

Evidence-Based Clinical Practice Guideline: Autologous Breast Reconstruction with DIEP or Pedicled TRAM Abdominal Flaps

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Summary: The American Society of Plastic Surgeons commissioned a multi-stakeholder Work Group to develop recommendations for autologous breast reconstruction with abdominal flaps. A systematic literature review was performed and a stringent appraisal process was used to rate the quality of relevant scientific research. The Work Group assigned to draft this guideline was unable to find evidence of superiority of one technique over the other (deep inferior epigastric perforator versus pedicled transverse rectus abdominis musculocutaneous flap) in autologous tissue reconstruction of the breast after mastectomy. Presently, based on the evidence reported here, the Work Group recommends that surgeons contemplating breast reconstruction on their next patient consider the following: the patient's preferences and risk factors, the setting in which the surgeon works (academic versus community practice), resources available, the evidence shown in this guideline, and, equally important, the surgeon's technical expertise. Although theoretical superiority of one technique may exist, this remains to be reported in the literature, and future methodologically robust studies are needed. (*Plast. Reconstr. Surg.* 140: 651e, 2017.)

According to the American Cancer Society, approximately one in eight women in the United States will develop invasive breast cancer in their lifetime, and an estimated 246,600 will be newly diagnosed in 2016 alone.¹ When breast-conserving surgery is not a viable option, a single or double mastectomy may be performed. After mastectomy, several reconstructive treatment options are available to patients.

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According to procedural statistics from the American Society of Plastic Surgeons, member surgeons performed 106,338 breast reconstruction procedures in 2015, a 35 percent increase from 2000. Among these procedures, 20,325 were performed with autologous tissue, or "flaps" taken from the abdomen, back, buttocks, or thigh to form the reconstructed breast.² The American Society of Plastic Surgeons Tracking Operations and Outcomes for Plastic Surgeons³ program reports a consistent record of free flap and pedicled transverse rectus abdominis myocutaneous flap breast reconstruction procedures relative to the total number of procedures entered annually. The American Society of Plastic Surgeons published the first clinical



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practice guideline on breast reconstruction with expanders and implants in 2013.⁴ The present publication intends to expand on the breast reconstruction treatment options available by providing evidence-based recommendations for the two most commonly performed autologous breast reconstruction procedures based on the Tracking Operations and Outcomes for Plastic Surgeons program.

Scope and Intended Users

This evidence-based guideline is based on a systematic review of evidence and specifically addresses the complications and patient satisfaction of patients undergoing breast reconstruction with autologous abdominal flap—specifically, the deep inferior epigastric perforator (DIEP) flap and the pedicled transverse rectus abdominis musculocutaneous

(TRAM) flap—to treat breast defects associated with the diagnosis or treatment of breast cancer. This guideline is intended to be used by the multidisciplinary team that provides care for patients with breast cancer through the use of breast cancer treatment, mastectomy, and breast reconstruction. Health care practitioners should evaluate each case individually, considering these evidence-based treatment recommendations and patient values and preferences, to determine the optimal treatment plan for each patient. This guideline is also intended to serve as a resource for health care practitioners and developers of clinical practice guidelines and recommendations.

Disclaimer

Evidence-based guidelines are strategies for patient management, developed to assist physicians in clinical decision-making. This guideline was developed through a comprehensive review of the scientific literature and consideration of relevant clinical experience, and describes a range of generally acceptable approaches to diagnosis, management, or prevention of specific diseases or conditions. This guideline attempts to define principles of practice that should generally meet the needs of most patients in most circumstances.

However, this guideline should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all the circumstances presented by the patient, the available diagnostic and treatment options, and available resources.

This guideline is not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all the facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. This guideline reflects the state of current knowledge at the time of publication. Given the inevitable changes in the state of scientific information and technology, this guideline will be considered relevant for a period of 5 years after publication, in accordance with the inclusion criteria of the National Guideline Clearinghouse.

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BACKGROUND

Autologous breast reconstruction using abdominal tissue is a common reconstructive procedure with widespread acceptance and a long history of success. Over the past 50 years, the techniques for performing abdominally based breast reconstruction have evolved. Historically, pedicled TRAM flap breast reconstruction was first described in the 1980s. The evolution from pedicled TRAM, to free TRAM, to DIEP flap reconstruction follows a shift from musculocutaneous flaps to muscle-sparing perforator flaps. Surgeons typically perform either pedicled TRAM or free DIEP flap procedures depending on their personal experience, comfort level with each procedure, and capabilities of their surgical facilities. It is important to note that DIEP flaps require additional technical skill and institutional infrastructure for microsurgery. As such, surgeons and patients sometimes find it difficult to determine which procedure provides the most acceptable outcome for a given patient. Thus, a systematic review was performed to identify the most relevant evidence to address these questions, with the aim of providing evidence-based recommendations to guide surgeons and patients in decision making for breast reconstruction. When considering the recommendations in this guideline, health care providers and patients should note that the studies used to develop the recommendations are retrospective and observational. No prospective or randomized studies were identified for the clinical questions included in this guideline.

Definitions

Pedicled TRAM flap: abdominally based flap containing skin, fat, and muscle that is partially resected and tunneled to the breast with the use of nonmicrosurgical methods.

DIEP flap: abdominally based, muscle-sparing flap containing skin and fat that is removed and reattached to the chest with the use of microsurgery.

Diagnostic Criteria

The patient usually presents to the plastic surgeon's office with a previous diagnosis of and/or treatment for breast cancer, or may be undergoing a prophylactic mastectomy. Patients who have had breast cancer may have had only a biopsy of the mass, a lumpectomy, or a mastectomy (alone or with axillary lymph node biopsy or dissection). Any of these surgical treatments may have been supplemented with radiation treatment to the breast/chest wall with or without regional lymph nodes, and systematic therapies including chemotherapy, immunotherapy, and endocrine therapy,

which may have an effect on the breast and chest wall. Related insurance coverage criteria can be found in Appendix 1.

