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One-stage and two-stage breast reconstruction have no meaningful difference in patient quality of life

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ABSTRACT A clinical decision report appraising Negenborn VL, Young-Afat DA, Dikmans REG, et al. Quality of life and patient satisfaction after one-stage implant-based breast reconstruction with an acellular dermal matrix versus two-stage breast reconstruction (BRIOS): primary outcome of a randomised, controlled trial. *Lancet Oncology.* 2018;19(9):1205-14. https://doi.org/10.1016/s1470-2045(18)30378-4.

Keywords: *Immediate one stage reconstruction, two stage breast reconstruction, quality of life*

Clinical Context

Grace Smith (pseudonym) is a 56-year-old African American woman with a history of Ductal Carcinoma In Situ with a planned bilateral mastectomy who presented to breast clinic requesting a possible immediate breast reconstruction to improve the appearance, shape, and contour of her chest following mastectomy. At this visit, Ms. Smith expressed thoughts of being “less of a woman” after surgery, with loss of confidence in her appearance, and even symptoms of depression. She felt that a reconstructive surgery would significantly improve her quality of life and allow her to regain the confidence lost through her illness. Through online searches, Ms. Smith had discovered one-stage breast reconstruction along with two-stage breast reconstruction, prompting her to ask the team whether a one-stage procedure would be suitable to attain the best quality of life. In her words, she wanted to "live life with confidence" in her appearance, without concern for complications down the line. Ms. Smith currently lives with her daughter, who accompanied her to the appointment. Her daughter voiced similar concerns, and desired her mother to have the procedure with the lowest risk. Of note, Ms. Smith does not currently hold a driver’s license and uses public transportation to travel to work; she has frequently missed medical appointments in the past due to these transportation issues. Her daughter drives her to and from her health appointments and will be caring for her after the surgery.

Clinical Question

How do patients and doctors evaluate one-stage versus two-stage breast reconstruction using quality of life as an outcome following bilateral mastectomy?

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Research Article

Negenborn VL, Young-Afat DA, Dikmans REG, et al. Quality of life and patient satisfaction after one-stage implant-based breast reconstruction with an acellular dermal matrix versus two-stage breast reconstruction (BRIOS): primary outcome of a randomised, controlled trial. *Lancet Oncology.* 2018;19(9):1205-14. https://doi.org/10.1016/s1470-2045(18)30378-4

Related Literature

A PubMed database search was conducted using search term “One Stage Breast Reconstruction." The initial search yielded 568 search results. A filter for “Clinical Trials” was added which eliminated 540 articles from the search. The remaining 28 articles were examined. Of the 28 articles that were initially found within the “Clinical Trials” filter, one of the published articles was removed since it was from 1998[1]. Of the 27 remaining articles, 2 were duplicates, and 22 were removed because they were not relevant to the clinical question; the reason for rejection included evaluation of tissue expanders[2,22,27], safety and efficacy of radiation therapy[3], the role of mitomycin C in preventing capsular contracture[4], follow up of post-operative scars[5], carbon dioxide versus saline tissue expanders[6,26], VMAT based treatment in breast cancer[7], bovine-derived dermal matrix in implant reconstruction[8], comparison of one versus two surgeons for a bilateral mastectomy[9], Silk derived biological scaffold in breast reconstruction[10], augmentation mastopexy[11], comparisons of different types of oncoplastic surgery[12], use of acellular dermal matrix[21,25], preoperative antibiotic prophylaxis in mastectomies[13], complications from radiotherapy[14,24], satisfaction from anatomically shaped versus round shaped implants[15], silicone implant core study[16], and institutional cost effectiveness[17]. A PubMed search of clinical trials was repeated yielded 36 results; however, all additional papers reviewed were irrelevant to the clinical question.

Out of the few relevant articles, the Zhong et al. study is an ongoing protocol with no established results[18], while another article by Dikmans et al. studied one-stage vs. two-stage approaches but did not use quality of life as a primary endpoint[19]. The only suitable randomized controlled trial (RCT) selected for critical appraisal, entitled “Quality of life and patient satisfaction after one-stage implant-based breast reconstruction with an acellular dermal matrix versus two-stage breast reconstruction (BRIOS): primary outcome of a randomised, controlled trial”[20], studies the clinical question of interest and also uses quality of life as a primary endpoint.

Per the strength of recommendation taxonomy (SORT), the lack of multiple RCTs on quality of life in one-stage vs. two-stage reconstruction confers an overall Strength of Recommendation B for the body of literature.[28]

Critical Appraisal

The BRIOS study is a multicenter, randomized controlled trial from eight different hospitals in the Netherlands that recruited 142 women age 18 and older who had breast carcinoma and intended to undergo mastectomy with immediate breast reconstruction from 2013 to 2015. 69 of the women were randomly assigned to receive one-stage and 73 were randomly assigned to receive two-stage breast reconstruction. The primary endpoint was the patient’s reported feelings on quality of life using the BREAST-Q quality of life scales/satisfaction scales. Randomization was stratified by center, and indication for surgery, whether it be oncological or prophylactic, was done in blocks of ten participants. The study was open label, with surgeons and patients both aware of whether a one stage or two stage surgery was being performed three days prior to the operative date. Patients were invited through email or postal mail to respond to the BREAST-Q survey before the initial surgery and one year after their respective final implant surgeries. This study was not blinded, which is a significant limitation for this study, but blinding would be difficult to achieve given the nature of the procedure. Per the SORT criteria, this is level 2 evidence.[28]

