Editorial Commentary

The use of mesh in direct-to-implant breast reconstruction—an assessment of short-term outcomes

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Introduction

Breast cancer is the most commonly diagnosed cancer among women in the world today (1). Current 5-year survival rates are reaching upwards of 90% in European and North American nations (2) and approximately one-fifth of those who undergo surgical treatment of their breast cancer ultimately opt for some form of reconstructive procedure (3). In addition, with the increasing percentage of at-risk women opting for prophylactic risk-reducing mastectomy (4), the topic of breast reconstruction has garnered tremendous interest within the global plastic surgery community. Among the options ranging from prosthetics to the use of autologous tissue, implant-based breast reconstruction is the most popular choice in Western countries (5-7). Historically, this has tended to be performed in multiple stages, with initial placement of a tissue expansion prosthesis, gradual expansion over a period of months, and later exchange for a permanent breast implant. However, a trend towards direct-to-implant (DTI) reconstruction with insertion of implants at the time of mastectomy has been observed over the past several years (8,9), particularly in the case of nipple- or skin-sparing mastectomy (10). Recent reports in the literature have supported the safety (11) and short-term cost-effectiveness (1) of DTI breast reconstruction when compared to a multi-stage approach utilizing tissue expanders.

Considerable emphasis has been placed on the utility of biologic or synthetic meshes in DTI breast reconstruction, with multiple studies citing its safety, potential to lower rates of capsular contracture, as well as its ability to provide a superior aesthetic result by improving the appearance of the inframammary fold (11-15). However, controversy within the literature does exist. Several groups have highlighted inconclusive results with respect to the value of mesh in DTI breast reconstruction (16-20), while others have found patients a much higher complication rate compared to those receiving multiple-stage reconstruction with tissue expanders (21).

The use of mesh in DTI breast reconstruction

Potter and colleagues recently identified the need for high-quality studies to provide definitive, evidence-based recommendations to the plastic surgery community on the risks and benefits of the use of mesh in DTI breast reconstruction. This served as the underlying motivation behind iBRA (implant Breast Reconstruction evAluation), a prospective, four-phase, multicenter cohort study based out of the United Kingdom and open to all breast and plastic surgery services where implant-based breast reconstruction is performed. Focusing on immediate implant-based breast reconstruction, it was ultimately designed to provide the foundational evidence to inform a possible future randomized clinical trial.

In their manuscript (22) published in the January 2019 edition of *Lancet Oncology* entitled "Short-term safety outcomes of mastectomy and immediate implant-based breast reconstruction with and without mesh (iBRA): a multicentre, prospective cohort study", Potter *et al.* present the second phase of their study. The group reports on 3-month outcomes data for over 2000 patients aged 16 or older who underwent skin- or nipple-sparing

mastectomy followed by immediate implant-based breast reconstruction between February of 2014 and June of 2016 across 81 sites. Patients receiving both therapeutic as well as prophylactic mastectomies were included, and the specifics of the reconstructive procedure (subpectoral versus prepectoral implant placement, use and type of mesh) were left to the discretion of the participating surgeon, provided the reconstruction was immediate and did not involve autologous tissue. An emphasis was placed on implant loss, clinically-significant infection requiring antibiotic or operative management, unplanned return to the operating room, and unplanned readmission to the hospital secondary to complications of breast reconstructive surgery. Furthermore, the authors sought to identify possible patient characteristics, from demographics to aspects of their breast cancer therapy or breast reconstruction surgery, that might influence the occurrence of such complications. All statistical analysis was conducted according to a predetermined plan for assessing the study data.

On analyzing their patient population, the group found that nearly two-thirds had undergone single-stage breast reconstruction with the use of mesh. Within this subset, biologic mesh had been used in greater than 80% of cases. In the initial 3-month post-operative period, Potter *et al.* reported a 25% rate of clinically-significant infection, readmission or reoperation in nearly 20%, and implant loss in almost 10%. The authors point out that all of these rates are in fact much higher than those suggested by the United Kingdom's published National Quality Standards (23). However, aside from the percentage of unplanned returns to the operating room, these findings were actually in line with what had previously been reported during the United Kingdom's National Mastectomy and Breast Reconstruction Audit (NMBRA) (24). Analysis of associated risk factors connected body-mass index and a history of smoking to the primary adverse outcomes reported and also suggested links between prior radiation and infection as well as longer operative time and unplanned reoperation. However, there was no association identified between the use of a particular type of mesh and the likelihood of a patient experiencing a complication, as all reconstructive methods yielded similar adverse outcomes rates.

Interpreting the study conclusions

Potter and colleagues should be commended on their compilation of a large-scale, multi-institutional study to explore the safety and utility of mesh in immediate implant-based breast reconstruction. Their study generates important data that informs the current conversation regarding this topic. Given the finding of similar complication rates across all reconstructive modalities, this manuscript contributes to the growing body of evidence suggesting the non-inferiority of the use of mesh from a perspective of safety and limiting adverse outcomes (11,15).

However, reported complication rates were much higher than anticipated across the board, which merits careful consideration of the possible underlying reasons and the ways they impact the study as a whole. The authors posit employing broad criteria for the diagnosis of a clinically-significant infection as well as aggressive management of complications in the presence of mesh as possible explanations. However, they also acknowledge that with no improvement in complication rates since the results of the NMBRA were reported in 2014, perhaps a lack of adherence to best practice standards affects the observed findings (25).

Additionally, the large number of institutions involved in the study, as well as the freedom given to individual practitioners to perform the reconstructive procedures according to their preferred practice habits opens the door for confounding influences to impact results. Should the randomized trial that the iBRA hopes to inform come to fruition, it will be crucial for those involved in study design to ensure a protocol that controls for and limits extraneous variables. However, the iBRA's inherent structure lends it a degree of generalizability that is unlikely to be replicated in the setting of a randomized trial, and for that, its contribution to the literature can be most appreciated.

Practical impact of this study

As a standalone manuscript, the *Lancet Oncology* article by Potter *et al.* is unlikely to dramatically alter the practice habits of plastic surgeons performing implant-based breast reconstruction. There is undoubtedly value in demonstrating that the use of biologic or synthetic mesh does not put patients at any higher risk of adverse post-operative outcomes. Furthermore, the equivalent complication rates across all reconstructive methods suggest that, as is often the case in plastic surgery, no single answer exists that will provide the safest and most reliable outcome for every patient.

The most likely impact of this study will be that it encourages practitioners to continue approaching breast reconstruction surgery in the way that they feel enables

them to best provide for their patients. However, the iBRA was designed not to be a study with far-reaching practical implications, but rather as one to further the plastic surgery community's understanding of the use of mesh in implant-based breast reconstruction and ultimately establish the high-quality, evidence-based background needed to set the stage for future trials aimed at establishing and defining best practice guidelines in immediate implant-based breast reconstruction.

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Footnote

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