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Review

Complications, patient-reported outcomes, and aesthetic results in immediate breast reconstruction with a dermal sling: A systematic review and meta-analysis

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Summary An inferior dermal flap ("sling") can be used to cover an implant with two layers of tissue following Wise pattern skin-reducing mastectomies. Here, we performed a systematic review of the risks and benefits of this technique, specifically regarding complications, patient-reported outcomes, and aesthetic outcomes. PubMed and other relevant databases were searched using specific key words, with inclusion criteria comprising studies of dermal sling use involving ≥ 5 patients and performance according to the PICO framework. A meta-analysis was performed using a random-effects model involving a binomial distribution with logit-link function. For each study, the 95% confidence interval (CI) was obtained based on exact limits from a binomial distribution, and heterogeneity testing was performed using a chi-squared test. A total of 428 abstracts were retrieved, with 24 studies meeting the inclusion criteria and including a total of 879 patients and 1184 reconstructed breasts. The mean complication rate was 21.6% (95% CI: 16.9–27.2%), with the most common complication involving wound-healing problems (mean, 11.4%; 95% CI: 8.5–15.2%), and the frequency of implant loss (<3 months) varied from 0% to 14% (mean, 2.2%; 95% CI: 1.1–4.4%). Seven articles reported patient-reported outcomes, and four reported aesthetic outcomes, with the quality of evidence

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classified as low for complications and very low for patient-reported outcomes and aesthetic outcomes. Our findings showed that although implant-based reconstruction with a dermal sling is widely used, there is little scientific evidence supporting the method.

Contents

Introduction

A dermal sling (DS) is an inferior dermal flap used as an adjunct to an implant or tissue expander (TE) in immediate breast reconstruction.[1] A DS comprises tissue normally discarded during a type IV skin-sparing mastectomy (Wise pattern mastectomy)[2] and is vascularised by perforators in the submammary fold. The DS covers the lower pole of the implant and is sutured to the inferior border of the *M. pectoralis major* in a manner similar to that of a mesh/matrix (acellular dermal matrix; ADM). Moreover, the DS is advantageous in that it is autologous, does not infer any additional costs,[3-5] and, theoretically, preserves the natural submammary fold while serving as an extra layer of protective vascularised tissue between the suture line and the implant.[1] The technique was first described in 1990 by Bostwick[1] in risk-reducing mastectomies and later introduced by Hammond[6] as a two-stage procedure in the treatment of breast cancer. It is now widely used in clinical practice[6,7]; however, there is little scientific literature associated with the method.

The aim of this study was to perform a systematic review and meta-analysis of the risks and benefits associated with immediate breast reconstruction with a DS and an implant or TE, specifically regarding complications, patient-reported outcomes, and aesthetic outcomes.

Methods

Data sources and search strategies

Medline, PubMed, CINAHL, AMED, EMBASE, Google Scholar, and the Cochrane Library databases were searched for articles and abstracts published between January 1990 and September 2018. No Grey literature sources were searched. The keywords included “dermal sling”, “dermal barrier” “inferior dermal flap”, “skin-reducing mastectomy”, “myodermal flap”, “myodermal pocket”, “autoderm”, “skin-envelope reducing mastectomy”, “Wise pattern mastectomy”, “Bostwick technique”, “breast reconstruction”, “implant”, and “tissue expander”. The keywords were combined with the Boolean operators “and” and “or”, and the search was limited to studies published in English, French, German, Italian, Swedish, Danish, and Norwegian. When inclusion eligibility could not be assessed using information in the abstract, the entire article was read and assessed. Moreover, all bibliographies of the included studies were manually checked.

Inclusion and exclusion criteria

Inclusion criteria were studies on DS comprising ≥ 5 patients, with review articles, comments, technical descriptions, communications, and editorials excluded. Included articles needed to meet the criteria defined in the PICO (Patient Intervention, Comparison, and Outcome) framework [8]: P, women of all ages who had a mastectomy; I, immediate breast reconstruction with a DS; C1, immediate breast reconstruction without a DS; C2, immediate breast reconstruction with a matrix/mesh; C3, different types of implants/TEs; C4, radiation; and O, complication rates, patient-related outcomes, and aesthetic outcomes. Only studies of implant-based breast reconstruction with an inferiorly based DS sutured to the inferior border of the *M. pectoralis major* to cover the implant were included. Studies

Table 1 Short-term complications (<3 months).

