralateral symmetrization: 76.6 ± 12 p = 0.36	Immediate contralateral symmetrization: 65.3 ± 14.7 Delayed contralateral symmetrization: 60.7 ± 12.9 p = 0.13
Casella, 2023[56]		Number of evaluated patients: 46 of which 13 (28.2%) received immediate contralateral breast symmetrization Evaluation: 1 month pre-op and 1 year post-op	↑ compared to pre-op (quantitative data not available)	↑ compared to pre-op (quantitative data not available)	decline slightly from pre-op to post-op evaluations, although this difference was not statistically significant	↑ compared to pre-op (quantitative data not available)	↑ compared to pre-op (quantitative data not available)
Dieterich, 2015 (n°1)[27]		Number of evaluated patients for each BREAST-Q domain (implant alone, implant with mesh) Breast (27, 34) Outcome (25, 34) Physical well-being (27, 33) Psychosocial well-being (27, 34) Sexual well-being (20,28) Mean FU: Implant alone: 18.0 months (range 1-40) TiLOOP® Bra: 17.5 (range 1-83) months	Implant alone: 60.6, 11.4 (41-85) Implant with mesh: 54.2, 16.5 (25-100) Difference of SD between groups: 5.1 p-value: 0.079	Implant alone: 75.4, 18.2 (27-100) Implant with mesh: 72.4, 22.7 (21-100) Difference of SD between groups: 4.5 p-value: 0.604	Implant alone: 64.5, 14.7 (43-100) 14.7 Implant with mesh: 65.7, 12.1 (50-100) Difference of SD between groups: 2.6 p-value: 0.654	Implant alone: 71.3, 15.9 (41-100) Implant with mesh: 68.1, 21.9 (34-100) Difference of SD between groups: 6.0 p-value: 0.370	Implant alone: 54.5, 20.2 (16-100) Implant with mesh: 52.4, 22.9 (34-100) Difference of SD between groups: 2.7 p-value: 0.508

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Author	Use of scale other than BREAST-Q	Notes	BREAST-Q domains				
			Satisfaction with breasts (mean ± SD or median, IQR)	Satisfaction with outcome (mean ± SD or median, IQR)	Physical well being (mean ± SD or median, IQR)	Psychosocial well being (mean ± SD or median, IQR)	Sexual well being (mean ± SD or median, IQR)
Dieterich, 2015 (n°2)[28]		Number of evaluated patients for each BREAST-Q domain (implant alone, implant with mesh) overall response rate 67.7% Breast (27, 34) Outcome (25, 34) Physical well-being (27, 33) Psychosocial well-being (27, 34) Sexual well-being (20, 28)	Implant alone: 61.0, 11.3 (41-85) Implant with mesh: 51.5, 16.5 (25-100) Difference of SD between groups: 5.2 p-value: 0.079	Implant alone: 75.0, 18.2 (27—100)Implant with mesh: 75.0, 22.7 (21—100)Difference of SD between groups: 4.5p-value: 0.604	Implant alone: 60.0, 14.7 (43-100) Implant with mesh: 66.0, 12.1 (50-100) Difference of SD between groups: 2.6 p-value: 0.654	Implant alone: 67.0, 15.9 (41—100)Implant with mesh: 63.0, 21.9 (34-100) Difference of SD between groups: 6.0p-value: 0.370	Implant alone: 50.5, 20.2 (16-100) Implant with mesh: 49.0, 22.9 (34-100) Difference of SD between groups: 2.7 p-value: 0.508
Esposito, 2017[52]	European Organization for Research and Treatment of Cancer Breast Cancer-Specific quality of life questionnaire (EORT QLQ-BR23): satisfaction rate of 72.6% Number of evaluated patients: N/A EORTC QLQ-BR23 administered at time of clinical FU (N/A)						
Gao, 2022[31]		Number of evaluated patients: 99 (85.3%) of 116, including 68 (86.1%) of 79 patients in the Surgisis® group and 32 (86.5%) of 37 patients in the TiLOOP® Bra group. Evaluation: at least 1 year following surgery	Surgisis®: N = 68 (86.1%) 58.0 (53.0-65.0) TiLOOP® Bra: N = 32 (86.5%) 54.0 (46.0-58.5) p = 0.051	Surgisis®: N = 68 (86.1%) N/A TiLOOP® Bra: N = 32 (86.5%) N/A	Surgisis®: N = 68 (86.1%) 39.6 ± 17.4 TiLOOP® Bra: N = 32 (86.5%) 35.5 ± 18.1 p = 0.282	Surgisis®: N = 68 (86.1%) 74.0 (60.0-87.0) TiLOOP® Bra: N = 32 (86.5%) 65.0 (58.0-93.0) p = 0.491	Surgisis®: N = 40 43.0 (36.0-68.0) TiLOOP® Bra: N = 24 56.0 (41.0-66.0) p = 0.424
Gentile, 2021[32]	Number of evaluated patients: 213 Evaluation: 2 years post-op values expressed as mean ± SD Mean satisfaction with the overall aesthetic result after breast reconstruction in patients who underwent DTI pre-pectoral immediate reconstruction after 2 years from surgery = 8.72 (scored on a 10-point scale ranging from 1 (very poor result) to 10 (excellent result).		Increased after subcutaneous pre-pectoral DTI reconstruction with TCPM mesh ($p < 0.05$) compared to TE reconstruction (quantitative data not available)			Increased after subcutaneous pre-pectoral DTI reconstruction with TCPM mesh ($p < 0.05$) compared to TE reconstruction (quantitative data not available)	Increased after subcutaneous pre-pectoral DTI reconstruction with TCPM mesh ($p < 0.05$) compared to TE reconstruction (quantitative data not available)