Physical Examination

Physical examination of the breast defect should include documentation of breast size and configuration of any missing tissue. The presence of scarring and radiation changes and the condition of the pectoralis major muscle, nipple-areola complex, and contralateral breast should also be noted.

METHODS

Work Group Selection Process

American Society of Plastic Surgeons members were invited to apply to the Work Group by means of Society e-mail and fax communication. All applicants were required to submit an online conflict-of-interest disclosure form for membership consideration. Members of the American Society of Plastic Surgeons Quality and Performance Measurement Committee reviewed and selected Work Group members to ensure a diverse representation of U.S. regions; practice type (large multispecialty group practice, small group practice, solo practice, and academic practice); and clinical, research, and evidence-based medicine experiences and expertise. Four stakeholder organizations—the American Society of Breast Surgeons, the American College of Radiology, the American Society of Clinical Oncology, and the American Society for Radiation Oncology—were also invited to participate in the guideline development process by nominating one member from their respective organizations to serve on the Work Group. A patient representative was included on the panel to provide insight related to patient values and preferences, and an American Society of Plastic Surgeons quality department staff member was assigned to manage the project and provide expertise in clinical practice guideline development methodology.

Clinical Question Development

Work Group members used a consensus-based approach to select the clinical questions to be addressed in this evidence-based guideline. Work Group members used a blinded process to submit clinical questions by means of individual e-mail to the American Society of Plastic Surgeons project manager, who compiled and dispersed the clinical questions for consideration and discussion at the introductory meeting. The clinical questions were

selected with a five-phase process that consisted of brainstorming, discussion, ranking/prioritizing, refining, and voting.

A total of 36 clinical questions were reviewed by the Work Group and ranked according to the following criteria to assess for potential impact: (1) relevance to guideline scope; (2) addresses a gap in care; (3) ability to develop into an actionable recommendation; (4) ability to develop into an implementable recommendation; (5) is controversial or of significant interest; and (6) is important to public health. The Work Group initially agreed on 11 clinical questions; however, the large scope of the overall topic of autologous breast reconstruction would not allow for a timely guideline. In 2016, the guideline was narrowed and the original 11 clinical questions were refined into the following two clinical questions:

1. In patients undergoing mastectomy and autologous breast reconstruction, which surgical technique, pedicled TRAM flap versus DIEP flap, is associated with the lower incidence of clinical complications?
2. In patients undergoing mastectomy and autologous breast reconstruction, which surgical technique, pedicled TRAM flap versus DIEP flap, is associated with the highest level of patient satisfaction?

Thus, the methodology and results described herein relate to the review of data and the development of recommendations for these clinical questions only. The remaining clinical questions may be considered for future guidelines.

Literature Search

The literature search was performed between 2012 and 2014 and aimed to identify relevant studies published during the previous 10-year period (January of 2003 to June of 2014). Electronic searches of PubMed, Cochrane Library, and Cumulative Index to Nursing and Allied Health Literature databases were performed. The journal *Plastic and Reconstructive Surgery Global Open* was searched separately, as publications from *Plastic and Reconstructive Surgery Global Open* were not indexed in the selected databases at the time of this review. Literature searches were performed by using appropriate combinations of the following MEDLINE Medical Subject Headings (MeSH) terms and keywords, as permitted by the search functionalities of each database/journal:

- MeSH terms (used in PubMed only): “Abdomen”[MeSH], “Abdominal Wall”[MeSH], “FreeTissueFlaps”[MeSH], “Hematomas”[MeSH], “Hernia”[MeSH], “Infection”[MeSH], “Mammoplasty”[MeSH], “Necrosis”[MeSH], “Patient Outcome Assessment”[MeSH], “Patient Satisfaction”[MeSH], “Postoperative Complications”[MeSH], “Pulmonary embolism”[MeSH], “Reoperation”[MeSH], “Risk”[MeSH], “Second-lookSurgery”[MeSH], “Seroma”[MeSH], “Surgical Flaps”[MeSH], “Surgical Mesh”[MeSH], “Surgical Wound Dehiscence”[MeSH], “Treatment Outcome”[MeSH], and “Venous Thrombosis”[MeSH].
- Keywords: Abdominal flap, abdominal free flap, abdominal pedicled flap, abdominal weakness, autologous breast reconstruction, bulge, complications, deep vein thrombosis, flap failure, outcomes, and patient satisfaction.

Initial study selection for each clinical question was performed by one reviewer with a two-level screening process. Level I screening involved a review of the title and abstracts of the articles captured by the search strategies, to identify potentially relevant studies for inclusion in level II screening. Level II screening involved a review of the full-text of articles to confirm relevance and compare study details with the inclusion and exclusion criteria below.

Inclusion Criteria:

- Published within the past 10 years (January 1, 2003, to June 14, 2014).
- Published in English language.
- Reported a meta-analysis/systematic review; randomized controlled trial; prospective or retrospective cohort/comparative, case-control, or case series.
- Reported outcomes of interest for clinical questions (complications and/or patient satisfaction).
- Included at least 30 patients.

Exclusion Criteria

- Published outside of inclusion date range.
- Published in language other than English.
- Reported a case report, economic analysis, animal study, cadaver study, narrative review, or editorial.
- Reported no outcomes of interest.
- Included fewer than 30 patients.

