

Optimizing Therapeutic Timing in Patients Undergoing Mastectomy Through Use of The Tiloop® Synthetic Mesh: Single-step Surgery

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Abstract. *Patients undergoing mastectomy for breast cancer have to face a long and elaborated therapeutic path, very often burdened by reoperation to replace the temporary expander, used to enlarge the submuscular pouch, with a definitive implant. Postoperative planning represents a critical moment of care, as it requires the integration of multiple treatments (chemotherapy, radiotherapy, hormonotherapy) each with a specific deadline. We believe that in such a complex multidisciplinary approach, coordination among the different therapeutic phases should be the key to success. The aim of the Breast Unit is to manage rapidly the ad hoc paths set out for each patient in order to guarantee compliance with adequate therapeutic timing. With this purpose in mind we tested the advantage of immediate reconstruction with definitive implants, by using a polypropylene mesh which, prolonging the inferolateral profile of the pectoralis major muscle (PMM), allows for direct accommodation of the desired implant volume. This leads to a single-step surgical approach, guaranteeing at the same time reduced interference with adjuvant therapies and good aesthetic results. We applied this technique to 4 patients, one of which was bilateral and, in spite of the restricted number of cases, our results seem to be promising.*

Breast cancer is a disease with significant social, economic and health impact, not only related to the high annual incidence (about 1.05 million new cases per year

worldwide), but also to diagnostic and therapeutic efforts, involving several medical and surgical specialists. Although the introduction of conservative surgery techniques, such as quadrantectomy, has revolutionized the surgical approach to breast cancer, mastectomy still remains the procedure of choice in cases of multicentricity, carcinoma *in situ* with an extensive intraductal component, history of previous irradiation, large tumors in relation to the size of the gland, presence of pre-existing comorbidities that preclude radiation therapy, inflammatory breast cancer, persistent positive margins after attempted conservative surgery, and finally patient choice (1).

The opportunity to perform breast-conserving surgery (BCS), that is to carry out radical procedures that preserve the breast skin (2) (skin-sparing mastectomy, SSM) and, when possible, the nipple-areola complex (3) (NAC) (nipple-sparing mastectomy, NSM), is continuing to promote an increasingly less mutilating approach, ever more a guarantor of the physical and psychological integrity of women.

Approximately 400 patients per year, bearers of malignant disease, join the Breast Unit of the Surgical Sciences Department at Perugia; at least 80 of them undergo mastectomy. The clinical course of these patients suffering from malignancy is complex, so that the coordination of various phases and specialists is critical in achieving therapeutic success. Moreover, the clinical course of mastectomy is further burdened by the need for a second surgical procedure, necessary to remove the temporary expander and place the definitive breast implant.

We propose a new technique in selected cases that offers the chance to combine both radical and reconstructive surgery in one procedure, avoiding a second operation to place the definitive prosthesis. This results in a lighter physical and psychological impact on the patient, who may terminate her surgical course in a single session, also leading to economic savings for the national health system.

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Patients and Methods

We applied this technique in four patients with breast cancer, of which one was bilateral. The first patient, aged 52 years, underwent a quadrantectomy with sentinel node (SN) biopsy that revealed a neuroendocrine carcinoma extended to excision margins and metastasis to both SNs. Therefore, she was subjected to NSM with immediate single-step reconstruction, thus avoiding additional surgery to remove the expander and implant a definitive prosthesis.

The second case was a 65-year-old patient with bilateral tumor and palpable axillary lymph nodes. Therefore, she was submitted to SSM with bilateral axillary dissection and immediate reconstruction with expander. During the subsequent months, while the patient was undergoing appropriate chemoradiotherapies, we proceeded to expander inflation. However, insufficient volume was obtained in the left breast, where, due to thin and hypotrophic muscle, the increase in volume was badly-tolerated. Therefore, several months later, this patient needed a reconstructive reintervention, using definitive implants and permanent synthetic mesh in order to restore the volume required for expansion of the muscle pouch.

The third patient, aged 66 years, who had already been subjected to quadrantectomy 13 years earlier, presented a locoregional recurrence and secondary bone localizations. As recently supported by influential reports, surgery is indicated in metastatic disease as it improves progression-free survival (4,5). Therefore, the patient was submitted to NSM with immediate reconstruction with definitive implant and mesh.