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Author	Use of scale other than BREAST-Q	Notes	BREAST-Q domains				
			Satisfaction with breasts (mean ± SD or median, IQR)	Satisfaction with outcome (mean ± SD or median, IQR)	Physical well being (mean ± SD or median, IQR)	Psychosocial well being (mean ± SD or median, IQR)	Sexual well being (mean ± SD or median, IQR)
Gschwantler-Kaulich, 2016[33]	Number of evaluated patients: -TiLOOP® Bra: n = 25 -Protexa®: n = 23 Evaluation at 3 time points (post-op within 2 weeks, after 3 months, and after 6 months). • Patients' satisfaction with the cosmetic outcome rated as very good in 87.5% of patients in the TiLOOP® Bra group vs 79.0% in the Protexa® group (p = 0.632) • Cosmetic outcome also valuated by medical professionals using the Harris Scale 6 months after surgery: o Harris Scale 3 and 4: TiLOOP® Bra = 95.8% vs Protexa® = 72.7%; surgeon: p = 0.034 and external specialists: p = 0.032, respectively) o Such differences failed to remain significant when the cases with failed reconstructions were excluded from the analysis (surgeon: p = 0.92, external specialists: p = 0.3).						
Guanglei Chen, 2019[34]		Number of evaluated patients: 59 Mean FU: N/A	- TiLOOP® Bra: 74.78 ± 0.7325 - implant alone: 72.91 ± 0.5146 p = 0.0368	N/A	- TiLOOP® Bra: 73.43 ± 0.3380 - implant alone: 72.43 ± 0.4105 p = 0.0689	- TiLOOP® Bra: 72.44 ± 0.6323 - implant alone: 73.06 ± 0.4444 p = 0.4168	- TiLOOP® Bra: 67.10 ± 0.5495 - implant alone: 65.83 ± 0.6780 p = 0.1590
Lo Torto, 2020[36]		Number of evaluated patients: 18 Evaluation: 1 month prior to surgery and 6 months post-op	↑ (p < 0.05) Quantitative data not available	NSS Quantitative data not available	NSS Quantitative data not available	↑ (p < 0.05) Quantitative data not available	↑ (p < 0.05) Quantitative data not available
Marcasciano, 2018[7]		Number of evaluated patients: 12 Mean follow up: 18 months (range: 12-24) BREAST-Q parameters, score 0-100, average: 92).	N/A	N/A	N/A	N/A	N/A
Marcasciano, 2023[37]		Number of evaluated patients: 25 Evaluation: 1 month prior to surgery and 1 year post-op	↑ (p < 0.05) Pre: 58.7 ± 10.2 Post: 67.7 ± 12 Δ = 9; p = 0.0065	NSS Pre: - Post: -73, 8 (± 12) Δ = - p = -	NSS Pre: 68.6 ± 9.9 Post: 67.1 ± 10.1 Δ = 1.5 p = 0.5945	↑ (p < 0.05) Pre: 62.2 ± 10.4 Post: 71.9 ± 13 Δ = 9.7 p = 0.0053	↑ (p < 0.05) Pre: 52.2 ± 7.6 Post: 57.8 ± 8.9 Δ = 5.6 p = 0.0199
Ng, 2021[39]		Number of evaluated patients: 49 FU (median, range): 21.0 months (18.8-26.5) [pre-pectoral group] 26.5 months (19.0-33.0) [dual plane group]	Pre-pectoral: 68.9 ± 17.0 Dual plane: 57.5 ± 20.0 p = 0.036	N/A	Pre-pectoral: 75.6 ± 12.9 Dual plane: 73.6 ± 15.5 p = 0.630	Pre-pectoral: 76.0 ± 17.5 Dual plane: 71.1 ± 21.5 p = 0.390	Pre-pectoral: 62.6 ± 22.4 Dual plane: 50.9 ± 28.3 p = 0.123

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Author	Use of scale other than BREAST-Q	Notes	BREAST-Q domains				
			Satisfaction with breasts (mean ± SD or median, IQR)	Satisfaction with outcome (mean ± SD or median, IQR)	Physical well being (mean ± SD or median, IQR)	Psychosocial well being (mean ± SD or median, IQR)	Sexual well being (mean ± SD or median, IQR)
Nguyen Strauli, 2021[40]	Number of evaluated patients: 63 Ater 6 to 12 months Values expressed as mean Observer ratings of cosmetic appearance using Harvard score: 1 = poor, 4 = excellent Observer 1: 3.0 (1-4), SD 0.8 Observer 2: 3.4 (1-4), SD 0.7 Mean: 3, range 1-4; SD 0.75						
Rathinaezhil, 2015[43]	Number of evaluated patients: 5 3 months post-op Values expressed as mean, median, mode, range Observer ratings of cosmetic appearance at 3 months (1 = poor, 10 = excellent) Patient 1: 7.4; 7; 7.8; 6-9 Patient 2: 7.4; 8; 8; 5-9 Patient 3: 7.7; 8; 8.9; 4-9 Patient 4: 7.7; 8; 8.9; 4-9						
Rezai, 2016[44]	EORTC C—30, EORTC B—23, FACT-G, and Breast Cancer Treatment Outcome Scale (BCTOS)70% of 217 patients answered the questionnaires significant improvement by use of tetanized polypropylene meshes in the aesthetic results (p = 0.049)						
Rulli, 2013[45]	Authors subjective evaluation: "excellent aesthetic results and high satisfaction rates"						
Thill, 2020 (n°2)[47]	BREAST-Q + evaluation by 2 independent physicians: • no radiotherapy: patients' score 65.0 ± 24.2, experts' score 76.8 ± 21.5 (p < 0.001); CR • neoadjuvant radiotherapy: patients' score 63.0 ± 20.5, experts' score 63.6 ± 22.4 • adjuvant radiotherapy: patients' score 56.4 ± 33.2, experts' score 69.8 ± 21.1 (p < 0.001); CR	98.6% of patients answered the BREAST-Q Evaluation: before (prior to surgery) and 12 months after surgery	Patients with AE had a significantly lower score at 12 months FU compared to pre-op (p < 0.05) Patients > 40 years (n = 164): pre-op: 66.6 ± 22.7; 12 months FU: 59.8 ± 19.0; p < 0.01; NC Unilaterally treated patients (n = 130): pre-pp: 59.2 ± 19.3; 12 months FU: 66.0 ± 22.5; p < 0.01; NC Bilaterally treated patients (n = 80): pre-op: 63.3 ± 24.1; 12 months FU: 63.6 ± 18.7; p < 0.01; NC		Patients > 40 years (n = 164): pre-op:73.4 ± 13.0, 12 months FU: 70.2 ± 16.0; p < 0.01; NC	Patients without AE had a significantly higher psychosocial well-being at 12 months FU (p < 0.001) Patients > 40 years (n = 164): pre-op: 71.0 ± 18.6; 12 months FU: 74.1 ± 21.2; p < 0.01; NC Unilaterally treated patients (n = 130): pre-op: 70.8 ± 18.1; 12 months FU: 74.7 ± 20.4; p < 0.05; NC	**Patients without AE had a significantly higher psychosocial well-being at 12 months FU (p < 0.001)**
Xiao, 2022[48]	BREAST Q - no significant differences between DTI breast reconstruction with mesh and BCT		N/A	N/A	N/A	N/A	N/A