The bibliographies of articles meeting inclusion criteria were manually searched to identify relevant articles missed during the electronic searches. These articles were screened as described above. Duplicate articles were eliminated. Studies meeting inclusion criteria were assessed for methodologic quality, as described below. Excluded studies and their reasons for exclusion were documented for review by the Work Group to confirm the final rejection or reconsider the study for inclusion. Additional references were included in this review if considered necessary for background or discussion; however, these references were not critically appraised or used in the development of recommendation statements.

Critical Appraisal of Evidence

The American Society of Plastic Surgeons evidence-based process includes a rigorous critical appraisal process to evaluate the methodologic quality of clinical studies and the strength of clinical evidence for the purposes of developing clinical practice guidelines and performance measures. The process is also used to rate individual studies published in *Plastic and Reconstructive Surgery*. Studies were appraised for methodologic quality with the American Society of Plastic Surgeons Critical Appraisal Checklists and assigned levels of evidence according to the American Society of Plastic Surgeons Evidence Rating Scales, which are designed for the evaluation of therapeutic, prognostic/risk, and diagnostic studies (see Appendix 2 for scales). The checklists and scales were developed in 2009 by an expert Task Force and are based on the principles of the Critical Appraisal Skills Programme and the Centre for Evidence Based Medicine. Each study was appraised by at least two reviewers. If a discrepancy existed between the reviewers, the study was appraised by a third reviewer, and the level of evidence was determined by consensus. Evidence ratings were not assigned to studies with inadequately described methods and/or worrisome biases. As such, these studies were excluded from further review.

Data Extraction and Outcomes Definitions

Quantitative and qualitative data relevant to the clinical questions were extracted from the studies that met inclusion criteria and qualified for a level-of-evidence rating. Data were compiled in Excel (Microsoft Corp., Redmond, Wash.) spreadsheets.

Quantitative data on complication outcomes were pooled across the studies to calculate the probability of the complication occurring for

each flap type. The following complications were evaluated, if reported in the studies:

- Donor-site complications: hernia, bulge, infection, necrosis, seroma, hematoma, and wound dehiscence.
- Flap-related complications: flap loss, necrosis, infection, seroma, hematoma, and wound dehiscence.
- Systemic complications: venous thromboembolism, including deep vein thrombosis and/or pulmonary embolism.
- Procedure-related complications: revision/reoperation and reconstruction failure rate.

Patient satisfaction was evaluated differently among the included studies. Because of the number and variety of scales used for assessing patient satisfaction, the reported scales were grouped into three categories: Michigan Breast Satisfaction Questionnaires, 10-point Likert scales, and other (e.g., Short-Form 36-Item Health Survey, Qualitative Assessment of Back Pain). The 10-point Likert scales were assessed similarly to the Michigan Breast Satisfaction Questionnaire by separating the level of satisfaction into binary groups (1 through 7 = not satisfied; 8 through 10 = satisfied).

Grading of Recommendations

Clinical practice recommendations were developed through a consensus process with consideration to the following three factors: (1) level of evidence (study quality); (2) assessment of benefits versus harms; and (3) patient preferences. Work Group members jointly drafted statements for each recommendation during conference call meetings and online discussions. After each meeting, members had an opportunity to individually comment and revise the draft recommendations by means of e-mail discussion. Work Group members participated in several rounds of revisions until unanimous consensus was achieved for each recommendation statement. Each recommendation in this guideline is accompanied by a grade indicating the strength of the recommendation, which was determined by considering the overall level of evidence supporting the recommendation and the judgment of the guideline developers.

Peer Review and Public Comment Process

The draft guideline was peer reviewed by the American Society of Breast Surgeons, the American College of Radiology, the American Society of Clinical Oncology, and the American Society for Radiation Oncology. American Society of Plastic

Surgeons members of the Quality and Performance Measurement and Healthcare Delivery Committees were also invited to participate in the peer review process. Peer reviewers were invited to review and provide feedback on the validity, generalizability, and clarity of the draft guideline using the Appraisal of Guidelines for Research & Evaluation II instrument. After peer review, the draft guideline was posted on the American Society of Plastic Surgeons Web site for a 2-week public comment period.

Guideline Approval Process

After the peer review and public comment processes, the guideline draft was reviewed and modified by the Work Group in consideration of peer review and public comments. The final guideline was approved by the American Society of Plastic Surgeons Executive Committee during its meeting in December of 2016.

Plan for Updating Guideline

In accordance with the inclusion criteria of the National Guideline Clearinghouse, this guideline will be updated within 5 years to reflect changes in scientific evidence, practice parameters, and treatment options.

RESULTS AND RECOMMENDATIONS

A total of 564 studies for clinical question 1 and 267 studies for clinical question 2 were retrieved through the literature search. After screening and critical appraisal were performed, 20 studies were selected for final review for this guideline (Figs. 1 and 2). Each study reported at least one outcome of interest (complications and/or patient satisfaction); 18 studies reporting clinical complications data and eight studies reporting patient

satisfaction data were used to develop practice recommendations. The recommendations listed below were based on level III and IV evidence. A summary of recommendation statements is shown in Table 2.^{5–24}

Recommendations Related to Clinical Complications

1. The Work Group suggests that clinicians may treat patients undergoing mastectomy and autologous breast reconstruction with either surgical technique (pedicled TRAM flap or DIEP flap, contingent on the use of mesh for pedicled TRAM procedures) because the risk of donor-site complications is comparable among procedures. Patient preference should have a substantial influencing role.