The last patient was a 61-year-old patient with a history of right breast cancer who had undergone BCS eight years earlier and came to our attention for a second 3-cm tumor of the left upper outer quadrant with palpable lymphadenomegaly. We subjected this patient to NSM combined with axillary dissection. Immediate reconstruction with mesh and definitive implant was performed, thus avoiding a second surgical step.

The patients we selected presented a rather elaborate therapeutic course, each for a different aspect. Therefore, subjecting them to further reconstructive surgery would, both in terms of care planning and of psychological standpoint, have been difficult to endure.

We used a non absorbable titanium-coated polypropylene mesh (TiLOOP Bra[®], SUNMEDICAL s.r.l., Cologno Monzese, Milan, Italy). Once implanted, the mesh is colonized by organic tissue whose cells grow through the pores.

After the performance of SSM or NSM, according to oncological requirements, we isolated the lateral margin of the pectoralis major muscle (PMM) that we then raised to create the muscular pouch. We then proceeded to digital dissection of the lower and medial portion of the PMM, with accurate hemostasis of the perforating vessels. The muscle was disconnected from the costal plane by at least 4-5 cm above the medial end of the inframammary sulcus. We then set the inferolateral edge of PMM on the perimeter of a pre-shaped mesh and attached them with a continuous prolene suture (Figure 1). The free edge of the mesh was then folded below the prosthesis to surround the lower pole. The pouch thus constituted was submuscular in the upper two-thirds and supra-prosthetic in the lower third (Figure 2).

Results

All of our patients tolerated the technique optimally. We only found mild erythema in the skin overlying the mesh, which,

however, spontaneously regressed in about 20 days; there was no case of superinfection or rejection, and no reintervention. All patients underwent the required adjuvant therapies at the proper time.

Discussion

In 1998, the Women's Health and Cancer Rights Act, with the approval of the US Departments of Labor and Health and Human Services, established that post-mastectomy reconstruction should be considered as part of breast cancer treatment (6).

In the past, reconstructive surgery was delayed months to years after mastectomy because it was thought that immediate reconstruction might interfere with adjuvant therapy and compromise surveillance on risk of local recurrence (7). This was disapproved by several scientific studies (8, 9) and nowadays we can state that immediate reconstruction is oncologically-feasible in terms of local recurrence and survival (10-13). Furthermore, immediate reconstruction offers psychological benefits, ensuring improved body image (7) and, therefore, a good level of self-confidence which translates into a lower incidence of postoperative anxiety and depression (14). Breast reconstructive surgery with autologous tissue provides the best results in terms of ptosis, profile and symmetry in the long term (15). But not all women are endowed with the necessary subcutaneous adipose tissue for autologous reconstruction, and sometimes they do not willingly accept morbidity related to removal of tissues from the donor site, consequent muscle weakness and prolongation of hospitalization (16).

Immediate breast reconstruction with breast implants is generally a two-step procedure but although the spared skin flaps in NSM would be sufficient to restore adequate breast volume, the submuscular pouch in which the implant would be seated appears stiff and lacks extensibility. The first surgical step consists of the placement of an expander, which is a particular type of prosthesis provided with a percutaneous access, through which saline solution can be added in subsequent sessions, which progressively stretches the implant and thus the muscular pouch. During the second surgical step, the expander is replaced with a permanent prosthesis which, being more anatomical, provides more natural aesthetic results and better tolerance.

In 1981, Little described a technique that allows the creation of a complete submuscular pouch, which he named "the living bra", using the PMM supported by the serratus anterior, the rectus fascia of the abdomen, the external oblique and the pectoralis minor (17). Such a conformed pouch, however, does not allow bulky prosthesis lodging. The lack of proportion between skin and muscle is responsible for the so-called muscle-skin paradox, so that while the muscle coat is gradually expanded, the skin flaps

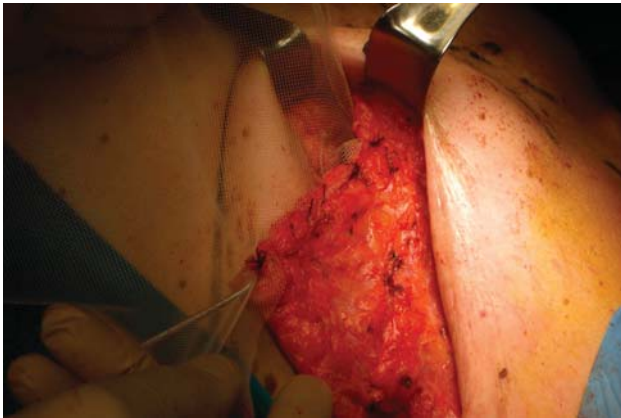


Figure 1. Fixing the mesh to the pectoralis major muscle with a continuous prolene suture.