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Table 4 (*continued*)

Author	Use of scale other than BREAST-Q	Notes	BREAST-Q domains				
			Satisfaction with breasts (mean ± SD or median, IQR)	Satisfaction with outcome (mean ± SD or median, IQR)	Physical well being (mean ± SD or median, IQR)	Psychosocial well being (mean ± SD or median, IQR)	Sexual well being (mean ± SD or median, IQR)
Yang, 2019[49]	"excellent/good" rate of the appearance of the reconstructed breast reached in 88.46% (23/26)						
Yao, 2019[50]	satisfaction rate of patients on cosmetic effects: prosthesis + TCPM group: 95.0% (38/40) simple prosthesis group: 75.90% (22/29) $p = 0.05$, $\chi^2 = 3.87$						

Abbreviations: AE = adverse event; BCT = breast conserving therapy; CI = confidence interval; CR = clinically relevant (Δ); DTI = direct-to-implant; FU = follow-up; IQR: interquartile range; N/A = not available; NC = not clinically relevant (authors considered a difference clinically relevant when Δ > 10); NSS = not statistically significant (Δ); pre-op = pre-operative (evaluation); post-op = post-operative; RHT = radiotherapy; SD = standard deviation; TE = tissue expander; TCPM = titanium-coated polypropylene mesh
Legend of symbols used:
n° = number (progressive number of the studies published by a same authors group, tabulated in a chronological order according to year/month of publication)

Table 5 Configuration of TiLOOP® (Bra vs Bra Pocket) used in studies meeting inclusion criteria.

Author	TiLOOP® Configuration used
Bernini, 2015	TiLoop® Bra
Casella, 2014	TiLOOP® Bra
Casella, 2015	TiLOOP® Bra
Casella, 2018	TiLOOP® Bra
Casella, 2019 (n°1)	TiLOOP® Bra
Casella, 2019 (n°2)	TiLoop® Bra
Casella, 2019 (n°3)	TiLoop® Bra
Casella, 2021	TiLoop® Bra
Casella, 2022	TiLoop® Bra
Casella, 2023	TiLoop® Bra
Chen, 2019	TiLOOP® Bra
Delmond, 2020	TiLOOP® Bra
Dieterich, 2012	TiLOOP® Bra
Dieterich, 2013	TiLOOP® Bra
Dieterich, 2015 (n°1)	TiLOOP® Bra
Dieterich, 2015 (n°2)	TiLoop® Bra
Eichler, 2019	TiLoop® Bra/TiMesh®[a]
Esposito, 2017	TiLoop® Bra
Gao, 2022	TiLoop® Bra
Gentile, 2021	TiLOOP® Bra
Gschwantler-Kaulich, 2016	TiLoop® Bra
Guanglei Chen, 2019	TiLoop® Bra
Klein, 2012	TiLoop® Bra
Krivorotko, 2021	TiLoop® Bra
Lo Torto, 2020	TiLoop® Bra Pocket
Marcasciano, 2018	TiLOOP® Bra
Marcasciano, 2023	TiLoop® Bra / TiLoop® Bra Pocket
Michno, 2022	TiLoop® Bra
Ng, 2021	TiLoop® Bra / TiLoop® Bra Pocket
Nguyen-Strauli, 2022	TiLoop® Bra Pocket
Ohlinger, 2021	TiLoop® Bra
Quah, 2019	TiLoop® Bra
Rathinaezhil, 2015	TiLoop® Bra
Rezai, 2016	TiLoop® Bra
Rulli, 2013	TiLoop® Bra
Schüler, 2021	TiLOOP® Bra
Thill, 2020 (n°1)	TiLoop® Bra Pocket
Thill, 2020 (n°2)	TiLoop® Bra
Xiao, 2022	TiLoop® Bra
Yang, 2019	TiLoop® Bra
Yao, 2019	TiLOOP® Bra

Legend of symbols used:
[a] TiMesh® is made up of the same material as TiLOOP® Bra but its use – as authors point out – is off label in breast reconstruction.