Level III, IV Evidence

Recommendation Grade: C

Donor-site morbidity includes hernia, bulge, infection, necrosis, seroma, hematoma, or wound dehiscence. The pooled evidence from 15 studies (some of which used mesh and some of which did not use mesh for the abdominal closure) suggests that there is a higher probability of hernia with the pedicled TRAM flap (pedicled TRAM flap, 3.50 percent; DIEP flap, 0.74 percent) and a slightly higher rate of bulging with the DIEP flap (DIEP flap, 4.62 percent; pedicled TRAM flap, 3.50 percent).^{5–19} Of note, this comparison did not examine free TRAM flap reconstruction. According to a comparative study of bilateral reconstruction, zero of 58 patients (0 percent) developed a hernia with the DIEP flap, whereas three of 105 (2.9 percent) developed a hernia with the pedicled TRAM flap. Similarly, four of 58 patients (6.9 percent) developed a bulge with the DIEP flap and three of 105 (2.9 percent) developed a bulge with the pedicled

Table 1. American Society of Plastic Surgeons Scale for Grading Recommendations

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences.
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V: Little or no systematic empirical evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit vs. harm; patient preference should have a substantial influencing role.

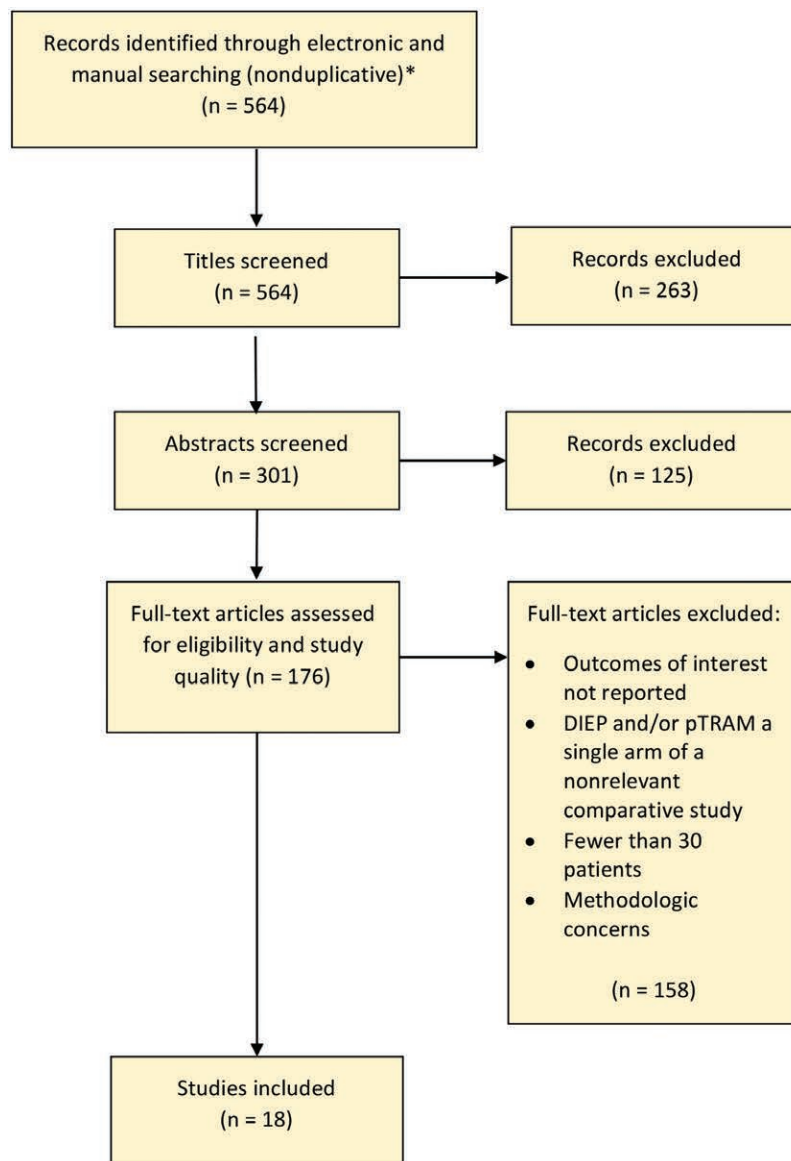


Fig. 1. Literature search process chart for clinical question 1. *Limits set in PubMed included publication date, human subjects, English language, and study types; the functionalities of the other databases did not allow for limit setting.

TRAM flap.⁵ Both complications (i.e., hernia or bulging) could be a result of whether or not mesh was used at the time of reconstruction. The reported probabilities of these complications are likely also dependent on variables other than flap type (e.g., surgical technique or the use of mesh). The evidence suggests that a higher probability of wound dehiscence, seroma, hematoma, and skin necrosis was associated with the DIEP flap.

Hernia rates were less than 3 percent in the five-case series of DIEP flaps^{8,9,11–13} and four-case series of pedicled TRAM flaps examined.^{14,16,17,19} When examining pooled data of bilateral DIEP and bilateral pedicled TRAM flaps, the hernia

rate was 1.3 percent versus 4.3 percent, respectively; and the bulge rate was 3.6 percent versus 2.8 percent.^{5,7,9,10,12,14,15,17} In the four-case series of pedicled TRAM flaps that specified what type of mesh was used, all used a synthetic (polypropylene) mesh, some in a folded-over fashion.^{14–17} In a comparative study, hernia rates were higher in pedicled TRAM flaps compared with DIEP flaps (16 percent versus 1 percent), but 86 percent of those patients did not have mesh.⁶ Bulge rates in the included case series were 0 to 5 percent in DIEP flaps^{9–13} and 0.5 to 5.7 percent in pedicled TRAM flaps.^{14–18} Garvey and colleagues demonstrated higher bulge rates in both groups,

