The Oncologic Outcome and Immediate Surgical Complications of Lipofilling in Breast Cancer Patients: A Multicenter Study—Milan-Paris-Lyon Experience of 646 Lipofilling Procedures

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Background: Lipofilling is now performed to improve the breast contour, after both breast-conserving surgery and breast reconstruction. However, injection of fat into a previous tumor site may create a new environment for cancer and adjacent cells. There is also no international agreement regarding lipofilling after breast cancer treatment.

Methods: The authors included three institutions specializing in both breast cancer treatment and breast reconstruction (European Institute of Oncology, Milan, Italy; Paris Breast Center, Paris, France; and Leon Berard Centre, Lyon, France) for a multicenter study. A collective chart review of all lipofilling procedures after breast cancer treatment was performed.

Results: From 2000 to 2010, the authors reviewed 646 lipofilling procedures from 513 patients. There were 370 mastectomy patients and 143 breast-conserving surgery patients. There were 405 patients (78.9 percent) with invasive carcinoma and 108 (21.1 percent) with carcinoma in situ. The average interval between oncologic surgical interventions and lipofilling was 39.7 months. Average follow-up after lipofilling was 19.2 months. The authors observed a complication rate of 2.8 percent (liponecrosis, 2.0 percent). Twelve radiologic images appeared after lipofilling in 119 breast-conserving surgery cases (10.1 percent). The overall oncologic event rate was 5.6 percent (3.6 percent per year). The locoregional event rate was 2.4 percent (1.5 percent per year).

Conclusions: Lipofilling after breast cancer treatment leads to a low complication rate and does not affect radiologic follow-up after breast-conserving surgery. A prospective clinical registry including high-volume multicenter data with a long follow-up is warranted to demonstrate the oncologic safety. Until then, lipofilling should be performed in experienced hands, and a cautious oncologic follow-up protocol is advised. (*Plast. Reconstr. Surg.* 128: 341, 2011.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, II.

Breast reconstruction is included in the treatment plans for each individual breast cancer patient to improve quality of life.[1–4] To obtain satisfactory results, surgeons focus on cosmetic issues and, even more importantly, on oncologic safety.[5] Despite various techniques of reconstruction with autologous tissues or prostheses, adipocyte tissue has been used more frequently in the recent era.[6–9] The indications for lipofilling include micromastia, tuberous breasts, Poland syndrome, postlumpectomy deformity, postmastectomy deformity, sequelae of postradiotherapy, secondary reconstruction after flap or prosthesis reconstruction, and nipple reconstruction.[10–13]

Recently, a number of new techniques of fat preparation have been described, with the ultimate goal of improving adipocyte purification and

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stem cell selection.[14–16] However, many fundamental studies have suggested that adipocytes and preadipocytes and their products are involved in the tumor cell cycle through autocrine, paracrine, and exocrine/endocrine secretions.[17,18] Such secretions delivered on tumor sites may play a role in tumorigenesis, tumor progression, and tumor recurrence or metastasis. In contrast, some of them could have an inhibitory effect on some particular stages of the tumor cycle. Breast cancer cells might still be present in the residual mammary parenchyma after conservative treatment or in the subcutaneous tissue after mastectomy. Therefore, based on these contradictory studies, a highly relevant clinical question is whether the lipofilling technique is a safe procedure after breast cancer treatment, especially in breast-conserving protocols.[19–24]

The review article by Lohsiriwat et al.[25] on experimental studies found that adipocyte, preadipocyte, and progenitor cell secretions can stimulate angiogenesis and cell growth. They also emphasized that the "tumor-stroma interaction" can potentially induce cancer reappearance by "fueling" dormant breast cancer cells in the tumor bed. However, there is a lack of translational research that proves this concern clinically. No study on the effects of lipotransfer on human cancer breast cells in vivo is available. The direct and indirect effects of lipotransfer in breast cancer patients, highlighting pro and con–related issues, remain unclear. Today, no informed consent can be given to our patients stating that lipofilling does not stimulate fueling of dormant cancer cells or eventually induce new cancer cells.[26]

There is no international agreement for lipofilling after breast cancer treatment. Depending on country, the safety of lipofilling is still a controversial issue. In 2007, the French Society of Plastic Reconstructive and Aesthetic Surgery (Société Française de Chirurgie Plastique Reconstructrice et Esthétique) addressed the question of cancer safety for lipofilling technique in breast cancer patients.[27] The Society sent a "recommendation to the French plastic surgeons to postpone the lipofilling in the breast with or without breast cancer history unless it is performed under prospective controlled protocol." In 2009, the American Society of Plastic Surgeons Fat Graft Task Force concluded that no reliable studies can confirm definitely the oncologic safety of lipofilling in breast cancer patients.[13] The Italian Society of Plastic Surgery in 2010 advised surgeons to perform lipofilling with caution and with a precise consent form but did not impose any restrictions regarding lipotransfer indications. Our purpose was to design a multicenter observational study on lipofilling after breast cancer with a significant number of cases to check the complication rate of the technique, the risk of modification of mammography and ultrasound, and the occurrence of a suspicious image, and to record oncologic follow-up.