2013[1] ($p = 0.463$). Gentile et al.[32] found that the number of patients with diabetes who developed complications was greater than that of those who did not ($p < 0.001$). However, of the 7 patients who developed complications, none suffered implant loss.

Radiotherapy

Previous radiotherapy was considered an exclusion criterion for reconstruction in 12 studies,[7,19-21,31,33,34,43,44,48,50,55]. In contrast, it was allowed in 17 studies.[1,5,22-25,27,28,32,38-41,46,47,51,56] Overall, the percentage of patients who previously underwent radiotherapy was 0–24%, while that of patients who received post-operative radiation therapy was 0–42.9%.

Casella et al.[23] found an association between complications and adjuvant radiotherapy in DTI but not in two-stage breast reconstruction ($p = 0.04$). When investigating the onset of aesthetic complications, the association failed to remain significant. Conversely, Thill et al.[47] found radiotherapy to negatively influence BREAST-Q domains "satisfaction with breasts," "sexual" and "physical well-being."

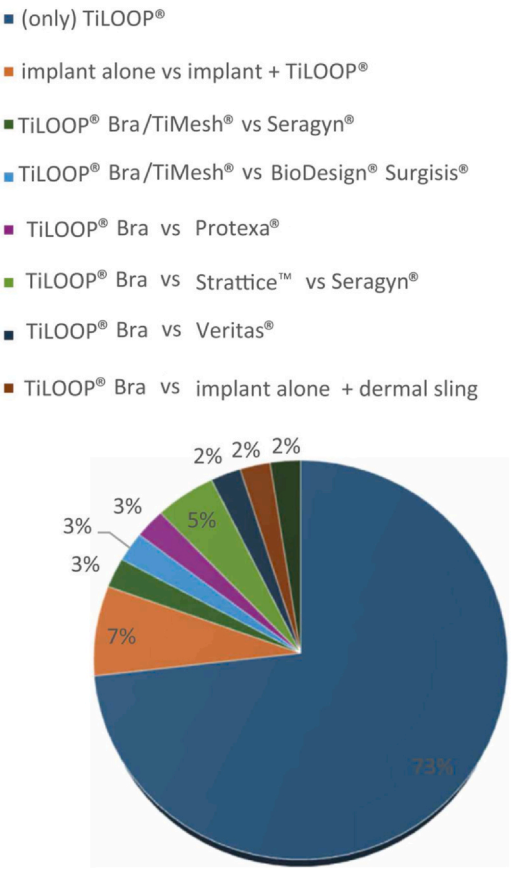

Figure 2 Devices evaluated according to study design. In 73% of studies (n = 30) the patient population was reconstructed only with TiLOOP®, while in 27% of studies, TiLOOP® Bra was compared with animal-derived or synthetic matrices (n = 6), to implant-only reconstruction (n = 4), or to breast-conserving surgery (using oncoplastic techniques) (n = 1).

Similarly, Ohlinger et al.[41] detected a negative influence of pre- and postoperative radiotherapy on wound infections ($p = 0.006$) and implant loss ($p = 0.037$). The detrimental effects of radiotherapy were greater with ADMs than with TiLOOP® Bra regarding postoperative seromas ($p = 0.014$), wound infections ($p < 0.001$), and implant losses ($p = 0.001$).[41] A trend toward statistical significance was delineated between radiotherapy and increased risk of capsular contracture, being 7.9% for TiLOOP® Bra ($p = 0.052$) and 18.8% for Strattice™ ($p = 0.093$).[41] Quah et al.[42] excluded the role of adjuvant radiotherapy in influencing the incidence of postoperative complications in either TiLOOP® Bra and Veritas®. The same conclusion was drawn by Rezai et al.,[44] with radiotherapy found to be neither detrimental to cosmetic outcome ($p = 0.754$) nor to body image ($p = 0.660$).

Good TCPM incorporation has been reported even in patients who underwent radiotherapy.[5] Nevertheless, the authors warned about the tolerability of TCPM in pre-radiated patients noting that this was still unclear because of the low number of patients receiving pre-operative radiotherapy in their clinical records ($p = 0.437$). The same caveat came from Michno et al.[38] and Ng et al.,[40] who failed to demonstrate a significant effect of radiotherapy on the rate of post-operative complications, likely because of the small sample sizes and short follow-up period.

Casella et al.[24] reported 5 (20%) cases of reintervention between the first and second stage as fat graft procedures over the tissue expander in patients who underwent post-operative radiation. In a later study by the same group of authors,[22] all patients reported to have grade IV capsular contracture had all undergone adjuvant radiotherapy, and in those with severe contracture, implant replacement was required after an average of 27 months. In Dieterich et al.[27]work, a patient who developed capsular contracture after radiotherapy had an early onset of soft tissue contracture (5 months) and mesh was removed after radiotherapy.

Body mass index

Casella et al.[23] found that body mass index (BMI) had a regression coefficient of -1.15 ($p = 0.001$) when investigated for complication onset after DTI but not after TE reconstruction. This association remained significant when evaluated for the onset of aesthetic complications ($p < 0.001$). Given the significant association between BMI and complications after DTI, they decided to test the odds ratio for each group, detecting an association between a BMI < 22 kg/m^2 and increased risk of developing both aesthetic and surgical complications ($p < 0.001$), thus considering underweight as a worse prognostic factor than overweight.[25]

BMI values > 25 kg/m^2 and 27 kg/m^2 were excluded as significant risk factors for complications and implant loss in two studies.[1,34]

Thill et al.[47] assigned patients to subgroups of BMI ≤25 kg/m^2 and > 25 kg/m^2. Preoperatively significantly higher BREAST-Q scores were found for the subgroup BMI ≤ 25 kg/m^2. These differences exceeded 10 points indicating their clinical relevance. At the 12 months follow-up, no differences were detected between the two groups for any of the BREAST-Q scales.