Reference	No. of patients/breasts	Total complications (%)	Wound-healing complications[1]	Infection	Seroma	Hematoma	Implant loss (<3 months)	Unplanned re-operation	Evidence level
Colizzi et al.[41]	18/22	2 (9.1)	2	NS	NS	NS	NS	1	4
De Vita et al.[26]	74/88	17 (19.3)	7	3	5	NS	2	5	4
Demiri et al.[42]	50/65	17 (26.2)	11	2	4	0	0	10	4
Dietz et al.[19]	43/43	3 (7)	NS	NS	NS	NS	NS	NS	4
Gentileschi et al.[43]	23/23	4 (17.4)	4	0	NS	NS	0	0	4
Filobbos et al.[50]	15/23	2 (8.7)	NS	1	NS	1	0	2	4
Goyal et al.[24]	21/28	12 (42.9)	6	3	3	NS	0	1	4
Hammond et al.[6]	8/12	3 (25)	2	NS	NS	NS	1	2	4
Hon et al.[20]	24/38	9 (23.7)	5	0	0	1	0	NS	4
Irwin et al.[44]	64/104	31 (29.8)	12	8	3	4	4	1	4
Kilgo et al.[14]	69/117	57 (48.7)	30	11	7	NS	7	3	3
King et al.[22]	16/19	6 (31.5)	3	2	NS	1	0	0	4
Korwar et al.[23]	92/116	30 (25.9)	7	2	12	8	1	1	4
Ladizinsky et al.[16]	110/170	40 (23.5)	28	6	2	4	2	34	4
Losken et al.[45]	27/34	15 (44.1)	5	4	6	NS	3	5	4
Nair et al.[21]	72/89	6 (6.7)	1	2	NS	1	2	NS	4
Nava et al.[46]	28/30	10 (33.3)	6	0	NS	NS	4	4	4
Nava et al.[18]	65/77	15 (19.5)	4	NS	NS	NS	11	12	4
Prathap and Harland[17]	6/6	0	0	0	0	0	0	0	4
Querci della Rovere et al.[47]	10/18	3 (16.7)	0	1	NS	1	1	1	4
Rathinaezhil et al.[15]	5/7	2 (28.5)	2	0	0	0	0	0	4
Ross[48]	10/20	2 (10)	1	1	0	0	0	0	4
Roy[49]	5/8	2 (28.6)	2	0	0	0	0	0	4
Siggelkow et al.[28]	24/27	4 (14.9)	3	0	NS	NS	0	0	4

NS = not stated.

[1] Flap necrosis, epidermolysis, wound dehiscence, fat necrosis.

