Pre-pectoral Breast Implant Reconstruction - The Need for Randomized Controlled Trials

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Editorial

Advances in Oncoplastic has meant that increasingly breast surgery has become more aesthetic, less radical and less mutilating with progress from complete mastectomy decades ago to now nipple/skin sparing mastectomy; this same principle has been used positively also for patients benefit in nodal surgery thus sparing patients with healthy lymph nodes the problems of axillary clearance with the use of sentinel node biopsy which accurately assesses axillary nodal basin [1,2].

A more recent instance of this “less is more” principle is the increasing use of prepectoral implant breast reconstruction which avoids completely any dissection or detachment of pectoralis major and sub-pectoral implant placement with consequent avoidance of animation defect and post-operative pain along with relatively shortened time of recovery from surgery it also has an added merit that it can be a prelude to subsequent autologous; the entire pectoralis muscle function is thus completely preserved [3,4]. Going further back even the sub-pectoral/dual-plane technique using ADM or de-epithelized flaps was an earlier less aggressive advancement from the previous and painful total muscle cover [4-7]. Against this background of less aggressive approach/advancement there are a paucity of adequately designed and preferably randomized studies examining the merits and demerits of prepectoral implant reconstruction. A review of world literature (from 1966 to 2019) using Medline/PubMed demonstrate absence of any randomized studies to address this particular topic. Indeed, most of the available studies are retrospective case series with relatively low numbers, and the few prospective studies all have inherent design faults and are mostly case series. Consequently, attempts at meta-analysis or systematic review of the literature only yields disappointing and weak evidence [7-10].

The initial study that specifically addressed this issue in Europe had inherent problems with relatively very short-term follow-up; whereas 100 patients were inducted; follow-up is still less than a 12 months in the medium term and this obviously is too early to make any meaningful conclusions on the merits of prepectoral implant reconstructions. The study also lacked obvious control group as have most of the other publications on pre-pectoral reconstruction [11]. Of the few comparative studies a consistent trend is the fact that pre-pectoral technique on balance confers a better cosmesis on the merits of prepectoral implant reconstructions. The study also lacked obvious control group and demerits of prepectoral implant reconstruction. A review of world literature (from 1966 to 2019) using Medline/PubMed demonstrate absence of any randomized studies to address this particular topic. Indeed, most of the available studies are retrospective case series with relatively low numbers, and the few prospective studies all have inherent design faults and are mostly case series. Consequently, attempts at meta-analysis or systematic review of the literature only yields disappointing and weak evidence [7-10].

To further illustrate the weak evidence thus far there has been recent concerns raised by radiation oncologists regarding demerits of the pre-pectoral modality where it concerns planning for post-surgery adjuvant radiotherapy [14]. We know that the last few years has witnessed an increase in indications for post-mastectomy radiation therapy with increasing requirement for exposure of the chest wall, supraclavicular and internal mammary nodes [15-17]. Mitchell MP et al. [14] reviewed their experience with prepectoral implant reconstruction; thirty patients were treated with ADM wrapped prepectoral tissue expanders. On review of radiation plans, the prepectoral cohort had anatomic variations, for whom standard dosimetric criteria were not met with partially wide tangent fields. Use of a medial electron field matched to steep photon tangents was not advised due to under-coverage of the tumour bed related to implant placement. Boost treatment was also omitted because of concerns regarding the implant location. The central issue and challenge is that whereas the pectoralis muscle pushes the tumour bed anteriorly in the sub-pectoral implant locus while in the pre-pectoral technique the implant occupies the tumour bed and thus no longer allows for cold spots posteriorly as before.

Further to this concern is the fact that with subcutaneous locus and the relatively short follow-up in all series pose questions in some quarters amongst clinicians/surgeons regarding ability to clinically detect recurrences since a sub-pectoral implant placement pushes the tumour bed more forward and subcutaneous thus in theory making any lesions on balance easier for patient to palpate.
as is also the case with clinicians, unlike the subcutaneous locus where the implant occupies the "tumor bed" with the pectoralis major more posterior. Mitchell MP et al. [14] concluded that while advances in Oncoplastic surgery may improve cosmetic and recovery outcomes for breast cancer patients, increased consideration of radiation oncology issues particularly with planning, protection of vital organs as well as avoiding of under-dosing needs to be addressed as a matter of great importance. These are issues that need to be considered and settled to appropriately select candidates for prepectoral implant reconstruction. Prospective trials are thus necessary to ensure that these new techniques do not compromise oncologic outcomes.

In addition, another well-documented challenge in sub-pectoral implant reconstruction patients who subsequently undergo radiation therapy post-surgery is capsular contracture, this demerit of sub-pectoral locus is counter-balanced by a merit of the prepectoral locus; a recent observation and merit of pre-pectoral patients is a significance reduction in the incidence of capsular contracture post-radiotherapy while we are aware that ADM confer less capsular contracture in rats [18-20].

In addition to the challenges with post-surgery radiation therapy there are a select group of patients were the place of prepectoral placement remains questionable particularly in those who are underweight or slim as well as those who are obese [9] and certain situations such as skin flap necrosis can more easily lead to implant exposure, whereas those of sub-pectoral fold all have underlying muscle to protect implant for the most parts. There have been a few retrospective and a couple of prospective studies that have attempted a comparative analysis between sub-pectoral versus prepectoral but the numbers involved have been quite small making any meaningful statistical analysis difficult [21-29].

In addition to its part in the plastic surgeon’s surgical repertoire, prepectoral reconstruction is now recognized part of the training syllabus for general surgeons with an advanced subspecialist breast interest [30]. Indeed, it can facilitate the re-establishment of aesthetic breast even following Neo Adjuvant Chemotherapy/tumour reduction thus ensuring not just thorough excisional surgery but excellent aesthetic outcome; hence the inability of breast surgeons to learn these techniques has significant consequences for the training of future Oncoplastic surgeons.

In an era of evidence-based medicine, allocation of restricted healthcare, and a more educated patient population, the onus is placed on researchers to demonstrate with reliable measurements the effectiveness of treatment in well-designed and prospective outcome studies that are preferably randomized. Furthermore, with the increasing relevance of health economics in contemporary healthcare delivery, there is an overwhelming necessity to carry out the sentinel project involving an economic evaluation of the benefits of in particular prepectoral implant reconstruction or the introduction of any newer techniques. Thus, the necessity for a randomized prospective trial involving prepectoral vs. sub-pectoral is a desired endpoint however the achievement is also fraught with ethical dilemmas and debates since there are already perceived merits of this new technique of the earlier established techniques.

References