Gentile et al.[32] observed that among patients with a BMI > 25 kg/m^2, the percentage of those who experienced major complications was greater than that of those who did not, but the difference was not statistically significant. A higher BMI was found to be a predictor for skin dehiscence ($p = 0.043$)[44] and a risk factor for implant infection.[51]

Michno et al.,[38] who also enrolled patients at extreme values of BMI [< 18.5 kg/m^2 (4.3%) and > 30 kg/m^2 (4.7%)], found a significantly increased risk of wound healing disorders, necrosis, and seroma for each increase in one BMI point [$p < 0.001$, $p = 0.003$, and $p = 0.004$, respectively].

Dieterich et al.[27] observed that the BMI of patients reconstructed with mesh was lower than that of patients reconstructed with implant alone ($p = 0.003$). They confirmed such result in another study[28] ($p = 0.003$) along with lower weights of mastectomy specimens ($p = 0.001$) and final implant volumes ($p = 0.008$) in TiLOOP® Bra patients.

Chemotherapy

The proportion of patients treated with neoadjuvant chemotherapy ranged between 0% and 71.8% whereas that of

Table 6 Summary of studies in which TiLOOP® was compared to other devices or to implant alone reconstruction.

Author	Comparison to other ADMs/meshes or to implant alone reconstruction	Condensed study result (complications)	Condensed study result (Patient Reported Outcomes)
Bernini, 2015	No		
Casella, 2014	No		
Casella, 2015	No		
Casella, 2018	No		
Casella, 2019 (n°1)	No		
Casella, 2019 (n°2)	No		
Casella, 2019 (n°3)	No		
Casella, 2021	No		
Casella, 2022	No		
Casella, 2023	No		
Chen, 2019	No		
Delmond, 2020	No		
Dieterich, 2012	No		
Dieterich, 2013	No		
Dieterich, 2015 (n°1)	Implant alone (n = 27 patients) vs implant + TiLOOP® Bra (n = 34 patients)		No statistically significant differences between implant alone breast reconstruction and TiLOOP® Bra in all BREAST-Q domains ($p > 0.05$)
Dieterich, 2015 (n°2)	Implant alone vs implant (n = 42 patients) + TiLOOP® Bra (n = 48 patients)	Using TiLOOP® Bra showed similar complication rates	Using TiLOOP® Bra showed similar satisfaction rates but a negative effect on "satisfaction with breast"
Eichler, 2019	TiLoop® Bra/TiMesh® (n = 192 patients) vs Seragyn® (n = 128 patients)	TiLoop® Bra/TiMesh® and Seragyn® did not differ significantly in complication rates	
Esposito, 2017	No		
Gao, 2022	TiLOOP® Bra/TiMesh® (n = 37 patients) vs BioDesign® Surgisis® (n = 79 patients)	No statistically significant differences between Surgisis and TiLOOP® Bra breast reconstruction in complication rates more than 1 year post-operatively	No statistically significant differences between Surgisis® and TiLOOP® Bra breast reconstruction in most patient-reported outcomes > 1 year post-operatively
Gentile, 2021	No		
Gschwantler-Kaulich, 2016	TiLOOP® Bra (n = 25 patients) vs Protexa® (n = 23 patients)	Similar complications rates in both groups ($p = 0.188$) but higher incidence of severe complications leading to implant loss in the Protexa® group ($p < 0.0001$).	No significant differences in patients' satisfaction with cosmetic results ($p = 0.632$), but significantly better outcomes with TiLOOP® Bra as graded by surgeons and external specialists ($p = 0.034$, $p = 0.032$, respectively).
Guanglei Chen, 2019	No		
Klein, 2012	No		
Krivorotko, 2021	No		
Lo Torto, 2020	No		
Marcasciano, 2018	No		
Marcasciano, 2023	No		
Michno, 2022	No		
Ng, 2021	No		
Nguyen-Strauli, 2022	No		
Ohlinger, 2021	TiLOOP® Bra (n = 143) vs Strattice™ (n = 43) vs Seragyn® (n = 95)	o Significantly higher implant loss rate when using porcine ADM compared to synthetic meshes o Implant loss rate with preoperative RHT: 70% (ADM) vs 25% (for each of the SMs) o Implant loss rate with postoperative RHT: 33.3% (ADM) vs 0% (for the SMs)	
Quah, 2019	TiLOOP® Bra (n = 120 patients) vs Veritas® (n = 30 patients)	o The Veritas® group (VG) showed a higher rate of postoperative complications compared with the TiLOOP® Bra Group (TG) [VG = 54% vs TG = 14%, $p < 0.01$%), including higher rates of seroma/non-integration of mesh (VG = 51.4% vs TG = 1.6%, $p < 0.01$), implant rotation (VG = 16.2% vs TG = 1.6%, $p < 0.01$), infection (VG = 18.9% vs TG = 2.1%, $p < 0.01$), and wound breakdown (VG = 10.8% vs TG = 0.5%, $p < 0.01$)] o The VG also had a higher rate of major interventions (VG = 35.1% vs TG = 7.8%, $p < 0.01$) and minor interventions (VG = 18.9% vs TG = 2.2%, $p < 0.01$) compared with TG	
Rathinaezhil, 2015	No		
Rezai, 2016	TiLOOP® Bra vs implant alone (n = 78 patients) + dermal sling (n = 79 patients)	Significant improvement by use of TiLOOP® Bra in the prevention of implant dislocation ($p = 0.009$)	Significant improvement by use of TiLOOP® Bra in the aesthetic results ($p = 0.049$)
Rulli, 2013	No		
Schüler, 2021	TiLOOP® Bra (n = 75 patients) vs Strattice™ (n = 34 patients) vs SERAGYN® BR (n = 48 patients)	ADM was associated with higher complication rates (major complications: Strattice™: 27.5% vs Seragyn® BR: 11.1% vs TiLOOP® Bra: 14.9%, $p = 0.005$), in particular, higher *seroma r*ate (27.5% vs 13% vs 4.3%, $p = 0.001$) and *wound dehiscence* (12.5% vs 1.9% vs 4.3%, $p = 0.018$)	
Thill, 2020 (n°1)	No		
Thill, 2020 (n°2)	No		
Xiao, 2022	Breast-conserving surgery (n = 40 patients) vs reconstruction with implant + TiLOOP® Bra (n = 40 patients)	No significant differences in terms of complications and mental/physical/sexual health ($p > 0.05$)	No significant differences in terms of mental/physical/sexual health ($p > 0.05$)