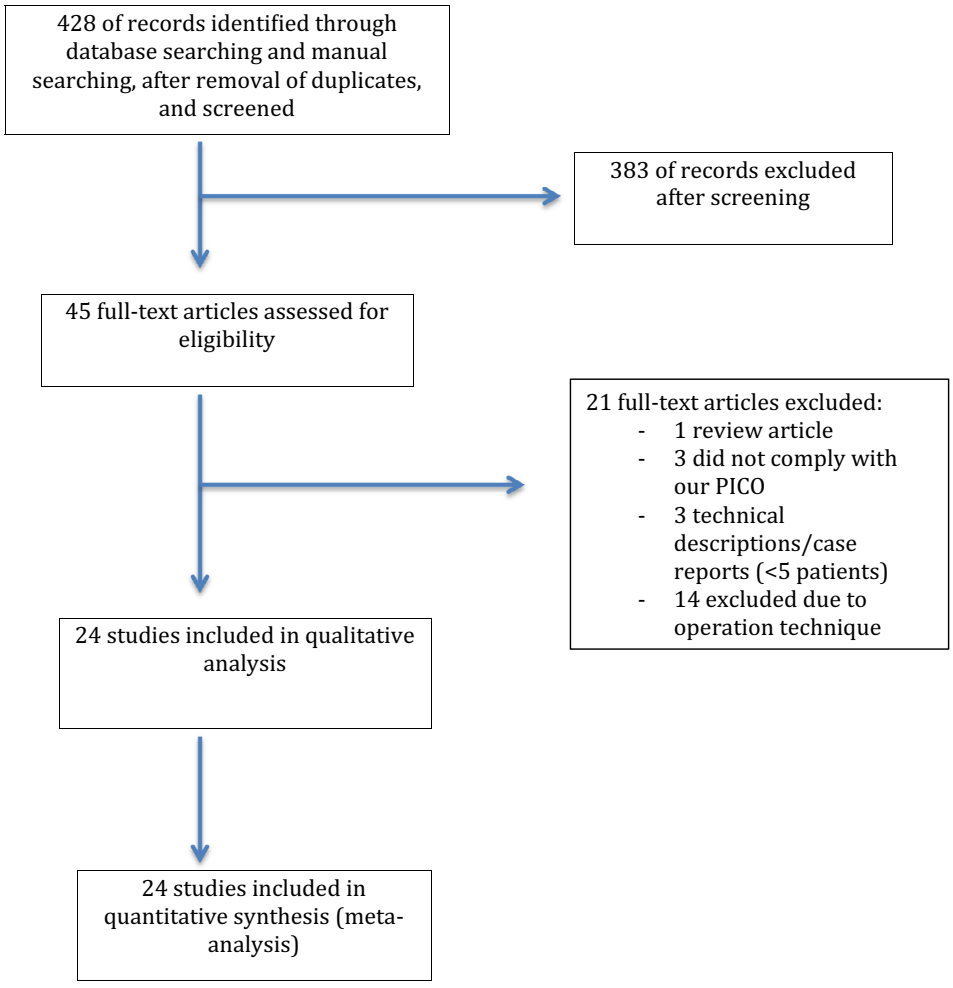

Figure 1 PRISMA diagram describing the process used for study inclusion according the established guidelines and the PICO framework.

using the DS as an extra layer to cover an ADM or prepectoral implants were excluded. Two of the authors (CJ and EH) independently assessed whether articles met the inclusion criteria, with disagreements resolved by discussion.

Study endpoints and measured outcomes

The endpoints of interest were incidence of complications, patient-reported outcomes, and aesthetic outcomes. Complications were classified as wound-healing complications (flap necrosis, epidermolysis, and/or wound dehiscence), implant loss (< 3 months), infection, seroma, hematoma, capsular contracture, unplanned re-operation (early operations; for example, due to a hematoma), and corrections (late operations; for example, unplanned change of implant, correction of implant position, and/or capsulectomy). Infection and wound-healing problems leading to implant loss were considered complications separate from implant loss. If the authors did not report a complication, this was not interpreted as the absence of complications, but rather that a complication was unspecified. Other complications not listed here [e.g., nipple-areola complex (NAC) necrosis and/or implant displacement and asymmetry] were subtracted from the total complication rate presented. Therefore, the total complications listed in Table 1 might differ from the total complications presented in the text.

Data extraction and grading of evidence

Data were collected in Excel (Microsoft Office; Microsoft, Redmond, WA, USA), and quality assessment was performed using QUADAS,[9] with disagreements resolved by discussion. The level of evidence in the selected articles was assessed according to guidelines in the Oxford Centre for Evidence-based Medicine 2009 (i.e., levels 1a–5).[10] Total evidence for the different research questions was graded according to the Grading Recommendation Assessment Development and Evaluation (GRADE)-system (i.e., high, moderate, low, or very low quality).[11]

Statistics

When possible, extracted data were pooled in meta-analyses. In this study, a random-effects model was used

to adjust for heterogeneity in the included studies, as we expected the studies to be diverse in regard to patient population, surgeon preferences, and risk factors, such as body mass index (BMI) and smoking status.[12] For each study, we obtained the number and percentage of breast-level events and 95% confidence intervals (CIs) for the percentages based on exact limits from a binomial distribution. Statistical heterogeneity between studies was examined using the chi-squared test and quantified according to the method of Higgins and Thompson,[13] which uses the I^2 index to describe the percentage of heterogeneity associated with the total variation derived from the between-study variance. To examine publication bias, a funnel plot was generated, with the number of complications presented on the X-axis, and the percentage with 95% exact binomial-confidence limits presented on the Y-axis and based on the observed meta-analysis estimate. Meta-analyses were performed using Laplace estimation and a random-effects model involving a binomial distribution with logit-link function in order to adjust for heterogeneity between studies. Because few studies stated the number of cases involving bilateral complications, data could only be analysed according to the number of breasts and not for individuals. Each study estimate (95% CI) and meta-analysis estimate (95% CI) is shown graphically in a forest plot. The relationship between proportions of events per number of breasts operated versus mean follow-up time was examined using Spearman correlation. All tests were two-tailed, with $p < 0.05$ representing statistical significance. All analyses were performed using SAS software (v9.4; SAS Institute, Cary, NC, USA).

Results

A total of 428 abstracts were retrieved following the exclusion of duplicates. Of these, 383 abstracts did not meet the inclusion criteria and were excluded, leaving 45 abstracts. After full-text review, a further 21 articles were excluded, leaving 24 articles for systematic analysis (Figure 1). Among these were 12 prospective and 12 retrospective case series, with 23 articles classified as evidence level 4 and one as level 3.[14] The studies included between five [15] and 110 [16] patients for a total of 879 patients and between six[17] and 170 [16] reconstructed breasts for a total of 1184 breasts. The mean follow-up time ranged from 3 months to 60 months, although this was not stated in five articles (Table 1, 2, 4 and 5).

