Commentary

Two-stage implant based breast reconstruction: should we always exchange the tissue expander for an implant right away?

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Two-stage implant based breast reconstruction (IBBR) accounts for more than 70% of reconstructions after any type of mastectomy in US in the year 2014 (1). As for reconstruction after nipple sparing mastectomy (NSM), a single-institution retrospective series on 482 cases [2007–2012] shows that direct-to-implant (DTI) reconstructions are 59.3%, tissue expander (TE)/two-stage 38.4% and autologous flaps 2.3% (2). In a recent paper on a multicentric Italian national registry of 1,006 NSM cases over a 6-year period [2009–2014] we report an overall TE/two-stage reconstruction rate of 64% (3). Moreover, a recent review regarding reconstruction after NSM from 1970 to 2013 displays that the overall number of TE/two-stage reconstructions is 45.5%, DTI is 40.7% and autologous flaps is 13.8% (4). Reasons for choosing a two-stage procedure in case of NSM vary from BMI, breast anatomical features, and the opportunity, at second intervention, to improve contour and inframammary fold and to perform a contralateral symmetrization procedure, as clearly exposed by Nahabedian in a 2016 review (5). Furthermore, while DTI is an ideal procedure in case of prophylactic mastectomy or DCIS, a two-stage procedure allows a more well-grounded approach for those tumors which might require additional therapies. Adjuvant radiation or systemic therapies can really jeopardize a reconstructive strategy and cannot always be anticipated. Therefore a two-stage approach may possibly delay the definitive reconstructive step after the completion of all the adjuvant treatments, and could possibly be tailored considering such treatments as well.

Impact of several adjuvant approaches on surgical outcomes after second stage in TE/implant reconstruction is the topic of a recent study (6). A large dataset of prospectively collected NSM TE/two-stage cases were analyzed, by means of multivariate analyses adjusting for several parameters, with a 26-month median follow-up after TE exchange for implant. Although an interaction between radiation treatment (RT) and tamoxifen has been largely demonstrated (7), in this experience endocrine therapy does not seem to add an increased risk of surgical complications, including implant loss, when started before second stage. Also chemotherapy and trastuzumab, either as primary or adjuvant treatment settings, do not reach a significant relevance as risk factors for surgical complications. Conversely, axillary lymph-node dissection (ALND) and RT significantly impact on surgical complications after TE/implant exchange.

The impact of RT, performed either pre- or post-mastectomy, seems to be quite impressive, with an implant loss rate of 15%, intravenous antibiotics-treated infections occurring in 26% of cases, infections requiring a surgical procedure in 19% and wound breakdown in 22%. Such data confirm previous papers on this topic. In a 2010 study by Berry and colleagues (8), which compares TE/two-stage and autologous reconstructions after mastectomy, the major complications rate reaches 45.4% in the IBBR group submitted to RT compared to the autologous one which doesn't show a significant difference in complications with or without RT. Among irradiated patients 70.1% completed their IBBR, while 10.3% were shifted to an autologous flap.

In our opinion a key-point is also represented by the health

related quality of life and satisfaction of irradiated patients. Albornoz *et al*. report a significant lower score in every section of the BREAST-Q© Reconstruction Module from a multicentric study of post-mastectomy RT either on a TE or on definitive implants (9). This occurrence doesn't seem to be replicated in autologous breast reconstructions (10).

The second significant finding of the paper by Wang *et al.* is the higher rate of surgical complications in NSM cases submitted to an ALND, both compared to sentinel lymph-node biopsy (SLNB) and no axillary surgery. Authors do not stratify ALND and SLNB according to the exact number of removed lymph nodes, although ten nodes is the minimum threshold to define an ALND (NCCN Guidelines Version 1.2016 Breast Cancer). Nonetheless, ALND is an independent risk factor for major surgical complications and significantly exposes to implant loss at multivariate analysis compared to SLNB. This is the first study, to date, showing such a result in TE/two-stage IBBR. Complications rates after ALND and second stage IBBR are once again quite impressive, with 17% of wound breakdown, 13% of infections requiring a surgical procedure and 13% of implant loss.

We don't think that the suggestion of preferring breast conservative surgery, when possible, could be a solution. This might be a confusing message, which could lead to interference between breast oncologic and reconstructive surgery. Moreover ALND is sometimes performed after an intra-operative positive pathological report of SLNB, and this would lead to a complete change of surgical strategy, which is not always possible and even difficult to pre-plan with the patient.

Also the possibility of treating the axilla by means of RT instead of surgery according to the AMAROS study (11) appears to be a conundrum, exposing patients to the aforementioned risks of RT in IBBR. AMAROS results, at this quite short follow-up time and without a control arm evaluating no axillary treatment, may underestimate the real outcome both in terms of efficacy and safety profiles for these different approaches (12). RT of the axilla could be in most of the case an overtreatment for the patients, and in the future a "biology-driven" treatment choice should be encouraged.

However, the initial promising results of such a relevant European Organisation for Research and Treatment of Cancer (EORTC) trial, and the recently published pivotal phase 3 trials on regional nodal irradiation (RNI) (13-15), will undoubtedly increase post-mastectomy and RNI indication worldwide.

The suggested lymphovascular bypass or free vascularized lymph nodes transfers still represent, in our opinion, experimental techniques. A bypass procedure at the time of mastectomy has never been described to our knowledge. A transfer procedure appears to be still lacking of any evidence and is reported in very small series in a recent review concerning animal and human cases (16).

On the other hand, we do believe that it is of utmost importance to give much attention to the site of incision and to the implant choice as recommended by the authors, in order to avoid some of the impairments caused by ALND. Moreover, in order to deal with potential RT harms, we believe that performing fat grafting over the TE, as an interval procedure in between the two stages of reconstruction, could be useful in thickening skin flaps and in restoring some viable tissue in a fibrotic scenario of irradiated cases, as shown in a paper by Ribuffo *et al.* (17).

Although not randomized, Wang's study (6) definitely constitutes a warning for reconstructive surgeons approaching a NSM reconstruction after ALND and/or RT. First of all, we believe that an adequate multidisciplinary counseling with the patient before any consent signature should be mandatory. All the options with their actual implications and complications should be addressed, without being molded in our opinions by the initial and pre-planned surgical strategy.

ALND will be less and less performed in the near future and axillary surgery will be probably limited to a staging procedure. Conversely, axillary RT indication might be enlarged, but should be always tailored on the single-patient, in a multidisciplinary discussion setting. Therefore, when RT has been administered, either pre- or post-mastectomy, an interval fat grafting over TE before exchange could be performed and an implant positioned after obtaining a good quality skin flap. Furthermore, when both ALND and RT are part of the treatment schedule, either anticipated or not, a "reconstructive shift" towards an autologous breast reconstruction should be carefully evaluated. In such cases a flap, chosen according with patient characteristics, could be an option, like in the Immediate-DElayed AutoLogous (IDEAL) breast reconstruction approach (18). TE can be exchanged with a completely de-epithelized flap placed under the entire skin envelope with nipple, kept in shape by TE itself, thus avoiding all the drawbacks of RT over an immediate one step implant or flap reconstruction.

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Footnote

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