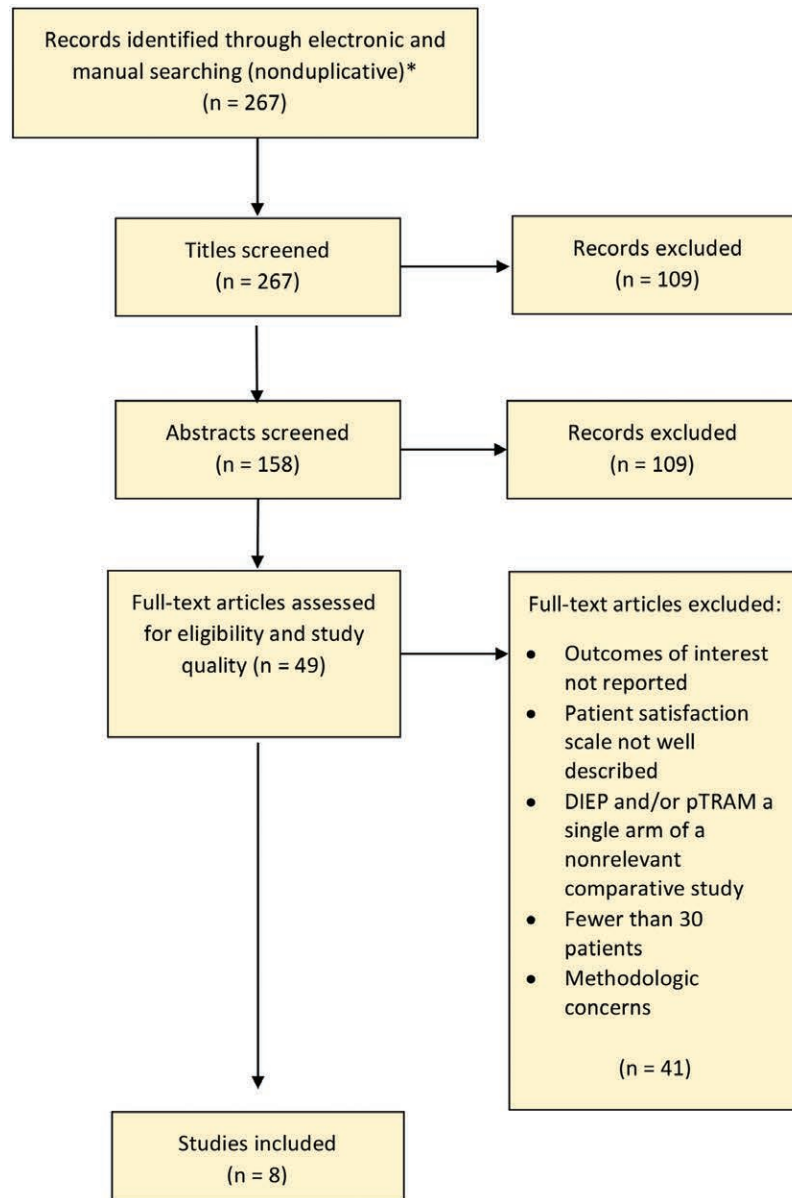


Fig. 2. Literature search process chart for clinical question 2. *Limits set in PubMed included publication date, human subjects, English language, and study types; the functionalities of the other databases did not allow for limit setting.

but patients did not receive mesh.⁶ Overall calculated probabilities of donor-site infection, necrosis, seroma, hematoma, and wound dehiscence were all higher with DIEP flaps than with pedicled TRAM flaps, but these differences were minimal.

Potential benefits of each procedure include shorter operative times with pedicled TRAM flaps; and preservation of the rectus muscle with DIEP flaps. Potential harms include increasing operative risks inherent in longer operative times of DIEP flap procedures and a theoretical decrease in abdominal strength with pedicled

TRAM flaps, although this has not been shown to affect daily activities and was not documented in the examined articles. If a patient sees a surgeon who is more experienced in one technique over the other, the majority of well-informed patients would most likely use this patient-care strategy, compared to alternative patient-care strategies or no treatment. Clinicians should be flexible in their decision-making process, and risk factors and patient preferences should be considered. The setting in which clinicians practice (e.g., academic or community practice) may also have a substantial influencing role.

Table 2. Recommendation Statements for Autologous Breast Reconstruction with DIEP or Pedicled TRAM Abdominal Flaps

Recommendation	Level of Evidence	Assessment of Benefits/Harms	Grade; Strength of Recommendation	References
1. The Work Group suggests that clinicians may treat patients undergoing mastectomy and autologous breast reconstruction with either surgical technique (pedicled TRAM flap or DIEP flap, contingent on the use of mesh for pedicled TRAM flap procedures) because the risk of donor-site complications is comparable among procedures. Patient preference should have a substantial influencing role.	III, IV	The balance between benefits and harms is unclear	C; Option	5–19
2. The Work Group suggests that clinicians may treat patients undergoing mastectomy and autologous breast reconstruction with either surgical technique (pedicled TRAM flap or DIEP flap) because the risk of flap-related complications is comparable among procedures. Patient preference should have a substantial influencing role.	III, IV	The balance between benefits and harms is unclear	C; Option	5–9, 11–13, 16–20
3. Based on little or no systematic empirical evidence, it is the consensus of the Work Group that clinicians may treat patients undergoing mastectomy and autologous breast reconstruction with either surgical technique (pedicled TRAM flap or DIEP flap) since the risk of systemic complications (DVT and PE) is indeterminate among procedures.	IV	The balance between benefits and harms is unclear	D; Option	9, 11–13, 18
4. Based on little or no systematic empirical evidence, it is the consensus of the Work Group that clinicians may treat patients undergoing mastectomy and autologous breast reconstruction with either surgical technique (pedicled TRAM flap or DIEP flap) because the risk of revision/reoperation and reconstruction failure is indeterminate among procedures.	IV	The balance between benefits and harms is unclear	D; Option	7, 11–13, 17–19, 21, 22
5. Based on little or no systematic empirical evidence, it is the consensus of the Work Group that clinicians may treat patients undergoing mastectomy and autologous breast reconstruction with either surgical technique (pedicled TRAM flap or DIEP flap) because there were no differences in patient satisfaction noted. However, it was found that the level of patient satisfaction is high for both procedures.	IV	The balance between benefits and harms is unclear	D; Option	5, 7, 13, 16, 18, 22–24

2. The Work Group suggests that clinicians may treat patients undergoing mastectomy and autologous breast reconstruction with either surgical technique (pedicled TRAM flap or DIEP flap) because the risk of flap-related complications is comparable among procedures. Patient preference should have a substantial influencing role.