Complications

Complications were reported in all 24 articles (Tables 1 and 2) comprising a total of 1184 breasts; however, all of the studies reported study limitations. Few articles stated how the authors defined and diagnosed complications or whether the patients were followed in a systematic fashion, with our meta-analysis demonstrating a high degree of heterogeneity (Figures 2 and 3). The total number of complications was 292 for 1161 operated breasts [meta-analysis: 21.6% (95% CI: 16.9-27.2%)]. Total complication rates of the individual studies ranged from 0%[17] to 49%[14], with the most common complications involving wound-healing problems ($n = 141/1161$ breasts), including flap necrosis, epidermolysis, wound dehiscence, and fat necrosis [meta-analysis: 11.4% (95% CI: 8.5-15.2%)]. The frequency of implant loss varied from 0% to 14%[18] [meta-analysis: 2.2% (95% CI: 1.1-4.4%)], and there was no significant correlation between the proportion of complications and mean follow-up time ($r_s = -0.01$; $p = 0.97$). Details concerning the meta-analyses of all complications are presented in Table 3.

There were two studies comparing immediate breast reconstruction with and without DS.[14,19] One study[14] compared DS ($n = 69$) with traditional elliptical skin-sparing mastectomy ($n = 89$) without considering breast size as a factor, finding that flap necrosis was more frequent in the DS group (26% vs. 11%), although differences in the rates of TE loss (6% vs. 2.2%) were not statistically significant ($p = 0.19$). Although breast size was not specified in the study, it is assumed that the women in the DS groups had larger breasts according to their higher BMI relative to that of women in the elliptical mastectomy group ($p = 0.04$).[14] The other study[19] compared patients with large breasts (specimen weight: 796-1108 g; $n = 21$) undergoing traditional elliptical skin-sparing mastectomy with patients operated on with DS ($n = 43$), finding that the risk of complications in patients with larger breasts appeared smaller when using the DS technique.

Two studies compared DS with matrix/mesh.[19,20] One study[20] compared DS ($n = 24$) with human-derived ADM ($n = 41$), concluding that the overall complication rates for the two methods were similar (31% vs. 22%). The other study was prospective[19] and compared DS ($n = 43$) in combination with lower pole coverage with *M. serratus* or with human-derived ADM ($n = 54$), reporting no differences in complication rates (7% vs. 7%).[19]

Five studies involved different implant types, but only four reported complications for each respective group. Nair et al.[21] reported a case of DS reconstruction combined with a permanent implant (PI; $n = 34$), a TE ($n = 31$), or use of a TE as a temporary "babysitter" while awaiting autologous reconstruction (an immediate-delayed approach; $n = 24$), with results involving one implant loss in the TE group (3%), one in the babysitter group (4%), and none in the implant group. King et al.[22] performed four TE reconstructions and 15 reconstructions using a PI, reporting no implant losses in either group, whereas Hammond et al.[6] performed 10 TE and two PI reconstructions, reporting one implant loss in the TE group. Additionally, Ladizinsky et al.[16] presented the results of a series of 170 reconstructions with a DS involving a TE in 72 cases and a PI in 98 cases, reporting a total implant loss of 1.2% ($n = 2$; implant type unspecified) and a positive correlation between skin necrosis and placement of a PI rather than a TE.

Regarding radiotherapy (RT), one retrospective study[23] compared DS patients not undergoing RT ($n = 47$) with those who had preoperative or postoperative RT ($n = 45$), with their results showing that early complication rates were similar in the two groups (17% vs. 13%), although the rate of late implant loss (3-12 months) was higher in the irradiated group (11%) than in the non-irradiated group (0%).

The quality of evidence for complication rates following immediate breast reconstruction with a DS is classified as low (GRADE ⊗⊗).

Table 2 Long-term complications (>3 months) and possible impact factors.

Reference	No. of patients/breasts	Follow-up min/mean (months)	Adjunct ADM/mesh	Radiation	Implant type	Adjustment surgery[1]	Capsular contraction	Evidence level
Colizzi et al.[41]	18/22	NS/14	No	NS	PI	NS	NS	4
De Vita et al.[26]	74/88	12/18	14/88 (SurgiMend PRS)	6	PI	48	15	4
Demiri et al.[42]	50/65	12/27	No	8	Becker	7	5	4
Dietz et al.[19]	43/43	NS/NS	No	6	TE	NS	NS	4
Filobbos et al.50	15/23	4/12	No	4	PI	NS	1	4
Gentileschi et al.[43]	23/23	NS/21	No	0	PI	NS	0	4
Goyal et al.[24]	21/28	2/21	No	3	TE	NS	NS	4
Hammond et al.[6]	8/12	NS/NS	No	NS	TE (10) or PI (2)	1	NS	4
Hon et al.[20]	24/38	NS/NS	No	NS	TE	NS	NS	4
Irwin et al.[44]	64/104	4/35	No	16	PI	NS	1	4
Kilgo et al.[14]	69/117	NS/35	113/117 (alloderm)	NS	TE	5	NS	3
King et al.[22]	16/19	10/24	No	6	PI (15) or TE (4)	NS	NS	4
Korwar et al.[23]	92/116	NS/20	No	45	PI (NS) or TE (NS)	18	17	4
Ladizinsky et al.[16]	110/170	NS/NS	No	NS	PI (98) or TE (72)	NS	NS	4
Losken et al.[45]	27/34	2/16	No	4	TE	NS	NS	4
Nair et al.[21]	72/89	5/26	No	38	PI (34) or TE (55)	NS	14	4
Nava et al.[46]	28/30	NS/13,6	No	0	PI	NS	0	4
Nava et al.[18]	65/77	24/36	No	10	PI	NS	0	4
Prathap and Harland[17]	6/6	NS/60	No	NS	PI	1	1	4
Querci della Rovere et al.[47]	10/18	6/27	No	1	Becker	1	NS	4
Rathinaezhil et al.[15]	5/7	<3/3	7/7 (Ti Loop)	NS	PI	NS	NS	4
Ross[48]	10/20	6/12	No	0	PI	0	0	4
Roy[49]	5/8	NS/NS	No	3	PI	0	0	4
Siggelkow et al.[28]	24/27	NS/13,6	No	0	PI	2	2	4