PATIENTS AND METHODS

We set up a multicenter study gathering information from three institutions with a large experience of breast cancer treatment and reconstruction (European Institute of Oncology, Milan, Italy; Paris Breast Center, Paris, France, and Leon Berard Centre, Lyon, France). A collective chart review of lipofilling procedures was performed for the registration of the cases.

We included all breast cancer patients with lipofilling after treatment of breast cancer. Patients could have undergone breast-conserving surgery or mastectomy, regardless of preoperative and postoperative treatment (i.e., radiotherapy, chemotherapy, or hormonal treatment). Both carcinoma in situ and invasive carcinoma were included. The exclusion criteria were lack of histology or lack of complete operative data, follow-up less than 6 months, and treatment for local or distant recurrence between the primary cancer treatment and the lipofilling procedure.

The patients' data from each institution were collected and registered systematically on the same case record form. All patients' preoperative clinical and radiologic data were registered. The techniques of lipofilling procedures were recorded. The missing data were completed by telephone call and/or appointment. Patient age, date and indication for oncologic surgery, radiotherapy, tumor histopathology and staging, indication for lipofilling, type of anesthesia, donor sites of fat harvesting, volume of preparation and injection, complications, and clinical and radiologic follow-up data before and after lipofilling were registered.

Surgical Technique

All three institutes performed lipofilling using the same technique. The procedure was performed under local or general anesthesia, depending on quantities of fat required and the patient's clinical conditions. The selected donor site was infiltrated with Klein's solution, which consists of 1 cc of epinephrine diluted in 500 cc of 0.001% lactated Ringer's solution; 50 cc of mepivacaine is added to the solution if the surgeon is operating using local anesthesia. For harvesting,

we use a Coleman blunt-tip cannula attached to a 10-cc Luer-Lok syringe or a controlled pressure vacuum machine. A combination of slight negative pressure and the curetting action of the cannula through the tissues allows the fat harvesting. Then, we centrifuge the fat at 3000 rpm for 3 minutes until the serum and oily components are separated from the adipose tissue. The cellular component is transferred immediately to a 1-cc Luer-Lok syringe and prepared for injection.

RESULTS

From December of 2000 to March of 2010, we reviewed 646 lipofilling procedures from 513 patients. There were 370 mastectomy patients (476 lipofilling procedures) and 143 breast-conserving surgery patients (170 lipofilling procedures). The average amount of lipofilling performed per session was 107.3 cc (range, 5 to 400 cc). The average number of sessions required was 1.25 (range, one to six sessions). Three patients had lipofilling immediately at the time of total reconstruction with prostheses. Thirty-seven underwent lipofilling within 6 months, and the rest underwent lipofilling more than 6 months after primary oncologic surgery.

There were 240 T1 tumors, 131 T2 tumors, 31 T3 tumors, and three T4 tumors.[28] There were 405 invasive carcinomas (78.9 percent) and 108 carcinomas in situ (21.1 percent) (ductal carcinoma in situ, $n = 101$; lobular carcinoma in situ, $n = 7$).

The average age of the patients was 52.1 years (range, 27.7 to 86.3 years). The average time between oncologic surgical interventions and lipofilling was 39.7 months (range, 0 to 216 months). The average follow-up time from the last lipofilling procedure to the last visit was 19.2 months (range, 1 to 107 months). The average time between oncologic surgical interventions and the last visit was 57.6 months (range, 6 to 260 months). Types of oncologic and reconstructive surgical intervention are listed in Table 1 and types of radiation therapy are listed in Table 2.

Table 1. Type of Surgery

Type of Surgery	No.
Mastectomy ($n = 370$)	
Mastectomy plus prosthesis	236
Mastectomy plus flap	125
Mastectomy plus flap plus prosthesis	9
Breast-conserving surgery ($n = 143$)	
Breast-conserving surgery alone	131
Breast-conserving surgery plus flap	10
Breast-conserving surgery plus prosthesis	2
Total	513

Table 2. Type of Radiation Therapy

Radiation Therapy	No.
With radiation therapy ($n = 395$)	
IORT	129
ERT	231
IORT plus ERT	35
Without radiation therapy	118
Total	513

IORT, intraoperative radiation therapy; ERT, external radiation therapy.

