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# Treatment Corollary of Breast Reformation Trials

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**Abstract**

Randomized controlled trials and non-randomized studies reporting at least one surgical complication of breast reconstruction surgery were included.

**Keywords:** Chest wall; Breast conservation; Reconstructive surgery; Patient attrition; Standardization; Clinical trials

## Introduction

Non-randomized studies were required to include at least 100 women to focus the review on studies that would be likely to influence practice. Surgical complications were defined as any adverse event identified by a health-care professional, which occurred as a direct result of the reconstructive procedure, whether or not additional interventions were required. Articles reporting exclusively on patient-reported outcomes were excluded. Articles describing all types of primary breast reconstruction surgery performed after a total mastectomy for breast cancer or pre-invasive disease in women aged 18 years or older were eligible. Articles evaluating chest wall reconstruction for recurrent disease, volume replacement following breast conservation, and prophylactic surgery were excluded. Articles were screened for inclusion by one reviewer and uncertainties discussed. Data Extraction We modified published criteria for the evaluation of surgical outcome reporting to reflect reconstructive practice [1]. Specific modifications included the exclusion of mortality reporting and the combination of inpatient and outpatient assessments of morbidity. We therefore assessed whether each study reported data on the prospective or retrospective accrual of data, duration of follow-up, proportion of complications defined, reporting of both total and procedure-specific complications, grading of complication severity, length of stay, and whether the analysis was adjusted for risk factors such as smoking or radiotherapy. In addition, the frequency with which each surgical complication was reported and defined in each article was recorded. Reported definitions of surgical complications were summarized [2]. Review of included studies identified more than 100 different surgical complications following breast reconstruction surgery. For pragmatic reasons, to be included in the detailed analysis of complication reporting, a specific complication needed to be reported in at least 20% of the articles. Each factor was independently, and discrepancies were resolved by discussion [3]. Critical Appraisal Studies were appraised according to study design. Non randomized studies were categorized as cohort studies if a comparison was made between groups of patients undergoing breast reconstruction and as case series if no comparison was made. Rct were evaluated using the Cochran Risk of Bias tool, which included assessment of adequacy of sequence generation, allocation concealment, blinding of outcome assessors, selective outcome reporting, completeness of outcome data, and other sources of bias such as patient selection and funding bias [4]. Selective outcome reporting was assessed by comparing the breadth and frequency of outcomes stated in the Methods and Results of the article. If the discrepancy between the number of pre-specified and reported outcomes was more than one, the study was considered to be at risk of selective outcome reporting. The completeness of outcome data was determined by assessing the reporting of patient attrition. Data from studies failing to account for patient attrition were considered incomplete. We also identified two additional potential sources of bias, including selection bias and bias resulting from industry funding of research [5]. Selection bias was evaluated by assessing whether studies reported clear inclusion and exclusion criteria or included consecutive patients. Finally, funding bias was assessed by determining whether included studies reported funding sources.

## Discussion

Applicable components of the Cochran Risk of Bias tool were also used to evaluate cohort studies and case series. Although developed for Rct, issues addressed within the tool, including blinding, reporting of incomplete outcome data, and selective outcome reporting, were also considered to be relevant to nonrandomized studies [6]. Thus, cohort and case series studies were assessed like Rct, but only longitudinal studies were assessed for Prior knowledge Decisions by both patients and physicians about breast reconstruction after mastectomy depend on current knowledge of surgical outcomes, but the quality of outcome reporting from surgical studies has not been evaluated. Study design Reporting of outcomes, complications, and study designs was examined in a systematic review of clinical trials, cohort studies, and case series that reported on various techniques of breast reconstructive surgery. Contribution Outcome reporting for breast reconstruction is inconsistent and lacks methodological rigor. There were disparities between methods and results in the numbers of complications reported, and information on duration of follow-up and risk factors for adverse outcomes was frequently omitted [7]. The development of a core outcome set for breast reconstruction is needed to standardize outcome reporting and to improve study comparability and the information available to both patients and surgeons. The review was restricted to randomized controlled trials and large cohort studies and case series in English, so potentially useful information from smaller or non-English language studies may have been missed. Selection and funding bias were also assessed. The risk of selection bias was evaluated by determining whether studies included consecutive patients, and potential funding bias was assessed by evaluating whether studies reported their funding source [8]. Finally, we developed two additional criteria that were