[1] Fat-grafting, implant substitution, dog-ears.

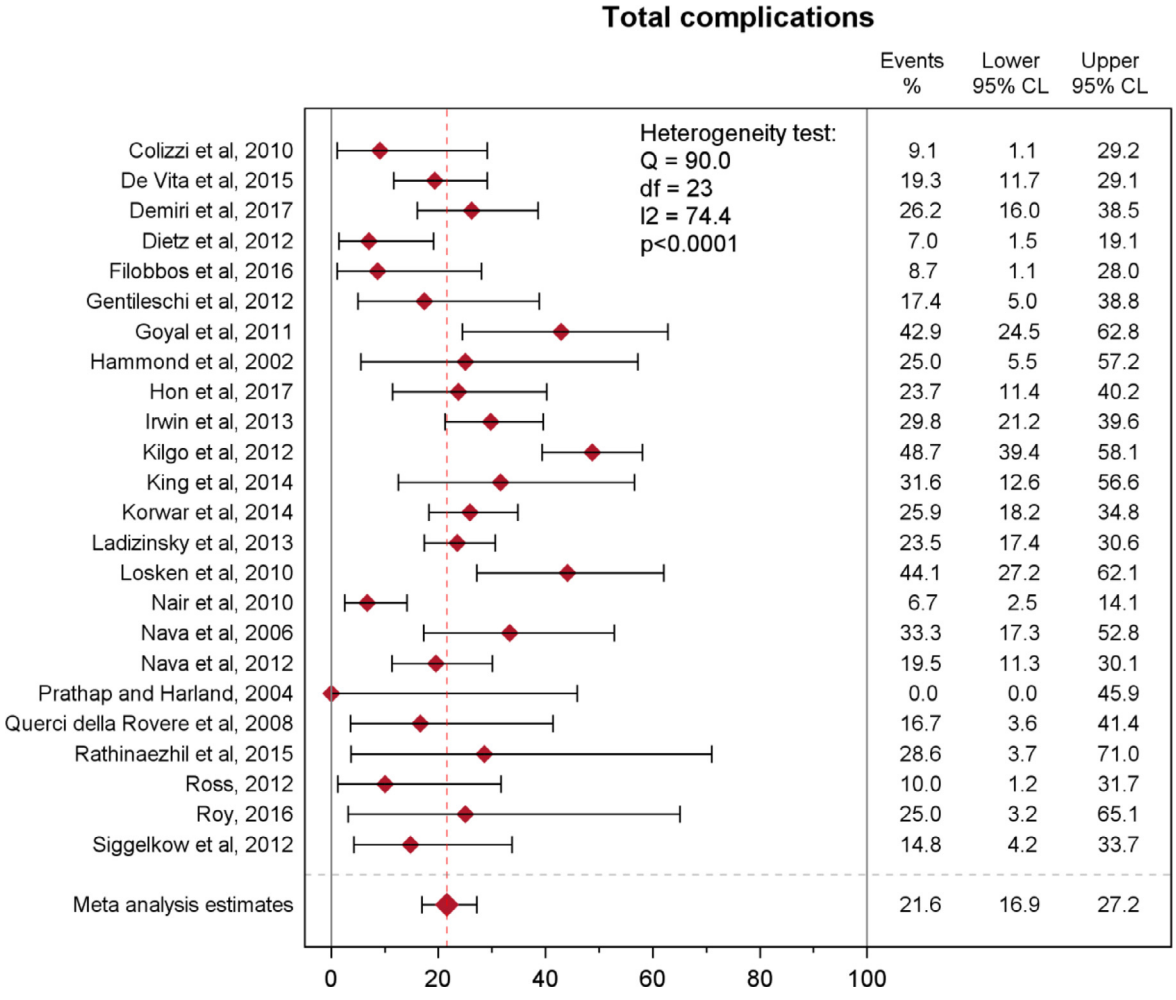

Figure 2 Assessment of study heterogeneity according to the reported percentage of complications associated with implant-based breast reconstruction.