(*continued on next page*)

Table 6 (*continued*)

Author	Comparison to other ADMs/meshes or to implant alone reconstruction	Condensed study result (complications)	Condensed study result (Patient Reported Outcomes)
Yang, 2019	No		
Yao, 2019	Implant alone (n = 29 patients) vs implant + TiLOOP® Bra (n = 40 patients)	No significant differences between the 2 groups ($p = 0.06$, $x^2 = 0.80$) in terms of postoperative complications.	Satisfaction rate of patients on cosmetic effects was 95.0% (38/40) in the prosthesis + TCPM group, significantly higher than that in the simple prosthesis group (75.90%, 22/29) ($p = 0.05$, $x^2 = 3.87$)

Abbreviations: ADM, acellular dermal matrix; RHT, radiotherapy; SM, synthetic mesh; TCPM, titanium-coated polypropylene mesh.

patients who underwent adjuvant chemotherapy ranged from 0% to 67.5%.

Overall, chemotherapy did not significantly influence the incidence of postoperative complications.

Dieterich et al.[1] failed to demonstrate an association between neoadjuvant ($p = 0.704$) or adjuvant ($p = 0.227$) chemotherapy and complications on univariate analysis. Gentile et al.[32] drew the same conclusion, that chemotherapy is not a significant risk factor for early complications or reconstruction failure. In addition, Quah et al.[42] did not find any difference between adjuvant chemotherapy and the rate of complications in multivariate analysis. Krivorotko et al.[35] concluded that neoadjuvant chemotherapy did not affect the incidence of complications and that adjuvant chemotherapy did not affect the final aesthetic result; however, it was capable of increasing the risk of wound infection (12.9% of cases) and "red breast syndrome" (48.4%). Esposito et al.[52], despite a relatively considerable percentage of patients developing complications during chemotherapy (30.8%), recorded only four major complications, concluding that in their experience, adjuvant and neoadjuvant therapies are not a contraindication for breast reconstruction with TiLOOP® Bra. Nguyen et al.[40] outlined that neoadjuvant chemotherapy could only be associated with wound-healing deficiencies in one patient.

Axillary lymph node dissection and/or sentinel lymph node biopsy

Patients who underwent reconstruction with TiLOOP® Bra had fewer axillary lymph node dissection procedures than those who underwent reconstruction with implant alone ($p = 0.001$)[28] or implant and biological ADMs ($p < 0.001$).[31] Rather, sentinel lymph node biopsy was more often performed in patients who underwent reconstruction with TiLOOP® Bra than in those who underwent reconstruction with implant alone ($p = 0.001$)[28] or implant and Surgisis® ($p < 0.001$).[31]

PROs

The BREAST-Q version for reconstructive surgery was the validated PRO instrument most often employed.[7,20-28,31,34,36,37,39,47,55,56] Regarding the "satisfaction with breasts" domain, when preoperative and postoperative variation in BREAST-Q was evaluated, an increase in patients' postoperative ratings was documented in 100% of cases.[21-25,36,37,47,56] In most cases, such an increase was recorded at the 12-months follow-up[21-25,37,47,56]; however, in one study, it was evident even after 6 months,[36] and in 2 studies it was still assessable at 2-year follow-up.[21,22] Gao et al.[31] compared TiLOOP® Bra and Surgisis® and found that "satisfaction with breasts" was significantly correlated with the mesh used ($p = 0.028$), and Surgisis® received higher scores during the follow-up ($p = 0.028$). When investigating the influence of relevant variables on each BREAST-Q domain, Dieterich et al.[28] revealed a negative effect of TiLOOP® Bra on "satisfaction with breasts" ($p < 0.001$); however, this effect was no longer observed for other domains. Conversely, Chen et al.[34] found that, when compared to implant-alone reconstruction, patients who underwent dual plane reconstruction with TiLOOP® Bra had a higher satisfaction rate regarding breast appearance, whereas psychosocial and physical health, and sexual well-being did not differ between the two ($p = 0.0368$).

Yao et al.[50] found that overall satisfaction of patients with the cosmetic effects was higher in the prosthesis + TCPM group (95.0%) than in the simple prosthesis group (75.90%) ($p = 0.05$). Rezai et al.,[44] using alternative PRO surveys, similarly observed a significant improvement using tetanized meshes in aesthetic results ($p = 0.049$), as well as in the prevention of implant dislocation ($p = 0.009$). Esposito .[52] found an overall satisfaction rate of 72.6% at the follow-up.

Casella et al.[23] found that patients who underwent reconstruction with TE were more satisfied with their breast appearance than patients who underwent DTI; however, the difference was not significant ($p = 0.82$). In contrast, Gentile et al.[32] found that overall satisfaction with breasts, psychosocial, and sexual well-being scores increased ($p < 0.05$) after pre-pectoral DTI reconstruction with a TCPM mesh.