Level III, IV Evidence

Recommendation Grade: C

Flap-related complications include flap loss, necrosis, infection, seroma, hematoma, and wound dehiscence. The evidence from 13 studies^{5–9,11–13,16–20} suggests that the rate of total flap loss is similar between pedicled TRAM and DIEP flaps. Of note, pedicled TRAM flaps that previously underwent a delay procedure were included in some studies, but were not considered separately in this analysis. Most studies suggest a slightly increased rate of flap loss with DIEP flaps compared with pedicled TRAM flaps, although

this difference does not reach statistical significance in most studies. A case series reported 16 cases (8.5 percent) of partial flap loss in pedicled TRAM procedures, with a high incidence of fat and skin necrosis.¹⁷ According to Kim et al., 72 of 505 patients (14 percent) experienced fat necrosis and 75 of 505 (15 percent) experienced skin necrosis.¹⁸ The DIEP flap was associated with slightly higher infection rates and a higher probability of seroma, hematoma, and wound dehiscence. However, some studies demonstrated similar outcomes between groups.⁶ For example, one of 58 DIEP flap patients (1.7 percent) developed a seroma, whereas only two of 105 patients (1.9 percent) developed a seroma with the pedicled TRAM flap.⁵ This systematic review was not able to comment on differences in surgical technique that could improve outcomes for either group to reduce flap-related complications.

Evidence comparing flap loss rates between DIEP and pedicled TRAM flaps for breast

reconstruction is limited. Two retrospective comparative studies that evaluated flap loss (partial or complete) between DIEP and pedicled TRAM flaps found no statistically significant difference between the techniques. Flap loss ranged from 1.7 to 3.1 percent in the DIEP flap groups and from 0 to 8.5 percent in the pedicled TRAM flap groups.^{5,6} Five retrospective case series reported rates of flap loss in DIEP flap breast reconstruction^{7-9,11,12} and three in pedicled TRAM flap breast reconstruction.¹⁶⁻¹⁸ In DIEP flap cases, rates of partial flap loss ranged from 1.8 to 4.7 percent,^{8,9,13} and rates of total flap loss ranged from 0 to 4.7 percent.^{7-9,11-13} In pedicled TRAM flap cases, Iretton and colleagues reported an 8.5 percent incidence of partial flap loss, whereas the pooled rate of total flap loss ranged from 0 to 0.2 percent.¹⁶⁻¹⁸ Given the small number of comparative studies comparing DIEP and pedicled TRAM flap reconstructive procedures and the low overall flap loss rates observed with these techniques, clinicians should be flexible in their decision-making process, and patient risk factors, patient preferences, and the setting in which clinicians practice should have a substantial influencing role. The balance between benefits and harms between DIEP and pedicled TRAM flap techniques with regard to flap loss is unclear.

Evidence comparing fat necrosis rates between DIEP flaps and pedicled TRAM flaps for breast reconstruction is limited. Two comparative studies retrospectively analyzed outcomes after DIEP or pedicled TRAM flap–based breast reconstruction. Chun and colleagues compared bilateral pedicled TRAM flaps with bilateral DIEP flaps and found a significantly higher fat necrosis rate in the DIEP group (19.8 percent versus 11.4 percent; $p = 0.04$).⁵ Garvey and colleagues compared unilateral DIEP flaps with unilateral pedicled TRAM flaps and reported a fat necrosis rate of 17.7 percent for DIEP flaps and 58.5 percent for pedicled TRAM flaps ($p < 0.001$).⁶ Several case series reported fat necrosis rates in DIEP or pedicled TRAM flaps; rates ranged between 2 and 12.5 percent for DIEP flaps^{7-9,11-13} and between 7.9 and 14.5 percent for pedicled TRAM flaps.¹⁶⁻²⁰ These mixed findings do not point to a specific technique that provides superior fat necrosis rates. These studies are limited in that not all report on the number of perforators captured with each DIEP flap. Given the lack of information and inconsistent results, clinicians should be flexible in their decision-making process, and patient risk factors, patient preferences, and the setting in which clinicians practice should have a substantial influencing role. The

balance between benefits and harms between DIEP and pedicled TRAM flap techniques with regard to fat necrosis is unclear.

Evidence comparing infection rates, seroma/hematoma rates, and wound dehiscence rates between DIEP flaps and pedicled TRAM flaps for breast reconstruction is limited. In a comparative study, rates of infection (DIEP, 12.5 percent; pedicled TRAM, 17.0 percent) and wound dehiscence (DIEP, 12.5 percent; pedicled TRAM, 13.8 percent) were similar between DIEP flap and pedicled TRAM flap groups.⁶ With regard to seroma and hematoma, two comparative studies found no statistically significant difference between DIEP flap cases and pedicled TRAM flap cases.^{5,6} Small case series of DIEP or pedicled TRAM flaps report an overall pooled seroma rate of 5.1 percent for DIEP flaps versus 2.4 percent for pedicled TRAM flaps and an overall pooled hematoma rate of 3.2 percent for DIEP flaps versus 2.5 percent for pedicled TRAM flaps.^{7-9,11-13,16-20} Given the small number of studies comparing DIEP and pedicled TRAM flap techniques and the low overall rates of infection, seroma/hematoma, and wound dehiscence between these reconstructive techniques, clinicians should be flexible in their decision-making process, and patient risk factors, patient preferences, and the setting in which clinicians practice should have a substantial influencing role. There are limited data regarding the impact of postmastectomy radiation therapy on flap complications, and neither technique emerged as superior in the setting of radiation therapy. The balance between benefits and harms between DIEP and pedicled TRAM flap techniques with regard to other flap-related complications is unclear.