Table 3 Meta-analysis: complications in immediate breast reconstruction with a DS.[1]

Complication	No. of studies	No. of breasts	No. of events	Heterogeneity (p/I^2 index)[2]	Frequencies	
					Mean	95% CI
Total complication rate	24	1184	292	<0.0001/74.4	21.6	16.9-27.2
Wound-healing complications	22	1118	141	<0.0001/61.3	11.4	8.5-15.2
Implant loss (<3 months)	22	1119	38	<0.0001/64	2.2	1.1-4.4
Infection	20	1030	46	0.060/32.5	4.0	2.6-6.1
Seroma	13	801	42	0.0030/59.7	4.5	2.5-7.9
Hematoma	13	683	21	0.40/0.0	2.8	1.6-5.0
Capsular contracture	13	676	55	<0.0001/72.9	3.7	1.2-10.4
Unplanned re-operation	21	1014	82	<0.0001/74.7	4.5	2.4-8.3
Corrections	10	477	83	<0.0001/91.9	8.9	3.8-19.4

[1] Heterogeneity testing was performed using a chi-squared test, with the I^2 index calculated according to the method described by Higgins and Thompson.[13] Meta-analyses were performed using Laplace estimation and a random-effects model involving a binomial distribution with logit-link function to adjust for heterogeneity between studies.

[2] I^2 index: percentage of heterogeneity = amount of the total variation due to between-study variance (0% = no heterogeneity, 25% = low, 50% = moderate, and 75% = high heterogeneity).

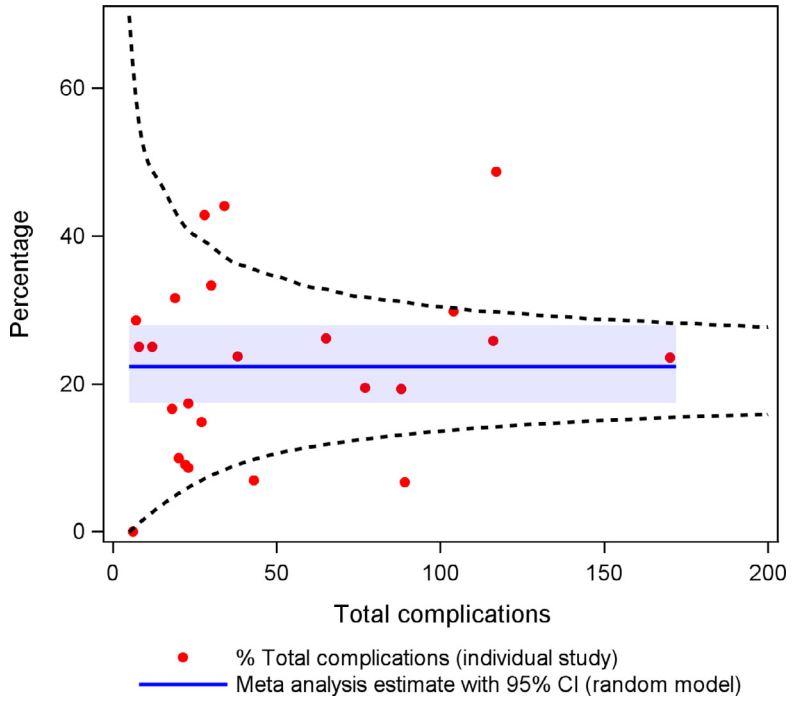

Figure 3 Funnel-plot based on the observed meta-analysis estimates demonstrating a high degree of heterogeneity and indicating a high risk of publication bias.

Patient-reported outcomes

Seven studies reported patient-reported outcomes (Table 4). Two studies[15,24] used BREAST-Q,[25] with one[24] reporting high scores for satisfaction, and the other[15] stating that all patients were satisfied but not reporting any scores. A retrospective study[26] ($n = 74$) using the Michigan Breast Reconstruction Outcome Scale[27] found that the majority of patients were highly or moderately satisfied with the reconstruction. Another retrospective study[23] using the Breast Evaluation Questionnaire compared patients operated on with DS and not undergoing RT ($n = 47$) with those who had preoperative or postoperative RT ($n = 45$), finding that overall satisfaction scores were similar in the two groups (4.03 vs. 3.71).[23] Other studies reported that the majority of patients were satisfied with their reconstruction according to in-house questionnaires.[18,21,28]

The quality of evidence for patient satisfaction with immediate breast reconstruction with a DS is classified as very low (GRADE ⊗).