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evaluated in all studies. These included the presence of a statistical power calculation to determine whether authors had considered the number of patients required to address their research question and the reporting of institutional review board approval as an indicator of study peer review. Each of these factors was assessed by two reviewers and any discrepancies were resolved by discussion. This systematic review indicates that clinical outcome reporting in breast reconstruction is inconsistent and lacks methodological rigor. Less than 65% of articles provided definitions for the reported outcomes, and those described were often inconsistent, thus precluding cross-study comparisons. Details such as the severity of complications duration of follow up, and overall complication rates were often omitted. Only half the studies identified considered risk factors for adverse outcomes in their analyses. In addition, a high proportion of articles suffered from methodological issues such as selective outcome reporting, potential selection bias, and lack of blinding. The Rct evaluated did not report adequate methods for random sequence generation or allocation concealment in more than 80% of cases. Previous work has summarized the inconsistency and limitations of morbidity reporting and its impact on the evaluation of surgical procedures. The complication grading systems subsequently introduced have been pivotal in improving the quality and consistency of outcome reporting in gastrointestinal cancer and have been shown to be valid and applicable worldwide in many fields of surgery. These grading systems are yet to be used in breast reconstruction and may also improve reporting standards in this setting. Survey data suggest that women considering breast reconstruction would like as much information as possible for decision making, and the most useful information may come from Rct, which provide the best evidence of outcomes [9]. Clinical trials in surgery are gaining in popularity, but they present challenges, particularly with respect to recruitment due to patients' and surgeons' preferences for particular reconstruction types, standardization of treatment, timing, and blinding. However, Rct in breast reconstruction have been described as unethical, impractical, and impossible, and only three trials have assessed the impact of the type and timing of reconstructive surgery. Another major challenge in the design of a successful RCT is the selection of appropriate outcome measures. Outcomes need to be valid and consistent to allow cross-study comparison and to facilitate meta-analysis [10]. The members of the Outcome Measures in Rheumatology Group were among the first to recognize this problem and have developed core outcome sets for specific conditions to improve the quality and value of clinical trials and longitudinal research. Core outcome sets include outcomes that are important to both patients and healthcare professionals. The omeract group uses a data driven, iterative alignment process to select measures that satisfy the criteria of the omeract filter truth, discrimination, and feasibility. Several approaches for obtaining a consensus when defining core outcome sets have been described, but involvement of all stakeholders in the process is vital to ensure that the selected outcomes are truly important. For interventions such as breast reconstruction where the ultimate aim is to improve cosmesis and quality of life, encompassing the patients' perspective would be essential. Traditional clinical outcomes remain important, but patient-reported outcomes such as satisfaction, body image, functional results, and cosmetic outcome will also need to be incorporated if the outcomes selected are to be of value to women making decisions about reconstruction. Another major challenge in the design of a successful rct is the selection of appropriate outcome measures. Outcomes need to be valid and consistent to allow cross-study comparison and to facilitate meta-analysis.

## Recommendations

The members of the Outcome Measures in Rheumatology Group were among the first to recognize this problem and have developed core outcome sets" for specific conditions to improve the quality and value of clinical trials and longitudinal research. Core outcome sets include outcomes that are important to both patients and health-care professionals [11]. The omeract group uses a data driven, iterative alignment process to select measures that satisfy the criteria of the omeract filter truth, discrimination, and feasibility .Several approaches for obtaining a consensus when defining core outcome sets have been described, but involvement of all stakeholders in the process is vital to ensure that the selected outcomes are truly important [12]. For interventions such as breast reconstruction where the ultimate aim is to improve cosmesis and quality of life, encompassing the patient perspective would be essential.

## Conclusion

Traditional clinical outcomes remain important, but patient-reported outcomes such as satisfaction, body image, functional results, and cosmetic outcome will also need to be incorporated if the outcomes selected are to be of value to women making decisions about reconstruction.

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### Conflict of Interest

None

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