3. Based on little or no systematic empirical evidence, it is the consensus of the Work Group that clinicians may treat patients undergoing mastectomy and autologous breast reconstruction with either surgical technique (pedicled TRAM flap or DIEP flap) because the risk of systemic complications (deep vein thrombosis and pulmonary embolism) is indeterminate among procedures.

Level IV Evidence

Recommendation Grade: D

Systemic complications include deep vein thrombosis and pulmonary embolism. The evidence from five studies^{9,11-13,18} is insufficient to offer a recommendation because of the lack of reporting on this outcome with the DIEP flap. The probability of deep vein thrombosis is heterogeneous between the two flaps. The evidence suggests a 1.6 percent probability of pulmonary

embolism with the pedicled TRAM flap,¹⁸ but the rate of pulmonary embolism with the DIEP flap is not reported. The balance between benefits and harms between these two reconstructive techniques with regard to deep vein thrombosis and pulmonary embolism is unclear.

No systematic empirical evidence is available to guide clinical practice regarding venous thromboembolism prevention in autologous breast reconstruction with DIEP or pedicled TRAM flaps. It is the consensus of the Work Group that clinicians should follow the previously developed American Society of Plastic Surgeons report on venous thromboembolism prophylaxis.²⁵

4. Based on little or no systematic empirical evidence, it is the consensus of the Work Group that clinicians may treat patients undergoing mastectomy and autologous breast reconstruction with either surgical technique (pedicled TRAM flap or DIEP flap) because the risk of revision/reoperation and reconstruction failure is indeterminate among procedures.

Level IV Evidence

Recommendation Grade: D

Procedure-related complications include revision/reoperation and reconstruction failure. The evidence from nine studies^{7,11–13,17–19,21,22} is insufficient to offer a recommendation because of minimal reporting on these outcomes with the pedicled TRAM flap. The probability of revision/reoperation is heterogeneous between the two flaps. Weak evidence suggests that the revision/reoperation rate may be higher with a pedicled TRAM flap than with a DIEP flap.^{11–13,17,19,22} The evidence suggests a 2.1 percent reconstruction failure rate with the DIEP flap¹¹ and a 0.2 percent failure rate with the pedicled TRAM flap.¹⁸

The available data come from case series. Importantly, the potential for publication bias exists regarding the timing of publication; case series of pedicled TRAM flaps were typically published a decade or more ago, whereas case series of DIEP flaps were published more recently, and because studies published before 2003 were excluded from this guideline, some relevant pedicled TRAM flap case series may not have been considered for this guideline. In addition, lower reoperation rates may represent refinements in reconstructive techniques over time for pedicled TRAM flaps or true differences in reoperation rates between the techniques. The balance between benefits and harms between these two reconstructive techniques with regard to revision/reoperation and reconstruction failure is unclear.

The Work Group suggests that clinicians should be flexible in their decision-making. Patient-specific risk factors, preferences, and the setting in which clinicians practice should have a substantial influencing role.

Recommendations for Patient Satisfaction

Reviewed patient satisfaction indicators include the Michigan Breast Satisfaction Questionnaire, overall patient satisfaction (10-point scale), the Qualitative Assessment of Back Pain, and various reports of single scales (e.g., Functional Assessment of Cancer Therapy-Breast, quality of life assessment, aesthetic satisfaction). Of the eight studies that met inclusion criteria, only two directly compared patient satisfaction in patients undergoing DIEP flap reconstruction versus those undergoing pedicled TRAM flap reconstruction. The Work Group concluded that more comparative data are needed to evaluate patient satisfaction in this therapeutic area. Multiple patient satisfaction scales were used among the eight studies; therefore, the Work Group elected to group the scales into three categories, as previously described, to analyze the data effectively. A high level of patient satisfaction was reported in all studies, with no differences noted when comparing DIEP with pedicled TRAM flaps. In addition, no differences were noted when comparing DIEP with pedicled TRAM flaps in patient-reported incidence of back pain.

5. Based on little or no systematic empirical evidence, it is the consensus of the Work Group that clinicians may treat patients undergoing mastectomy and autologous breast reconstruction with either surgical technique (pedicled TRAM flap or DIEP flap) because there were no differences in patient satisfaction noted. However, it was found that the level of patient satisfaction is high among both procedures.

Level IV Evidence

Recommendation Grade: D

The potential for a negative impact on satisfaction as it relates to donor-site morbidity and flap fat necrosis were considered in these studies. In addition, several articles come from the same institution and are thus somewhat redundant. In evaluating a study, the variables that might be associated with benefit and harm include flap failure, fat necrosis, need for secondary surgery, decreased function in abdominal wall muscles, and satisfaction with reconstruction. The eight studies selected for this question focus on satisfaction with reconstruction.^{5,7,13,16,18,22–24} The

balance between benefit and harm with regard to this particular aspect is unclear. In addition, if a patient sees a surgeon who is more experienced in one technique over the other, the majority of well-informed patients would most likely use this patient-care strategy, compared with alternative patient-care strategies or no treatment. Clinicians should be flexible in their decision-making process, and patient risk factors, patient preferences, and the setting in which clinicians practice should have a substantial influencing role.