Aesthetic outcomes

Four studies reported aesthetic outcomes (Table 5). A retrospective study[20] comparing DS ($n = 24$) with human-derived ADM ($n = 41$) reported no differences in aesthetic outcomes between the two methods according to two reviewers using a scale generated in-house. The other studies, which also used reviewer or patient reports and in-house scales,[18,20,26] reported that the majority of reviewers rated the aesthetic outcome as excellent or good.

The quality of evidence for aesthetic outcomes from immediate breast reconstruction with a DS is classified as very low (GRADE ⊗).

Discussion

A DS used as an adjunct in immediate breast reconstruction was first described in 1990 [1] and is now widely used in clinical practice; however, there is little scientific literature associated with use of this method. This represents the first systematic review and meta-analysis examining the risks and benefits of DS use as an immediate breast reconstruction technique.

Methodological issues

The selection of relevant studies and subsequent data extraction represent fundamental aspects required for the validity of a meta-analysis.[29] Given that this review focuses on a field in which little scientific data exist, we needed to include small studies ($n \geq 5$ patients) in the analyses. To minimize the risk of selection bias, two of the authors reviewed all of the studies and extracted data independent of one another. Unclear cases were discussed in order to eliminate the risk of inter-individual variation. We are confident that the broad criteria applied for inclusion eligibility, as well as the rigorous screening and data-extraction processes, resulted in acquisition of the best data available for answering the research questions posed by the review. Nevertheless, results of meta-analyses are ultimately dependent upon the methodological quality of the included studies.[29]

Table 4 Studies reporting patient-reported outcomes in immediate breast reconstruction with a DS.

Reference	No. of breasts	No. of patients	Evaluation tool	Time of evaluation	Outcome	Response rate (%)
De Vita et al.[26]	88	74	Questionnaire from the Michigan Breast Reconstruction Outcome Scale	NS	32 (43.3%) Highly satisfied 34 (45.9%) moderately satisfied 8 (10.8%) not satisfied	100
Goyal et al.[24]	28	21	Breast-Q	21 months (median)	Median: 60% (range: 46–100%) satisfied with breast reconstruction Median: 75% (range: 61–100%) satisfied with outcome	67
Korwar et al.[23]	116	92	The Breast Evaluation Questionnaire	NS	Mean overall score: no RT, 4.03; RT, 3.71 (range: 1–5)	76
Nair et al.[21]	89	72	Outcome evaluated by patients as excellent, good or poor	NS	24 (33%) excellent 42 (59%) good 6 (8%) poor	NS
Nava et al.[18]	77	65	Outcome evaluated by patients as good, medium, or poor	3, 9, 12 months and annually thereafter (median: 36 months)	77.3% good 21.2% medium 1.5% poor	100
Rathinaezhil et al.[15]	7	5	Breast-Q	3 months	All patients were satisfied with care, information, and outcome (scores not provided)	80
Siggelkow et al.[28]	27	24	Questionnaire evaluating satisfaction with breast reconstruction, information provided about alternatives, and satisfaction with volume reduction	6 months	47.5% very good, 54.2% good, and 8.3% unsatisfactory	100

Table 5 Studies reporting aesthetic outcomes in immediate breast reconstruction with a DS.

Reference	No. of breasts	No. of patients	Evaluation tool	Time of evaluation	Outcome
De Vita et al. [26]	88	74	Photographs assessed by three external surgeons. Scores based on projection, symmetry, and scar quality/NAC, vitality, and visibility of prosthesis. Classified as excellent, good, or poor based on score.	6 and 12 months	39 (52.7%) excellent 27 (36.5%) good 8 (10.8%) poor
Hon et al.[20]	38	24	Aesthetic 3-point Outcome Scale (Nguyen et al., 2012). Photographs assessed by two blinded senior residents.	NS	No significant difference between ADM and DS reconstruction
Nava et al.[18]	77	65	Shape and symmetry rated by surgeons in outpatient clinic as good, medium, or bad.	3, 9, 12 months and annually thereafter (median: 36 months)	Shape: 78.9% good, 19.7% medium, 1.5% bad **Symmetry:** 50% good, 42.4% medium, 7.6% bad
Rathinaezhil et al.[15]	5	4	Photographs assessed by 15 allied health professionals and administrative staff. Cosmetic outcome scored from 1–10 (1 poor, 10 excellent).	3 months	Average rating (range): 7.4–7.7

A serious scientific flaw in the studies used for this review concerned the scarcity of the patient information provided. Because many of the studies were small case series, there is a clear risk of publication bias, given the likelihood that a larger number of successful rather than unsuccessful cases have been published.[30] Furthermore, few of the studies provided clear inclusion and exclusion criteria, with the criteria presented frequently showing considerable variation between studies. For example, some studies excluded all patients that had undergone RT or where RT was planned, whereas others did not. Additionally, some studies excluded smokers while others did not. Therefore, it is uncertain whether the patients included in this review constitute a representative sample of those subjected to immediate breast reconstruction. As a result, some of the reported complication frequencies might be falsely low.