Forty eight of the 69 women assigned to one-stage breast reconstruction and 44 of the 73 women assigned to two-stage breast reconstruction completed the BREAST-Q quality of life and satisfaction scales. This is a significant amount of attrition bias. The study found no significant difference in the BREAST-Q quality of life/satisfaction scales between the two groups of patients, with the patients in the one-stage group having a mean BREAST-Q score of 78, and the patients in the two-stage group having a mean score of 79. As there was no significant difference between the two interventions, effect size is negligible. According to regression analysis, there were also no statistically significant differences between the groups for any of the other five BREAST-Q scales. Pain in the postoperative setting did not differ between the two group; the mean pain scoring seen in the one stage breast construction group

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was 1.58 with a standard deviation of 0.87 in the one-stage group, while the mean scoring in the two stage breast reconstruction group was 1.41 with a standard deviation of 0.66 (p=0.875).

Despite its strengths, the study also has notable weaknesses. Firstly, the BREAST-Q survey was only actually completed by a total of 92 study participants. From those who were assigned one-stage breast reconstruction, eight were excluded (three withdrew, five put surgery on hold). From those who were assigned two-stage breast reconstruction, eleven were excluded (one died, eight withdrew, two put surgery on hold). After surgery, one withdrew from one-stage breast reconstruction and four withdrew from two-stage breast reconstruction (one did not receive second surgery, one died, one received different treatment). All patients were analyzed in the groups to which they were assigned, but this is still a significant study limitation and a potential source of sampling error and non-response bias. The study also had no age stratification, and age could have been confounding variable in how satisfied the women felt after surgery. It is also unknown how patients were recruited to participate in the study, and there was no clear mention of the demographics of the sample pool. This could have created an underlying selection bias that cannot be assessed, and it can be reasonably inferred that this study sample from the Netherlands may not perfectly represent Ms. Smith. Funding for the study was provided by Pink Ribbon, Nuts-Ohra, and LifeCell. Pink Ribbon and Nuts-Ohra are health foundations, while LifeCell is a corporation that releases technology related to breast reconstruction. LifeCell's involvement in the study could have potentially created a conflict of interest; however the authors did not disclose any conflicts or funding bias.

Overall, the study provided a focus on the quality of life of patient before and after two different breast reconstruction procedures. Despite its limitations, the study, while showing no significant difference, may be useful to women considering the outcomes of one stage versus two stage breast reconstruction. The study is important in clarifying the similar endpoints that can be achieved from the two procedures.

Clinical Application

Ms. Smith would have met inclusion criteria for this study, as she is a patient confirmed to have breast cancer, is age 18 or older, and wanted a mastectomy followed by immediate breast construction. Returning to Ms. Smith's original question about one-stage reconstruction versus two-stage reconstruction, the study showed no significant difference in quality of life between both surgeries, which allows her to consider other variables when making her decision. While

Ms. Smith could qualify to receive either procedure, with all else being equal it would be more beneficial for her to receive a two-stage breast reconstruction, as one-stage reconstruction confers a greater risk for post-operative complications[19]; notably, the BRIOS trial also demonstrated a higher incidence of post-operative implant removal in the one-stage breast reconstruction group. Ms. Smith was very concerned with the potential harm of a one stage breast reconstruction. Considering the quality of life was not significantly different between the two surgeries, this was not a guiding factor in the clinical decision making. The harm of post-operative complications was more worrisome to Ms. Smith and therefore two stage was selected over one stage despite her travel issues. Although Ms. Smith's travel restrictions could make a two-step procedure more challenging, it is also true that these restrictions could create issues with monitoring for post-operative complications. Ms. Smith was subsequently advised to have a two-stage breast reconstruction, which she agreed to after lengthy discussion with the surgical team.

New Knowledge Related to Clinical Decision Science

Ms. Smith's options for one stage vs. two stage breast reconstruction were discussed in clinic with special attention to her social and emotional needs, including travel restrictions and quality of life issues. As our case illustrates, reconstructive surgery after mastectomy is just as much about the patient's emotional health and well-being as it is about physical health; thus, special attention must be paid to the patient's priorities when planning for surgery. In Ms. Smith's case, a critical review of the literature revealed that quality of life was unlikely to make a difference between the two surgeries, which made it easier for her to commit to a two-stage reconstruction to lower her risk of post-operative complications. This application of clinical decision science illustrates that literature review as a part of informed consent that includes the patient's values empowers both physicians and patients to make treatment decisions with greater clarity of potential risks and benefits. Moreover, we see in this case that supporting patients emotionally is

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not separate from evidence-based clinical medicine; rather, the two can support one another to improve overall outcomes. Informed consent is an interactive conversation, not a written documented with defined numerical risks of harm and benefit.

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