Figure 2. Final results after insertion of both the mesh and the definitive prosthesis.

may present retraction (18). To overcome the limitations of an inextensible muscular pouch compared with a large and redundant skin envelope, several methods that use the submuscular pouch have been developed, also by partially detaching the pectoral from its rib and sternal insertions. These partial submuscular pouches present the benefit of limiting upper pole expansion and inframammary sulcus ascent. The submuscular expander is gradually inflated during the months following surgery, concurrently with chemotherapy which generally starts four to six weeks after surgery. It has been shown that in these patients the risk of infection is remarkably increased compared to that of those not subjected to chemotherapy (10.7% vs. 1.5%) (19). Chemo-induced immunosuppression makes these patients noticeably more vulnerable to minimally invasive techniques, such as even simple percutaneous inflation of the expander. Furthermore, the postoperative course can become complicated, with the formation of seroma, skin necrosis, capsular contracture, expander exposure or extrusion (20). The onset of these complications may be responsible for a delay of adjuvant therapy (21) and can sometimes lead to second-look surgery for expander removal. Even in our own experience, locoregional inflammatory phenomena occurred, that led us to stop expander inflation. Postoperative planning, therefore, represents a critical moment regarding care, as it requires the integration of multiple treatments, each with specific deadlines. A recent review of the literature of the past three years concluded that radiotherapy should be started as soon as possible in a window between six and 20 weeks after surgery, but also highlighted that since chemotherapy should be administered before radiotherapy, patients proposed for chemotherapy should begin radiotherapy seven months after surgery, unless postoperative complications arise (22). Hence the delay of one of the

treatment stages may inhibit an early beginning of radiation therapy and thereby also affect its efficacy. We believe that in such a complex therapeutic approach, coordination of different therapeutic phases should be the key to success.

The aim of the Breast Unit is to manage rapidly and *ad hoc* the tailored paths traced for each patient in order to guarantee compliance with adequate therapeutic timing. With this purpose, we tested the opportunity of immediate reconstruction with definitive implants using a polypropylene mesh which prolongs the infero-lateral profile of the PMM and allows for immediate accommodation of the desired implant volume. Such a solution lets us hope for a reduction of perichemotherapy infectious complications, thereby facilitating punctual execution of phases of the therapeutic course. From the perspective of postoperative radiotherapy, the presence of a definitive implant of previously determined volume can presumably simplify the planning.

Finally, the results of such a technique also appeared satisfactory in terms of aesthetics, as it ensured suitable projection of the lower pole and a natural ptosis, avoiding unesthetic dilatation of the upper pole. In the described cases in compliance with a purpose of oncological radicality, adequate aesthetic results were achieved, with no evidence of additional complications. We report only one erythematous reaction affecting the skin overlying the mesh, which spontaneously regressed in about 20-30 days.

The possibility of routinely performing this type of reconstruction can revolutionize the therapeutic process of such patients, relieving them from the need for reintervention and minimizing the psychological trauma related to acceptance of postoperative changes in body image. As part of the multidisciplinary approach to disease, this technique simplifies coordination among the various phases, which is responsible for the therapeutic outcome.

Finally, in patients with breast cancer, single-step immediate reconstruction has a positive economic impact on health care costs by reducing both the number of hospitalizations and the required operating sessions.

Conclusion

The need to ensure proper timing of the complex and elaborated diagnostic, therapeutic and rehabilitative course of patients with breast cancer led us to experiment with single-step immediate reconstruction with implant and mesh, as a solution that enables us to complete the surgical procedure in a single session, limiting the weight of this step in the overall therapeutic process. We found excellent aesthetic results and high satisfaction rates among our patients, but what impressed us most was the linearity of the therapeutic course. Although the cases we have treated so far are few in number, we expect a confirmation of the good results achieved with time.

Financial Disclosure

None.

Conflicts of Interest

None.

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