Another scientific flaw with the studies used for this review was their lack of explanation concerning how they defined complications, who evaluated the patients, and which complications were included/excluded in their report. This suggests the likelihood of a high degree of diversity in the operational definition of the evaluated variables.[29] For example, an infection was sometimes defined as a condition requiring antibiotics and other times as a condition with particular clinical signs. Moreover, a hematoma was sometimes defined as the presence of early postoperative swelling and other times as a condition requiring re-operation. The frequencies of a given complication might also have suffered from evaluator bias in the form of omitted or under-reported complications by a non-blinded participant (e.g., the operating surgeon). Therefore, the data on which this review is based could be flawed as a result of inconsistent definitions greatly affecting the frequencies of complications. Moreover, the results of our assessment of study heterogeneity could represent characteristics associated with these potential shortcomings (Table 3 and Figures 2 and 3). Nevertheless, there is little inherent variation in the definitions of some of the most serious complications, such as implant loss and unplanned operations.

The results of meta-analyses are susceptible to the methods used to analyse the data.[29] A statistical shortcoming in this review was that most of the studies reported a number of patients, breasts, and complications but not how many patients experienced bilateral complications. Moreover, patient characteristics were frequently unspecified; therefore, the meta-analysis had to be performed based on complication per breast (aggregate data) rather than complications per individual (individual participant data). Although the availability of individual participant data might have resulted in a more rigorous analysis, this was impossible based on the shortcomings of the data extracted from the included studies.[31]

The number of studies comparing outcomes associated with 1) use of the DS with reconstruction, 2) reconstruction without use of a DS, 3) reconstruction using a matrix/mesh, 4) reconstruction involving the use of different types of implants/TEs, and/or 5) the effect of RT was too limited to generate a meaningful pooled analysis. Therefore, the research questions concerning patient-reported and aesthetic outcomes could not be adequately explored using meta-analysis due to the diversity of the methodologies employed by the included studies.

The lack of scientific rigor employed by many of the studies used for this review warrants caution when interpreting the findings. However, the goal of a meta-analysis is to reduce the uncertainties associated with small studies, and, to that end, we used the best data currently available concerning immediate breast reconstruction with a DS for this review.

Findings and previous studies

The overall reported complication rates in the included studies varied between 0%[17] and 49%.[14] Similar ranges of complication frequencies have been reported for immediate breast reconstruction with or without the use of ADM and/or meshes.[32] However, it should be noted that patients reconstructed with a DS generally have large-volume breasts and ptosis, with large-volume breasts[33-35] and larger mastectomy weights[36] representing independent risk factors for complications in immediate breast reconstructions. Moreover, a DS reconstruction infers a Wise pattern mastectomy (type IV skin-sparing mastectomy[2]), which is accompanied by a high risk of complications based on the length of the mastectomy flaps and wound breakdown at the T junction (reported in up to 25% of patients[14]).[34,37,38] Indeed, the most common complication in this review involved wound healing [meta-analysis: 11.4% (95% CI: 8.5–15.2%)].

Theoretically, a DS should be protective in cases of wound breakdown, as it forms an extra tissue layer between the implant/TE and the skin[1] that could potentially enable healing by secondary intention.[6,26,39] No definitive conclusions can be made regarding long-term complications, such as capsular contracture, as most studies had follow-up times of < 2 years (Table 2). Our findings suggest that a DS does not constitute a risk factor for short-term complications.

There are few studies evaluating patient-reported and aesthetic outcomes in immediate breast reconstruction with a DS, and those that exist are of poor quality. Such data are important, because the information enables patients to make an informed decision regarding which implant-based breast-reconstruction technique is optimal for them based on their particular goals.[40] Because a DS is a relevant method only in patients with large-volume and ptotic breasts and requiring a Wise pattern mastectomy, the results of its use need to be directly compared with the results of other techniques applied in this patient population.

Conclusion

The scientific quality of the available studies focused on the use of DS in immediate breast reconstruction is low, thereby resulting in a similarly low volume of evidence for or against use of the method. The available studies suggest that the risk for short-term complications is no greater for a DS than for other forms of implant-based breast reconstruction in women with large-volume and ptotic breasts. However, little is known about long-term complications from DS use, such as the risk of capsular contracture, or the associated patient-reported and aesthetic outcomes.

Conflicts of interest

The authors report no conflicts of interests. The authors alone are responsible for the content and writing of this article.

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Supplementary materials

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