First events were classified into local, regional, distant, and death events. Recurrence in breast tissue, skin around previous tumor sites, previous scar, and nipple-areola complex were categorized as local recurrence. Axillary, infraclavicular, and internal mammary nodal recurrences were categorized as regional recurrence. Locoregional recurrence refers to the cumulative number of local recurrence and regional recurrence. The overall event rate was 5.6 percent (3.6 percent per year). The locoregional event rate was 2.4 percent (1.5 percent per year). The distant metastasis rate was 3.1 percent (1.9 percent per year). A summary of all events is provided in Table 3.

We observed 18 complications from 646 procedures (2.8 percent). The most common complication was liponecrosis, which accounted for 2.0 percent. Other complications were three local infections (0.5 percent), one seroma (0.2 percent), and one pneumothorax (0.2 percent). Liponecrosis detection was based on physical examination. Regarding the liponecrosis rate in patients who underwent irradiation, we had 13 cases of liponecrosis (seven patients received external radiation therapy, one patient received intraoperative radiation therapy, and two patients received both radiation therapies). We did not study the absorption rate. The details of complications are listed in Table 4.

We follow up all breast-conserving surgery cases with systematic yearly mammograms. We have prelipofilling and postlipofilling radiologic imaging from 119 of 143 breast-conserving surgery cases: 12 radiologic images appeared after lipofilling. Seven images showed benign calcifications, two showed benign opacity masses, and three showed suspicious lesions. Seven of them were processed for tissue diagnosis; however, five of them were not submitted to any further investigation because of typical benign characteristic images. From seven histopathologic reports, there were five benign lesions (liponecrosis, $n = 2$; scarring, $n = 2$; and fibrocystic lesion, $n = 1$), and two of them were proven to be local breast relapses.

Table 3. Summary of All Events

	Cases (%)	LR (%)	RR (%)	Distant Metastasis (%)	Total (%)
Histology					
Invasive	405 (78.9)	3 (0.7)	6 (1.5)	16 (3.9)	25 (6.1)
In situ	108 (21.0)	4 (3.7)	0 (0.0)	0 (0.0)	4 (3.7)
Type of surgery					
BCS	143 (27.8)	2 (1.3)	3 (2.0)	6 (4.1)	11 (7.6)
Mastectomy	370 (72.1)	5 (1.3)	3 (0.8)	10 (2.7)	18 (4.8)
Subgroup					
BCS plus in situ	25 (4.8)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
BCS plus invasive	118 (23.0)	1 (0.8)	3 (2.5)	6 (5.0)	10 (8.4)
Mastectomy plus in situ	83 (16.1)	3 (3.6)	0 (0.0)	0 (0.0)	3 (3.6)
Mastectomy plus invasive	322 (62.7)	2 (0.6)	3 (0.9)	10 (3.1)	15 (4.7)
All patients	513 (100.0)	7 (1.3)	6 (1.1)	16 (3.1)	29 (5.6)

LR, local recurrence; RR, regional recurrence; BCS, breast-conserving surgery.

Table 4. Complications

Complication	No. of Procedures (%)
Liponecrosis	13 (2.0)
Infection	3 (0.5)
Seroma	1 (0.2)
Pneumothorax	1 (0.2)
All	18 (2.8)

DISCUSSION

Fat transfer following breast cancer treatment is a growing indication of oncoplastic surgery to improve the morphologic results after total or partial breast reconstruction. It is a simple technique that usually provides a low complication rate and good cosmetic results, even after radiotherapy. In our series, 18.1 percent of patients required more than one lipofilling procedure. We cannot provide the definite reabsorption rate in our series. The patients who need only one lipofilling procedure can also have a partial lipofilling, with an acceptable aesthetic result. In the literature, the fat reabsorption rate after lipofilling is approximately 10 to 30 percent.

We observed 18 complications from 646 procedures (2.8 percent), mostly liponecrosis (2.0 percent), which is inferior to the results published by the American Society of Plastic Surgeons of 12.7 percent (infections, 1.1 percent; calcifications, 4.9 percent; fat necroses, 5.7 percent; and unspecified superficial lumps, 1.1 percent).[13]

Lipofilling can modify the radiologic follow-up of breast-conserving surgery patients. In our series, there were 12 modified radiologic images from 119 breast-conserving surgery cases. Two of them were breast relapses. The interference with radiographic examination caused by lipofilling has been well studied in the literature. Usually, the images resulting from fat injection are easily distinguished from the neoplastic images.[29,30] Compared with previous studies, there is no evidence that fat grafting to the breast interferes with breast cancer detection; however, the authors emphasize the need for biopsy in cases of doubt. The American Society of Plastic Surgeons also concluded that fat grafting to the breast could potentially interfere with breast cancer detection; however, no evidence was found that strongly suggests this interference. Radiologic studies suggest that imaging technologies (i.e., ultrasound, mammography, and magnetic resonance imaging) can identify the grafted fat tissue, microcalcifications, and suspicious lesions; biopsies may be performed if needed for additional clarification.[13]