Thill et al.[47] found a lower score at 12 months follow-up compared with the pre-operative period in patients who developed adverse events ($p < 0.05$) and in those aged >40 years ($p < 0.01$). The subgroup of patients with a BMI $\leq 25\ kg/m^2$ had significantly higher preoperative scores than the subgroup with a higher BMI; however, at the 12 months follow-up, no difference was detected between the two groups.

Greater satisfaction with the breasts was documented when contralateral symmetrization was performed immediately ($p = 0.04$)[26] and in the pre-pectoral implant location compared to the dual plane ($p = 0.036$).[39]

The psychosocial well-being domain significantly increased between the pre-operative and post-operative period.[21-25,36,37,47,56] An increase at 12-months follow-up was documented, even in patients who underwent unilateral reconstruction ($p < 0.05$).[47] Patients with no complications and no previous breast surgeries were more satisfied at 12-months follow-up ($p < 0.001$).[27,28,34]

Sexual well-being was ameliorated ($p < 0.05$) between pre-operative and post-operative ratings[21–25,36,37,47,56] and was negatively influenced by adverse events.[47]

Yao et al.[50] found lower satisfaction with family life and sexual interest in patients who underwent reconstruction with a prosthesis alone than in those who underwent reconstruction with a prosthesis + TCPM ($p = 0.03$).

The only factors that impacted physical perception were BMI and smoking on one side and previous breast surgery on the other, with negative and positive effects, respectively.[28]

Yao et al.[50] found that the postoperative quality of life in the simple prostehsis group was significantly lower that that in the prostehsis and TCPM group. Additionally, the incidence of arm pain and fatigue was higher in the first group ($p = 0.04$).

Other complications

Chen et al.[34] reported two unique complications of TiLOOP® Bra-associated reconstruction. The first was the "pectoralis major disconnection syndrome," a breast moving up with the muscle when this is contracted strenously. The second was "mesh area skin fibrosis," which is the thinning of the skin and subcutaneous fat in the mesh area.

Discussion

Thus far, a large number of devices are available, and ongoing scientific research is oriented toward developing an "ideal" material that should integrate well with overlying tissue, prevent contracture, and be associated with few postoperative complications.[42] Notwithstanding the great efforts made over the last decades, none of the available matrices, biological or synthetic, have proven superiority in all these areas.[42]

ADMs have been used for many years and are considered the gold standard for soft tissue replacement in breast surgery. However, they are also prone to infections and seromas[19]. Another reason an alternative solution to ADMs has been sought is theirhigher cost (up to 3000 € vs 350 € for synthetic meshes).[28,30]

Our review showed that the population eligible for breast reconstruction with synthetic meshes is largely comparable to that for ADMs: patients undergoing skin-nipple sparing and skin-reducing mastectomies and candidates for DTI reconstruction. Nevertheless, authors using ADMs and synthetic meshes in their clinical practice do not consider the two products to be completely interchangeable, choosing between the two, resting on the availability of soft tissues after mastectomy of at least 8 mm.[5,26,32,33,57] The thicker nature of ADMs compared to TiLOOP® Bra greater flexibility and lower intrinsic thickness, underscore this caution. This is particularly true in pre-pectoral reconstruction, thin patients, and in DTI reconstructions, where the implant pushes the fenestrated mesh against the skin, which becomes stretched, making dots more visible and increasing the risk of extrusion into poorly vascularized flaps.[57]

In the majority of studies, no significant correlation between BMI and complications was identified, even for BMI $> 25\ kg/m^2$.[1,23,32,34] In addition, from a cosmetic viewpoint, patients with a higher BMI were equally satisfied after reconstruction[47] and showed a lower risk of dissatisfaction when DTI was performed.[23] In only 2 cases, higher BMI was associated with a greater risk of wound dehiscence,[44] necrosis, and seroma.[38] However, one of these studies enrolled patients with extreme BMI.[38]

Studies comparing mesh-assisted and implant-only reconstructions showed that patients in the mesh group had a significant lower BMI, what is unlike is the preparation of an additional dermal flap (patients without a large breast usually do not undergo a skin reduction mastectomy).[27].

Considering these data, mesh-assisted breast reconstruction can be an alternative to ADMs or dermal flaps in normal/medium-weight women with small and non-ptotic breasts.

Regarding smoking habits, a consensus seems to have been developed, and smokers have shown a trend toward a higher complication rate, mainly due to infection, necrosis, and wound healing problems.[28,32,38,51] Negative effects on aesthetic outcome have also been outlined.[44] It is more difficult to draw firm conclusions about the risk of complications related to diabetes, given a very small proportion of patients with diabetes enrolled (3.2%). In the only study that reached statistical significance, patients with diabetes who developed complications did not suffer implant loss.[32] These data confirm the integration of TiLOOP® Bra with patient tissues, thus improving the chances of revascularization even in sub-optimal recipient bed conditions.

The fenestrated look of TiLOOP® Bra has also been advocated as a useful way for drainage of secretions, preventing the accumulation of seromas.[7] In our study, the incidence of seroma ranged from 0% to 14.3%, excluding an outsider value of 61%[54]. This high percentage was reported in a retrospective study that referred to patients and was far different from the value reported in a later prospective study by the same authors' group, where the incidence of seroma dropped to 10.7% in breasts.[47]

The incidence of seromas in ADM-assisted breast reconstruction ranges from 1% to 29%.[58] The iBAG study,[59] using Braxon®, reported a seroma incidence up to 7.7%. In contrast, Reitsamer et al.,[3] in their study using Strattice™, Artia™, and TIGR®, showed an incidence of 14.5%, very close to that identified in our study.