One important aspect of breast reconstruction is patient satisfaction with the reconstructive approach and outcome. Comparisons of patient satisfaction between pedicled TRAM and DIEP flaps have been difficult to consolidate in the past. In general, it can be concluded that both pedicled TRAM and DIEP flaps are associated with a high level of patient satisfaction. At the time of this review, no studies have been published that used patient-reported outcome measures such as the BREAST-Q to compare outcomes between pedicled TRAM and DIEP flaps.

CONCLUSIONS AND FUTURE DIRECTIONS

The Work Group assigned to draft this guideline was unable to find evidence of superiority of one technique over the other (DIEP versus pedicled TRAM flap) in autologous tissue reconstruction of the breast after mastectomy. The available evidence addressing the questions posed in this guideline varied from level III to IV and the recommendations provided were graded C or D level. Although theoretically such superiority may exist, this remains to be seen until future, methodologically robust studies are undertaken. Unfortunately, the outcomes research movement of the past three decades has received belated attention by organized plastic surgery. This was clear in the paucity of comparative studies reporting the critical outcomes of reconstruction or outcomes from the patient's perspective.

Presently, based on the evidence reported here, the Work Group recommends that surgeons contemplating breast reconstruction on their next patient consider the following: the patient's preferences and risk factors; the setting in which the surgeon works (academic versus community practice); resources available; the evidence shown in this guideline; and, equally important, the surgeon's technical expertise. Despite the limited data regarding the impact of

radiation therapy on complication rates between the types of autologous reconstruction, radiation therapy is known to impact complication rates in the setting of any type of reconstruction. A multidisciplinary approach is key, with integration of radiation oncology early in the planning process for patients who may require postmastectomy radiation therapy. The Work Group strongly recommends that centers performing a high volume of breast reconstructions undertake comparative studies in which the population, procedures (standard versus novel), setting (community versus academic), outcomes, and period of the study are clearly defined.

In terms of outcome reporting, future investigators should use validated patient-reported outcome measures such as the BREAST-Q. In addition, authors should consider coupling economic evaluations to future prospective studies to determine whether the novel techniques are cost-effective from the patient, third-party payer, and societal perspectives. These cost studies and economic analyses should specifically compare the two procedures. Future investigators proclaiming superiority, noninferiority, or equivalence of breast reconstruction techniques must ensure that the studies evaluating the techniques have been performed with a randomized controlled trial design and have followed the guidelines established by the Consolidated Standards of Reporting Trials group, specifically addressing the variations of randomized controlled trial design.

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APPENDIX 1. INSURANCE COVERAGE CRITERIA

International Classification of Diseases, 10th Revision, Clinical Modification Codes

Diagnosis	ICD-10-CM Code
Malignant neoplasm of female breast	C50.01–
Malignant neoplasm of male breast	C50.02–
Secondary malignant neoplasm of other specified sites; breast	C79.81
Carcinoma in situ of breast	D05.9–
Capsular contracture of breast implant	N64.89
Unspecified abnormal mammogram	R92.8
Acquired absence of breast	Z90.1–
Encounter for breast reconstruction following mastectomy	Z42.1
Personal history of malignant neoplasm of breast	Z85.3
Family history of malignant neoplasm of breast	Z80.3
Genetic susceptibility to malignant neoplasm of breast	Z15.01

ICD-10-CM, *International Classification of Diseases, 10th Revision, Clinical Modification*.

Current Procedural Terminology Codes

Procedure	CPT Codes
Breast reconstruction with free flap	19364
Breast reconstruction with TRAM flap, single pedicle, including closure of donor site	19367
Breast reconstruction with TRAM flap, single pedicle, including closure of donor site; with microvascular anastomosis (supercharging)	19368
Breast reconstruction with TRAM flap, double pedicle, including closure of donor site	19369
Immediate insertion of breast prosthesis following mastopexy, mastectomy, or in reconstruction	19340
Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion	19357
Microsurgical techniques, requiring use of operating microscope (list separately in addition to code for primary procedure)	69990

CPT, Current Procedural Terminology.

Healthcare Common Procedure Coding System (HCPCS) Codes*

Procedure	Code
Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site, and shaping the flap into a breast, unilateral	S2068

*Please check payer’s policies.

APPENDIX 2. AMERICAN SOCIETY OF PLASTIC SURGEONS EVIDENCE RATING SCALES

Evidence Rating Scale for Therapeutic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort or comparative study; or systematic review of these studies
III	Retrospective cohort or comparative study; case-control study; or systematic review of these studies
IV	Case series with pretest/posttest; or only posttest
V	Expert opinion developed via consensus process; case report or clinical example; cadaver study; or evidence based on physiology, bench research, or “first principles”

Evidence Rating Scale for Diagnostic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, cohort study validating a diagnostic test (with “gold” standard as reference) in a series of consecutive patients; or a systematic review of these studies
II	Exploratory cohort study developing diagnostic criteria (with gold standard as reference) in a series of consecutive patients; or a systematic review of these studies
III	Diagnostic study in nonconsecutive patients (without consistently applied gold standard as reference); or a systematic review of these studies
IV	Case-control study; or any of the above diagnostic studies in the absence of a universally accepted gold standard
V	Expert opinion developed via consensus process; case report or clinical example; cadaver study; or evidence based on physiology, bench research, or “first principles”

Evidence Rating Scale for Prognostic/Risk Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, prospective cohort or comparative study with adequate power; or a systematic review of these studies
II	Lesser-quality prospective cohort or comparative study; retrospective cohort or comparative study; untreated controls from a randomized controlled trial; or a systematic review of these studies
III	Case-control study; or systematic review of these studies
IV	Case series with pretest/posttest; or only posttest
V	Expert opinion developed via consensus process; case report or clinical example; cadaver study; or evidence based on physiology, bench research, or “first principles”

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