Recently, Rietjens et al. reported a series of lipofilling procedures in breast cancer treatment and reconstruction. They followed 158 patients and found that postoperative complication rates are very low (3.6 percent) and that there is little alteration in follow-up mammograms (5.9 percent).[31] Another series of 880 lipofilling procedures by Delay et al. demonstrated a low complication rate (3 percent fat necrosis) and positive results. They also suggested that preoperative and postoperative examination by a radiologist specializing in breast imaging is necessary to limit the risk that a cancer may occur coincidentally with lipofilling.[9]

However, injection of fat into a previous tumor site may create a new environment for cancer cells and adjacent cells because of cell purification or by adding stimulus factors. The "tumor stromal interaction" or paracrine action of the injected fat may affect locoregional recurrence rates, especially in breast-conserving surgery. To evaluate the oncologic events in our series of patients, we compared our results with two articles published recently from the European Institute of Oncology, the first organization dedicated to breast-conservative treatment and the second one dedicated to

the results of total mastectomy with or without breast reconstruction. We focused on locoregional recurrence, which is the sum of regional recurrence and local recurrence. In our series, locoregional recurrence rates were higher in the breast-conserving surgery group than in the mastectomy group (2.07 percent versus 1.38 percent per year), and in situ carcinoma tends to have a higher chance of locoregional recurrence than invasive carcinoma (2.33 percent versus 1.44 percent per year). The incidence of locoregional recurrence in a series of 2784 breast-conserving surgery patients from the European Institute of Oncology is 0.4 percent per year as compared with 2.07 percent in our series of lipofilling.[32] The locoregional recurrence rate after mastectomy with lipofilling is consistent with the results of the study published by Petit et al.: 1.38 percent versus 1.1 percent.[33]

The distant metastasis rate in our series was 1.95 percent per year, and all of the distant events occurred in the invasive carcinoma group. We found 2.78 percent and 1.75 percent rates of distant metastasis in the breast-conserving surgery group and the mastectomy group, respectively. Compared with data from our institute, there are 1.52 percent and 2.38 percent distant metastasis rates in the breast-conserving surgery group and the mastectomy group, respectively.[32,33] Such comparison with the two series of the European Institute of Oncology shows a small increase of locoregional recurrence in the breast-conserving surgery group after lipofilling and no difference for the mastectomy group. No definitive conclusion can be drawn from such comparison between retrospective studies. Our purpose was, first, to eliminate the risk of finding a consistent increase of the local or distant events in the follow-up of patients after lipofilling. To report at the level of drawing conclusions, our next program will compare our cases with a control group of patients undergoing breast reconstruction without lipofilling, matched according to the usual cancer criteria: staging, histology, biological markers, hormonal receptors, and the same period of time without adverse oncologic events between the primary cancer surgery and the date of lipofilling. A longer period of follow-up is also required to focus on oncologic results.

Few articles have focused on the oncologic safety of lipotransfer. Illouz and Sterodimas concluded that the locoregional recurrence in cancer patients in their series was comparable to that in the aesthetic group.[34] However, these results are retrospective, with no information on the quality of the cancer follow-up. No cancer staging has been provided by the authors.

Another study based on cancer evolution by Rigotti et al. compared the number of locoregional recurrences of the same group of patients in the prelipofilling and postlipofilling periods.[35] Such methodology could be criticized, because the risk of locoregional recurrence decreases with time and cannot be considered as equivalent in the prelipofilling and postlipofilling periods. Moreover, we cannot understand why the authors did not use the 104 conservative treatments of their series, which could be the patients most at risk for locoregional recurrence.[36]

Because of the purpose of our study, we cannot provide definitive proof regarding the safety of lipofilling in terms of cancer recurrence or distant metastasis. We only provided the preliminary results of oncologic follow-up and early complications of surgical and radiologic follow-up. We have not reported the efficacy of the lipofilling procedure in terms of aesthetic follow-up or fat reabsorption.

CONCLUSIONS

This multicenter study from three institutions confirms that lipofilling following breast cancer treatment leads to a very low rate of complications and does not affect the radiologic follow-up after breast-conserving surgery. We cannot provide the definitive proof of the safety of lipofilling in terms of cancer recurrence or distant metastasis. Further studies are required with a longer follow-up, a larger group of patients, and a control group matched according to the cancer status of the lipofilling group. Until then, lipofilling should be performed in experienced hands, and a cautious oncologic follow-up protocol is advised.

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