A direct comparison between TiLOOP® Bra and ADMs was made in 3 studies.[31,33,42] In all cases, a higher incidence of seroma was reported in the biological group, without reaching statistically significance except in one case,[42] with a percentage of seroma up to 1.7% in TiLOOP® Bra and 51.4% in the Veritas® group ($p < 0.01$).

The factors involved in seroma genesis likely differ between the two products. For example, most biological meshes lack perforations (with the exception of bovine ADM).[43]

All that considered, seroma incidence is not very different when considering animal and synthetic devices and is likely due to an inflammatory response that is part of the healing process and bio-integration of any device.[5,22]

The immunosuppression caused by chemotherapy may be a mattern of concern when using a foreign body (breast implant) and a metallic device (TiLOOP® Bra), given the

reduced antibiotic delivery to non-vascularized tissues. The use of TiLOOP® Bra also seems safe in patients requiring chemotherapy, thus not lenghtening the time intervals between surgery and adjuvant treatments.[1,32,35,40,42,52]

According to the present study, the risk of malposition/rotation of the implant when using TiLOOP® Bra is $< 5\%$,[22-24,30,31,39,40,42-45,47,54], thus lower than that of implant alone reconstruction (up to 9.8%).[60] Also ADMs exhibit a protective effect against implant malposition and in both cases an integration of the device with host tissues can be hypothesized.[61] However, Quah et al.[42] observed a higher rate of implant rotation and non-integration with Veritas® ($p < 0.01$). Given the non-resorbable nature of TiLOOP® Bra as compared to all other biological devices, a longer time for complete integration with host tissues has been invoked as responsible of this observed difference.[42]

Another challenging problem when considering alloplastic reconstruction is capsular contracture, the incidence of which in our study ranged from 0% to 11.4% when considering clinically relevant grades (Baker III or IV).

In the literature, the incidence of capsular contracture when using ADMs is 0.2%–9%[41,59,62]; however, in patients who have undergone adjuvant radiotherapy this value rises to 10.7%–18.8%.[41,62] In another study, the incidence ranged from 16.1% to 52.2%.[63]

All things considered, the incidence of capsular contracture seems similar between synthetic meshes and ADMs, even though the last may be more prone to developing capsular contracture because of their need for rehydration (which protracts intraoperative exposure and consequent risk of infection) and their lack of fenestrations as compared to TiLOOP® Bra, which could promote a faster colonization of connective tissue.[22] In any case, capsular contracture using TiLOOP® Bra is reduced compared with implant-alone reconstruction.[34] This improvement is probably due to the absence of muscle compression of the prosthesis, allowing enlargement and loosening of the prosthesis cavity.[34]

Regarding the drawbacks of our study, we highlight the marked variability in the design or sample size of the included articles and the non-uniform description of the data. The grading of complications is often lacking or is interpreted differently among studies. Moreover, some data about the demographics and characteristics of patients were not available or were referred to as patients in some articles and to as breasts in others, complicating or skewing the percentages calculation.

Noteworthy is also the heterogeneity of the design of the included articles. Indeed, despite the vast majority of the studies was focused on TiLOOP® as the only mesh considered, in some articles a comparison between TiLOOP® and either animal-derived matrices orother synthetic meshes or implant alone reconstruction was done (see Figure 2), but the criteria by which some patients were reconstructed with one device rather than another or with implant alone were not made explicit.

Furthermore, all articles published by the same group of authors, even within a short time frame, were included in our study, with the possibility that some women enrolled in the latter studies may have already been recruited in previous studies. The reason why we decided to do so rests on the fact that the design of the study was, in any case, changed from one article to another, the patient population was enlarged, or the follow-up was extended. The recurrence of the same authors' group across the literature search emphasizes the lack of awareness regarding the potential of this device among reconstructive surgeons.

Lastly, only TiLOOP® Bra mesh was considered. We intentionally decided to exclude other synthetic devices because of their current limited availability, the lack of expertise of most surgeons, and ad hoc trials with adequate cohorts of women. Moreover, further evidence needs to be gained about the use of TiLOOP® Bra in delayed breast reconstruction, which, according to this review, accounted for only a small percentage of reconstructed breasts (2.6%).

To conclude, the outcomes of breast reconstruction are influenced by so many variables that the conclusions we have tried to draw in this review must be read critically, with the understanding that they may have been affected by multiple other factors other than the simple choice of a mesh rather than another. In order to represent a global view of all possible interfering factors affecting breast reconstruction outcomes, we have collected as many demographic and perioperative data as possible, but the lack of a statistical analysis makes it impossible to discern the relative effect of every single factor.

Conclusion

Although ADMs are considered the gold standard for soft tissue replacement in breast reconstruction, their high cost, incompatibility with some cultural or religious beliefs, and high rates of seroma and infection have prompted research on cheaper alternatives with at least a “non-inferior” safety profile. TiLOOP® Bra can be proposed to the same population of women offered ADMs (namely, non-smokers patients undergoing skin-nipple sparing and skin-reducing mastectomies) with particular attention to preoperative tissue thickness and BMI. Indeed, a greater risk of complications is more likely to develop in patients with a weight at the extremes of BMI (too much underweight or overweight). The beneficial effect of ADMs in patients who underwent radiotherapy is also mantained with TiLOOP® Bra, and the incidence of seroma and capsular contracture is not higher. In conclusion, TiLOOP® Bra can be considered a valid and effective alternative to ADMs in appropriately selected patients.

Ethical approval

Not required.

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Declaration of competing interest

The authors have no conflict of interest to declare.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.bjps.2024.07.060.

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